Exhibit A
(Berkley Declaration)

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

KNOWLEDGE ECOLOGY INTERNATIONAL,

Plaintiff,

v.

NATIONAL INSTITUTES OF HEALTH, *et al.*,

Defendants.

Case No. 8:18-cv-01130-PJM

DECLARATION OF DALE D. BERKLEY, PH.D., J.D.

I, Dale D. Berkley, pursuant to 28 U.S.C. § 1746, hereby declare as follows:

1. I am an attorney at the NIH[1] Branch of the Office of General Counsel for the U.S. Department of Health and Human Services ("HHS").

2. Through its technology transfer program, NIH makes patents and other intellectual property owned by the United States available to public and private companies, through the granting of exclusive and non-exclusive licenses to use that technology.

3. Licenses granted through the technology transfer program, in almost all cases, require the licensees to pay royalties to the United States. Royalties obtained through licensing provide a return to NIH that supports further research and provide compensation to government employee inventors.

4. On December 20, 2017, NIH published the Notice of Intent in the Federal Register.

5. The Notice of Intent provided that "the public may file comments or objections," relating to the Proposed License, and that "the prospective exclusive license may be granted unless

[1] Capitalized terms not otherwise defined are given the meanings ascribed to them in the *Memorandum in Support of Motion to Dismiss*.

within fifteen (15) days from the date of this published notice, [NCI] receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404."

6. On January 4, 2018, James Love – apparently affiliated with KEI – wrote to Francis S. Collins ("Collins") and David Lambertson ("Lambertson") to "express [KEI's] opposition to the [P]roposed [License]." A copy of the January 4, 2018 email from Mr. Love to Collins and Lambertson, with an attachment, is attached as **Exhibit 1**. Mr. Love attached a five-page document outlining KEI's opposition to the Proposed License. *See* Exh. 1.

7. On January 25, 2018, Lambertson responded to Mr. Love by email and attached a response, explaining that "[w]hile your comments have been given full consideration, they do not persuade us that the [Proposed License] would be inconsistent with the regulations and, furthermore, advance public health." A copy of the January 25, 2018 email from Lambertson to Mr. Love, with an attachment, is attached as **Exhibit 2**.

8. On February 14, 2018, Andrew Goldman – also with KEI – emailed Collins and Lambertson asking about KEI's appeal rights, asking Collins and Lambertson to "let [KEI] know what formal procedures the NIH requires for these appeals …." A copy of the February 14, 2018 email from Mr. Goldman to Collins and Lambertson is attached as **Exhibit 3**.

9. On February 26, 2018, Lambertson responded to Mr. Goldman, noting that under 37 C.F.R. § 404.1(a)(3), an appeal can be taken by only "a person who can demonstrate to the satisfaction of the agency that such person may be damaged by the action," NIH "determined that there is no likelihood that KEI will be damaged by the agency action," and that NIH "will not entertain an appeal of our decision." A copy of the February 26, 2018 email from Lambertson to Mr. Goldman is attached as **Exhibit 4**.

10. Also on February 26, 2018, Mr. Goldman responded to Collins and Lambertson, attaching KEI's appeal of NIH's response to KEI's opposition to the Proposed License. A copy of the February 26, 2018 email from Mr. Goldman to Collins and Lambertson, with attachments, is attached as **Exhibit 5**. In the attached appeal, KEI represented that it is "a public interest organization" that "represents taxpayers and patients, including cancer patients, who are stakeholders in the outcome of the NIH decision," and also stated that KEI "represents persons who will be damaged by the decision to proceed with [the Proposed License] …." *See* Exh. 5, at p. 3 of 11.

Dale D. Berkley, Ph.D., J.D.
Office of General Counsel, HHS

Exhibit 1
(January 4, 2018 Email)

Lazerow, Alan (USAMD)

From:	James Love <james.love@keionline.org>
Sent:	Thursday, January 4, 2018 5:04 PM
To:	NIH Executive Secretariat; Lambertson, David (NIH/NCI) [E]; Kochenderfer, James (NIH/NCI) [E]
Cc:	Andrew S. Goldman; Manon Ress; Diane Singhroy; Kim Treanor; Claire Cassedy; Thiru Balasubramaniam
Subject:	Prospective Grant of an Exclusive Patent License: The Development of an Anti-CD30 Chimeric Antigen Receptor (CAR) for the Treatment of Human Cancer
Attachments:	KEI-KITE-CAR-T-NIH-4Jan2018.pdf

Dr. Francis Collins, M.D., Ph.D., Director
National Institutes of Health
9000 Rockville Pike
Bethesda, Maryland 20892
Email: execsec1@od.nih.gov

David A. Lambertson, Ph.D., Senior Technology
Transfer Manager, NCI Technology Transfer Center,
Rockville, MD 20850-9702
Email: david.lambertson@nih.gov.

Dear Director Collins and Dr. Lambertson:

Knowledge Ecology International (KEI) is writing to express our opposition to the proposed exclusive license of a portfolio of patents to Kite Pharma, since October a wholly-owned subsidiary of Gilead, for chimeric antigen receptors that recognize the CLD30 protein, as posted in the Federal Register notice 82 FR 60406.

We object to the granting of the exclusive license, and request that if the NIH proceeds with the license, public interest safeguards are included.

Our comments are included in the attached PDF file.

--
James Love. Knowledge Ecology International
http://www.keionline.org/donate.html
KEI DC tel: +1.202.332.2670, US Mobile: +1.202.361.3040, Geneva Mobile: +41.76.413.6584,
twitter.com/jamie_love

January 4, 2017

Dr. Francis Collins, M.D., Ph.D., Director
National Institutes of Health
9000 Rockville Pike
Bethesda, Maryland 20892
Email: execsec1@od.nih.gov

David A. Lambertson, Ph.D., Senior Technology
Transfer Manager, NCI Technology Transfer Center,
Rockville, MD 20850-9702
Email: david.lambertson@nih.gov.

Dear Director Collins and Dr. Lambertson:

Knowledge Ecology International (KEI) is writing to express our opposition to the proposed exclusive license of a portfolio of patents to Kite Pharma, since October a wholly-owned subsidiary of Gilead, for chimeric antigen receptors that recognize the CLD30 protein, as posted in the Federal Register notice 82 FR 60406.

We object to the granting of the exclusive license, and request that if the NIH proceeds with the license, public interest safeguards are included.

1. Background

The Federal Register notice identified several forms of cancer that may be treated with the technology, including Hodgkin's Lymphoma (HL), Non-Hodgkin's Lymphoma (NHL), diffuse large B cell lymphoma (DLBCL), peripheral T-cell lymphoma not otherwise specified (PTCL-NOS), anaplastic large cell lymphoma (ALCL), and angioimmunoblastic T-cell lymphoma (AITL).

The inventor listed in the patent applications referred to in the Federal Register notice is James N. Kochenderfer, M.D.

The technology to be licensed appears to be undergoing an NIH funded Phase 1 trial with the ClinicalTrials.gov identifier: NCT03049449.

The NIH proposed worldwide rights, and has filed a patent application with the WIPO PCT seeking protection in the following countries:

Pub. No.: WO/2017/066122
International Application No.: PCT/US2016/056262
Publication Date: 20.04.2017
International Filing Date: 10.10.2016
Applicants: THE UNITED STATES OF AMERICA, AS REPRESENTED BY THE SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES [US/US]; Office of Technology Transfer National Institutes of Health
Inventors: KOCHENDERFER, James N.

Designated States:

AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

African Regional Intellectual Property Organization (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW)

Eurasian Patent Organization (AM, AZ, BY, KG, KZ, RU, TJ, TM)

European Patent Office (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR)

African Intellectual Property Organization (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

2. It is premature to grant an exclusive license, given the fact that the NIH is funding a Phase 1 trial.

We object to the NIH licensing this promising technology before the patent has been granted, and before the NIH concludes and evaluates the results from the ongoing Phase 1 trial, which

began on March 17, 2017 and currently has an estimated primary completion date of June 30, 2021, according to the NIH database ClinicalTrials.Gov.

In an environment where there is widespread alarm over the escalating costs of treatments for cancer and Congressional concerns over the pricing of NIH-funded biomedical inventions, it is unwise for the NIH to create a monopoly on this NIH-funded invention, before the NIH can evaluate both the evidence from the ongoing Phase 1 trial and the costs of moving the technology forward to FDA approval, if the Phase 1 results are encouraging.

Evaluating the costs of obtaining FDA approval would entail a comparison of the costs that the NIH would incur directly if it were to conduct the result itself, versus the costs imposed on U.S. patients, employers and taxpayers if the NIH grants a legal monopoly to Gilead.

If the costs of the NIH funding the R&D itself directly leads to significant savings over the costs to U.S. residents of granting a legal monopoly, the NIH should not grant the monopoly.

3. **If the NIH grants an exclusive license, it should include clear safeguards in the license to protect U.S. residents from excessive prices and access barriers.**

    a. The price should not discriminate against U.S. residents.

At a very minimum, the NIH should include a provision in the licenses that would ensure that the price for a product or service that relied upon the invention would not be more expensive in the United States than the median price charged for a group of countries that include Canada plus the eight largest economies in the world that also have a nominal per capita income at least 50 percent of that of the United States (as measured by GNI, World Bank Atlas method).

    b. The price should not constitute an unreasonable barrier to access in the United States.

If there is a significant gap between the number of patients who would benefit from the treatment and the number of patients who receive the treatment, the monopoly should be terminated.

    c. The price should not be higher than CAR T treatments of similar efficacy, taking into account differences in patient populations, if the cumulative revenue per indication is less than $300 million.

