

IP FRONTIERS

Patent rights issues regarding the 2018 Changes to the Bayh-Dole Act

Any person or organization that has accepted government funds for research and development has been touched by the Bayh-Dole Act.

Bayh-Dole addresses the rights to inventions made in the performance of federally funded agreements and is implemented by title 37 of the Code of Federal Regulations parts 401 and 404 (37 CFR § 401 and 404). Last year, the National Institute of Standards and Technology ("NIST") made significant changes to the Act, which contractors must follow or risk losing their rights to inventions they develop under a federal R&D contract.

For example, one of the most significant changes is that a provisional application must now be converted to a non-provisional application within 10 months of its filing date or the government can claim title to the invention. This article will provide a summary of the revisions to part 401 of the Bayh-Dole Act and detail some of the issues related to these changes.

Summary of 2018 Changes to the Act

The following is a summary of the 2018 changes to 37 CFR § 401, which were published as a final rule in the April 13, 2018 Federal Register. More information is available at: <https://www.federalregister.gov/documents/2018/04/13/2018-07532/rights-to-federally-funded-inventions-and-licensing-of-government-owned-inventions> (the published April Federal Register) and <https://www.nist.gov/tpo/bayh-dole/bayh-dole-regulations-faqs> (published FAQs).



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Daily Record
Columnist

include provisional applications and Patent Cooperation Treaty ("PCT") applications. More specifically, an initial patent application means, as to a given subject invention, the first provisional or non-provisional U.S. application, the first PCT application which designates the U.S., or the first application for a Plant Variety Protection certificate. 37 CFR§ 401.2(n)

• The term "statutory period" has been defined to mean the one-year period before the effective filing date of a claimed invention to be consistent with the Leahy-Smith America Invents Act ("AIA"). 37 CFR§ 401.2(o)

• A federal agency employing a co-inventor in a subject invention may submit an initial patent application, provided that the federal agency first consults with the contractor of the federally funded agreement, and the contractor retains the right to elect to retain title to the invention. 37 CFR§401.10(a)(2)

• If the initial patent application on a subject invention is a U.S. provisional patent application, a contractor must file a U.S. non-provisional application, PCT applica-

tion and/or non-PCT foreign application within 10 months of the filing of the U.S. provisional application. Additionally, if the initial patent application is a U.S. non-provisional application, a contractor must file a PCT and/or a non-PCT foreign application within 10 months of the filing date of the U.S. non-provisional application. 37 CFR§ 401.14(c)(3)

• The term "initial patent application" has been redefined to include provisional applications and Patent Cooperation Treaty ("PCT") applications.

More specifically, an initial patent application means, as to a given subject invention, the first provisional or non-provisional U.S. application, the first PCT application which designates the U.S., or the first application for a Plant Variety Protection certificate. 37 CFR§ 401.2(n)

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tion and/or non-PCT foreign application within 10 months of the filing of the U.S. provisional application. Additionally, if the initial patent application is a U.S. non-provisional application, a contractor must file a PCT and/or a non-PCT foreign application within 10 months of the filing date of the U.S. non-provisional application. 37 CFR§ 401.14(c)(3)

• When a contractor has requested an extension for filing a non-provisional application after filing a U.S. provisional application, a one-year extension will automatically be granted without the need to provide additional information unless the federal agency notifies the contractor within 60 days of receiving the request. 37 CFR§ 401.14(c)(5)

• The 60-day window for a federal agency to request title after it learns of the failure of the contractor to disclose or elect title to a subject invention within the times specified in 37 CFR 401.14 (c) has been eliminated. 37 CFR§ 401.14(d)(1)

• The government may obtain title to any non-provisional application in which the contractor decides not to continue prosecution. 37 CFR§ 401.14(d)(3)

• A contractor is now required, by written agreement, to obtain an assignment from its researchers of the entire right, title and interest in and to each subject invention made under a federally funded agreement and to execute all papers necessary to file patent applications and establish the government's rights in an invention. 37 CFR§401.14(f)(2)

