



1621 Connecticut Avenue NW
Suite 500
Washington, DC 20009
www.keionline.org

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The Honorable Elijah Cummings
Chairman
US House of Representatives
Committee on Oversight and Reform
2157 Rayburn House Office Building
Washington, DC 20515

The Honorable Jim Jordan
Ranking Member
US House of Representatives
Committee on Oversight and Reform
2157 Rayburn House Office Building
Washington, DC 20515

Via email to oversight.democrats@mail.house.gov

Dear Chairman Cummings and Ranking Member Jordan:

Before an agency such as the National Institutes of Health (NIH) may license a federally-owned invention, it must notify the public of its intent to do so, consider any objections submitted during a public comment period, and determine that certain statutory criteria have been met, including that “the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application[.]”¹

Knowledge Ecology International (KEI) is a nonprofit organization dedicated to promoting access to medicines at affordable prices. Since 2015, we have commented on more than 40 exclusive licenses proposed by the NIH. Our attempts to obtain basic information from the NIH regarding the prospective licenses have been met with unnecessary secrecy and avoidance. We write to bring to your attention some recent examples of the NIH’s misconduct and illustrate how the NIH’s obfuscation possibly violates the law and harms the American public.

Background

The Bayh-Dole Act was enacted in 1980 to promote the commercialization of federally-funded technology and to ensure that federal inventions are made available to the public on reasonable

¹ 35 USC § 209(a)(2).

terms.² During congressional debate, lawmakers and public commentators raised concerns that the statute would lead to windfall profits for large manufacturers and predatory, monopolistic behaviors.³ The version that was signed into law incorporated safeguards to protect the American public from such dangers and balance America's interest in innovation with the public's need to access new technologies on reasonable terms, including prices.⁴

Section 209 of the Act is one of those safeguards: it authorizes federal agencies to grant exclusive or partially exclusive licenses in drugs or therapies owned by the federal government, but only if all five of the following conditions are met:

- (1) granting the license is a reasonable and necessary incentive to—
 - (A) call forth the investment capital and expenditures needed to bring the invention to practical application; or
 - (B) otherwise promote the invention's utilization by the public;
- (2) the Federal agency finds that the public will be served by the granting of the license, as indicated by the applicant's intentions, plans, and ability to bring the invention to practical application or otherwise promote the invention's utilization by the public, and that the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application, as proposed by the applicant, or otherwise to promote the invention's utilization by the public;
- (3) the applicant makes a commitment to achieve practical application of the invention within a reasonable time, which time may be extended by the agency upon the applicant's request and the applicant's demonstration that the refusal of such extension would be unreasonable;
- (4) granting the license will not tend to substantially lessen competition or create or maintain a violation of the Federal antitrust laws; and
- (5) in the case of an invention covered by a foreign patent application or patent, the interests of the Federal Government or United States industry in foreign commerce will be enhanced.⁵

Section 209 gives the public a role in licensing decisions: Whenever an agency proposes to license a federally-owned invention, it must publish notice of its intent to do so, allow a minimum

² 35 USC § 200. Specifically, Section 200 of the Act, "Policy and objective", lists, among others, the following legislative objectives: "to promote the commercialization and public availability of inventions made in the United States by United States industry and labor[;]" and ". . . to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions[.]" *Id.*

³ See Peter S. Arno & Michael H. Davis, *Why Don't We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed Upon Patents Deriving in Whole or in Part from Federally Funded Research*, 75 Tul. L. Rev. 631 (2001).

⁴ *Id.*

⁵ 35 USC § 209. Nearly identical federal regulations are codified at 37 CFR § 404.7(a)(1).

15-day period for public comment, consider all comments submitted, and conclude that the above-listed criteria have been met.⁶

The NIH is the federal agency that most frequently transfers technology to private companies under the Bayh-Dole Act, spending \$39 billion⁷ of taxpayer dollars annually on medical research and development. Thus, its actions - or inaction - regarding exclusive licensing pose grave consequences for the American public. Granting unnecessary or overly-broad exclusive licenses can lead to high prices that prevent Americans from accessing life-saving drugs or therapies, and can impose high costs on third parties that pay for medical inventions, including employers, state, local and federal governments, and programs such as the Veterans Administration, Medicare, and Medicaid.