We note that the two previous CAR T procedures approved by the FDA involved a small number of patients in trials, including, for example, Yescarta, also licensed by the NIH to Gilead/Kite, whose FDA press release stated “The safety and efficacy of Yescarta were established in a multicenter clinical trial of more than 100 adults . . . ”

d. The price should not increase faster than the rate of inflation as measured by the consumer price index, unless the increase can be justified by a need to earn a reasonable profit on the risk adjusted investments in research and development.

Alternatively, if revenues are robust, there could be a requirement that prices decline as companies reach certain benchmarks.

e. The revenues earned under exclusive rights should not be excessive.

When the cumulative global revenue for the product exceeds a particular benchmark, the monopoly should end. We recommend the benchmark for this product be $300 million, for each approved FDA indication, or $1 billion for all indications.

4. **The NIH should protect patients in countries with per capita incomes that are less than one third of U.S. per capita income.**

The NIH should either limit the exclusive rights to countries that have at least one third U.S. per capita income, as measured by the World Bank Atlas method GNI per capita, or place requirements that products in such countries be affordable.

5. **The NIH should require transparency with regards to R&D outlays.**

It is an unnecessary and reason-inhibiting fact that actual R&D outlays are often hidden from the public, although speculation about R&D costs is used to justify high prices. The NIH can remedy this by requiring that companies that license NIH-owned technologies disclose to the public the actual R&D costs for commercializing inventions, along with all public sector R&D subsidies, such as the Federal R&D and Orphan Drug tax credits.

Sincerely,

James Love
Knowledge Ecology International
1621 Connecticut Avenue, Suite 500
Washington, DC 20009
http://keionline.org
james.love@keionline.org

Cc:
James N. Kochenderfer, M.D.
Center for Cancer Research
National Cancer Institute
Bethesda, MD 20892
kochendj@mail.nih.gov

Exhibit 2
(January 25, 2018 Email)

Lazerow, Alan (USAMD)

From: Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>
Sent: Thursday, January 25, 2018 9:04 AM
To: 'James Love'
Subject: RE: Prospective Grant of an Exclusive Patent License: The Development of an Anti-CD30 Chimeric Antigen Receptor (CAR) for the Treatment of Human Cancer
Attachments: A-039-2018_Response to KEI Objection.pdf

Good morning Mr. Love,

Thank you for your comments with regard to the Notice of Prospective Grant of an Exclusive License to Kite Pharma, Inc. regarding NIH technology reference E-001-2016/0. We have considered your comments, and provide the attached response. Please let me know if you have any questions.

Regards,

David A. Lambertson, Ph.D.
Senior Technology Transfer Manager
Technology Transfer Center
National Cancer Institute/NIH
david.lambertson@nih.gov
http://ttc.nci.nih.gov/

9609 Medical Center Drive, Rm 1-E530 MSC 9702
Bethesda, MD 20892-9702 (USPS)
Rockville, MD 20850-9702 (Overnight/express mail)
Phone (Main Office): 240-276-5530
Phone (direct): (240) 276-6467
Fax: 240-276-5504

From: James Love [mailto:james.love@keionline.org]
Sent: Thursday, January 04, 2018 5:04 PM
To: NIH Executive Secretariat ; Lambertson, David (NIH/NCI) [E] ; Kochenderfer, James (NIH/NCI) [E]
Cc: Andrew S. Goldman ; Manon Ress ; Diane Singhroy ; Kim Treanor ; Claire Cassedy ; Thiru Balasubramaniam
Subject: Prospective Grant of an Exclusive Patent License: The Development of an Anti-CD30 Chimeric Antigen Receptor (CAR) for the Treatment of Human Cancer

Dr. Francis Collins, M.D., Ph.D., Director
National Institutes of Health
9000 Rockville Pike
Bethesda, Maryland 20892
Email: execsec1@od.nih.gov

David A. Lambertson, Ph.D., Senior Technology Transfer Manager, NCI Technology Transfer Center, Rockville, MD 20850-9702

Email: david.lambertson@nih.gov.

Dear Director Collins and Dr. Lambertson:

Knowledge Ecology International (KEI) is writing to express our opposition to the proposed exclusive license of a portfolio of patents to Kite Pharma, since October a wholly-owned subsidiary of Gilead, for chimeric antigen receptors that recognize the CLD30 protein, as posted in the Federal Register notice 82 FR 60406.

We object to the granting of the exclusive license, and request that if the NIH proceeds with the license, public interest safeguards are included.

Our comments are included in the attached PDF file.

--
James Love. Knowledge Ecology International
http://www.keionline.org/donate.html
KEI DC tel: +1.202.332.2670, US Mobile: +1.202.361.3040, Geneva Mobile: +41.76.413.6584,
twitter.com/jamie_love

25 January 2018

VIA E-MAIL ONLY

James Love
Knowledge Ecology International
1621 Connecticut Ave. NW, Suite 500
Washington, DC 20009

IN RE: Prospective Grant of an Exclusive License (NIH License Application A-039-2018) to Kite Pharma, Inc., published on 20 December 2017 in *Federal Register* Vol. 82, No. 243, pages 60406-7

Dear Mr. Love:

Thank you for providing us with your comments regarding the notice of the proposed license to Kite Pharma, Inc. (Kite), by the National Cancer Institute (NCI).

Prior to posting a notice for a proposed grant of an exclusive license, the NCI determines that the criteria set forth in 37 CFR 404.7(a)(1)(ii-iii) have been satisfied and that the company is qualified both technically and financially to be granted an exclusive license to the Government's intellectual property in the fields of use as specified. The notice period provides an opportunity for public comment and possible objection to the proposed license. We consider all comments prior to negotiating the proposed license.

While your comments have been given full consideration, they do not persuade us that the grant of an exclusive license to Kite for NCI technology E-001-2016/0 in the limited field of use that has been advertised would be inconsistent with the regulations and, furthermore, advance public health. The reasons for this determination are set forth below:

1) With respect to your comment that it is premature to grant an exclusive license, thereby creating a monopoly, because the NIH is funding a Phase I clinical trial and may be able to fund subsequent trials depending on the outcome, the comment is not entirely accurate.
    a. First, because the field of use is limited only to specific anti-CD30 CARs using a specific antibody targeting component, a monopoly will not be created. There will remain fields of use available where another company can develop an anti-CD30 CAR using distinct targeting moieties, and these can compete with the CARs to be developed by Kite.
    b. Second, the ongoing Phase 1 clinical trial suggests that the time to license the invention is immediate. The NIH does not have the appropriate funding to conduct Phase 2 or Phase 3 clinical trials; if the Phase 1 trial ends prior to a license being executed with a company that can fund later clinical trials, there will be a significant delay in the development of the invention for public use, which is in direct contrast to the NIH mission.
2) With respect to your recommendations regarding pricing of products made by the licensee, NIH has not included pricing provisions in its licenses for many years, for reasons that have been extensively discussed in the literature, which is readily and publicly available.
3) With respect to the suggestion in your letter regarding Kite's research and development costs, etc., NCI does not have the authority to require a licensee to publicly disclose financial or business confidential information, and this would be inconsistent with the licensing regulations. We respectfully refer you to 37 C.F.R. 404.14.

In conclusion, NCI has determined that your objection did not raise an issue that would preclude the grant of the proposed exclusive license, and the NCI intends to proceed with the negotiation of the proposed exclusive license, the terms of which have not yet been negotiated. All of the regulations and statutes governing the grant of an exclusive license have been adhered to during the evaluation of the Kite license application. If I can be of any further assistance, please let me know.

Sincerely,

David A. Lambertson, Ph.D.
Senior Technology Transfer Manager
National Cancer Institute, TTC
david.lambertson@nih.gov

Exhibit 3
(February 14, 2018 Email)

Gmail **Andrew Goldman <andrewspencergoldman@gmail.com>**

RE: NIH decision to proceed with the license of the anti-CD30 CAR tech to Kite/Gilead

Andrew Goldman <andrew.goldman@keionline.org> Wed, Feb 14, 2018 at 3:40 PM
To: david.lambertson@nih.gov
Cc: Jamie Love <james.love@keionline.org>, francis.collins@nih.hhs.gov

Dear Dr. Lambertson:

In your email of Jan. 25, 2018 to Knowledge Ecology International, you stated NIH's intention to proceed with the license of anti-CD30 CAR technology to Kite Pharma/Gilead, as noticed in the Federal Register Vol. 82, No. 243, pp. 60406-7.

It is our understanding that under 37 CFR 404.11, there is a right of appeal of "any decision or determination concerning the grant, denial, modification, or termination of a license." Knowledge Ecology International timely filed its comments on this particular proposed license and qualifies for the right of appeal under subsection (a)(3) as a public interest organization representing patients and taxpayers that will be damaged by the agency action.

Please let us know what formal procedures the NIH requires for these appeals, as I did not see relevant guidelines or policies any on the NIH website. If there are none, we will follow up this email with a document detailing the arguments of our appeal.

As a side note, the link to chapter 307 of the HHS Technology Transfer Policies on NIH Procedures for Handling Requests for Reconsideration and Appeals of Licensing Decisions appears to be broken: https://spweb.od.nih.gov/OTT/DTDT/TTPB/US%20PHS%20Technology%20Transfer%20Policy%20Manual/PHS%20TT%20Manual%20Chapters%20-%20Approved%20by%20TTPB/307-Procedure.pdf

Sincerely,

Andrew S. Goldman
Counsel, Policy and Legal Affairs
Knowledge Ecology International
andrew.goldman@keionline.org // www.twitter.com/ASG_KEI
tel.: +1.202.332.2670
www.keionline.org

Exhibit 4
(February 26, 2018 Email)

Lazerow, Alan (USAMD)

From: Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>
Sent: Monday, February 26, 2018 4:06 PM
To: 'Andrew Goldman'
Cc: 'Jamie Love'
Subject: RE: NIH decision to proceed with the license of the anti-CD30 CAR tech to Kite/Gilead

Dear Mr. Goldman:

Thank you for your email of February 14, 2018.

