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Updated Bayh-Dole Regulations Increase Certain Risks of Losing Title to Federally Funded Inventions

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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 that implement the Bayh-Dole Act. The revised obligations under Bayh-Dole should be reviewed by anyone who has accepted or is considering accepting government funding. Of particular note, the update to 37 C.F.R. §401.14(d)(1) eliminates the previous sixty day objection period that allowed a fund recipient to retroactively correct defects in complying with disclosure and election of title obligations. Other key updates to the regulations relate to obligations to file new patent applications, to include a notice clause in employee agreements, and to give notice of a decision to abandon an application.

The Bayh-Dole Act permits businesses and nonprofit organizations that conceive or reduce to practice inventions with the assistance of federal funding to elect to retain title of such inventions, if certain obligations are met. To allow for a uniform patent policy among the funding agencies, specific obligations of the parties are set out in Bayh-Dole and the agencies are required to use standard funding agreement clauses. 37 C.F.R. §401.14(a).

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 are met.

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).

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.

A contractor is also 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 in the U.S. 37 C.F.R. § 401.14(c)(3). The updated regulations now specify that if the initial patent application is a provisional application, a non-provisional application must be filed within 10 months of filing the provisional application. *Id.* As revised, 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). The timing of the existing obligation to file in additional countries or international patent offices within 10 months is unchanged, and the contractor will still retain title in that country even if an application was filed after the specified time as long as a written request 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 updated Bayh-Dole regulations also require contractors to 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). This change increases 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). This section was revised to specifically apply only to non-provisional applications, not provisional applications.

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).

Businesses and non-profits should consider the on-going obligations associated with accepting 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 changes to 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 new regulations.

[1] The final rules were issued on April 13, 2018, amending 37 C.F.R. part 401. See 83 Fed. Reg. 15954-15963. The new rule may be applied prospectively to existing funding agreements that are so amended at the agency's discretion.

[2] Bayh-Dole as enacted in 1980 applied to small businesses and non-profits, but Executive Order 12591, issued in 1987, extended the Bayh-Dole Act to large businesses. Revised 37 C.F.R. § 401.1(b) confirms that the regulations apply to all recipients of federal funding regardless of size.

[3] Notably, the contractor must provide the government with a nonexclusive license to use the invention even if the government does not take title.

[4] Under 37 C.F.R. § 401.14(c)(5), requests for extension of time to meet disclosure, election of title, and filing obligations may, at the discretion of the agency, be granted.

[5] As a practice tip, consider submitting the written request to extend to one year along with the notification that a provisional application is (to be) filed.

[6] The application in additional countries or international patent offices can alternatively be filed within six months from the date permission is granted by the US Patent Office to file foreign patent applications where such filing has been prohibited by a Secrecy Order.

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