The NIH has radically reduced the time for the public to comment on exclusive licenses

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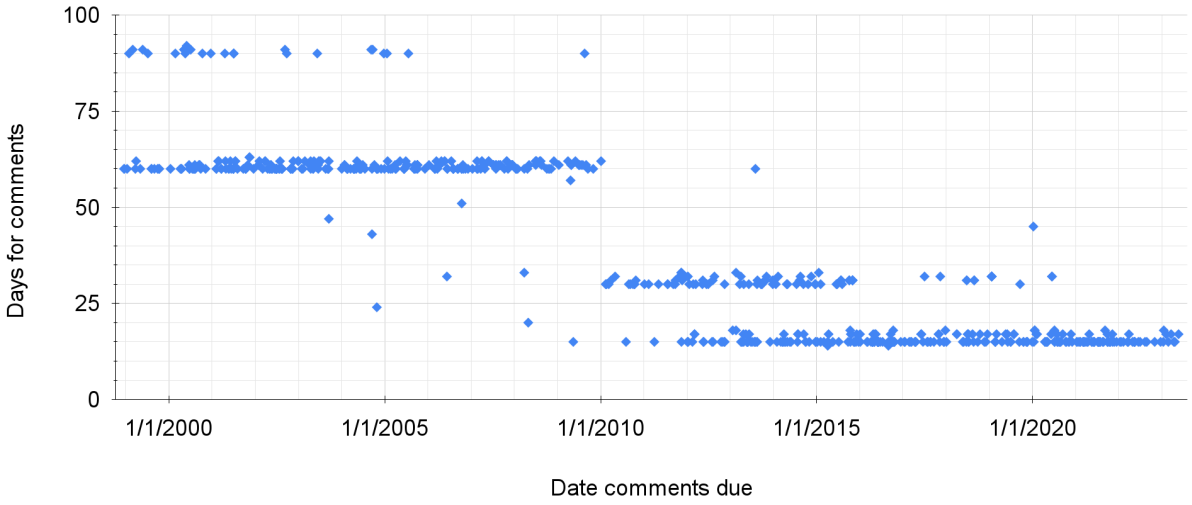
Introduction

Federal agencies in the U.S. have a limited authority to grant exclusive or partially exclusive licenses over government-owned patents, provided that they comply with the requirements set forth in 35 U.S. Code § 209, 37 CFR § 404, and other norms. Pursuant to 35 U.S. Code § 209, federal agencies may grant exclusive patent licenses only if they are “a reasonable and necessary incentive” to induce investments, and in most cases, after providing the public notice and an opportunity to file comments.

Since the Bayh-Dole Act was enacted, the National Institutes of Health (NIH) has drastically decreased the time available to the public to comment on exclusive patent licenses. These changes include a dramatic shift in the time given the public to comment in 2010, months after Dr. Francis Collins became the Director of the NIH, and another significant shift in 2016.

Figure: Days allowed for the public to comment on prospective NIH exclusive patent licenses



Shrinking the length of public comment periods is part of a broader set of policies implemented by NIH officials over the past fifteen years to make the NIH technology transfer practices less transparent, and to reduce the influence of consumer and taxpayer interests.

When the Bayh-Dole Act was first enacted through Public Law 96-517, statute 35 USC § 209 had a different title, “Restrictions on licensing of federally owned inventions,” and the statute did not set out the amount of time for public notice on an exclusive license. The implementing regulation, however, did set out a number of days for comment.

The March 12, 1985 version of 37 CFR § 404.7 required that the opportunity to file comments should be available for “a 60-day period.” The text of the regulation, as provided in 1985, was as follows:

> 37 CFR § 404.7, March 12, 1985 version
>
> (i) Notice of a prospective license, identifying the invention and the prospective licensee, has been published in the Federal Register, providing opportunity for filing written objections within a 60-day period;

The July 1, 1997 revision of 37 CFR § 404.7 still required federal agencies to provide “opportunity for filing written objections within a 60-day period.”

Public Law 106-404, enacted on November 1, 2000, amended several aspects of the Bayh-Dole Act, including 35 USC § 209. One of these amendments changed the title of Section 209 to “Licensing federally owned inventions,” and two changes were made regarding public notice. The statute now provided that the public was to be given “at least 15 days before the license is

granted" to comment, and the change also eliminated the public notice requirement for exclusive licenses granted to parties of Cooperative Research and Development Agreements (CRADAs).

> *35 U.S. Code § 209, as amended through Public Law 106-404*
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> (e) Public Notice.—No exclusive or partially exclusive license may be granted under section 207(a)(2) unless public notice of the intention to grant an exclusive or partially exclusive license on a federally owned invention has been provided in an appropriate manner at least 15 days before the license is granted, and the Federal agency has considered all comments received before the end of the comment period in response to that public notice. This subsection shall not apply to the licensing of inventions made under a cooperative research and development agreement entered into under section 12 of the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3710a).