As you noted, 37 CFR 404.11 (a)(3) permits an appeal for a person who can demonstrate to the satisfaction of the agency that such person may be damaged by the action.

We have considered your objection and determined that there is no likelihood that KEI will be damaged by the agency action. Accordingly, we will not entertain an appeal of our decision.

Best regards,

David A. Lambertson, Ph.D.
Senior Technology Transfer Manager
Technology Transfer Center
National Cancer Institute/NIH
david.lambertson@nih.gov
http://ttc.nci.nih.gov/

9609 Medical Center Drive, Rm 1-E530 MSC 9702
Bethesda, MD 20892-9702 (USPS)
Rockville, MD 20850-9702 (Overnight/express mail)
Phone (Main Office): 240-276-5530
Phone (direct): (240) 276-6467
Fax: 240-276-5504

From: Andrew Goldman [mailto:andrew.goldman@keionline.org]
Sent: Wednesday, February 14, 2018 3:40 PM
To: Lambertson, David (NIH/NCI) [E]
Cc: Jamie Love ; Collins, Francis (NIH/OD) [E]
Subject: RE: NIH decision to proceed with the license of the anti-CD30 CAR tech to Kite/Gilead

Dear Dr. Lambertson:

In your email of Jan. 25, 2018 to Knowledge Ecology International, you stated NIH's intention to proceed with the license of anti-CD30 CAR technology to Kite Pharma/Gilead, as noticed in the Federal Register Vol. 82, No. 243, pp. 60406-7.

It is our understanding that under 37 CFR 404.11, there is a right of appeal of "any decision or determination concerning the grant, denial, modification, or termination of a license." Knowledge Ecology International timely filed its comments

on this particular proposed license and qualifies for the right of appeal under subsection (a)(3) as a public interest organization representing patients and taxpayers that will be damaged by the agency action.

Please let us know what formal procedures the NIH requires for these appeals, as I did not see relevant guidelines or policies any on the NIH website. If there are none, we will follow up this email with a document detailing the arguments of our appeal.

As a side note, the link to chapter 307 of the HHS Technology Transfer Policies on NIH Procedures for Handling Requests for Reconsideration and Appeals of Licensing Decisions appears to be broken: https://spweb.od.nih.gov/OTT/DTDT/TTPB/US%20PHS%20Technology%20Transfer%20Policy%20Manual/PHS%20TT%20Manual%20Chapters%20-%20Approved%20by%20TTPB/307-Procedure.pdf

Sincerely,

Andrew S. Goldman
Counsel, Policy and Legal Affairs
Knowledge Ecology International
andrew.goldman@keionline.org // www.twitter.com/ASG_KEI
tel.: +1.202.332.2670
www.keionline.org

Exhibit 5
(February 26, 2018 Response Email)

Lazerow, Alan (USAMD)

From: Andrew Goldman <andrew.goldman@keionline.org>
Sent: Monday, February 26, 2018 4:24 PM
To: Lambertson, David (NIH/NCI) [E]; Collins, Francis (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]
Subject: Appeal of NIH/NCI Decision to Proceed anti-CD30 license to Kite
Attachments: A-039-2018_Response to KEI Objection (2).pdf; Feb 14 2018 Email from Andrew Goldman to Lambertson and Collins re intention to appeal.pdf; Feb 15 2018 Email from Karen Rogers re 40 U.S.C. 559.pdf; KEI-March_10_2017-3rd-Comments-Zika.pdf; KEI-KITE-CAR-T-NIH-4Jan2018.pdf; Appeal of NIH NCI decision to proceed with anti-CD30 license to Kite, 26Feb2018.pdf

Dear Dr. Lambertson, Dr. Collins:

Attached please find our appeal of the NIH/NCI decision to proceed with the anti-CD30 license to Kite, as well as five attachments referred to within the document.

We are in receipt of your email of a few minutes ago wherein you state that you have considered our standing to appeal and determined that we do not meet the requirements, in spite of not having yet seen our appeal. We would request that you at least consider our finalized document before making your determination on this point.

If you do consider your position to be final on the point of standing under 404.11(a)(3), please let me know promptly and we will proceed accordingly.

Sincerely,

Andrew S. Goldman
Counsel, Policy and Legal Affairs
Knowledge Ecology International
andrew.goldman@keionline.org // www.twitter.com/ASG_KEI
tel.: +1.202.332.2670
www.keionline.org

25 January 2018

VIA E-MAIL ONLY

James Love
Knowledge Ecology International
1621 Connecticut Ave. NW, Suite 500
Washington, DC 20009

IN RE: Prospective Grant of an Exclusive License (NIH License Application A-039-2018) to Kite Pharma, Inc., published on 20 December 2017 in *Federal Register* Vol. 82, No. 243, pages 60406-7

Dear Mr. Love:

Thank you for providing us with your comments regarding the notice of the proposed license to Kite Pharma, Inc. (Kite), by the National Cancer Institute (NCI).

Prior to posting a notice for a proposed grant of an exclusive license, the NCI determines that the criteria set forth in 37 CFR 404.7(a)(1)(ii-iii) have been satisfied and that the company is qualified both technically and financially to be granted an exclusive license to the Government's intellectual property in the fields of use as specified. The notice period provides an opportunity for public comment and possible objection to the proposed license. We consider all comments prior to negotiating the proposed license.

While your comments have been given full consideration, they do not persuade us that the grant of an exclusive license to Kite for NCI technology E-001-2016/0 in the limited field of use that has been advertised would be inconsistent with the regulations and, furthermore, advance public health. The reasons for this determination are set forth below:

1) With respect to your comment that it is premature to grant an exclusive license, thereby creating a monopoly, because the NIH is funding a Phase I clinical trial and may be able to fund subsequent trials depending on the outcome, the comment is not entirely accurate.
    a. First, because the field of use is limited only to specific anti-CD30 CARs using a specific antibody targeting component, a monopoly will not be created. There will remain fields of use available where another company can develop an anti-CD30 CAR using distinct targeting moieties, and these can compete with the CARs to be developed by Kite.
    b. Second, the ongoing Phase 1 clinical trial suggests that the time to license the invention is immediate. The NIH does not have the appropriate funding to conduct Phase 2 or Phase 3 clinical trials; if the Phase 1 trial ends prior to a license being executed with a company that can fund later clinical trials, there will be a significant delay in the development of the invention for public use, which is in direct contrast to the NIH mission.
2) With respect to your recommendations regarding pricing of products made by the licensee, NIH has not included pricing provisions in its licenses for many years, for reasons that have been extensively discussed in the literature, which is readily and publicly available.
3) With respect to the suggestion in your letter regarding Kite's research and development costs, etc., NCI does not have the authority to require a licensee to publicly disclose financial or business confidential information, and this would be inconsistent with the licensing regulations. We respectfully refer you to 37 C.F.R. 404.14.

In conclusion, NCI has determined that your objection did not raise an issue that would preclude the grant of the proposed exclusive license, and the NCI intends to proceed with the negotiation of the proposed exclusive license, the terms of which have not yet been negotiated. All of the regulations and statutes governing the grant of an exclusive license have been adhered to during the evaluation of the Kite license application. If I can be of any further assistance, please let me know.

Sincerely,

David A. Lambertson, Ph.D.
Senior Technology Transfer Manager
National Cancer Institute, TTC
david.lambertson@nih.gov

Gmail **Andrew Goldman <andrewspencergoldman@gmail.com>**

RE: NIH decision to proceed with the license of the anti-CD30 CAR tech to Kite/Gilead

Andrew Goldman <andrew.goldman@keionline.org> Wed, Feb 14, 2018 at 3:40 PM
To: david.lambertson@nih.gov
Cc: Jamie Love <james.love@keionline.org>, francis.collins@nih.hhs.gov

Dear Dr. Lambertson:

In your email of Jan. 25, 2018 to Knowledge Ecology International, you stated NIH's intention to proceed with the license of anti-CD30 CAR technology to Kite Pharma/Gilead, as noticed in the Federal Register Vol. 82, No. 243, pp. 60406-7.

It is our understanding that under 37 CFR 404.11, there is a right of appeal of "any decision or determination concerning the grant, denial, modification, or termination of a license." Knowledge Ecology International timely filed its comments on this particular proposed license and qualifies for the right of appeal under subsection (a)(3) as a public interest organization representing patients and taxpayers that will be damaged by the agency action.

Please let us know what formal procedures the NIH requires for these appeals, as I did not see relevant guidelines or policies any on the NIH website. If there are none, we will follow up this email with a document detailing the arguments of our appeal.

As a side note, the link to chapter 307 of the HHS Technology Transfer Policies on NIH Procedures for Handling Requests for Reconsideration and Appeals of Licensing Decisions appears to be broken: https://spweb.od.nih.gov/OTT/DTDT/TTPB/US%20PHS%20Technology%20Transfer%20Policy%20Manual/PHS%20TT%20Manual%20Chapters%20-%20Approved%20by%20TTPB/307-Procedure.pdf

Sincerely,

Andrew S. Goldman
Counsel, Policy and Legal Affairs
Knowledge Ecology International
andrew.goldman@keionline.org // www.twitter.com/ASG_KEI
tel.: +1.202.332.2670
www.keionline.org

Gmail **Andrew Goldman <andrewspencergoldman@gmail.com>**

question regarding NIH tech transfer and 40 U.S.C. 559

Rogers, Karen (NIH/OD) [E] <rogersk@od.nih.gov> Thu, Feb 15, 2018 at 8:33 AM
To: Andrew Goldman <andrew.goldman@keionline.org>
Cc: Jamie Love <james.love@keionline.org>

Dear Mr. Goldman:

Thank you for your inquiry. 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.

