PATENTS *under the Bayh-Dole Act of 1980*

Whenever an Institution's research work is funded either in whole or in part through NIH research grants, contracts, and cooperative agreements, ("Recipient"), the funded work is subject to the requirements of the Bayh-Dole Act of 1980 (referred to as "Bayh-Dole" or "the Act"). Recipients have rights to elect title to inventions their employees create in performance of the grant, so long as they abide by the required notification and reporting procedures, as summarized in pertinent part below:

INTRODUCTION *(back to top)*

Bayh-Dole established a uniform federal patent policy that is designed to encourage Recipients to collaborate with industry. These collaborations are expected to promote the use, development and commercialization of technology invented with federal funding ("Subject Invention"). To accomplish this goal, the Act gives Recipients the right to retain ownership to inventions developed with federal funding - so long as they adhere to certain requirements designed to ensure protection of the intellectual property and commercialization of the technology. These requirements of Recipients include:

- filing patent applications on the inventions they elect to own;
- giving preference in licensing of such rights to small businesses;
- agreeing that the federal government retains a non-exclusive license to practice the invention throughout the world; and
- agreeing that the federal government may exercise "march-in" rights to get the technology developed and commercialized, if the technology is not adequately used.

In the event the Recipient chooses not to retain ownership, the NIDDK has the opportunity to determine whether the U.S. government will retain title and file a patent application. If neither the Recipient nor the U.S. government chooses to file a patent application, one or more of the

inventors may request to retain ownership, with the understanding that all the responsibility and requirements, including filing a patent application and notifying the NIDDK will then fall to the inventor. See Implementation of Inventor Certifications for Inventions Waived to the Inventor for more information.

Procedures created for implementing the Act apply to all inventions conceived or first actually reduced to practice during the performance of research that is partially or fully funded by a federal agency, such as the NIDDK. The Recipient has the obligation to disclose all inventions derived from NIDDK-funded research to the NIDDK within two months after the inventor has reported it to the Recipient Institution. The Recipient has the choice as to whether it will retain ownership of the invention. It must notify the NIDDK of its decision within two years after its first disclosure of the invention to the NIDDK, but not longer than ten months following an article or abstract publication or presentation resulting from the research. This shorter period is to ensure that patent rights are not inadvertently lost. If the Recipient elects to retain ownership, it must file a patent application within one year, or sooner if any information on the research has been published or presented. Within ten months following the first patent application filing, Recipient must notify the agency whether it will seek patent protection outside the U.S. This is to ensure that worldwide rights are not inadvertently lost. If the Recipient Institution (or inventor who has been given title) chooses not to file abroad, the agency may then file on its own behalf outside the U.S. For answers to commonly asked questions on reporting, please see A "20-20" View of Invention Reporting to the National Institutes of Health.

As a condition of retaining ownership of the invention and any patent that issues from it, the Act requires that the Recipient grant the federal government a non-exclusive, irrevocable, paid-up license to practice the invention, or to have it practiced on behalf of the U.S., throughout the world. Recipient may not assign invention rights to third parties, unless the assignment is to a patent management organization.

Manufacture of an invention product by an exclusive licensee of Recipient must be substantially in the U.S. The NIDDK may waive this requirement, but only upon a showing that reasonable efforts to locate a company agreeable to manufacturing in the U.S. has been unsuccessful. When licensing, Recipient must give preference to small business, so long as the company has the resources and the capability to bring the invention to a practical application. If a large company has provided research support leading to the invention, however, that company should reasonably be granted the license.

Recipient must share royalties, or other income, derived from the invention with the inventor(s), according to a statutory formula. Income to Recipient remaining after expenses are recovered must be used to support scientific research or education.

Only in exceptional cases may a federal agency, such as the NIDDK, determine that ownership is better held by the federal government. In these instances, the agency files a Determination of Exceptional Circumstances with the Department of Commerce, which will then decide who will own the intellectual property. In other cases, the agency may require the Recipient to grant a license to a third party. Examples of such cases occur in matters of health and safety, when public use of the invention is in jeopardy, or the invention is otherwise not brought to practical

use within a reasonable time. Complete regulations for implementing the Act can be found at 37 CFR 401.

The following is excerpted from the Federal Register, Vol. 59, No. 215, November 8, 1994, pp 55674-55679:

RECIPIENT RESPONSIBILITIES *(back to top)*

In keeping with the objectives and policies of Bayh-Dole, the Recipients are required to effectively and efficiently transfer technology to industry for commercial development. However, in doing so, Recipients must also comply with the specific terms of the Act, its implementing regulations, and the terms and conditions of each NIH award, and ensure that such compliance is reflected in their agreements with commercial entities.

