

## **Brief Overview: The National Institute of Standards and Technology Proposals**

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The National Institute of Standards and Technologies (NIST) is proposing modifying the regulations that implement the Bayh-Dole Act in ways that would weaken or eliminate the Act's public interest safeguards and enable pharmaceutical companies to charge unreasonable prices for taxpayer-funded inventions without threat of legal repercussion.

The proposals are contrary to the language and objectives of the Bayh-Dole Act and would harm the public interest in the affordability of taxpayer-funded inventions.

For NIST's summary of the proposals, see 86 Fed. Reg. 35 (2021). Following is an overview of five of the proposed changes.

### **1. Eliminate Unreasonable Prices as a Standalone Basis for March-in Rights (Modify 37 C.F.R. § 401.6)**

#### *The Current Public-Interest Safeguard*

The Bayh-Dole Act authorizes the government to "march in" and issue a compulsory license to a federally-funded invention if the contractor fails to achieve "practical application" of the invention. 37 C.F.R. § 401.14(j)(1). "Practical application" is defined as manufacturing, practicing, or operating a subject invention "under such conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or Government regulations available to the public *on reasonable terms*." 37 C.F.R. § 401.2(e)(emphasis added).

Since 2002, drug companies and other patent holders have argued that federal agencies should reject arguments that "to the public on reasonable terms" applies to the prices paid by the public, for example, for a drug.

There is currently a march-in request before the Department of Defense for the cancer drug Xtandi, on the grounds that charging U.S. cancer patients three to five times more for Xtandi than the prices in ANY OTHER COUNTRY is not making Xtandi available to the public "on reasonable terms". See

<https://www.keionline.org/wp-content/uploads/enzalutamide-march-in-royalty-free-Clare-Love-David-Reed-Army-4Feb2019.pdf>.

#### *The NIST Proposal*

NIST proposes adding language stating that march-in authority "shall not be exercised exclusively based on the business decisions of the contractor regarding the pricing of commercial goods and services arising from the practical application of the invention."

### *Why it Matters*

Members of the public will be deprived of the ability to petition agencies to take action when a company charges an exorbitant price for a taxpayer-funded invention, and pharmaceutical companies will feel emboldened to impose even greater price increases.

## **2. Redefine “Subject Invention” to Narrow the Inventions to Which Government Rights Attach (Modify 37 C.F.R. § 401.14)**

### *The Current Public Interest Safeguard*

This issue concerns all public interest safeguards under the Bayh-Dole Act, because the safeguards only apply to “subject inventions,” and the proposed changes would narrow the definition of what constitutes such an invention.

As it currently stands, a “subject invention” is “any invention of the contractor conceived or first actually reduced to practice in the performance of work under [a funding agreement.]” 37 C.F.R. § 401.14(a)(2). “Separate accounting for the two funds used to support the project in this case is not a determining factor” in what constitutes a “subject invention”. 37 C.F.R. § 401.1(a). For a project supported by both public and private funds, it does not matter if public funds do not actually support the development of an invention. As long as a contractor is performing work within the scope of a funding agreement, and conceives or reduces to practice an invention, the invention is a “subject invention” and subject to Bayh-Dole public interest safeguards.

### *The NIST Proposal*

NIST proposes adding a 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.” In addition, NIST proposes deleting the language stating that “[s]eparate accounting for the two funds used to support the project in this case is not a determining factor” when deciding whether an invention is a subject invention.

### *Why it Matters*

Companies prefer to retain full ownership over publicly-funded inventions, without any rights reserved by the government. If the proposals are adopted, businesses will accept public funding for their research but avoid having any resulting invention be classified as “a subject invention” by using separate accounting systems. Furthermore, considering the asymmetry of information between the public and pharmaceutical companies, contractors may falsely claim that an invention was developed exclusively with private money, even if that was not the case, and it will be nearly impossible to prove them wrong. This will pave the way for even more underreporting of subject inventions and even less accountability of contractors.

### **3. Deny Members of the Public Standing to Appeal Government Licenses. (Modify 37 C.F.R. § 404.11)**

#### *The Current Public Interest Safeguard*

Under the current regulations, a person or organization has standing to appeal an agency's decision to grant an exclusive patent license to a federally-owned government, as long as they "may be damaged by" the license. 37 C.F.R. § 404.1.

#### *The NIST Proposal*

NIST proposes modifying 37 C.F.R. § 404.11 so that a person who may be damaged by a license must also demonstrate that they were damaged by the license specifically by losing the "opportunity to promote the commercialization" of the licensed invention.

#### *Why it Matters*

Exclusive licensing of government-owned patents has broad policy implications, including in terms of the price at which the technology would be available in the market. High prices and other potential consequences of exclusive licenses can harm patients, payers and the public in general, all of whom should have the opportunity to comment on and appeal decisions that may damage them. Furthermore, under constitutional law on standing, all that is required to have standing is to demonstrate the possibility of damage.

### **4. Weaken Working Requirements for Government Patent Licenses (Modify 37 C.F.R. § 404.2)**

#### *The Current Public Interest Safeguard*

A company that holds a license to a federally-owned invention is required to achieve practical application of the licensed invention, and the government may terminate an exclusive, partially exclusive, or non-exclusive license if the licensee fails to do so. 35 U.S.C. § 209(d)(3)(A).

#### *The NIST Proposal*

NIST proposes adding text stating that "[i]n negotiating licenses, the Government may consider payments under a licensing agreement as a means for promoting the practical application of a subject invention[.]"

#### *Why it Matters*

Government scientists conceive important inventions, including recently a spike protein technology used in the Pfizer vaccine, and another potential COVID-19 vaccine itself. If this

NIST proposal is successful, agencies would be able to enter into licenses stating that a licensee achieves practical application simply by making license payments to the government, which is already required. This would eliminate the requirement that an invention is actually used and useful to the public in a product or service, as well as the authority to terminate the license if the prices are unreasonable.

## **5. Make the Licensing Process Even Less Transparent (Modify 37 C.F.R. § 404.7)**

### *The Current Public Interest Safeguard*

When an agency intends to grant an exclusive license to a federally-owned invention, the agency must first notify the public of the prospective license, “identifying the invention and the prospective licensee”, and “providing opportunity for filing written objections within at least a 15-day period [.]” 37 C.F.R. § 404.7(a)(1)(I). The agency may not grant the license until it considers all timely objections. *Id.* §(a)(1)(II).

### *The NIST Proposal*

NIST proposes eliminating the requirement that agencies notify the public of the identity of prospective licensees. The words “and the prospective licensee” would be eliminated from 37 C.F.R. § 404.7(a)(1)(I).

### *Why it Matters*

Agencies may not grant exclusive licenses to federally-owned inventions unless, among other requirements, the license will benefit the public. 37 C.F.R. § 404.7(a)(1)(II)(A). An exclusive patent license will not benefit the public if the licensee is unqualified, has no experience commercializing inventions, is a shell company, or is acquiring a monopoly in a specific area. Moreover, the Bayh-Dole Act gives the public a voice in licensing decisions, and the public cannot meaningfully exercise its right to comment without access to basic information related to the legality of proposed licenses. The public will not know if a licensee is qualified without knowing who the licensee is, which is basic information not made confidential by the Bayh-Dole Act. Transparency is a major issue in the NIH’s responses to questions about proposed exclusive licenses, and the NIST proposal would worsen the situation.