Best regards, Karen

Karen L. Rogers

Acting Director

Office of Technology Transfer

National Institutes of Health

6011 Executive Boulevard, Suite 325

Rockville, MD 20852

E-Mail: RogersK@nih.gov

Phone: 301-435-4359

Fax: 301-402-8678

From: Andrew Goldman [mailto:andrew.goldman@keionline.org]
Sent: Tuesday, February 13, 2018 11:51 AM
To: Rogers, Karen (NIH/OD) [E] <rogersk@od.nih.gov>; Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>
Cc: Jamie Love <james.love@keionline.org>
Subject: question regarding NIH tech transfer and 40 U.S.C. 559

Dear Ms. Rogers, Mr. Lambertson:

[Quoted text hidden]

March 10, 2017

Commander
U.S. Army Medical Research and Materiel Command
ATTN: Command Judge Advocate
MCMR-JA, 504 Scott Street
Fort Detrick, MD 21702-5012
Via Fax: +1 (301) 619-5034
Via Email: barry.m.datlof.civ@mail.mil

Dear Command Judge Advocate:

This is the third set of comments signed or cosigned by KEI, including our comments on December 21, 2017 and the joint NGO comments January 12, 2017, with regards to the grant of an exclusive license of patents on a Zika Vaccine by the U.S. Army to Sanofi.[1]

Before responding to the question of the license itself, we offer this comment on the process. We had hoped to obtain answers to several questions about the proposed license, but none have been forthcoming from the Army. Whose interests are served by the lack of transparency: the large French drug and vaccine manufacturer Sanofi, or the U.S. taxpayers and residents who pay for the Army's research budget, and will have to pay if the vaccine is approved by the FDA? The lack of transparency seems to be designed to protect the French company from efforts to avoid compliance with the provisions of 35 U.S.C. § 209 and 35 U.S.C. § 201(f), and to protect the Army from informed criticism of the decision to grant an exclusive license, or their terms.

Our comments today address the issue of the statutory definition of "practical application."

The Army is required to evaluate, before granting an exclusive license on a patent, whether the licensee will bring the invention to "practical application," which is further defined in the Bayh-Dole Act as requiring that the licensee make the invention "available to the public on reasonable terms."[2] As we detail in this submission, courts and other fora in the United States,

[1] Department of the Army, Intent To Grant an Exclusive License of U.S. Government-Owned Patents, 82 Fed. Reg. 8611 (Jan. 27, 2017); Department of the Army, Intent To Grant an Exclusive License of U.S. Government-Owned Patents, 81 Fed. Reg. 89087 (Dec. 9, 2016).
[2] 35 U.S.C. § 201(f).

the United Kingdom, South Africa, and the World Trade Organization all have taken the position that "reasonable terms" includes, logically, considerations of price.

Table of Contents

Practical Application

The term "practical application" is mentioned seven times in 35 U.S.C. § 209 as a condition for the grant of an exclusive license on a federally-owned patent, including:

- once in § 209(a)(1)(A),
- twice in § 209(a)(2),
- once in § 209(a)(3),
- once in § 209(c) and,
- twice in § 209(d)(3)(A).

Practical application is defined in 35 U.S.C. 201(f) 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.)

"Available to the public on reasonable terms" is thus a statutory requirement.

The definition is <u>not</u> simply "available to the public." The definition is "available to the public on reasonable terms." When an agency only requires a product to be available on <u>any</u> terms,

including at unreasonable prices, the public is denied the protection that the statute seeks to offer.

Statements by Former Senators Bayh and Dole Regarding Reasonable Terms

Some patent holders have argued that "available to the public on reasonable terms" does not have anything to do with the price — as if there is some other set of terms that excludes price that are covered by the statute. In support of this view, rights holders have referred to statements by former Senators Birch Bayh and Bob Dole, including an April 2002 letter to the Editor of the Washington Post,[3] signed by both, and a statement by Senator Bayh at an NIH meeting on the 2004 request for the use of march-in rights on the patents on the HIV drug ritonavir.[4]

The notion that "available to the public on reasonable terms" does not extend to the price is itself an unreasonable interpretation of the plain language of the statute, which is anchored by the context of "available to the public." Why would Senators Dole and Bayh make that argument? Like many former members of Congress, both Dole and Bayh took lucrative jobs in Washington, DC, to influence the Congress and the Executive branch. Both have several commercial conflicts. In Senator Bayh's case, he has even argued more than one side of the issue, depending upon who, at the time, was paying him.

Bob Dole joined the law and lobbying firm Verner, Liipfert in 1997. In 1998, Pfizer hired Dole to promote the use of Viagra.[5] In 2000, Bob Dole also filed lobbyist reports for Bob Dole Enterprises. From 2000 to 2002, Bob Dole Enterprises listed the pharmaceutical company Johnson and Johnson as its largest client, paying $820,000 in fees in three years.

Senator Bayh also became a lobbyist and a paid influencer after leaving the senate in 1981.

In 1997, Bayh was hired by Cellpro, Inc. — a small Washington State firm manufacturing an FDA medical device that was used in bone marrow transplants — to pursue a march-in case against Johns Hopkins University over NIH-funded patents. In a March 3, 1997 petition, Birch Bayh and Lloyd N. Cutler (who had served as White House Counsel for Jimmy Carter and Bill Clinton) asked Health and Human Services Secretary Donna E. Shalala to grant a march-in license to CellPro. The petition focused on the obligation to set "reasonable terms" in the licensing of the invention, and the impact of the licensing decisions on the prices faced by consumers. Bayh and Cutler wrote that "the interests of the public which paid for the research that led to the patents and is now being asked to pay again — cry out for a far lower royalty payment by CellPro." The petition also made reference to royalty layering as "a common problem that leads to

[3] Birch Bayh and Robert Dole, "Our Law Helps Patients Get New Drugs Sooner," *Washington Post*, A28 (Apr. 11, 2002).
[4] Statement of Senator Birch Bayh to the National Institutes of Health, May 25, 2004, available at: http://www.essentialinventions.org/drug/nih05252004/birchbayh.pdf
[5] "Pfizer Hires Bob Dole for TV Ad Campaign," Associated Press, December 12, 1998, available at: http://articles.latimes.com/1998/dec/12/business/fi-53139

unreasonably high royalties (and prices of medical care) that should be dealt with by regulation."[6] They wrote:

> "CellPro submits that there may well be reason for the government to adopt regulations covering situations like the present where the same product may be claimed to be covered by patents arising out of work done by more than one federal grantee. Moreover, investigation may be needed to determine whether the royalty "layering" that plainly exists in the present case -- where federal grantee Johns Hopkins has licensed to Becton Dickinson, which apparently marked up the price and relicensed to Baxter, which in turn clearly marked up the price and relicensed to Systemix and Applied Immune Systems -- is a common problem that leads to unreasonably high royalties (and prices of medical care) that should be dealt with by regulation."

On June 14, 2001, Birch Bayh joined Venable, Baetjer, Howard & Civiletti as a partner, where he focused on "the firm's growing public policy advocacy practice." The following year, Bayh joined Dole in writing a letter to the editor of the Washington Post attacking the notion expressed by Professors Peter Arno and Michael Davis — argued in a March 27, 2002 Washington Post editorial[7] — that "available to the public on reasonable terms" includes a requirement to set "reasonable prices."

Bayh also took this position in the 2004 ritonavir march-in case, when he claimed that he was not paid to provide evidence in the hearing. But, Bayh did not disclose that Venable, the firm where he was a partner, represented Abbott, the holder of the ritonavir patents. Bayh would continue to appear on behalf of the firm to give evidence of what the Bayh-Dole Act meant, including, for example, in a December 23, 2010 amicus brief in *Stanford University v. Roche Molecular Systems*,[8] where the Supreme Court rejected Bayh's interpretation.[9]

---

[6] Lloyd N. Cutler and Birch Bayh, Letter to Secretary of Health and Human Services Donna E. Shalala, March 3, 1997, available at: https://ia800409.us.archive.org/19/items/nih_cellpro/foia_cellpro1.pdf.

[7] Peter Arno and Michael Davis, "Paying Twice for the Same Drugs," *Washington Post*, A21, Mar. 27, 2002, https://www.washingtonpost.com/archive/opinions/2002/03/27/paying-twice-for-the-same-drugs/c031aa41-caaf-450d-a95f-c072f6998931/; Peter Arno and Michael 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 Tulane L. Rev. 631-98 (2000).

[8] Brief of Birch Bayh as *Amicus Curiae* in Support of Petitioner (Dec. 23, 2010), *Stanford Univ. v. Roche Molecular Systems, Inc.*, 563 U.S. 776 (2011), available at: https://ogc.stanford.edu/sites/default/files/brief_amicus_curiae_of_birch_bayh_december_23_2010.pdf; John F. Cooney and Michael A. Gollin, *Venable team files Amicus Brief for Senator Bayh in support of Bayh-Dole Act in Stanford v. Roche*, January 14, 2011, available at: https://www.venable.com/venable-team-files-amicus-brief-for-senator-bayh-in-support-of-bayh-dole-act-in-istanford-v-rochei-01-14-2011/.