The NIH's Lack of Transparency

Since 2015, KEI has submitted more than 40 comments on exclusive licenses proposed by the NIH.⁸ As far as we know, the NIH has systematically rejected KEI's requests to include provisions in the licenses that would protect US residents from excessive prices, limit the term of exclusivity to that which is reasonably necessary, obtain transparency of R&D outlays on NIH-licensed inventions, and address other public interest concerns. But the issue KEI seeks to highlight here is not the outcome of NIH's decisions, but how it arrives at them.

In order for KEI to comment effectively on a proposed license, we need information from the NIH about the subject invention, the terms of the proposed licenses, and the prospective licensee. Due to the lack of detail in the NIH's public notices and on its website, KEI often has no choice but to request the information directly from the NIH. Yet when KEI asks basic questions during the 15-day comment period, the NIH responds with unnecessary secrecy and hostility, evincing the NIH's treatment of the notice and comment period and licensing considerations as a mere formality, rather than a serious responsibility mandated by law.

Some of the questions NIH has refused to answer include the following:

- (1). The scope of the proposed license;
- (2). How much money the NIH has invested in the subject invention and what stages of R&D have been completed;

⁶ 37 CFR 404.7(a). Although in recent years most public notices limit the comment period to the minimum of 15 days required by the statute, the NIH has the authority to provide longer comment periods. In some specific cases KEI has asked for an extension of the deadline to file comments, and some of those requests have been granted. However, most of KEI's recent requests for an extension of the deadline to file comments have been rejected by the NIH.

⁷ <https://www.nih.gov/about-nih/what-we-do/budget>.

⁸ <https://www.keionline.org/nih-licenses>.

- (3). Information about the prospective licensee, such as the names of its principals, members of the board, address, or website;
- (4). Whether the NIH has sought the advice of the U.S. Attorney General, in compliance with 40 USC § 559; and
- (5). How the NIH evaluates public comments/objections and applies the statutory criteria in determining whether to grant an exclusive license.

Below is a discussion of the relevance of each of the above-listed questions, and examples of NIH's responses.

(1) Scope of the license

When an agency proposes to license a federally-owned technology on an exclusive basis, it must limit the scope of that license. The scope of a license includes but is not limited to such items as the field of use, the geographic area, and the term of exclusivity. Other limitations or obligations include such items as requirements that the invention be commercialized in a reasonable amount of time or that the benefits of the invention be available to the public on reasonable terms.

Pharmaceutical companies tend to favor licenses with the broadest possible set of rights, but the Bayh-Dole Act mandates that an agency limit the scope of the license, when the narrower scope is sufficient to bring an invention to practical application.

KEI is particularly concerned that the NIH routinely grants a term of exclusivity that is the life of a patent, even when a shorter term is sufficient.⁹ In the past, the NIH has used shorter terms in licenses to reduce the harm to the public associated with a monopoly. For example, the term of protection for the license in ddl (an HIV drug) was 10 years, rather than the life of the patent, and that led to an earlier introduction of low priced generic alternatives.¹⁰ In the case of the cancer drug Taxol, the NIH licensed rights in test data that had a term of just five years, and that

⁹ When the Bayh-Dole Act enacted in 1980, Universities had to request permission from the federal government to grant a term of exclusivity greater than 5 years.

¹⁰ See Videx® Expanding Possibilities: A Case Study, NIH Office of Technology Transfer, September 2003, available at <https://www.ott.nih.gov/sites/default/files/documents/pdfs/VidexCS.pdf> ("The technology transfer challenge was to negotiate a license that would provide a strong incentive for a drug company to make the significant investment necessary for the rapid development of a new drug while ensuring the long-term public health benefits. This balance was struck by offering a license that was initially exclusive, but which could become non-exclusive early, prior to the expiration of the NIH patents. Several companies competed for the license. . . . National Institutes of Health Office of Technology Transfer exercised its prerogative to have the license become nonexclusive in October 2001.").

was sufficient to attract several companies, even though the contract also had a reasonable pricing clause.¹¹

It is difficult for KEI to comment on whether NIH has negotiated appropriate licensing terms, in the cases where the NIH insists on making those terms secret.

The NIH has been generally forthcoming about the field for use for licensed technologies, but has refused to provide other highly relevant and basic details about the scope of licenses.

