

Federally Funded Inventions and Compliance with the Bayh-Dole Act

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Organizations that receive federal funds or that license technology from third parties that receive Federal funds need to be aware of Federal funding obligations under the Bayh-Dole Act. Any invention conceived *or* reduced to practice with the assistance of the Federal funding is subject to the Bayh-Dole Act. Bayh-Dole permits businesses and nonprofit organizations to elect to retain title of such inventions, if certain obligations are met. However, the government retains certain rights to the invention. To allow for a uniform patent policy among the funding agencies, specific obligations of the parties are set out in the Bayh-Dole Act and Federal agencies are required to use standard funding agreement clauses setting out such obligations. 37 C.F.R. §401.14(a). Furthermore, businesses and nonprofits that receive funding under a Federal government agreement (*e.g.*, contract, cooperative agreement, or grant) executed after May 14, 2018, are subject to the updated regulatory provisions of the Bayh-Dole Act. Certain Federal agencies, *e.g.*, NIH, have given notice that grant renewals will also be subject to the updated provisions (*see, e.g.*, NIH's ["Notice Regarding 2018 Bayh-Dole Act Final Rule - Rights to Federally Funded Inventions and Licensing of Government Owned Inventions"](#)).

The government established an electronic system ([iEdison](#)) for grantees and contractors to report inventions arising out of federal funding and to comply with other on-going reporting obligations, as required by the Bayh-Dole Act. Certain key obligations owed to the funding agency include:

- **Disclosure of the invention** to the funding agency within **two (2) months** after an inventor discloses it in writing to the contractor.
- **Election to retain title of the invention** (in writing) within **two (2) years** after disclosing the invention to the agency or within **60 days** prior to the end of any one year statutory period (*e.g.*, publication, on sale bar, public use, etc.), whichever is sooner.
- **Filing an initial patent application** on the invention within **one (1) year** of election of title or prior to the end of any statutory period, and filing in additional countries or international patent offices within **10 months** of filing the initial application.
- Extensions of time for disclosure, election, and filing may be granted *at the discretion of the agency*.

Disclosure

First, compliance with Bayh-Dole starts prior to the filing of a patent application. The standard funding agreement obligates a businesses or nonprofit organization (referred to in Bayh-Dole as a "contractor") to disclose each invention developed using government funds to the funding agency within **two months** after an inventor discloses it *in writing* to the contractor personnel responsible for patent matters. 37 C.F.R. § 401.14(c)(1). This allows the funding agency time to determine whether it has an interest in taking title to the invention if certain "exceptional circumstances" or other conditions apply.

- Disclosure is through iEdison and includes submission of a written description of the invention, *i.e.*, an "Invention Disclosure Document."
- iEdison submission includes reporting an "Invention Report Date," which is defined as "the date that the inventor discloses the subject invention in writing to the recipient institution."
- A disclosure report also includes the following: the applicable grant number(s), the inventor(s), and any publication, on sale or public use of the invention.
- If a manuscript describing the invention was submitted for publication and/or accepted for publication, it must also be reported. After disclosure, the contractor must also notify the agency of the acceptance of any manuscript describing the invention for publication or any on sale or public use planned by the recipient.

Election

Second, a contractor must also elect *in writing* to retain title to an invention within **two years** of disclosing the invention

to the agency or no more than 60 days prior to the end of any one year statutory period for excluding certain types of prior art. 37 C.F.R. § 401.14(c)(2). For example, if an action (*e.g.*, publication, on sale bar, public use, etc.) by an inventor has started a one year clock to file a patent application in the U.S., the agency may shorten the time period for election to be no more than 60 days prior to the end of the one year “grace period.”

- The “Title Election Date” entered into iEdison is the legally binding date that the contractor elected to retain title to an invention.
- The Title Election Date starts the one-year period during which the initial patent application must be filed, if a one year extension has not been requested.
- iEdison provides an option to request a one year extension of time to file the initial patent application.

Filing

Third, a contractor is obligated to file an initial patent application on the invention within **one year** of election of title or prior to the end of any statutory period, whichever comes first. U.S. 37 C.F.R. § 401.14(c)(3). Under the updated regulations, if the initial patent application is a provisional application, a non-provisional application must be filed within 10 months of filing the provisional application. The regulations also state that a request to extend the 10 months for filing a non-provisional application will automatically be granted for one year, unless the agency notifies the contractor to the contrary within 60 days of the request. 37 C.F.R. § 401.14(c)(5). In addition, the contractor must file patent applications in additional countries or international patent offices within either 10 months of the initial patent application or 6 months from the date the USPTO allows the invention to be filed if there was a Secrecy Order in place. However, the contractor will still retain title in a non-U.S. country even if an application was filed after the specified time as long as a written request (to take title) from the agency was not received prior to filing in that country. 37 C.F.R. § 401.14(d)(2). Furthermore, the updated regulations specify that if a government employee co-invents with a contractor, the agency may submit an initial patent application, but must consult with the contractor and the contractor retains the right to elect title under 35 U.S.C. 202(a). 37 C.F.R. § 401.14(c)(4).