• A contractor now has 60 days (previously 30 days) to notify the federal agency of any decisions not to continue to prosecute a

non-provisional patent application. 37 CFR§ 401.14(f)(3)

- Disclosures, election of title, close-out reports, and all compliance documents now “must” be electronically filed in iEdison. 37 CFR§401.16(a), (b), & (c)

Issues Related to 2018 Changes to the Act

The effective date is in conflict among the federal agencies. NIST is the official regulating agency of the rules governing the Bayh-Dole Act and has published (in the April 2018 Federal Register) the effective date to be May 14, 2018. However, other federal agencies have published different effective dates for these same rules in direct conflict with NIST. For example, the National Institutes of Health (“NIH”) has published its effective date for these rules to be October 1, 2018 (see NIH Notice No.: NOT-OD-18-233 at: <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-233.html>).

When asked why NIH published a different effective date than NIST’s, NIH responded that it needed a reasonable time to amend its own regulations to conform to the rule changes and, therefore, set its effective date to coincide with the beginning of its 2018 fiscal year, which was October 1.

However, when asked to point out the legal authority that allowed other agencies to set different effective dates for implementation of the rules, NIST legal department’s response was: “We are unaware of any other authority that would delay implementation at an agency. From NIST’s perspective as the regulating agency, the rule was effective as of the effective date in the Federal Register.”

As of the writing of this article, this apparent conflict between the NIST and NIH effective dates (or any other effective date set by any other agency) has not been resolved. Accordingly, it is imperative that contractors of any federally funded agreement check

with their issuing agency to verify the effective date published by that agency and compare it to the NIST effective date. Contractors should treat the earlier of the two dates as the effective date in order to avoid any legal risks.

Provisional applications must be converted to non-provisional applications within 10 months. One of the most significant changes to Bayh-Dole is that an initial U.S. provisional application must be converted to a non-provisional within 10 months of filing the provisional. Additionally, an initial U.S. non-provisional application must be converted to a PCT or foreign application within 10 months of filing the U.S. non-provisional.

The reasoning behind this change was to give the government a reasonable time period to take title to a provisional or non-provisional application if the contractor decides not to pursue the subject invention any further. However, during the comment period, the government received several comments pointing out that the proposed rule change would eliminate valid strategic options not to convert a provisional application, without abandoning the subject invention itself.

In response to those comments, NIST revised the regulations dealing with extensions of time to grant upon request an automatic one-year extension of time to convert a provisional to a non-provisional application, unless the agency objects in writing within 60 days of the request. Additionally, NIST revised the regulations dealing with notification requirements to make it clear that a strategic decision to abandon a provisional application is not required to be reported to the government.

Accordingly, a contractor must take care to convert a provisional application to a non-provisional application within 10 months of its filing date or to obtain an extension of time to do so, in order to avoid the risk of losing title in the subject invention to

the government. Alternatively, if a contractor does not convert but obtains an extension of time, the contractor may later decide to abandon the provisional application without consequence, even if the contractor does not communicate the decision to the government. However, if the contractor does not convert and does not obtain an extension of time, then the contractor may be liable to the government for breach of contract if he decides to abandon the provisional application.

Requirements to report any decision not to prosecute applies to office actions. A contractor now has 60 days (previously 30) to notify the government of any decision not to prosecute a non-provisional patent application. The scope of this rule also extends to any decision not to prosecute any office action. Therefore, under the revised regulations, contractors must now take care to report a decision not to respond to an office action within 60 days of its final deadline date (generally about four months from the mailing date of the office action) or risk losing title to the subject invention.

In Conclusion

The 2018 changes to the Bayh-Dole Act are relatively complex and, in some cases, have unresolved issues. Contractors should work closely with their patent professionals to make sure they are adhering to the new rules during the performance of any federally funded contract.

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