(a). Years of exclusivity

One area of particular concern to KEI is the lack of information about the number of years a license will be exclusive. For an example of a typical exchange, for a proposed license to a company called Molecular Targeting Technologies, Inc., the NIH refused to disclose the number of years of exclusivity offered in the proposed agreement, stating that the “terms of the license have yet to be negotiated but are, in general, confidential.”¹² One has to ask, how can the term of exclusivity on a federally-owned patented medical invention be considered confidential, and what conceivable interest is served by making the term of exclusivity secret other than to shield the NIH itself from scrutiny? When asked the same question with respect to a license to Tailored Therapeutics, the NIH responded: “These terms will be the subject of negotiation and are not known at this time.”¹³ This has become a standard response from the NIH.

(b). Geographic area

The NIH has also been unwilling, in several cases, to state what the geographic area of a license will be, other than to state that the license “may be worldwide.” “May be worldwide” is somewhat helpful, but certainly not as informative as it should be, in cases where the NIH has yet to even file for patents in national patent offices.

When a patent or patent application is fairly new, the NIH may have filed the patent with the World Intellectual Property Organization’s Patent Cooperation Treaty (PCT), with an intent to file the patent in almost every country on earth, including nearly every country in Africa. But the NIH typically narrows the actual filings to a much smaller number of countries, in the “National Phase” of the application process. If the NIH has a plan to file in some countries but not others,

¹¹ U.S. House of Representatives, Committee on Small Business, Subcommittee on Regulation, Business Opportunities, and Energy, Exclusive Agreements between Federal Agencies and Bristol-Myers Squibb Co. for Drug Development. Serial No. 102-35. July 29.

¹² See Comments regarding 84 FR 28063 Doc 2019-12708 - Prospective Grant of Exclusive Patent License: Lutetium-177 Radiotherapeutics Against Somatostatin-Receptor Expressing Neuroendocrine Tumors, available at <https://www.keionline.org/31152>.

¹³ See Comments regarding 84 FR 28063 - Prospective Grant of an Exclusive Patent License: Development and Commercialization of Cell Therapies for Cancer, available at <https://www.keionline.org/31138>.

they will not share that information with groups like KEI or Médecins Sans Frontières (MSF) during the public comment period on the exclusive license.

This information is completely relevant to the decision whether to make the license worldwide or in selected countries and if the terms of the license should include obligations to make products affordable in developing countries. The NIH itself is subject to policy guidance on this issue, as set out in “United States Public Health Service Technology Transfer Policy Manual, Chapter No. 300, PHS Licensing Policy,” which states the following: “PHS seeks to promote commercial development of inventions in a way that provides broad accessibility for developing countries.”¹⁴

By withholding information on where patents applications will enter the national phase, the NIH makes it harder to evaluate the incentives available from markets where patents are filed and whether the NIH is meeting its obligations under the PHS Licensing Policy to promote “broad access” to medical inventions in developing countries.

Given the NIH’s responses to our inquiries about the scope of proposed licenses, we are left to conclude that the NIH has adopted a position that is contrary to law: that the public is not entitled to or able to comment on the scope of a proposed exclusive license, other than the field of use, and with incomplete information on the geographic area.

(2) Stage of R&D completed and funding contributed by the NIH

The stage of research and development (R&D) that has been completed for a federally-owned technology is also obviously relevant to whether the licensing incentive “is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application[,]” and to the scope of rights necessary to do so.

If a company is licensing technologies in very early stages of development where no trials have been funded or subsidized, they will need more robust incentives (i.e., broader exclusivity) than in the case of a company licensing a technology that already further along, and for which the government has or is funding trials.

The CD30 CAR Multiple Myeloma Trial

One appalling example of the NIH’s secrecy regarding R&D information is its 2018 decision to grant an exclusive license in a cancer treatment known as “Anti-CD30 Chimeric Antigen

¹⁴ <https://www.ott.nih.gov/sites/default/files/documents/policy/pdfs/300.pdf>.

Receptors [CAR]" to Kite Pharma, which was acquired by Gilead Sciences for \$11.9 billion in 2017.¹⁵

KEI was concerned that granting a fully-exclusive license to the cancer treatment was premature, considering the fact that a Phase 1 clinical trial funded by the NIH¹⁶ was underway.

Delaying a licensing decision until the conclusion of the trial would have given the NIH greater leverage in negotiations with Kite/Gilead - the value of the technology would be much higher if the trial was successful, such that the NIH presumably could negotiate a shorter licensing term - and consumers and taxpayers would pay less for the therapy.

Aside from the fact that trial was being conducted and funded by the government, the actual cost of the trial was material in determining the nature of the incentive that would be needed to commercialize the treatment.

