

Kathryn Ardizzone
Counsel, Knowledge Ecology International

National Institute of Standards and Technologies
Rights to Federally Funded Inventions and Licensing of Government Owned Inventions
Docket No.: 201207-0327
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March 26, 2021

Re: The Proposal to Deny Members of the Public Standing to Appeal Government Licenses

I am writing to express my strong opposition to NIST's proposal to modify 37 C.F.R. § 404.11 to artificially narrow the class of people that have standing to appeal federal agencies' decisions to grant exclusive licenses in federally-owned inventions. The Bayh-Dole Act gives the public a voice in such decisions, as it requires federal agencies to consider all timely-submitted public comments before executing an exclusive license. The NIST proposal is an attempt to silence that voice. It would limit standing to appeal licensing decisions to those who can show that they are able to commercialize the licensed invention.

I oppose the proposal because it conflicts with the public's statutory right to comment on licenses in federally-owned inventions and would have harmful implications. If the NIST proposal is implemented and members of the public could not seek review on unlawful licensing decisions, agencies would become even less willing to give their comments meaningful consideration. If agencies continue to be dismissive of public comment, without a possibility of review, the legal framework in which the public has a voice in exclusive patent licenses would be upended.

I am counsel for Knowledge Ecology International (KEI) and have submitted comments and appeals on agency licensing decisions. KEI's experience submitting more than 70 comments on licenses in the past four years and several appeals teaches that if NIST should be doing anything on this, it should be *strengthening* the public's right to comment and appeal, not weakening it.

The Current Regulation Governing Standing to Appeal

This proposal concerns the rules governing standing to appeal exclusive licenses in federally-owned inventions under the Bayh-Dole Act.

Under the current regulation, a person who timely filed comments opposing an exclusive license has standing to appeal as long as they “may be damaged by” the license. 37 C.F.R. § 404.11.

Concerning public comment, the Bayh-Dole Act states that agencies may not grant exclusive licenses unless they provide notice of their intent to grant the license, allow at least 15 days for the public to comment, and consider all timely-submitted comments. 35 U.S.C. § 209(e). In the original version of the Act, the comment period was 60 days.

The NIST Proposal

NIST is proposing 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. The new language would state in full:

- (3) A person who timely filed a written objection in response to the notice required by § 404.7 and who can demonstrate to the satisfaction of the Federal agency that such person may be damaged by the agency action due to being denied the opportunity to promote the commercialization of the invention.

Why it Matters

The NIST proposal on standing is inconsistent with the intent of the Bayh-Dole Act, as expressed through the licensing procedures at 35 U.S.C. § 209(e). By giving the public a right to comment on exclusive licenses and requiring agencies to consider their comments, Congress signaled its desire to give members of the public a powerful voice in these decisions. The right to comment cannot be meaningful if the public cannot appeal licenses. The proposal is also inconsistent with a stated policy and objective of the Act: to “protect the public against nonuse or unreasonable use of inventions.” 35 U.S.C. § 200.

The proposal would likely contribute to agencies’ dismissiveness of public comment as it stands today. Over the past several years, the National Institutes of Health (NIH) has become increasingly unresponsive and non transparent about its licensing decisions, undermining the public’s voice. As an example of this lack of responsiveness and possible hostility to the public’s right to appeal, KEI’s previous counsel asked the NIH to provide him copy of the NIH’s appeals procedures for an appeal that KEI wanted to submit, but the NIH initially refused to forward him the policy, asserting that KEI did not have standing. It was impossible for the NIH to know that KEI did not have standing before KEI even had an opportunity to be heard on why it did. And despite KEI notifying the NIH on multiple occasions over the years, the link to the Department

of Health and Human Services appeals procedures remains broken on the NIH Office of Technology Transfer website.