In carrying out Recipient's responsibilities, Recipients need to concern themselves with

- maintaining academic freedom for institutions and investigators;
- fair access to information;
- timeliness of notification and reporting requirements;
- rational licensing to commercial entities; and
- adherence to the specific requirements of the Act and NIH funding agreements.

Notification Requirements and Records *(back to top)*

In Sponsored Research Agreements, as in other contexts, Recipients must also ensure that invention, patent and license notification requirements are made timely. Timeliness considerations include prompt (1) employee notification to Recipient administrators of an invention made under NIH funding, (2) written disclosure to NIH in sufficient technical detail to adequately describe the invention, (3) written election to the NIH of whether or not the Recipient will retain title to such invention, (4) adherence to time frames for initial filing of patent applications in the United States and the filing of foreign patent applications, (5) execution and delivery of all documents necessary to establish or confirm NIH rights throughout the world in the subject inventions to which the Recipient has elected to retain title, (6) notification to the NIH of any decision not to continue patent prosecution, pay fees, or defend the patent in a reexamination or opposition proceeding on a patent, in any country, and (7) conveyance of title to NIH when requested. Recipients must also specify in any United States patent applications and any patents that cover a subject invention that the invention was made with government support.

Specifically, as conditions of NIH grants and cooperative agreements, Recipients must give NIH timely notice when an invention has been created. A final invention statement and certification listing all inventions that were conceived or first actually reduced to practice during the course of work under the funding agreement is required within ninety (90) days following the expiration or termination of support on the related project. Additionally, Recipients need to adhere to the specific requirements contained in the patent clauses of their contracts as well as to the general provisions of the Federal Acquisition Regulations.

Recipients must also document their compliance with the requirements of the Act, regulations, and terms and conditions of NIH awards generally, and as related to Sponsored Research Agreements. Recipient records must be available for review by authorized Federal officials in accordance with the terms and conditions of the award. For example, concerning access and retention of records under NIH grants and cooperative agreements, regulations require grantees to retain financial and programmatic records, supporting documents, statistical records, and all other grantee records which may reasonably be considered pertinent to a grant or subgrant.

Since October 1995, there have been two ways that invention utilizations can be reported to the NIH: by paper correspondence, or as a feature of the Interagency Edison Internet-based invention reporting system (http://iedison.gov). Using either approach, utilization reporting involves response to 8 questions relating to the status of commercialization, extent of licensing, and an indication as to whether or not any invention-related products have reached the market.

The reporting procedure and a new list of utilization questions, adopted by NIH in 2002, are summarized below.

- Annual utilization reporting is required according to a grantee/contractor-defined 12-month cycle.
- Recipient organizations may report via paper or through the iEdison electronic reporting system, though the use of iEdison is strongly recommended by the NIH.
- For each invention whose principal rights have been retained (elected) by the Recipient Institution, the following questions must be answered as part of the utilization report:
    - Indicate the latest stage of development of any product arising from the invention, according to the following categories: Not Licensed/Licensed/Commercialized.
    - Report the total income received during the reporting period as a result of license or option agreements for the invention. Specific patent costs reimbursement is not to be included.
    - Identify the calendar year of the first commercial sale of any product arising from the invention that has reached the market.
    - Indicate whether during the designated reporting period the grantee/contractor organization or any of the exclusive licensees requested a waiver of the U.S. manufacturing requirements for the invention. Also indicate how many waivers were obtained.
    - Report the number of exclusive licenses and/or options that have been awarded for the invention during the designated reporting period.
    - Report the number of non-exclusive licenses and/or options that have been awarded for the invention during the designated reporting period.
    - Indicate for the invention the number of licenses and/or options of any types that were awarded to small businesses (<500 employees) during the designated reporting period.
    - Provide the commercial name of any FDA-approved products, utilizing the invention, that have reached the market.

The content of all Bayh-Dole-related reports are maintained by the NIDDK, and the NIH, as confidential, releasable only through the Freedom of Information Act.

INDUSTRY SPONSORED RESEARCH ALSO INVOLVING NIH FUNDING *(back to top)*

While Sponsored Research Agreements frequently are used where basic research is involved and no invention exists to disclose nor intellectual property to license at the time the agreement is executed, Recipients should anticipate these issues and consider the following points when developing a Sponsored Research Agreement.

The first section, Universal Points for Consideration, highlights several requirements and issues that Recipients should consider in all proposed Sponsored Research Agreements. The second section, Points for Special Consideration, delineates circumstances that suggest heightened scrutiny. The third section, Other Points for Consideration by Nonprofit Recipients, contains additional considerations that apply only to nonprofit Recipients.