The trial in question was NCT03049449, which now has an enrollment of 79 patients. The first two CAR T treatments that were approved by the NIH had trials involving 63 and 100 patients, respectively. The cost of the 79 patient trial NCT03049449 would have been highly informative as to both the expected costs that Kite/Gilead might incur to obtain FDA approval, and also as to the costs that Gilead or Novartis may have incurred in the earlier approvals of Kymriah, which could be compared to the revenues those CAR T treatments had earned following approval.

The scope of the license in a CAR treatment is a particularly compelling public health concern. Despite the government's role in funding their development, CAR therapies for cancer have been extremely profitable for the pharmaceutical companies that hold rights in them, and prohibitively expensive for patients. Moreover, the patent landscape of CAR therapies has become increasingly concentrated.

When KEI asked the NIH how much it had invested in the Phase 1 trial, the NIH refused to answer. KEI can understand why a pharmaceutical company might want to shield the government's contribution to clinical trials from the public; the company answers to investors, not taxpayers, and pharmaceutical manufacturers often cite their supposed investments in risky R&D to justify high prices and large profit margins. But it makes no sense for the NIH, which is a publicly-funded agency and has no particular allegiance to private companies, to refuse to disclose how much taxpayers are contributing to develop cancer drugs that everyday Americans could later be priced out of buying.

¹⁵

<https://www.gilead.com/news-and-press/press-room/press-releases/2017/8/gilead-sciences-to-acquire-kite-pharma-for-119-billion>.

¹⁶ The trial is NCT03049449, available at <https://clinicaltrials.gov/ct2/show/study/NCT03049449>.

Other examples of exchanges between KEI and the NIH regarding federal funding and R&D follow below:

84 FR 2537

KEI: “How much money has the NIH spent on research directly related to the technology to be licensed?”

NIH: “The NIH does not have the specific funding data you requested.”¹⁷

84 FR 33272, 84 FR 33270

KEI: “At what stage of development are the inventions listed?”

NIH: “This question “either ha[s] been answered previously or [is] not related to the criteria set forth in 37 CFR 404.7(a)(1)(ii-iii) regarding a decision by a federal agency to grant an exclusive license.”¹⁸

These answers don’t pass muster. While it is possible that the licensing agent for an NIH institute is not aware of what the NIH has invested in a technology that the NIH is making available for licensing, certainly someone at the NIH does know. More importantly, however, the licensing agency should know what the public investments have been, and where the technology is in terms of the stage of development. Otherwise, how can they possibly fulfil the requirements of Section 209?

(3) Information about the prospective licensee

Information about the prospective licensee is necessary for the public to assess the ability of the company to bring the drug or therapy to market, and also to investigate cases of malfeasance or conflicts of interest. For example, in an extended story on an NIH license to Kite Pharma, the New York Times examined the relationship between Kite Pharma CEO Dr. Belldegrun and NIH scientist Dr. Rosenberg. The December 19, 2016 story was titled: *PUBLIC LABS, CORPORATE GAINS. Harnessing the U.S. Taxpayer to Fight Cancer and Make Profits*, by Matt Richtel and Andrew Pollack,¹⁹ and included reports on emails obtained by KEI through FOIA that described Dr. Rosenberg’s appearances at Kite investor events.²⁰

Often, surprisingly little is publicly available about prospective licensees. Many of the companies are privately-held and thus have not made any SEC filings. Sometimes, it has been impossible to locate their website.

¹⁷ See Attachment A, Email Correspondence between KEI and NIH regarding 84 FR 2537.

¹⁸ See Attachment B, Email Correspondence between KEI and NIH regarding 84 FR 33272 and 84 FR 33270.

¹⁹

<https://www.nytimes.com/2016/12/19/health/harnessing-the-us-taxpayer-to-fight-cancer-and-make-profits.html>.

²⁰ <https://www.keionline.org/23238>.

Given the fact that the NIH exclusive licenses can be worth billions of dollars, and are negotiated in secret, without a competitive bidding process, and sometimes to former NIH employees, it is highly inappropriate for the NIH to conceal information about the companies seeking the exclusive licenses.

Typical exchanges between KEI and NIH regarding licensee information follow below:

83 FR 58262

KEI: “1. Does ElevateBio have a web page?”

NIH: “Generally, the existence of web pages is publicly available and information that can be ascertained by the commenting party using any number of internet search engines.”

KEI: “2. Does ElevateBio have any SEC filings?”