Following this amendment, the implementing regulation was also changed on July 1, 2002, to reduce the deadline for public comments from 60 to "at least 15 days."

While the statute and regulation permitted the shorter comment period, the practice at the NIH was normally to give the public 60 or more days to comment on the non-CRADA exclusive licenses.

Data and descriptive analysis

Marshall Pentes (KEI) has reviewed each of the NIH Federal Register notices on prospective exclusive patent licenses, from October 19, 1998 to May 2023, and calculated the number of days given for the public to provide comments. (Link here).

From July 1, 2002 to December 31, 2009, the NIH published 222 notices in the Federal Register asking for comments on a prospective patent license. Ninety-six percent of these notices gave the public 60 days or more to comment. But beginning in 2010, a few months after Dr. Francis Collins became Director of the NIH, the practice changed.

From 2010 to 2015, the NIH published 155 notices. Only 1 of the 155 notices was open for 60 days or more. Among the 154 notices with a shorter comment period, half had a comment period of 30 to 33 days, and half had a period of 15 to 18 days.

Beginning in 2016 and through 2022, the NIH has given the public 15 to 18 days to comment on licenses 93 percent of the time.

Table: Number of days for public notice by year

Year	Total Federal Register Notices	Less than 60 days of public notice	24, 43, 45, or 47 days notice	30 to 33 days public notice	15 to 20 days public notice	Percent less than 60 days notice	Percent 30 to 33 days notice	Percent 15 to 18 days notice
2000	27	0	0	0	0	0.0%	0.0%	0.0%
2001	30	0	0	0	0	0.0%	0.0%	0.0%
July 1, 2001	11	0	0	0	0	0.0%	0.0%	0.0%
2002	36	0	0	0	0	0.0%	0.0%	0.0%
2003	26	1	1	0	0	3.8%	0.0%	0.0%
2004	30	2	1	0	0	6.7%	0.0%	0.0%
2005	28	0	0	0	0	0.0%	0.0%	0.0%
2006	30	2	0	1	0	6.7%	3.3%	0.0%
2007	28	0	0	0	0	0.0%	0.0%	0.0%
2008	18	2	0	1	1	11.1%	5.6%	5.6%
2009	15	2	0	0	1	13.3%	0.0%	6.7%
2010	13	13	0	12	1	100.0%	92.3%	7.7%
2011	18	18	0	14	4	100.0%	77.8%	22.2%
2012	20	20	0	9	11	100.0%	45.0%	55.0%
2013	39	38	0	17	21	97.4%	43.6%	53.8%
2014	32	32	0	12	20	100.0%	37.5%	62.5%
2015	33	33	0	13	20	100.0%	39.4%	60.6%
2016	33	33	0	0	33	100.0%	0.0%	100.0%
2017	26	26	0	2	24	100.0%	7.7%	92.3%
2018	24	24	0	8	16	100.0%	33.3%	66.7%
2019	23	23	1	1	21	100.0%	4.3%	91.3%
2020	30	30	0	2	28	100.0%	6.7%	93.3%
2021	38	38	0	0	38	100.0%	0.0%	100.0%
2022	17	17	0	0	17	100.0%	0.0%	100.0%
2023	6	6	0	0	6	100.0%	0.0%	100.0%
July 1, 2001 to 2009	222	9	2	2	2	4.1%	0.9%	0.9%
2010 to 2015	155	154	0	77	77	99.4%	49.7%	49.7%
2016 to 2022	191	191	1	13	177	100.0%	6.8%	92.7%

Why does the comment period matter?

The shorter notice periods, which include weekends and holidays, make it more difficult for the public to assess and influence the NIH's licensing policies. Why is this relevant? These are some examples of issues that may concern the public:

