

Comments of Luis Gil Abinader of Knowledge Ecology International on the redefinition of “Subject Invention” to Narrow the Inventions to Which Government Rights Attach (Modify 37 CFR § 401.14)

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My name is Luis Gil Abinader. I’m a senior researcher at Knowledge Ecology International (KEI). My comments focus on the National Institute of Standards and Technology (NIST) proposal to change the definition of “subject invention.”

Summary of Changes

The public interest safeguards under the Bayh-Dole Act only apply to “subject inventions,” as that term is defined in the statute and implementing regulations. 37 CFR § 401.14 defines “subject invention” as follows.

“(2) Subject invention means any invention of the contractor conceived or first actually reduced to practice in the performance of work under this contract, provided that in the case of a variety of plant, the date of determination (as defined in section 41(d) of the Plant Variety Protection Act, 7 U.S.C. 2401(d)) must also occur during the period of contract performance.”

NIST proposes to modify 37 CFR § 401.14 to add a new sentence stating that “[a]n invention that is conceived and reduced to practice without the use of any federal funds is not considered a subject invention.” This would significantly narrow the current definition of “subject invention”, which merely requires that an invention be made “in the performance of work” under a government contract. Additionally, NIST proposes to eliminate the scope discussion currently available at 37 CFR § 401.1. That section includes several important clarifications about the scope of the regulations, including, among other issues, that “[s]eparate accounting for the two funds used to support the project in this case is not a determining factor” when determining whether an invention is a “subject invention.” NIST proposes to eliminate those clarifications.

Detailed Overview

The current text in 37 CFR § 401.1 on scope is 1077 words set out in nine paragraphs and subparagraphs. The new version will have 277 words.

The **existing** section 401.1(a) includes the following text:

(a) . . . Notwithstanding the right of research organizations to accept supplemental funding from other sources for the purpose of expediting or more comprehensively accomplishing the research objectives of the government sponsored project, it is clear that the ownership provisions of these regulations would remain applicable in any invention “conceived or first actually reduced to practice in performance” of the project.

Separate accounting for the two funds used to support the project in this case is not a determining factor. [emphasis added]

All of the text quoted above in section 401.1(a) is eliminated in the proposed revision of section 401.1. The proposed text for 37 CFR § 401.14 includes the following changes:

“(2) Subject invention means any invention of [delete: “the”] [add: “a”] contractor conceived or first actually reduced to practice in the performance of work under [add: “this contract”] [delete: “a funding agreement”]; provided that in the case of a variety of plant, the date of determination (as defined in section 41(d) of the Plant Variety Protection Act, 7 U.S.C. 2401(d)) must also occur during the period of contract performance. [add: “An invention that is conceived and reduced to practice without the use of any federal funds is not considered a subject invention.”]

Collectively, this is a massive change in the circumstances under which the public obtains rights.

Note that while the current regulation text closely tracks that language in the statute, the proposed regulation would eliminate the public’s rights when there is a claim that non-federal funds were used. In contrast, the current statute only provides that a subject invention is “any invention in the performance of work under a funding contract.”

35 U.S.C. §201. Definitions.

(e) The term “subject invention” means any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement: Provided, That in the case of a variety of plant, the date of determination (as defined in section 41(d) 1 of the Plant Variety Protection Act (7 U.S.C. 2401(d))) must also occur during the period of contract performance.

Impact

The proposed regulation would eliminate the public’s rights in patents “under a funding agreement” when claims are made that the non-federal co-funders’ money was used for the invention, a distinction contrary to the statute and existing regulation.

A significant number of research projects are co-funded with non-federal and federal funds. If the modifications proposed by NIST are adopted, contractors that received federal funds and can claim that a project utilized a combination of federal and non-federal funds would be able to eliminate the government’s rights, by claiming that the funding of the patentable invention was from the co-funder, not the government. This not only changes the current system in a way that works to the disadvantage of the public, it is also creates a system that is costly, difficult to manage, and subject to obvious abuses.

Under the proposed change in the regulation, a contractor would be able to strategically book most of the expenses prone to generate patentable inventions under the non-federal funds; and

most of the expenses unlikely to generate patentable inventions under the federal funds. As a net result many inventions would escape the public safeguards provided in the Bayh-Dole Act.

Even if the contractor actually did fund the inventions with federal resources, the language proposed by NIST would give them the opportunity to argue that only non-federal money was used to conceive and reduce the inventions into practice. Because contractors are typically untransparent about the specific resources that were used to fund each invention, in most cases it will be nearly impossible to prove them wrong. This will pave the way for even greater under-reporting of subject inventions and even less accountability of contractors.

The tendency of contractors to try to circumvent government rights in federally-funded inventions is illustrated by an experience involving Regeneron's contract with the U.S. government to perform research and development on a COVID-19 treatment.

Regeneron was working under a large funding award to perform R&D on a COVID-19 treatment when it conceived an invention related to the treatment. KEI determined that Regeneron did not properly acknowledge this funding in a patented invention (<https://www.keionline.org/34258>). When asked about the issue, Regeneron disagreed with the premise that the invention was a "subject invention" on the grounds that the invention was not conceived using federal funds. This illustrates how a company will claim that the inventions only relied upon private funds, even though the project was co-funded by the federal government. It's also important to note that the government was funding 80 percent of the development costs on this project, and that the Regeneron contract used an exception to the Bayh-Dole Act norms known as Other Transactions Authority to weaken certain public interest provisions in the Bayh-Dole Act.

If the Bayh-Dole regulations are modified to permit what Regeneron did for its COVID contract, contractors will have a strong incentive to behave exactly as Regeneron did, so that they can resist calls for "march-in rights" and other exercises of public rights in publicly-funded inventions.

During a roundtable organized by KEI in January 2021, Fred Reinhart, Senior Advisor for technology transfer at UMass Amherst and a Past President of AUTM, offered his opinions on this particular proposed change. Reinhart acknowledged that "a company could cheat that way," and further suggested that "the other abuse would be reaching in to claim government rights to huge amounts of investment of time and money, over the next five or six years, long after the federal grant is over." [See video of the roundtable: https://www.youtube.com/watch?v=6Wyd_qaQU34&t=1s]

Despite Reinhart's second suggestion, however, there does not seem to be evidence of over-reporting of government rights in inventions; on the contrary, the problem that agencies are facing is under-reporting of government rights in inventions that were funded with federal funds. KEI has worked on numerous cases where we have provided evidence to the NIH of under-reporting of government rights (<https://www.keionline.org/bayh-dole/failure-to-disclose>) requesting the government investigate these failures to disclose, and these instances are probably just a handful of the actual number of cases where this occurs. Narrowing the

definition of “subject invention” and paving the way for contractors to manipulate and game the system with a separate accounting system, would exacerbate the issue of under-reporting of government rights in inventions funded by federal agencies.

The proposed change in the text of the regulation defining subject invention may be the most consequential and impactful measure in the proposed regulations, as it relates to a threshold issue of whether the Bayh-Dole Act’s safeguards apply, and if enacted will predictably be used to aggressively erode the public’s rights in inventions from federally-funded contracts and grants.

For these reasons, I oppose the proposed redefinition of the concept of “subject invention.”

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