NIH: “Similar to Question 1 above, a search for SEC filings can be performed by the commenting party via the SEC website.”²¹

80 FR 16389

KEI: “Can you provide any information about the pharmaceutical company that is seek[ing] the exclusive license in the previously mentioned federal register notice, such as names, addresses or titles in the company (board of directors or shareholders)?”

NIH: “Virotas Biopharmaceuticals, LLC is a privately held start-up company with founders experienced in drug development and commercialization.”²²

In the first example, during the comment period, KEI was not able to locate a website or SEC filings for the company that were publicly-available online. In the second, it is hard to conceive of why the NIH could not provide additional details. Certainly, the names or titles of principals is not confidential information.

(4) Antitrust considerations

The NIH has refused to answer our questions about whether it is fulfilling its duty to consider possible anticompetitive effects of its licensing decisions. Section 209 of the Bayh-Dole Act prevents a federal agency from licensing federally-owned technologies unless it determines that “granting the license will not tend to substantially lessen competition or create or maintain a violation of the Federal antitrust laws[.]”²³ One federal antitrust law relevant to Section 209 is 40 USC § 559, which prohibits an executive agency from “dispos[ing] of property to a private

²¹ See Attachment C, Email Correspondence between KEI and NIH regarding 83 FR 58262/ElevateBio.

²² <https://www.keionline.org/22752>. For more information about NIH’s lack of transparency regarding the Virotas license, see <https://www.keionline.org/wp-content/uploads/KEI-letter-OSTP-03-04-16.pdf>.

²³ 35 USC § 209(a)(1)(4).

interest until the agency has received the advice of the Attorney General on whether [doing so] would tend to create or maintain a situation inconsistent with antitrust law.”²⁴

Incorporating antitrust considerations into Bayh-Dole makes sense considering the legislative history of the statute - namely, concerns that granting effective monopolies in publicly-owned rights would lead to undue market concentration. Yet despite this context and the clear mandate of Section 209, as far as we can determine, NIH never seeks the advice of the Attorney General on this issue. The NIH has claimed that the Bayh-Dole Act preempts the requirements of 40 USC § 559, even though this statute is not among the 21 statutes specifically preempted in 35 USC § 210(a), “Precedence of chapter.”

When asked whether it sought the advice of the Attorney General with respect to two recent licenses, the NIH never responded. Last year, when asked about 40 USC § 559 in relation to the Gilead/CAR license, Karen Rogers, Acting Director of NIH’s Office of Technology Transfer, stated:

“The statute you reference is directed to the disposal (assignment) of government property. It has little relevance to our patent licensing activities, which are principally governed by the Bayh-Dole Act and its regulations.”²⁵

This response is perplexing. Presumably, the NIH understands that their licenses assign rights in government-owned intellectual property (the process is called “technology transfer,” after all), and that the Bayh-Dole Act incorporates by reference federal antitrust laws.

Several exclusive licenses granted by the NIH present risks of market concentration and anti-competitive actions.

There are multiple examples of cases where the NIH has proposed several exclusive licenses to the same company in closely-related technologies. For instance, Kite Pharma, Inc. has appeared as the prospective licensee in at least nine different Federal Register notices, all of which seem to be related to cell therapies. A list of these nine different Federal Register notices is available below.

Selected Federal Register notices where Kite Pharma, Inc. was the prospective licensee

Prospective licensee	Date of the notice	Notice URL
Kite Pharma, Inc.	07/12/2019	https://www.federalregister.gov/d/2019-14823

²⁴ 40 USC § 559(b)(1).

²⁵ See Email Correspondence, “question regarding NIH tech transfer and 40 U.S.C. § 559,” available at <https://www.keionline.org/wp-content/uploads/2018/06/NIH-Motion2Dismiss-BerkeleyDeclaration.pdf> at page 27.

Kite Pharma, Inc.	07/12/2019	https://www.federalregister.gov/d/2019-14822
Kite Pharma, Inc.	12/20/2017	https://www.federalregister.gov/d/2017-27416
Kite Pharma, Inc.	10/05/2016	https://www.federalregister.gov/d/2016-24030
Kite Pharma, Inc.	08/17/2016	https://www.federalregister.gov/d/2016-19549
Kite Pharma, Inc.	06/26/2015	https://www.federalregister.gov/d/2015-15657
Kite Pharma, Inc.	10/16/2014	https://www.federalregister.gov/d/2014-24502
Kite Pharma, Inc.	03/25/2014	https://www.federalregister.gov/d/2014-06412
Kite Pharma, Inc.	01/24/2012	https://www.federalregister.gov/d/2012-1383

In some cases, the NIH proposes a new exclusive license for the same patents that have already been licensed to a previous company, but in a different field of use.