[9] *Stanford Univ. v. Roche Molecular Systems, Inc.*, 563 U.S. 776 (2011); James E. Nelson and Stephanie T. Anelli, *Stanford v. Roche: The Importance of Precise Contract Drafting*, Venable (July 2011), https://www.venable.com/files/Publication/cef85449-cb09-463a-ab1e-26f57aa40ffc/Preview/PublicationAttachment/257797c5-1f44-46c8-a8be-375f530357eb/Stanford_Roche_7-19-11.pdf

Bayh argued in 2004 that Arno and Davis misinterpreted the legislative history of the Bayh-Dole Act as regards protections against unreasonable prices.[10] However, Bayh's criticism focused on the nuances of the legislative history of the march-in provisions of the Bayh-Dole Act (35 U.S.C. § 203), and not the arguments made by Arno and Davis with regards to the way that the courts have interpreted "reasonable terms" to include a "reasonable price." And, while Bayh's written submission for the ritonavir case is correct to point out that the section of the Committee report (S. Rep. No. 96-480) on S. 414 (which became the Bayh-Dole Act) that addresses "windfall profits" does not apply to the current march-in rights provision, he does not address the definition of "practical application." Bayh also acknowledged that there were concerns about patent owners taking unfair advantage of the government-funded patent rights, a topic for which the march-in provision was often cited as a remedy in the discussion of more than one bill on government-funded patent rights.

In further evaluating the legislative history of the march-in provision, Bayh stated that Arno and Davis misquoted an exchange at a 1979 Committee hearing on S. 414 between himself and the Comptroller General of the United States, Elmer Staats, to imply that Bayh believed that the intention of the march-in provision of the bill was to prevent "the large, wealthy corporation to take advantage of Government research dollars and thus to profit at the taxpayers' expense." Bayh is correct to note that this statement was not made with explicit reference to the march-in provision, however, as Bayh himself noted in his own 2004 testimony on the ritonavir case, he stated in his 1979 testimony that he believed that, overall, "We thought we had drafted this bill in such a way that this was not possible." Moreover, neither his statement nor Staats' addressed the definition of "reasonable terms" or the prices of patented inventions.[11] Thus, it appears that, in 1979, Bayh did believe that the bill was drafted to prevent "corporations [taking] advantage of Government research dollars" and from unduly "profit[ing] at the taxpayer's expense," a position he also took in the 1997 Cellpro case (see above), where he expressed concern over the impact of the patent licensing terms on the prices charged to consumers.

Bayh also argued that the NIH has concluded that reasonable pricing requirements in relation to industry collaborations is contrary to the Bayh-Dole Act. The NIH language he quotes — from a non-binding report issued 21 years after the passage of the Bayh-Dole Act — does not, however, make any legal conclusions, but rather argues that the Bayh-Dole Act should be interpreted in light of present-day policy realities.

Reasonable Terms in U.S. Case Law

"Reasonable terms" has been regularly interpreted in case law in both federal and state courts to include price.

[10] Statement of Senator Birch Bayh to the National Institutes of Health, May 25, 2004. Available at: http://www.essentialinventions.org/drug/nih05252004/birchbayh.pdf

[11] *The University and Small Business Patent Procedures Act*, Hearings before the S. Comm. on the Judiciary on S. 414, 96 Cong. 44 (May 16, 1979).

In *American Liberty Oil Co. v. Fed. Power Comm'n*, the Fifth Circuit Court of Appeals interpreted the Natural Gas Act's provision allowing the Federal Power Commission to establish "reasonable terms and conditions" as including price.[12] *See also*, *United States v. Mississippi Vocational Rehab. for the Blind*, 812 F. Supp. 85, 87-89 (S.D. Miss. 1992) (interpreting 20 U.S.C. § 107d-3 provision allowing for federal entities to negotiate reasonable terms as including price).

In a case regarding the abuse of monopoly power, the Sixth Circuit Court of Appeals in *Byars v. Bluff City News Co.* stated that "The difficulty of setting reasonable terms, especially price, should be a substantial factor when confronted with the latter situation."[13]

In *Topps Chewing Gum, Inc. v. Major League Baseball Players Ass'n*, 641 F. Supp. 1179 (S.D.N.Y. 1986), an antitrust case, the Court recounted facts on the record, including a willingness of the players association to negotiate a license on "commercially reasonable terms," which the Court "assume[d] means at a price higher than Topps currently pays under its player contracts." *Id.* at 1191.

In contractual and commercial matters governed by the Uniform Commercial Code, Art. 9, § 610, on the disposition of collateral after default, contains an official comment on the "Relevance of Price" that suggests that price may not allow for a per se violation, but is to be considered: "While not itself sufficient to establish a violation of this Part, a low price suggests that a court should scrutinize carefully all aspects of a disposition to ensure that each aspect was commercially reasonable." See also *68A Am. Jur. 2d Secured Transactions* § 646 (1993) (stating that price is a term of commercial reasonableness, but low price alone will not render a sale commercially unreasonable).

Under the proceeds test under Article 9, some courts have accordingly held that price is a term of commercial reasonableness. *See, e.g.*, *ITT Indus. Credit Co. v. Chasse*, 25 U.C.C. Rep. Serv. (CBC) 914, 917-18 (Conn. Super. Ct. 1978); *Farmers Bank v. Hubbard*, 276 S.E.2d 622, 626-27 (Ga. 1981) (price is term of commercial reasonableness that secured party must establish is fair and reasonable); *McMillian v. Bank S., N.A.*, 373 S.E.2d 61, 62 (Ga. Ct. App. 1988) (sale's method and manner were commercially reasonable, but that price was a "term"); *FDIC v. Herald Square Fabrics Corp.*, 439 N.Y.S.2d 944, 955 n.8 (N.Y. App. Div. 1981) (stating that a "wide or marked discrepancy in disposal and sale prices is an independently adequate reason to question the commercial reasonableness of a disposition").

Reasonable Terms in U.K. Patent Law

In the United Kingdom, the Patents Act 1977 includes a "reasonable terms" requirement in § 48A, on compulsory licensing in the case of WTO proprietors, providing for the ability to obtain

[12] 301 F.2d 15 (5th Cir. 1962).
[13] 609 F.2d 843, n.58 (6th Cir. 1979).

compulsory licenses in cases where "demand in the United Kingdom for that [patented] product is not being met on reasonable terms," or for a refusal to license on reasonable terms.[14] The U.K. Manual of Patent Practice, an official government document provided by the Intellectual Property Office, explains that the requirement of reasonable terms is meant to contemplate price:

> **48A.03**
> The applicant needs to show that such a demand is not being met on reasonable terms. What constitutes "reasonable terms" depends on a careful consideration of all the surrounding circumstances in each case, eg the nature of the invention, the terms of any licences under the patent, the expenditure and liabilities of the patentee in respect of the patent, and the requirements of the purchasing public. The price charged by the patentee should be a bona fide one and not one adopted to suppress or depress demand.[15]

The Manual of Patent Practice cites the case of *Brownie Wireless Co Ltd's Applications* (1929) 46 RPC 457 as instructive. In that case, the Court addressed the question of reasonable terms in a case involving a refusal to license patents used for radio amplifiers. The case involved a prior version of the UK patent law (§ 27 of the Patents and Designs Act 1907 and 1919), which provided for compulsory licenses in cases of an abuse of the patent right, explicitly including excessive pricing.[16] The Court stated that "reasonable terms" was an "elastic phrase:"

> The grant of the licence which is refused must be a grant "on reasonable terms", an elastic phrase which can only be construed with certainty with reference to the actual facts of each particular case. No one can hope to lay down any exhaustive rules to enable the question whether the terms of a proposed licence are reasonable or not to be answered with certainty in every case. The answer to the question must in each case depend on the careful consideration of all the surrounding circumstances. The nature of the invention covered by the patent, the terms of the licences (if any) already granted, the expenditure and liabilities of the patentee in respect of the patent, the requirements of the purchasing public, and so on.[17]

In the case of *Cathro's Application* (1934) 51 RPC 75, the Court addressed an application for a compulsory license of patents pertaining to electric valves, on grounds that demand was not being met on reasonable terms under § 27 of the Patents and Designs Acts 1907 to 1932.[18] The Court cited *Brownie Wireless*, stating:

---

[14] The Patents Act, 1977 (as amended), Section 48A(1)(a)-(b).
[15] The Manual of Patent Practice is available at https://www.gov.uk/guidance/manual-of-patent-practice-mopp.
[16] *Brownie Wireless Co Ltd's Applications* (1929) 46 RPC 457. Available at https://goo.gl/oK9KBY.
[17] *Id.* at 473.
[18] *Cathro's Application* (1934) 51 RPC 75. Available at https://goo.gl/FUbKe2.

> Now I think in the first place that the expression "on reasonable terms" in paragraph (c) refers mainly to the price charged for the patented article, and I am fortified in this view by a consideration of the summary of the kinds of abuses dealt with by Section 27 given by Mr. Justice Luxmoore in Brownie Wireless Company's Applications (46 RP.C. at page 471) where the reference to "excessive price" (see line 31) clearly refers to the abuse covered by paragraph (c). No doubt, however, this statement of the 30 learned Judge should not be considered to be exhaustive as to the scope of the paragraph, and it may be that in some cases other terms than those referring merely to price should be taken into account.[19]

Reasonable Terms in South African Patent Law

South Africa has a similar provision in its patent law for compulsory licenses where there has been an abuse of the patent right, including where "demand for the patented article in the Republic is not being met to an adequate extent and on reasonable terms."[20]

In a case on this issue, *Afitra Ltd v. Carlton Paper of SA* 1992 BP 331, the Court of the Commissioner of Patents referred to the UK decisions in *Cathro's Application* and *Brownie Wireless* among others as being persuasive, and held that "on the charge of not granting a licence, the Court should be provided with evidence indicating, with reasonable precision, what reasonable terms are."[21] While the compulsory license in that case was denied, it failed because the petitioner had not met its evidentiary burden of demonstrating the price to be unreasonable.

