

Don't Forget the Bayh-Dole Act If Your Research Is Federally Funded

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The *Bayh-Dole Act*, signed into law in 1980, is U.S. legislation directed to inventions arising from research funded by the Federal government. (See 35 U.S.C. § 200-212, and 37 C.F.R. §§ 401 and 404.) The Act encourages commercialization of inventions arising from research by individuals, universities, nonprofit institutions, and businesses of all sizes that is funded by Federal agencies such as the NIH, FDA, SBA, and the Department of Agriculture. The purpose of the Act was to spur the interaction between public and private research so the public would receive the benefits of innovative science sooner.

Some of the Bayh-Dole Act requirements relating to the preparation of patent applications describing and claiming such federally-funded inventions include:

- Employees of the grantee must disclose each invention promptly in writing.
- The grantee must disclose the invention to the Federal agency within two months.
- The grantee must elect whether to retain ownership of the invention or relinquish ownership to the Federal agency (the election can be made at the time of disclosure to the Federal agency).
- The grantee must file an initial patent application (provisional, utility, or PCT) within one year after election to retain ownership of the invention (or prior to expiration of any statutory bar).
- The grantee must execute and promptly deliver all instruments necessary to establish/confirm the government's rights in the invention.
- If the initial patent application is a provisional, it must be converted to a U.S. utility, PCT, and/or foreign national application within 10 months (but grantee may request a two-month extension).
- Patent applications must include a statement that the invention was made with federal funding and the government has certain rights in the invention.
- The grantee must notify the Federal agency of any decision not to continue prosecution of a patent application. (The Federal agency may take over prosecution of the application, but title to the invention does not transfer automatically to the government.)
- The grantee must agree that any products produced through the use of the invention by grantee or any exclusive licensee will be manufactured substantially in the U.S.

Noteworthy is the fact that ownership of inventions resulting from federally-funded research may only be granted by the funding agency to the grantee by abiding by the terms of the Act.



Some terms of the Act have changed since its inception. For example, the conversion requirement for provisional applications was changed from 12 to 10 months as of May 14, 2018. Requests for a two-month extension are said to be automatically granted. If the conversion application is not filed before the 10-month deadline, and the grantee did not request an extension, the Federal agency may request conveyance of title to the application or invention. However, if the Federal agency does not request conveyance of title before the grantee files a late conversion application (US, PCT, or foreign), the grantee may still retain title.

It is also important to note that the Act established "march-in rights" for Federal agencies to federally-funded inventions and patents under certain circumstances, e.g., where:

- (1) the invention is being made outside the U.S.
- (2) the grantee fails to make the invention available to the public on reasonable terms
- (3) the grantee fails to adequately satisfy the health or safety needs for the invention.

These march-in rights enable the Federal agency to require the grantee to license the patent or invention to a third party on terms that are reasonable under the circumstances and, if the grantee refuses, to grant such a license itself.

In a recent example, on August 4, 2020, 34 state attorneys general requested that the Federal government exercise its march-in rights under the Bayh-Dole Act to force Gilead Sciences, Inc., to lower the price and increase the availability of the drug Remdesivir, because it is the only FDA-approved drug for treating COVID-19.

Clearly, ignoring the Bayh-Dole Act's requirements may come at a steep price, and possibly lead to the loss of rights to an invention made with federal funding. Thus, smart grant recipients (and their patent attorneys) will keep close track of these requirements in order to retain ownership of the fruits of their labor.

For more information, please contact Shann Kerner, William Scofield, or your regular Lathrop GPM contact.