The NIH has also proposed exclusive licenses to patents that appear to cover platform technologies, which enable the development of many different therapies and other applications, and which normally should not be subject to exclusive licensing.

For example, the license proposed in the notice 83 FR 65694, to Sixfold Biosciences, related to “multifunctional RNA nanoparticles” and “RNA/DNA hybrid nanoparticles modified with single stranded RNA toeholds.”²⁶ According to an expert advisor consulted by KEI, the patents can be considered a platform technology that should be licensed non-exclusively.²⁷

The NIH does not appear to have a compelling interest in or commitment to curing or avoiding anticompetitive conduct, and we are concerned that the NIH has refused to comply with 40 § USC 559, which would ensure that an agency with more experience in competition issues would be consulted.

(5) How NIH applies Section 209 criteria and considers comments

The NIH refuses to answer KEI’s questions about how it applies the Section 209 criteria and offers only vague, conclusory, and formulaic responses to our comment submissions.

²⁶ <https://www.federalregister.gov/d/2018-27671>.

²⁷ <https://www.keionline.org/29526>.

Recently, KEI submitted 10 questions to the NIH regarding 84 FR 33272 and 84 FR 33270. The NIH responded with an email that acknowledged Questions 1-9, but made no reference to Question 10, which asked: “Considering Kite/Gilead currently has CAR T therapy Yescarta (axicabtagene ciloleucel) on the market at a price of \$373,000, has/will the NIH seek license terms that will ensure the resultant therapy is available to patients on reasonable terms?”²⁸

Below are two recent examples of NIH’s final responses to our comments, which fail to show that the NIH considered them in any meaningful way.

84 FR 23798

NIH: “Thank you for proving KEI comments to the recent Federal Register Notice referenced above regarding the National Cancer Institute’s proposed intent to grant an exclusive license to GLG Pharma LLC. The notice period provides an opportunity for the public to comment and possible objection to the proposed license. We consider all comments prior to negotiating the proposed license. We will give your comments and suggestions serious consideration.”²⁹

82 FR 47547

NIH: “Prior to posting a notice for a proposed grant of an Exclusive Patent License, the NIAID determines that the criteria set forth in 37 CFR 404.7 have been satisfied with respect to granting the organization an exclusive license to the Government’s intellectual property rights in the field of use as specified. The notice period provides an opportunity for public comments on and possible objection to the proposed license. Before negotiating the proposed license, we consider all comments received.”³⁰

In one of its final responses to KEI’s comments, the NIH specifically addressed our concern that the agency failed to provide us with information about how it applies 35 USC § 209. The NIH responded as follows:

84 FR 2537

NIH: “On page four of your submission, you assert that the NIH has not provided ‘meaningful’ information regarding how the proposed license meets the requirements specified in 35 USC §209. The determination made pursuant to 35 USC §209 is based, in part, on business confidential information provided by the prospective licensee and cannot be shared.”³¹

²⁸ See Attachment B, Email Correspondence between KEI and NIH regarding 84 FR 33272 and 84 FR 33270, *supra* n. 19.

²⁹ See Attachment D, Letter from the NIH to KEI regarding STAT3 Inhibitor, GLG-302.

³⁰ <https://www.keionline.org/wp-content/uploads/2017/11/NIAIDresponsetoKEIandMSF.pdf>.

³¹ https://www.keionline.org/wp-content/uploads/Response-to-KEI_3-11-19.pdf.

The NIH apparently takes the position that confidentiality prohibits the NIH from sharing the information that is necessary for public participation and comment under 35 USC § 209. But the statute grants it no such license to favor private over public concerns.

Other Problematic Behavior by the NIH

A complete history of the NIH's problematic responses to KEI's inquiries is beyond the scope of this letter. But two noteworthy examples are the agency's refusal to provide any documents to KEI within the 15-day comment window and failure to ensure basic information such as the appeals procedures are publicly accessible online, ever after issues with access were brought to the agency's attention.