The failure of agencies to consider public comments and appeals would have a harmful impact. If this proposal is implemented and NIH licensing officers prefer to enter into licenses that violate the restrictions set forth at 35 U.S.C. § 209, the Public Health Service obligation to promote access in developing countries, and the requirement under 40 U.S.C. § 559 to seek the advice of the Attorney General, the officers would be even more willing to dismiss the comments on both process and substance, knowing that the public would not be able to seek review of their actions. These restrictions, however, are all important because they are all intended to protect the public interest concerning the licensing of inventions paid for and owned by the public. As such, they deserve serious assessment and consideration when making licensing decisions. It is also unreasonable to expect potential developers of federally-owned technologies to advocate for public interest safeguards, since they share the same interests as other companies seeking to commercialize federal inventions, such as by charging high prices and engaging in anticompetitive practices or under-serving persons living in developing countries. The public is uniquely situated to provide an important and necessary check on agencies' licensing decisions.

I also oppose this proposal because it is inconsistent with more accepted and more equitable standards on standing.

Under constitutional law on standing, there is no special requirement to demonstrate a particular form of an injury. It is unclear why NIST is trying to erect this unnecessary hurdle, to require appellants to show not just that they submitted comments but that they were damaged in the way NIST thinks they should be damaged. I am astonished that NIST wants to limit the right to appeal to drug companies and other commercial entities, as if they are the only stakeholders in the granting of exclusive licenses. If anything, the public should have greater ability to establish standing than provided under the concept of Article III standing.

Exclusive licenses in government-owned patents have broad implications, including on the price at which the technology would be available in the market. They give companies monopolies in inventions paid for and owned by the American public, and these monopolies have consequences. During the period of exclusivity, companies face no competition regarding the licensed inventions, and thus are able to set higher prices for the resultant products. 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. They are no less damaged by the licenses simply because they themselves do not have the opportunity to commercialize an invention. There can be no doubt that when the public pays for and owns an invention, it has a stake in how it is licensed.

If the public role in the licensing process were taken seriously and supported rather than undermined, this would likely have a beneficial impact on ensuring that licenses to federally-owned inventions comport with the Bayh-Dole Act and serve the public interest. In my experience asking questions on pending licenses and submitting comments and appeals, the NIH does not give proper consideration to the criteria governing exclusive patent licenses and is unreasonably secretive about them. Although the Bayh-Dole Act sets forth strict limits on agencies' authority to grant exclusive licenses and on the permissible scope of the agreements, the NIH routinely flouts these requirements. For example, as noted above, the Bayh-Dole Act stipulates that the scope of exclusivity must not be broader than the incentive necessary to induce a company to invest in commercializing an invention, while in our experience the NIH model exclusive license agreement is to make the period of exclusivity as long as possible—the duration of the last-filed patent in the licensed patent estate. Based on our conversations with the NIH, this is also what takes place in practice. The practice of routinely granting licenses with the maximum possible period of exclusivity is contrary to past practice, in which the NIH used shorter terms of exclusivity when appropriate, for example, as it did in the license to Bristol Myers Squibb for the commercialization of the HIV drug ddI.

I strongly believe that to preserve the public's role in the licensing process and best ensure agencies comply with their statutory requirements regarding exclusive patent licenses, NIST must rescind this proposal. But rescission, in my opinion, would not go far enough, because it is disturbing and highly concerning that NIST would issue this proposal in the first place. Upon reading this proposal together with the rest of NIST's regulatory package, a theme emerges: NIST is doing everything it can to maximize the privatization aspect of the Bayh-Dole Act and erode its public interest safeguards. When I joined KEI as their lawyer, I never expected, but increasingly learned the extent to which federal agencies like NIST and the NIH sidestep or distort Congressional intent on the Bayh-Dole Act, in order to diminish the public interest in the affordability of taxpayer-funded inventions in service of private interests.

Congress should conduct oversight on the NIST proposals in general, and ask NIST specifically why it thought that undermining the public's right to participate in the licensing process was beneficial and consistent with the text and intent of the Bayh-Dole Act.

For additional information on this or other issues with the proposed regulations, I can be contacted via email at Kathryn.Ardizzone@keionline.org