

NIH Revises Rules Governing Inventions Developed Under Bayh-Dole Act



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The National Institutes of Health (NIH) recently issued its revised Grant Policy Statement (GPS), which implements significant changes to the Bayh-Dole rules governing inventions developed under NIH-funded grants and cooperative agreements, as well as changes to other GPS requirements. The changes took effect on October 1, 2018.

Companies, universities, hospitals and nonprofit entities that receive NIH funding under grants or cooperative agreements should pay particular attention to the ownership and licensing rights associated with intellectual property — especially patentable inventions developed under these agreements. The revised GPS imposes new requirements and modifies certain duties and reporting timelines for disclosing inventions, electing title to

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inventions, and filing patent applications. Failure to satisfy each of these requirements could result in forfeiture of the funding recipient's ownership and licensing rights. Now is a good time for NIH funding recipients to examine the changed requirements, assess the impact that those changes may have on their operations, and revise their compliance policies and procedures, as necessary.

For grants and cooperative agreements awarded before October 1, 2018, the earlier version of the NIH GPS still governs those agreements. However, new and continuation awards made on or after that date will be subject to revised GPS. Below we summarize some of the most important provisions and changes in the revised GPS.

Disclosure of Subject Invention — Two Months. A recipient of NIH funding is required to formally disclose each subject invention developed under the grant or cooperative agreement within two months of the inventor's disclosure of the invention to the recipient official responsible for patent matters. This reporting requirement remains unchanged as to timing. NIH now requires that **all** subject invention disclosures must be made using the government web portal, iEdison. Paper disclosures are no longer permitted. The funding recipient should retain electronic copies of all invention disclosures.

Initial Patent Application. The "initial patent application" has been redefined to mean the first provisional or nonprovisional patent application filed in the United States or the first international application filed under the Patent Cooperation Treaty, which designates the United States or the first application for a Plant Variety Protection certificate. 37 CFR 401.2(n).

Ten Months to File Nonprovisional Application. If the initial patent application for a subject invention is a provisional application, NIH has shortened the period of time for filing a nonprovisional application from 12 months to 10 months after filing the provisional application. Even though the patent statute allows up to one year to file a nonprovisional application, for NIH purposes, the agency has truncated that statutory period. Accordingly, a recipient's patent counsel must be made aware that a provisional application is directed to an invention that was funded in whole or in part by an NIH grant or cooperative agreement and is therefore subject to the shortened time period for filing the nonprovisional application.

Election to Retain Title to Subject Inventions — Two Years or Less. The NIH funding recipient still has two years following timely disclosure of a subject invention in which to file the required notice of its election to retain title to the subject invention. This election period may be shortened under several circumstances, including if the subject invention has been used publicly, sold or offered for sale in commerce, disclosed in a publication or publicly displayed, or any other event that would trigger the *one-year statutory period wherein valid patent protection can still be obtained*. In that case, the period for filing the election notice may be shortened by the agency to a date that is not more than 60 days before the end of the statutory period. Again, recipients should fully inform patent counsel and compliance personnel of all activities that could shorten the period for filing the election notice with the agency and timely filing the initial patent application.

Funding Attribution in U.S. Patent Applications. When claiming a subject invention in a patent application, the recipient is required to include a funding attribution statement in each application that informs the world that U.S. government funding supported development of the claimed invention. The required attribution is: “This invention was made with government support under [identify contract no.] awarded by [identify agency]. The government has certain rights in the invention.” It is important that the recipient inform patent counsel that the claimed subject invention was funded, in whole or in part, with government support.

Notification of Initial Patent Application. Within one year after filing the notice of title election, or before expiration of the statutory period for obtaining valid patent protection in the United States, the recipient must inform NIH of the date of filing the initial patent application, the application number and the title of the patent application. This information must also be provided for all subsequently filed patent applications. The deadline for submitting this information may be extended by NIH upon request.

Extensions of Time for Disclosure of Subject Invention, Election of Title Notification, and Notification of Initial Patent Application. So long as the applicable period of time has not lapsed, the recipient may request in writing an extension of time for disclosure of a subject invention, a notice of title election, or a notification of an initial patent application. This is important. Unless a request for extension is received before the applicable filing period has expired (two months for subject invention disclosure, two years or less for title election notification, and one year or less for notification of an initial patent application), NIH will not grant an extension. A late request for an extension will not be considered.

Forfeiture of Right to Own Subject Invention. It is a common misperception among recipients that, at the time of award, they will be the legal owner of any subject inventions. That is simply wrong. Under the NIH GPS, recipients have a right to retain ownership — but that right can only be perfected if the recipient timely complies with the requirements to disclose the subject invention to the agency, timely files its notice of election to retain title to the subject invention, and timely files a patent application. Overlooking any one of these requirements results in forfeiture of the recipient's ownership rights, and NIH then has the right to retain ownership of the subject invention.

Government Election to Own or Forgo Ownership of Subject Invention Forfeited by Contractor. Once NIH first learns of the subject invention and the recipient's failure to timely disclose the subject invention or timely file a notice of election to retain title, NIH may, at any time thereafter, elect to retain title or forgo ownership of the subject invention. Previously, NIH had to act on its rights within 60 days — after which, if it did not inform the recipient of its decision, title to the subject invention would revert back to the recipient. That provision has been deleted in the revised GPS. If the recipient has failed to comply, NIH now has an indefinite period of time in which to decide whether it wants to own the subject invention or not. If the subject invention happens to be a blockbuster new therapy, vaccine or device, the forfeiture of the recipient's ownership rights could prove to be quite costly to the recipient. And, if that is not bad enough, the failure to timely disclose a subject invention or elect to retain title will also result in the loss of any right to receive a license to the invention if the government decides to retain title to that invention. The recipient could find itself without any legal remedy and, more importantly, no legal entitlement to participate in the marketplace.

iEdison Is Mandatory. This government-wide portal is now the only mechanism permitted by NIH for filing the disclosure of a subject invention, notice of election to retain title, close-out reports and all other compliance documents. As of October 1, 2018, recipients "must" use the portal for all filings for all grants and cooperative agreements awarded or continued on or after that date.

Training Requirement. Recognizing that NIH's compliance requirements associated with inventions and patents are complicated, NIH requires recipients to conduct appropriate training to mitigate the risk that their employees may unintentionally overlook one or more reporting requirements and, in so doing, compromise the recipient's ownership and licensing rights in subject inventions. Recipients should actively engage and educate to ensure an adequate understanding of, and compliance with, these requirements.

There are many other changes embodied in the revised GPS, and recipients should undertake appropriate due diligence to review the new requirements; assess the impact the new rules will have on their rights, remedies, duties and obligations under NIH grants and cooperative agreements; and modify, as necessary, their policies and procedures to insure that they are fully compliant with the updated GPS.

If you have any questions on your possible compliance burden, please contact Hilary S. Cairnie, N. Nicole Stakleff, or a member of Pepper Hamilton's Government Contracts Practice Group or Intellectual Property Department.