Comments of Knowledge Ecology International (KEI) regarding the NIST proposed changes in § 404.2 that would undermine the working requirement for licenses to federally-owned inventions

Docket: NIST-2021-0001-0001: Rights to Federally Funded Inventions and Licensing of Government Owned Inventions
April 5, 2021

Summary:

The proposed modifications to § 404.2 would undermine both the need to protect the public against nonuse and the need to protect the public from unreasonable use of inventions. The proposal would effectively eliminate the working requirements in the Bayh-Dole statutes. KEI opposes the revision.

Commentary:

NIST is proposing to revise § 404.2. The current text is a single sentence.

> § 404.2 Policy and objective.
> It is the policy and objective of this subpart to use the patent system to promote the utilization of inventions arising from federally supported research or development.

The statute, 35 U.S.C. § 200, Policy and Objective, is much longer and more nuanced, and includes words on the need to protect the public from both nonuse and unreasonable use of inventions:

> "to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions. . . "

NIST says the revision to the regulation would:

> "clarify the link between establishing patent license financial terms and the goal of promoting commercial use, by noting that the government may consider licensing payments as a means to ensure commercialization by the licensee and thus promote the practical application of a subject invention."

The specific proposal, as published in the Federal Register notice for comment is as follows:

> Revise § 404.2 to read as follows:
> § 404.2 Policy and objective.
> It is the policy and objective of this subpart to promote the results of federally funded research and development through the patenting and licensing process. In negotiating licenses, the Government may consider payments under a licensing agreement as a means for promoting the practical application of a subject invention and as a method to ensure commercialization by the licensee.

Note that the words "promote the utilization of inventions" would be changed to "promote the results of federally funded research and development through the patenting and licensing process."

The proposed modification of the regulation would also add:

> "the Government may consider payments under a licensing agreement as a means for promoting the practical application of a subject invention and as a method to ensure commercialization by the licensee."

While the proposal stops short of a "shall consider" reference to licensing payments as a means to achieve practical application, KEI opposes the revision.

The statutory definition of practical application, in 35 U.S.C. § 201(f), reads as follows:

> (f)The term "practical application" means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, 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. [emphasis added]

Money to the government from licensing is never enough to satisfy the working obligation. The proposal appears to stray far from the traditional understanding of what it means to "manufacture" or "practice inventions" or make the benefits of invention "available to the public on reasonable terms" despite the clear wording in the statutory definition of practical application.

The notion that the federal government is receiving a royalty from a product does not erase the damage to the public caused when medical products are sold at unreasonable prices, or when a firm fails to manufacture or operate an invention in a way that provides benefits to the public.

In addition to the reasonable pricing issue, there are cases where companies block or delay development of technologies for commercial reasons, and where the working requirement in a license can and should be exercised.

The proposed regulation would undermine both the need to protect the public against **nonuse**, AND the need to protect the public from **unreasonable use** of inventions. Not quite a hat trick, but still a bold reversal of policies, objectives and obligations found in the statute.

Relationship to subject inventions not owned by the federal government

The proposed regulation to consider licensing payments satisfying obligations to achieve practical application has been presented by NIST in the context of federally owned inventions. But such a regulation will also be seen as weakening the working requirement for other subject inventions, since the term "practical application" is relevant to any subject invention, regardless of the ownership.

ANNEX

Why is the definition of practical application important?

Presently, the government has the option of granting a march-in petition or terminating a license if the licensee fails to turn an invention into a product or services that people actually use, and makes it available "on reasonable terms."

> 35 U.S. Code § 203 - March-in rights
> (1)action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use;
>
> 35 U.S.C. § 209 - Licensing federally owned inventions
> d)Terms and Conditions.—Any licenses granted under section 207(a)(2) shall contain such terms and conditions as the granting agency considers appropriate, and shall include provisions—
> . . .
>
> (3)empowering the Federal agency to terminate the license in whole or in part if the agency determines that—
> (A)the licensee is not executing its commitment to achieve practical application of the invention, including commitments contained in any plan submitted in support of its request for a license, and the licensee cannot otherwise demonstrate to the satisfaction of the Federal agency that it has taken, or can be expected to take within a reasonable time, effective steps to achieve practical application of the invention;

The termination authority can be used by the government to end a license, to convert an exclusive license to a nonexclusive license, or to modify other important terms.

Terminating a licensee's exclusive rights over a publicly-owned invention is an important legal tool that can be used to remedy unreasonable prices, and also refusals to collaborate and/or sublicense rights in cases where the original licensee is unable or unwilling to permit the use of the invention in an important field of use.