Universal Points for Consideration *(back to top)*

Academic Freedom

Recipients may enter into Sponsored Research Agreements with commercial entities from which Recipients receive funding or other consideration to support their research in return for preferential access and/or rights to intellectual property deriving from Recipient research results. In these cases, Recipients should be aware that their interest in the scientific endeavor covered by the Sponsored Research Agreement and the interest of the industrial sponsor may not be totally consonant. As a result, in general, Recipients should ensure that Sponsored Research Agreements preserve the freedom for academic researchers to

- select projects;
- collaborate with other scientists;
- determine the types of sponsored research activities in which they wish to participate, and
- communicate their research findings at meetings, and by publication and through other means.

Academic researchers should be made aware of any agreements executed by their Institutions that may restrict their ability to pursue research activities and publish research results. Recipients also should maintain their independence to pursue their own mission without undue influence or restraint by their industrial sponsors. For example, an agreement that gives an industrial sponsor the ability to direct the research mission of a Recipient would be inappropriate.

Dissemination of Research Results *(back to top)*

Recipients must ensure that the timely dissemination of research findings is not adversely affected by the conditions of a Sponsored Research Agreement. For example, in the case of research grants, the PHS Grants Policy Statement, incorporated as a condition of each NIH research grant, details policies on publication of research results, responsibilities to disseminate information on unique research resources, and standards of conduct for the organization's employees.

Utilization *(back to top)*

The NIH also has a concern that federally funded technology be developed and commercialized in an expedited and efficient manner. In deciding to enter into an agreement with a commercial entity, Recipients should consider whether the organization has the experience, capability, and commitment to bring its inventions to commercial status.

License Options: Additionally, Recipients should not enter into Sponsored Research Agreements that permit a sponsor to tie up the development of a technology by acquiring exclusive licensing rights to the product of given research results ***before*** deciding whether or not it will actively develop and commercialize that product. Recipients could provide a sponsor with an option to pursue licensing rights. It is reasonable for such options to be limited to no more than six (6) months after disclosure to the authorized representative of the sponsor. However, individual circumstances may dictate a shorter or longer period of time. After the option period expires, the technology should become available for licensing to other entities. Moreover, once a sponsor decides not to exercise its option, normally, the agreement should not provide for a second opportunity to obtain licensing rights by matching other parties' offers for the rights. Such actions enable Grantees to license to companies presenting a bona fide commercialization plan, thus expediting the availability of products to the public.

Benchmarks & Monitoring Licensees: In order to ensure that technology is developed rapidly and is not being subjected to delays, Recipients should also establish, maintain, and actively administer policies and procedures that ensure that licenses arising from Sponsored Research Agreements contain due diligence requirements and benchmarks to monitor performance. When future rights to as-yet- undiscovered inventions are included in a Sponsored Research Agreement, benchmarks for development of each such invention should be established as they become available for commercial development. In addition, Recipients should actively monitor licensees in accordance with those requirements and benchmarks to assure compliance with Recipient obligations under the Act.

Reporting: Recipients also need to ensure that they have internal systems to provide required utilization reports to the NIH on each invention. Those reports are required by Department of Commerce regulation and include such items as the status of development, first commercial sale, and amount of gross royalties received. Further information about the precise utilization report requirements can be obtained from the NIH Office of Extramural Research.

U.S. Manufacture *(back to top)*

The Bayh-Dole Act requires that products developed with federal funds, and used and sold in the United States, be substantially manufactured here. In granting exclusive rights to use or sell any Subject Invention in the United States, Recipients must ensure that each agreement requires that any products embodying the Subject Invention or produced through the use of the Subject Invention will be manufactured substantially in the United States. In individual cases, a request for waiver may be considered by the NIH. A determination will be made based upon a showing by the Recipient that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or, that under the circumstances, domestic manufacture is not commercially

feasible. In granting a waiver of the U.S. manufacture requirement, the NIH may consider other benefits conferred on the United States by the potential license including the rapid availability of a product of benefit to the health of the people of the United States.

Points for Special Consideration *(back to top)*

The NIH has identified several situations, outlined below, in which Recipients should exercise heightened sensitivity and scrutiny in the development of Sponsored Research Agreements.

First, Recipients should apply heightened scrutiny to their Sponsored Research Agreements when one or more of the following threshold criteria are present:

- The amount of financial support from the sponsor meets or exceeds $5 million in any one year, or, $50 million total over the total period of funding under the agreement;

- The proportion of funding by the sponsor exceeds 20 percent of the Recipient's total research funding;

- The sponsor's prospective licensing rights cover all technologies developed by a major group or component of the Recipient organization, such as a large laboratory, department or center, or the technologies in question represent a substantial proportion of the anticipated intellectual output of the Recipient's research staff; or

- The duration of the proposed agreement is for more than 5 years.