1. The proposed exclusive license may involve a company with a bad track record or no record at all of successfully bringing products to market.
2. A different licensee may be preferred if there is one that has better policies regarding pricing or access in developing countries.
3. The exclusive license may not be needed to bring a product to market, for example, if the product already has late-stage clinical trials results, and/or is eligible for other subsidies, such as the Priority Review Voucher, regulatory exclusivities on test data, or qualifies for orphan drug exclusivity, which are types of intellectual property protection that are significant, but also often shorter than the life of a patent. The scope of the rights in the license may be excessive for other reasons too. For example, it has been argued in some cases that the license need not be exclusive in the United States if the licenses are exclusive in Europe or other high-income markets.
4. The public may object to a license if the licensing process lacks transparency, regarding the terms offered, or the identity of the licensee. In some cases, the NIH licenses technologies to companies with no web pages or SEC filings, and where there is no information available at all regarding the ownership, board of directors, or management team.
5. An objection can be submitted if the license allows manufacturing outside the United States, or if the NIH failed to comply with the requirement in 40 USC § 559 regarding seeking the advice of the Attorney General with respect to antitrust law, for patents with a market value more than $3 million.
6. The NIH may propose a life of patent exclusivity for the license when a shorter term of exclusivity is more appropriate, and certainly consistent with the requirements in 35 USC § 209 that the scope of rights is limited to those which are reasonably necessary to induce investment.
7. The proposed royalty may be inadequate.
8. The NIH may have failed to provide sufficient rights for the use of the invention by third parties involved in research.
9. The NIH could be asked to provide for technology transfer on manufacturing at some point in the license.
10. The Field of Use may be too broad.
11. Understanding patent status globally is critical to examining a proposed license. Researching patent landscapes can be a complex and time-consuming endeavor. In recent years, the NIH has typically provided PCT numbers and identifiers for applications that have already entered into the national phase. Nevertheless, to adequately comment on a proposed license, interested parties may still need to cross-check the list of patent application numbers provided in the Federal Register notice with information available in databases hosted by national intellectual property offices. Without this cross-checking,

the procedural status, geographical scope, claimed subject matter, and legal strength of the patent rights may be unclear. This type of due diligence often takes significant time.

12. Whether the terms of a proposed license are appropriate may depend on the inventions claimed in the patents. Exclusive licenses over inventions relating to platform technologies and research tools are considered inappropriate by many experts and stakeholders. Determining the scope and nature of the inventions subject to a proposed exclusive license can require a relatively complex analysis of the patent claims. Given the diversity of technologies licensed by the NIH, interested parties often need to consult with subject matter experts to understand their nature. This again can take considerable time and resources.
13. The working requirements can be too lax.

These are just some of the issues that can be raised by the public during the comment period. In some cases, time is needed to evaluate the proposed license, and a 15 day window from the publication in the Federal Register makes this difficult. Not everyone reads the Federal Register daily, and it may take a while before people with an interest in the license even know about the request for comments. Additionally, the NIH itself is often unwilling to provide essential information about the license terms or the prospective licensee at all, or does not provide timely responses to questions asked.

The public not only has a right to provide comments to an agency on a prospective license, but they have some limited rights to appeal a decision by the agency to reject comments. This includes an administrative and a judicial appeal. In one licensing decision, KEI sued the NIH in federal court, but the case was dismissed on the grounds that KEI did not have staff or members who had the specific disease for the field of use in the license and therefore lacked standing. When KEI is faced with a 15-day notice period, there can be a scramble to analyze the technology, disease, and license, and if there are serious objections to be raised, it is necessary to reach out to patients or companies that would have sufficient standing to allow the public to sue the NIH in a federal court to enforce the public interest safeguards in the Bayh-Dole Act. A short 15-day comment period makes it very difficult to do any of this and has the practical and, we believe, intended result to undermine the public interest safeguards in the Bayh-Dole Act.

ANNEX:

The right of the public to appeal licensing decisions was narrowed to companies trying to commercialize inventions in 2023

It has always been challenging for the general public to appeal an NIH licensing decision in federal court, given the current requirements to obtain standing, but until 2023, it was possible to request an administrative appeal of a decision. There is an administrative appeal pending for the NIH rejection of the Xtandi march-in request. The appeal was filed on March 23, 2023, by three prostate cancer patients, and supported by eight NGOs on May 2, 2023.

On March 24, 2023, the National Institutes of Standards and Technology (NIST) issued sweeping new changes in the regulations concerning Rights to Federally Funded Inventions and Licensing of Government Owned Inventions (88 FR 17730). These new rules became effective April 24, 2023, and included a significant change in 37 CFR 404.11, Appeals.

Before April 24, 2023, among the parties who could appeal a decision included:

> (1) A person whose application for a license has been denied;
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> (2) A licensee whose license has been modified or terminated, in whole or in part; or
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> (3) A person who timely filed a written objection in response to the notice required by § 404.7(a)(1)(i) or § 404.7(b)(1)(i) and who can demonstrate to the satisfaction of the Federal agency that such person may be damaged by the agency action.

The change in the regulations modified (3), which now reads:

> (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.

By adding the words, “due to being denied the opportunity to promote the commercialization of the invention,” the Biden Administration, in adopting a rule proposed by the Trump Administration, has eliminated the right of anyone but an entity seeking “the opportunity to promote the commercialization of the invention” to appeal a decision. This change was designed to eliminate the right of patients or public interest groups to seek an administrative review of decisions that harm the public as consumers, taxpayers, or citizens, but does ensure that drug companies and other commercial entities have robust rights of appeal.

KEI had filed objections to this proposal on March 26, 2021, which were rejected by NIH in 2023. KEI's 2021 comments, filed by Kathryn Ardizzone, included these passages:

> 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.
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> 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.
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> 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.
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> . . .

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.

. . .

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.