Reasonable Terms as Interpreted by the World Trade Organization

In the dispute settlement case of Mexico-Telecoms brought before the World Trade Organization (case DS204), the WTO addressed the question of what constituted "reasonable terms." The complaint brought by the United States alleged, *inter alia*, that Mexico had violated its commitments under GATS by failing to ensure access to and use of public telecommunications transport networks and services on reasonable and non-discriminatory terms and conditions for the supply of basic and value-added telecommunications services.[22]

The United States put forward an argument regarding restricted supply directly linked to pricing:

---

[19] *Id.* at
[20] Patents Act No. 57 of 1978, section 56(2)(c). Available at http://www.cipc.co.za/files/9513/9452/7965/Patent_Act.pdf.
[21] *Afitra Ltd v. Carlton Paper of SA* 1992 BP 331, available at http://www.wipo.int/scp/en/exceptions/replies/safrica.html.
[22] Available at https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds204_e.htm.

> IV.230 In terms of the context, the United States argues that the interconnection obligations of Section 2 are especially important for the cross-border supply of basic telecom services – particularly in markets like Mexico, which legally bar foreign service suppliers from owning facilities and therefore force foreign suppliers to rely on the major supplier to deliver their services to the end-user. In such cases, foreign suppliers have no choice but to pay a domestic service supplier (such as Telmex) an interconnection rate to terminate their calls. As a result, the major supplier has the power and incentive to price this input at levels which extract as much revenue as possible from cross-border suppliers. Thus, by raising the wholesale price of cross-border interconnection, the major supplier has the power to raise the retail price, reduce demand for the retail service, and thereby restrict the cross-border supply of services into Mexico.

The Panel found that “terms” would implicitly include pricing elements:

> VII.325 As discussed in part B of these findings, the words "terms and conditions" may have many meanings. In relation to contracts and agreements, the word "terms" is defined to mean "conditions, obligations, rights, price, etc., as specified in contract or instrument", while "condition" is defined, inter alia, as "a provision in a will, contract, etc., on which the force or effect of the document depends". **Although the words "terms" and "conditions" are closely related, and are frequently used concurrently, the ordinary meaning of the word "terms" suggests that it would include pricing elements, including rates charged for access to and use of public telecommunications transport networks and services.** (Emphasis added.)

Conclusion

In our past submissions, provided as separate attachments along with this letter, we have argued that an exclusive license in this case is contrary to provisions in the Bayh-Dole Act that require that the Army evaluate the “reasonable and necessary” incentives required by Sanofi. Sanofi already receives significant funding from the government to conduct clinical trials, has a CRADA with the Army, and would receive both significant data exclusivity protections and a priority review voucher for successfully bringing a Zika vaccine to market.

If, however, the Army decides to grant an exclusive license, it has a clear obligation to ensure that the license includes terms that provide for a reasonable price.

We request a meeting to discuss these issues with you in further detail.

Sincerely,

Andrew S. Goldman, Esq.
Counsel, Policy and Legal Affairs
andrew.goldman@keionline.org

Zack Struver
Communications & Research Associate
zack.struver@keionline.org

James Love
Director
james.love@keionline.org

Knowledge Ecology International
1621 Connecticut Ave NW Suite 500
Washington, DC 20009
+1 (202) 332-2670
http://keionline.org

January 4, 2017

Dr. Francis Collins, M.D., Ph.D., Director
National Institutes of Health
9000 Rockville Pike
Bethesda, Maryland 20892
Email: execsec1@od.nih.gov

David A. Lambertson, Ph.D., Senior Technology
Transfer Manager, NCI Technology Transfer Center,
Rockville, MD 20850-9702
Email: david.lambertson@nih.gov.

Dear Director Collins and Dr. Lambertson:

Knowledge Ecology International (KEI) is writing to express our opposition to the proposed exclusive license of a portfolio of patents to Kite Pharma, since October a wholly-owned subsidiary of Gilead, for chimeric antigen receptors that recognize the CLD30 protein, as posted in the Federal Register notice 82 FR 60406.

We object to the granting of the exclusive license, and request that if the NIH proceeds with the license, public interest safeguards are included.

1. Background

The Federal Register notice identified several forms of cancer that may be treated with the technology, including Hodgkin's Lymphoma (HL), Non-Hodgkin's Lymphoma (NHL), diffuse large B cell lymphoma (DLBCL), peripheral T-cell lymphoma not otherwise specified (PTCL-NOS), anaplastic large cell lymphoma (ALCL), and angioimmunoblastic T-cell lymphoma (AITL).

The inventor listed in the patent applications referred to in the Federal Register notice is James N. Kochenderfer, M.D.

The technology to be licensed appears to be undergoing an NIH funded Phase 1 trial with the ClinicalTrials.gov identifier: NCT03049449.

The NIH proposed worldwide rights, and has filed a patent application with the WIPO PCT seeking protection in the following countries:

Pub. No.: WO/2017/066122
International Application No.: PCT/US2016/056262
Publication Date: 20.04.2017
International Filing Date: 10.10.2016
Applicants: THE UNITED STATES OF AMERICA, AS REPRESENTED BY THE SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES [US/US]; Office of Technology Transfer National Institutes of Health
Inventors: KOCHENDERFER, James N.

Designated States:

AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

African Regional Intellectual Property Organization (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW)

Eurasian Patent Organization (AM, AZ, BY, KG, KZ, RU, TJ, TM)

European Patent Office (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR)

African Intellectual Property Organization (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

2. It is premature to grant an exclusive license, given the fact that the NIH is funding a Phase 1 trial.

We object to the NIH licensing this promising technology before the patent has been granted, and before the NIH concludes and evaluates the results from the ongoing Phase 1 trial, which

began on March 17, 2017 and currently has an estimated primary completion date of June 30, 2021, according to the NIH database ClinicalTrials.Gov.

In an environment where there is widespread alarm over the escalating costs of treatments for cancer and Congressional concerns over the pricing of NIH-funded biomedical inventions, it is unwise for the NIH to create a monopoly on this NIH-funded invention, before the NIH can evaluate both the evidence from the ongoing Phase 1 trial and the costs of moving the technology forward to FDA approval, if the Phase 1 results are encouraging.

Evaluating the costs of obtaining FDA approval would entail a comparison of the costs that the NIH would incur directly if it were to conduct the result itself, versus the costs imposed on U.S. patients, employers and taxpayers if the NIH grants a legal monopoly to Gilead.

If the costs of the NIH funding the R&D itself directly leads to significant savings over the costs to U.S. residents of granting a legal monopoly, the NIH should not grant the monopoly.

3. **If the NIH grants an exclusive license, it should include clear safeguards in the license to protect U.S. residents from excessive prices and access barriers.**

    a. The price should not discriminate against U.S. residents.

At a very minimum, the NIH should include a provision in the licenses that would ensure that the price for a product or service that relied upon the invention would not be more expensive in the United States than the median price charged for a group of countries that include Canada plus the eight largest economies in the world that also have a nominal per capita income at least 50 percent of that of the United States (as measured by GNI, World Bank Atlas method).

    b. The price should not constitute an unreasonable barrier to access in the United States.

If there is a significant gap between the number of patients who would benefit from the treatment and the number of patients who receive the treatment, the monopoly should be terminated.

    c. The price should not be higher than CAR T treatments of similar efficacy, taking into account differences in patient populations, if the cumulative revenue per indication is less than $300 million.

We note that the two previous CAR T procedures approved by the FDA involved a small number of patients in trials, including, for example, Yescarta, also licensed by the NIH to Gilead/Kite, whose FDA press release stated “The safety and efficacy of Yescarta were established in a multicenter clinical trial of more than 100 adults . . . ”

d. The price should not increase faster than the rate of inflation as measured by the consumer price index, unless the increase can be justified by a need to earn a reasonable profit on the risk adjusted investments in research and development.

Alternatively, if revenues are robust, there could be a requirement that prices decline as companies reach certain benchmarks.

e. The revenues earned under exclusive rights should not be excessive.

When the cumulative global revenue for the product exceeds a particular benchmark, the monopoly should end. We recommend the benchmark for this product be $300 million, for each approved FDA indication, or $1 billion for all indications.

4. **The NIH should protect patients in countries with per capita incomes that are less than one third of U.S. per capita income.**

The NIH should either limit the exclusive rights to countries that have at least one third U.S. per capita income, as measured by the World Bank Atlas method GNI per capita, or place requirements that products in such countries be affordable.

5. **The NIH should require transparency with regards to R&D outlays.**

It is an unnecessary and reason-inhibiting fact that actual R&D outlays are often hidden from the public, although speculation about R&D costs is used to justify high prices. The NIH can remedy this by requiring that companies that license NIH-owned technologies disclose to the public the actual R&D costs for commercializing inventions, along with all public sector R&D subsidies, such as the Federal R&D and Orphan Drug tax credits.

Sincerely,

James Love
Knowledge Ecology International
1621 Connecticut Avenue, Suite 500
Washington, DC 20009
http://keionline.org
james.love@keionline.org

Cc:
James N. Kochenderfer, M.D.
Center for Cancer Research
National Cancer Institute
Bethesda, MD 20892
kochendj@mail.nih.gov

Dr. Francis Collins, M.D., Ph.D., Director
National Institutes of Health
9000 Rockville Pike
Bethesda, Maryland 20892
Email: francis.collins@nih.hhs.gov; collinsf@mail.nih.gov

David A. Lambertson, Ph.D., Senior Technology
Transfer Manager, NCI Technology Transfer Center,
Rockville, MD 20850-9702
Email: david.lambertson@nih.gov

February 26, 2018

Dear Director Collins and Dr. Lambertson:

Knowledge Ecology International ("KEI") writes to appeal the decision of the National Institutes of Health ("NIH") and National Cancer Institute ("NCI") to proceed with the exclusive license of a portfolio of patents to Kite Pharma, a wholly-owned subsidiary of Gilead, for chimeric antigen receptors ("CAR") that recognize the CD30 protein, as posted in the Federal Register notice 82 FR 60406.