If one or more of these criteria are present, it is more likely that the proposed Sponsored Research Agreement will adversely affect open commercial access, especially for small businesses, to a Recipient's federally funded research activities and may delay or impede the rapid development and commercialization of the technology.

Second, Recipients should be concerned if the scope of the Sponsored Research Agreement is so broad that the subsequent exclusive licensing of technology under the agreement provides a single sponsor with access to a wide array of Recipient research findings and technologies as this may effectively exclude other organizations from reasonable access to a Recipient's technology. This type of arrangement can also delay commercialization if the sponsor does not have the interest or the capability to develop the technology.

Third, if the sponsor's contribution of funds is to support a Recipient's general operations rather than specifically defined research projects, the Recipient should consider the amount of the sponsor's general funding in relation to funds from other sources when determining what prospective intellectual property rights the sponsor will obtain from the results of the Recipient research. There should be a reasonable relationship between the amount of money contributed by the sponsor and the rights that it is granted both to review and license resulting technology or inventions. Additionally, Recipients should also consider the level of risk that the sponsor will be assuming in order to obtain rights. In general, the greater the

restrictions on a sponsor's rights, the higher the sponsor's risk in receiving benefit from its support. As an extreme example, a sponsor should not be able to provide 5 percent of the Recipient's total support, review 100 percent of the Recipient's inventions, and receive rights or a first option to 50 percent of the research results generated by the Recipient. Where general funding is involved, a Recipient may consider a number of alternative actions, including establishing some mechanism to limit the review and licensing rights of the sponsor to a particular segment or percentage of the inventions for a set period of time. Since, by its nature, general funding is less directed and its results more imprecise, Recipients should carefully monitor the impact on open competition and fair access by small business of the sponsor's licensing practices for technology supported by general funding.

Fourth, Recipients should avoid any other unusual practice or stipulation that might generate public concern or undermine rather than serve the public interest.

Other Points for Consideration by Nonprofit Recipients *(back to top)*

The following points are to aid nonprofit Recipients in administering the Act and in complying with the requirements of NIH funding agreements.

First, Recipients must ensure that the rights to inventions resulting from Federal funding are not assigned without NIH approval. An exception to this is when the assignment is made to an organization that has as one of its primary functions the management of inventions, in which case, the assignee will be subject to the same provisions as the Recipient.

Second, Recipients must share royalties collected on NIH supported inventions with the inventors under the statutory formula and the balance of any royalties or income earned, after payment of expenses, including payment to inventors and incidental expenses to the administration of subject inventions, must be used for the support of scientific research or education.

Third, Recipients must employ reasonable efforts to attract licensees of subject inventions that are small business firms. Further, Recipients must provide a preference to small business firms when licensing a subject invention if Recipients determine that small business firms have plans or proposals for marketing the invention that, if executed, are equally as likely to bring the invention to practical application as any plans or proposals from applicants that are not small business firms. However, Recipients must be satisfied that the small business firms have the capability and resources to carry out plans or proposals. The decision whether to give a preference in any specific case is at the discretion of the Recipient. However, since Sponsored Research Agreements typically provide exclusive licenses or options to such rights to the sponsor, Recipients should seriously consider and provide for these issues when negotiating such agreements.

RESEARCH TOOLS *(back to top)*

The use of patents and exclusive licenses is not the only, nor in some cases the most appropriate, means of implementing the Act. Where the subject invention is useful primarily as a research tool, inappropriate licensing practices are likely to thwart rather than promote utilization, commercialization and public availability of the invention. NIH has offered principles and guidelines for implementing the Act with regard to research tools:

In determining an intellectual property strategy for an NIH-funded invention useful primarily as a research tool, Recipients should analyze whether further research, development and private investment are needed to realize this primary usefulness. If it is not, the goals of the Act can be met through publication, deposit in an appropriate data bank or repository, widespread non-exclusive licensing or any other number of dissemination techniques. Restrictive licensing of such an invention, such as to a for-profit sponsor for exclusive internal use, is antithetical to the goals of the Bayh-Dole Act.

Where private sector involvement is desirable to assist with maintenance, reproduction, and/or distribution of the tool, or because further research and development are needed to realize the invention's usefulness as a research tool, licenses should be crafted to fit the circumstances, with the goal of ensuring widespread and appropriate distribution of the final tool product. Exclusive licensing of such an invention, such as to a distributor that will sell the tool or to a company that will invest in the development of a tool from the nascent invention, can be consistent with the goals of the Bayh-Dole Act.

For further information on Principles and Guidelines for sharing NIH-funded biomedical research resources, See the Federal Register, Vol. 64, no. 246, December 23, 1999