

Bayh-Dole Compliance for Tech Transfer: Q&A Part One

With the recent regulation changes in Bayh-Dole compliance quite a few questions have been brought to us by clients as we work with them to assure that they remain compliant with disclosures, both pre and post May 14, 2018. What became apparent at the AUTM Compliance Course in October, where I led a presentation alongside NIH and other agencies, is that the manner in which agencies want institutions to comply is far from uniform. This presents a challenge for institutions and in response I've been asked to dedicate the next few articles on Tech Transfer Compliance Central to questions that have come up from you. Here we go...

1) If you report an invention after the 60-day deadline, can the Government take title?

Yes. The Government can come in at any time and take title if compliance is not completed. Most agencies request that you report invention disclosures within 60 days of receipt or as soon as you become aware of federal funding thereafter. It is critical to elect title upon filing of the first U.S. filing (which is considered to be the provisional filing as of May 14, 2018). Agencies review applications and patents with federal support clauses to make sure that they are in Edison. When they are not, that increases the likelihood that the Government will attempt to take title. It is important to use best efforts to report inventions prior to the deadline. However, it is always better to report late than not at all.

2) What happens if you are late in submitting utilization reports? Can the Government take title?

Yes, this is possible. The Government wants to know about licensing and commercialization of federally funded inventions. In many instances, the majority of overdue notifications in Edison pertain to utilization reports, which are due annually. In recent years, NIH has targeted institutions with a large number of outstanding notifications. The notification includes a deadline for remediating all notifications, with a warning of loss of funding if the compliance is not completed.

3) If disclosure is rejected for lack of description, does that delay the 60 day reporting requirement?

Yes. Frequently it takes time to gather the appropriate disclosure documents. If this is the case, it is best to elect title if you have filed, enter the patent filings, and complete all other compliance while you work on clearing the disclosure rejection. This will reduce the likelihood of the Government asserting title.

If you have not filed a patent application and you need to waive the invention, it cannot be waived until the disclosure is accepted.

If there is still confusion around this group of questions or you have additional questions that I can help with, drop me a line at [Borman & Company](#). We'll be happy to respond to you directly and share the topic in an upcoming Q&A blog post.