Pursuant to 37 C.F.R. § 404.11, KEI requests a hearing as part of the appeal.

Procedural Background

On December 20, 2017, the NIH posted a notice of intent in the Federal Register (the "Notice") regarding the proposed grant of a worldwide exclusive license to Kite of patents for CAR technology for the treatment of human cancer.[1] The Notice specifically referred to "United States Provisional Patent Application No. 62/241,896, filed 15 October 2015 and entitled ''Anti-CD30 Chimeric Antigen Receptors'' [HHS Reference No. E–016–2018/0–US–01]; PCT Patent Application PCT/US2016/ 056262, filed 10 October 2016 and entitled ''Anti-CD30 Chimeric Antigen Receptors'' [HHS Reference No. E–016– 2018/0–PCT–02]; and U.S. and foreign patent applications claiming priority to the aforementioned applications" (collectively, the "CD30 CAR technology").

[1] 82 Fed. Reg. 60406-7 (Dec. 20, 2017).

The Notice additionally specified that this CD30 CAR technology would provide treatment for rare cancers, "including Hodgkin lymphoma (HL), Non-Hodgkin's Lymphoma (NHL), diffuse large B cell lymphoma (DLBCL), peripheral T cell lymphoma not otherwise specified (PTCL–NOS), anaplastic large cell lymphoma (ALCL), and angioimmunoblastic T cell lymphoma (AITL)."

The Notice provided a window for public comment on the proposed exclusive license that spanned two national holidays, closing on January 4, 2018.

On January 4, 2018, KEI timely submitted written comments ("Comments" or "KEI's Comments") to the NIH in response to the Notice, objecting to the exclusivity of the license and requesting the inclusion of public interest safeguards in any license to be executed.[2] KEI's comments are attached and incorporated by reference.

On January 25, 2018, Dr. David Lambertson, Senior Technology Transfer Manager at NCI, sent an email (attached) to KEI acknowledging receipt of KEI's comments, rejecting all of KEI's substantive suggestions and objections, providing a list of reasons for the "determination," and stating that ". . . NCI intends to proceed with the negotiation of the proposed exclusive license. . . ."

On February 13, 2018, KEI sent an email to Dr. Lambertson and Karen Rogers, Acting Director of NIH Office of Technology Transfer, asking whether NIH requests and obtains advice of the Attorney General with respect to antitrust laws prior to transferring patents and related rights from the NIH to private interests, as required by 40 U.S.C. § 559 of the Federal Property and Administrative Services Act ("FPASA").

On February 14, 2018, KEI sent an email to Dr. Lambertson and Dr. Francis Collins, Director of NIH, signaling an intent to appeal the decision to proceed with the exclusive license of the CD30 CAR technology to Kite.

On February 15, 2018, Ms. Rogers replied via email (attached) to KEI's February 13th inquiry to say that the NIH does not follow the requirements of 40 U.S.C. § 559 in its patent licensing activities.

KEI Has a Legal Basis for Appeal Under 37 C.F.R. § 404.11 as a Public Interest Organization Representing Individuals Who Will be Damaged By the Decision to Proceed with the Exclusive License[3]

37 C.F.R. § 404.11 governs appeals concerning, "any decision or determination concerning the grant, denial, modification, or termination of a license." Dr. Lambertson's email rejecting KEI's

[2] https://www.keionline.org/wp-content/uploads/2018/01/KEI-KITE-CAR-T-NIH-4Jan2018.pdf

[3] KEI sent an email to Dr. Lambertson and Dr. Collins on February 14, 2018 (attached) stating the desire to appeal the decision to proceed, and requesting information regarding any formal procedures that the NIH requires for such an appeal as no such procedures are specified in regulations or available on the NIH website. To date, we have not received any reply. If there are formal requirements and this document does not conform to those requirements, KEI would ask for the opportunity to make any necessary corrections.

comments is self-evidently a determination/decision to proceed with the negotiation of the exclusive license subject to appeal.

KEI is granted the right of appeal under subsection (a)(3) as a public interest organization that timely filed a written objection to the NIH's notice. Furthermore, KEI represents taxpayers and patients, including cancer patients, who are stakeholders in the outcome of the NIH decision as persons who need new treatments but who also need these treatments to be affordable.

Kite was purchased by Gilead Sciences in October 2017 for $11.9 billion, and is now a wholly-owned subsidiary. Gilead already has one CAR T treatment, axicabtagene ciloleucel (marketed as Yescarta), priced at $373,000 per treatment. A second CAR T therapy, tisagenlecleucel (marketed by Novartis as Kymriah), is priced at $475,000 per treatment. Prices for costs of care related to the treatment have been estimated to be as high as $1.5 million, creating severe hardship for patients, payers, and health budgets.[4]

KEI represents persons who will be damaged by the decision to proceed with an exclusive license on CAR T technology without safeguards against excessive pricing or access barriers.

§ 404.11 Appeals.
(a) In accordance with procedures prescribed by the Federal agency, the following parties may appeal to the agency head or designee any decision or determination concerning the grant, denial, modification, or termination of a license:
(1) A person whose application for a license has been denied;
(2) A licensee whose license has been modified or terminated, in whole or in part; or
(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.
(b) An appeal by a licensee under paragraph (a)(2) of this section may include a hearing, upon the request of the licensee, to address a dispute over any relevant fact. The parties may agree to Alternate Dispute Resolution in lieu of an appeal.

Argument

It is Premature to Grant an Exclusive License Prior to the Completion of Phase 1 Clinical Trials.

In KEI's submitted comments, we objected to the proposed exclusive license as being premature, given that Phase 1 clinical trials are underway and are not scheduled to be completed until 2021. KEI recommended waiting until the NIH could do an analysis of the costs

[4] Kaiser Health News, "Cascade of costs could push CAR-T therapy to $1.5M per patient," Oct. 17, 2017. https://endpts.com/cascade-of-costs-could-push-new-gene-therapy-above-1-million-per-patient/

that the NIH would incur were the agency to fund the clinical trials completely, versus the costs imposed on patients, employers, and taxpayers via the grant of the patents to Gilead:

> In an environment where there is widespread alarm over the escalating costs of treatments for cancer and Congressional concerns over the pricing of NIH-funded biomedical inventions, it is unwise for the NIH to create a monopoly on this NIH-funded invention, before the NIH can evaluate both the evidence from the ongoing Phase 1 trial and the costs of moving the technology forward to FDA approval, if the Phase 1 results are encouraging.[5]

The KEI comment went to the issue of whether or not the NIH decision to license was premature, both in determining if an exclusive license was necessary at all, and if, pursuant to 35 U.S.C. § 209, "the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application."

In response to this point, Dr. Lambertson replied that (1) because the field of use in the proposed license is limited, "only to specific anti-CD30 CARs using a specific antibody targeting component," there will be no monopoly; and that (2) the NIH does not have the appropriate funding to conduct Phase 2 or Phase 3 trials, and that therefore the time to license is "immediate."[6]

With regard to Dr. Lambertson's first point, the grant of an exclusive license is designed to create a twenty-year right to exclude competitors from the marketplace via the patents (plus time added for patent extensions). The suggestion that the license field of use restriction creates a situation where there is "no monopoly" is patronizing and incorrect. The NIH could offer a non-exclusive license, and avoid a monopoly, but instead it has proposed an exclusive license that would grant a monopoly on "specific anti-CD30 CARs using a specific antibody targeting component." Considering the extremely high prices associated with the earlier Kite/Gilead CAR T treatment (more than the median sales price for new houses sold in the United States) also licensed from the NIH, it is hard to see how the NIH can claim no monopoly is involved.

Dr. Lambertson provides no evidence to support his second point regarding NIH funding. In considering this point, it would be helpful to know what the NIH is actually spending on the current Phase 1 trial. On February 14, 2018, KEI called Brenna Hansen, who is listed as the NIH contact for the clinical trials for the CD30 CAR technology at issue, to ask what the budget was for the current CAR T trial being funded by the NIH.[7] She declined to provide any information. The NIH/NCI can and should divulge this information, as well as estimates of what it believes a necessary budget would be for Phase 2 and/or Phase 3 trials.

---

[5] KEI Objection, at p. 3.
[6] Email of Dr. Lambertson to James Love, Jan. 25, 2018.
[7] https://www.keionline.org/25808

We do know that for the first two CAR T treatments approved by the FDA, the number of patients in the trials were very small. According to the FDA press release for the initial approval of Kymriah (updated August 30, 2017), "the safety and efficacy of Kymriah were demonstrated in one multicenter clinical trial of 63 pediatric and young adult patients with relapsed or refractory B-cell precursor ALL."[8] The FDA press release for Gilead's Yescarta cited evidence from "over 100" patients. As of January 27, 2017, 111 patients were enrolled in the ZUMA-1 Phase 1/2 trials.[9]

The NIH is currently funding the Phase 1 trial NCT03049449, titled "T Cells Expressing a Fully-Human Anti-CD30 Chimeric Antigen Receptor for Treating CD30-Expressing Lymphomas," which has an expected enrollment of 76 patients, more than were enrolled in the trial cited by the FDA for the approval of Kymriah and nearly as many as in the Zuma-1 trial used to approve Yescarta.