(1) Failure to provide documents to KEI within the comment period

KEI often requests documents from the NIH in order to enable us to provide meaningful comments on a prospective license. Because the NIH typically only allows the public 15 days from the date that notice is posted to submit comments, it is important that we are able to quickly obtain the documents. NIH always refuses to provide the documents to KEI directly and requires us to request them under the Freedom of Information Act (FOIA), stating, for example, that "[i]t is not consistent with [the NIH's] mission to create reports requested by the public."³²

Simply because FOIA provides one mechanism for disseminating executive agencies' documents to the public does not mean that the agency cannot provide them directly to the requesting party. Yet, in an effort to comply with the NIH's directive and still have time to obtain and respond to the documents within the 15-day comment period, KEI has submitted a FOIA request that asked for expedited processing, explaining the obvious: that KEI needed the documents on an expedited basis to meet the 15-day deadline that the NIH established for submitting comments.

Incredibly, NIH declined our request for expedited processing, stating that we failed to demonstrate an urgent need for the materials.³³ And when we asked for an extension of the 15-day comment period, which is only a minimum statutory window, the NIH refused to grant one.³⁴

The NIH's behavior often makes it extremely difficult or impossible for the public to provide meaningful comment within the 15-day deadline that the agency insists upon.

³² See Attachment E, Letter from NIH to KEI re: 83 Federal Register 29127 (June 22, 2018), "Prospective grant of an exclusive patent license: Methods of modulating erythropoiesis with arginine vasopressin receptor 1B molecules".

³³ See Attachment F, Letter from NIH to KEI Re: FOI [sic] Case No. 48080.

³⁴ In the past, the NIH has, in a limited number of cases, agreed to such extensions, but more recently, has stuck to the minimum 15 day comment period.

(2) Failure to make the NIH's appeal procedures publicly available

In early 2018, KEI asked NIH to explain the process for appealing a licensing decision, noting that the link to such procedures on NIH's website was broken.³⁵ The broken link was again brought to the NIH's attention in litigation between KEI and the NIH. More than a year and a half later, the link still does not work. In July 2019, KEI asked the NIH about its appeal procedures, and "where they are disclosed to the public[.]"³⁶ NIH responded by attaching its appeal procedures to an email. Because KEI assumes that other members of the public might be interested in appealing a licensing decision, we asked "[w]here online would a member of the public interested in the appeals procedures be able to locate this policy[.]"³⁷ NIH referred KEI to the (still nonfunctioning) link.³⁸ Only July 10, 2019, KEI asked the NIH to "please ... check to see if the linking is working ... and confirm whether NIH is going to correct the problem[.]"³⁹ The NIH still has not responded.

Conclusion

Given the importance of prescription drug costs to the American public,⁴⁰ members of Congress on both sides of the aisle have proposed a variety of legislative reforms.⁴¹ However, one legal safeguard that was enacted decades ago is being rendered ineffective by the NIH.

The examples above are only a non-exhaustive list of the many unnecessary barriers created by the NIH when KEI tries to access the information it needs to comment on proposed licenses of publicly-owned technology. The NIH's non-answers to some of the most germane questions about proposed licenses evince the agency's attitude, contrary to the law, that the public is not entitled to weigh in meaningfully on the existence and scope of such licenses.

The NIH has grown less responsive over time, and this lack of transparency will likely persist unless Congress exerts pressure on the agency to comply with 35 USC § 209. KEI respectfully urges the Oversight Committee to investigate the NIH's actions with regard to licensing and take any action it deems appropriate.

³⁵ Email from Andrew Goldman, KEI to Dr. David Lambertson, NIH re: "NIH decision to proceed with the license of the anti-CD30 CAR tech to Kite/Gilead," available at <https://www.keionline.org/wp-content/uploads/2018/06/NIH-Motion2Dismiss-BerkeleyDeclaration.pdf> at 18.

³⁶ See Attachment G, Email Correspondence between NIH and KEI regarding "NIH's [sic] Response to KEI's Comments Regarding Exclusive License in STAT3 Inhibitor, CLG-302".

³⁷ See *id.*

³⁸ See *id.*

³⁹ See *id.*

⁴⁰ <https://www.kff.org/health-costs/poll-finding/kff-health-tracking-poll-february-2019-prescription-drugs/>.

⁴¹ <https://www.healthaffairs.org/doi/10.1377/hblog20190530.353251/full/>.

Sincerely,
James Love, Director
Kathryn Ardizzone, Counsel
Luis Gil Abindar, Research Associate
Knowledge Ecology International

Attachments