- The patent application(s) must include a statement reciting the following: “This invention was made with government support under [*identify the contract*] awarded by [*identify the Federal agency*]. The government has certain rights in the invention.”
- Contractors must notify the Federal agency of any decisions not to continue the prosecution of a patent application, pay maintenance fees, or defend in a reexamination or opposition proceeding on a patent, in any country, not less than **sixty days** before the expiration of the response period required by the relevant patent office. 37 C.F.R. § 401.14(f)(3). The updated regulation increased the notification time from 30 days to 60 days, reducing the decision-making time for the contractor to decide whether to proceed with prosecution or maintain a patent.
- If a contractor elects not to continue the prosecution of any *non-provisional* application, the government can obtain title upon request. 37 C.F.R. § 401.14(d)(3).

Other Obligations

- Contractors are also required to have clauses in employee agreements that provide for timely notification of new inventions to the employer/contractor, and an obligation of assignment of new inventions to the employer/contractor. 37 C.F.R. § 401.14(f)(2).
- Contractors must provide the government with a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced the invention. 37 C.F.R. §401.14(b). The license should be recorded with the USPTO Assignment Branch.
- Contractors must submit periodic reports as requested (no more than annually) on the utilization of the invention or on efforts at obtaining such utilization.
- Contractor nor any assignee can grant to any person the exclusive right to use or sell any subject inventions in the U.S. unless such person agrees that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the U.S.
 - ◊ Subject to any waiver granted by the Federal agency upon a showing 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.

Failure to Comply

Businesses and non-profits should consider the on-going obligations associated with accepting government funds or licensing technology created using government funds. If federal funds are used, the recipient must exercise diligence in meeting the timelines under the Bayh-Dole regulations and abide by the terms of each funding agreement to reduce the risk of the government having a right to take title. If the government takes title, it takes all rights. The contractor will not even retain the right to practice the invention. Failure to meet the requirements of the funding agreement can cause a recipient to lose its patent rights even absent any particularized harm to either the funding agency or the public. See *Campbell Plastics v. Brownlee*, 389 F.3d 1243 (Fed. Cir. 2004). Thus, all businesses and non-profits engaging in funding agreements should review the Bayh-Dole regulations and timely comply with all obligations. Licensees or purchasers of IP should make sure that the licensor or assignor of government funded IP complied with the appropriate regulations.

Of particular note, the 2018 update to Bayh Dole eliminated the previous sixty day objection period that allowed a fund recipient to retroactively correct defects in complying with disclosure and election of title obligations. Prior to this update, if a contractor failed to meet these disclosure or election obligations within the required time periods, the government had sixty days after discovery of the failure to object and request title. This allowed a contractor the opportunity to correct such a defect and if the government did not object within sixty days, the defect was cured. However, under the revised regulations, there is no longer an objection period. 37 C.F.R. § 404.14(d)(1). Instead, the government can object at any time and obtain title, presumably, even if an effort to correct the mistake was made. Thus, anyone receiving federal funding must timely notify the agency of any invention developed using the funding and timely elect to retain title to avoid a potential cloud over the invention title.

- If the funding agreement is dated after May 14, 2018 (or the renewed funding agreement was amended to incorporate the updated regulations), failure to timely meet the disclosure and election obligations may not be curable.
- If the funding agreement is dated before May 14, 2018 (and was not renewed under the updated rules), it may still be possible to remedy defects in complying with disclosure and election obligations under the old version of the regulations assuming correction is made and the government does not object within 60 days.
- An extension of time for meeting the disclosure obligation may be granted *at the discretion of the agency*. 37 C.F.R. § 401.14(c)(5). It is unclear whether retroactive extensions will be granted.

Practice Tips

- If your organization accepts or is contemplating accepting government funds, employment agreements should be reviewed to ensure the agreements require the employee to provide timely notification of new inventions to the employer, and an obligation of assignment, or a vesting of title, for new inventions to the employer/contractor.
- Invention disclosures and patent department workflow should be updated to allow for flagging inventions conceived or reduced to practice using government funds, and to provide time for reporting inventions to the funding agency.
- At the time of giving election notice to the agency, consider submitting a written request to extend the one year deadline to file the initial application. Requests can be made through iEdison.
- At the time of notifying the agency of a provisional application filing, consider submitting a written request to extend the 10 month non-provisional and foreign filing obligation. Requests can be made through iEdison.
- During due diligence, be sure to check that the potential assignee or licensor of government funded IP complied with all Bayh-Dole obligations.
- If any deadlines are missed, efforts to correct and request any available extensions should be made as soon as possible.
- [iEdison](#) provides useful information and tips including Q&A. Furthermore, specific questions and requests, *e.g.*, for disclosure extensions, can be emailed to edison@od.nih.gov.