If the NIH invented the technology and is funding the development through a 76-patient trial, it is reasonable to ask why the NIH believes an exclusive license is needed to fund the remaining trials, and how extensive the scope of rights should be to meet the 35 USC § 209 obligations to restrict such rights to those that are "reasonably necessary to provide the incentive for bringing the invention to practical application." The NIH needs to offer more information about the projected costs of the trials to justify the term of the monopoly the NIH proposes to give Gilead.

Any License Should Include Safeguards Against Excessive Pricing and Barriers to Access for U.S. Residents, and Should Limit the Exclusive Rights in Poorer Countries.

In KEI's Comments, in addition to objecting to the proposed exclusive license, we also made a number of suggestions regarding the need to include safeguards in any license that may be executed, including safeguards against excessive pricing and barriers to access, both for U.S. residents and for poorer countries. These recommendations included:

> (1) a clause to protect against excessive prices in the U.S. relative to a set of reference countries;
> (2) provisions to terminate monopoly rights if the price creates access barriers in the U.S.;
> (3) provisions preventing the price from exceeding that of CAR-T treatments of similar efficacy (*e.g.* Yescarta);
> (4) provisions to terminate monopoly rights upon achieving certain global revenue benchmarks; and
> (5) provisions to either limit exclusive rights or otherwise require that the treatment be made affordable in countries with less than one-third the per capita income of the U.S.

[8] https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm574058.htm
[9] http://cancerres.aacrjournals.org/content/77/13_Supplement/CT019

In reply, Dr. Lambertson simply points to the fact that the NIH has not included pricing provisions for years, a fact we do not dispute. However, the failure of the NIH in the past to limit the scope of rights to that which is reasonably necessary to induce investments in the development of a product is not an argument as to why it should never enforce this requirement to protect the public from unreasonable use of inventions.

To meet the requirements of 35 USC § 209, the NIH could choose to include safeguards on pricing, a concession that would limit the scope of rights associated with a monopoly. Alternatively, the NIH could limit the number of years of exclusivity, which was the approach taken for the NIH/ddI license to BMS.[10] According to an NIH report on the negotiation:[11]

> "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 became non-exclusive early, prior to the expiration of the NIH patents. Several companies competed for the license. Criteria for selecting the licensee included the company's technical ability to develop this compound into a drug and manufacture it in large quantities, its willingness to work cooperatively with the NIH, and its willingness to make development of this compound a priority. The Bristol-Myers Squibb plan was judged superior by the selection panel, and the license was signed in January 1988. NIH exercised its prerogative to have the license become nonexclusive in October 2001."

Instead the NIH seems to be offering to do neither measure to limit the scope of rights, and proposes to just give Gilead the maximum term of years and the maximum flexibility on pricing. This appears contrary to the statutory requirements of § 209.

KEI also notes that the Bayh-Dole Act does not begin and end with a mandate to bring products to market, but rather includes the need to, "protect the public against nonuse or unreasonable use of inventions"[12]

The inclusion of protections against "unreasonable use" is not inconsequential, and the Bayh-Dole Act contains related provisions in numerous places demonstrating that it is not

---

[10] See *Exclusive Agreements Between Federal Agencies and Bristol-Myers Squibb Co. For Drug Development: Is the Public Interest Protected?: Hearing Before the Subcomm. On Regulation, Business Opportunities, and Energy of the H. Comm. on Small Business*, 102nd Congress 350-377 at 362 (NCI's Response to Questions Raised in Rep. Ron Wyden Letter dated Aug. 1, 1991) ("...NCI negotiated this term with Bristol, which originally requested an exclusive license for the duration of the life of the patent. ...At the time that this license was granted by the National Technical Information Service (NTIS) as the licensing agent for DHHS, NTIS frequently limited the exclusive period in license agreements to ten years.").

[11] Videx® Expanding Possibilities: A Case Study, National Institutes of Health Office of Technology Transfer, September 2003. https://www.ott.nih.gov/sites/default/files/documents/pdfs/VidexCS.pdf

[12] 35 U.S.C. § 200.

merely "nonuse" that is of concern. 35 U.S.C. § 209, governing the license of federally-owned inventions, includes a requirement of "practical application" — a defined term under 35 U.S.C. § 201(f) that requires the invention be made "available to the public in reasonable terms."

"Reasonable terms" itself is understood both in the United States and abroad, in jurisprudence as well as official statutory/regulatory interpretative documents, to include reasonable pricing. *See* KEI 10 March 2017 Comments on Army Exclusive License on Zika Virus Vaccine Patents to Sanofi, attached and incorporated by reference.[13]

The inclusion of safeguards and conditions on access and affordability are consistent with the obligations in the Bayh-Dole Act to make the benefits of the inventions "available to the public on reasonable terms", and are the right policy for protecting the public interest.

The NIH Should Require Transparency of R&D Outlays for the Public to Better Understand the Relationship of R&D to High Prices.

KEI's Comments additionally suggested that the NIH should require transparency with regard to research and development (R&D) costs, along with public sector subsidies such as the Orphan Drug Tax Credit. This information would better allow the public to understand what relationship there is, if any, between the R&D expenditures and high prices.

Dr. Lambertson stated in his reply that NIH/NCI does not have authority to require such disclosures, and points to 37 CFR § 404.14 requiring that any plan submitted under 37 CFR § 404.8(h) and § 404.5(b)(6) be treated as confidential and not subject to disclosure under FOIA.

Neither of the specified regulatory requirements referred to within § 404.14 are a flat bar to transparency obligations regarding the development of product, and the requests KEI made were not inconsistent with licensing regulations. § 404.8(h) is relevant to the plan itself submitted as part of an application for a license, but is silent as to the actual expenditures and subsidies themselves. § 404.5(b)(6) requires periodic reporting by the licensee, "on the utilization or efforts at obtaining utilization that are being made by the licensee, with particular reference to the plan submitted but only to the extent necessary to enable the agency to determine compliance with the terms of the license." But this requirement does not explicitly refer to the costs of R&D or the extent of federal subsidy.

During an earlier dispute regarding the failure to adequately supply the market with Fabrazyme, Genzyme, Inc. and later Sanofi were required to provide the NIH with detailed monthly reports on patent litigation in Europe and on measures taken to address access to the drug in the United States. These documents were subsequently made public by the NIH and are on the KEI web page.[14]

[13] Also available at https://www.keionline.org/23296.
[14] https://keionline.org/sites/default/files/Fabrazyme-NIH-Sinai_2011u.pdf

The Decision to Proceed with the Exclusive License Should Be Stopped Until NIH Receives Antitrust Advice from the Attorney General Pursuant to 40 U.S.C. § 559.

By admission of Ms. Rogers, the NIH has not followed the law of 40 U.S.C. § 559, because it does not believe the law pertains to the licensing of patents. This interpretation is not supported by the law.

The Federal Property and Administrative Services Act (40 U.S.C. §§ 101 *et seq.*) was enacted to govern the procurement, utilization and disposal of property.[15]

Under 40 U.S.C. § 559(b), the NIH as a federal executive agency is required to seek and obtain the antitrust advice of the Attorney General prior to disposing of property to a private interest.

"Property" is defined at 40 U.S.C. § 102 to mean "any interest in property", with certain exceptions that do not include patents. Similarly, § 559 includes certain exceptions for where the requirement does not apply, but these exceptions do not include patents.

40 U.S. Code § 559 - Advice of Attorney General with respect to antitrust law

(a)Definition.—In this section, the term "antitrust law" includes—

(1) the Sherman Act (15 U.S.C. 1 et seq.);
(2) the Clayton Act (15 U.S.C. 12 et seq., 29 U.S.C. 52, 53);
(3) the Federal Trade Commission Act (15 U.S.C. 41 et seq.); and
(4) sections 73 and 74 of the Wilson Tariff Act (15 U.S.C. 8, 9).

(b)Advice Required.—

(1)In general.—
An executive agency shall not dispose of property to a private interest until the agency has received the advice of the Attorney General on whether the disposal to a private interest would tend to create or maintain a situation inconsistent with antitrust law.
(2)Exception.—This section does not apply to disposal of—
(A)real property, if the estimated fair market value is less than $3,000,000; or
(B)personal property (other than a patent, process, technique, or invention), if the estimated fair market value is less than $3,000,000.

(c)Notice to Attorney General.—

(1)In general.—
An executive agency that contemplates disposing of property to a private interest shall promptly transmit notice of the proposed disposal, including probable terms and conditions, to the Attorney General.
(2)Copy.—

[15] 40 U.S.C. § 101.

> Except for the General Services Administration, an executive agency that transmits notice under paragraph (1) shall simultaneously transmit a copy of the notice to the Administrator of General Services.
>
> (d)Advice From Attorney General.—
> Within a reasonable time, not later than 60 days, after receipt of notice under subsection (c), the Attorney General shall advise the Administrator and any interested executive agency whether, so far as the Attorney General can determine, the proposed disposition would tend to create or maintain a situation inconsistent with antitrust law.
>
> (e)Request for Information.—On request from the Attorney General, the head of an executive agency shall furnish information the agency possesses that the Attorney General determines is appropriate or necessary to—
>
> (1) give advice required by this section; or
> (2)determine whether any other disposition or proposed disposition of surplus property violates antitrust law.
>
> (f)No Effect on Antitrust Law.—
> This subtitle does not impair, amend, or modify antitrust law or limit or prevent application of antitrust law to a person acquiring property under this subtitle.

Federal regulations at 41 C.F.R. 102-75.270 clarify the point by explicitly including patents among the property that trigger the requirement of considering the antitrust ramifications in a contemplated disposal to a private interest:

> **41 CFR 102-75.270 - Must antitrust laws be considered when disposing of property?**
>
> Yes, antitrust laws must be considered in any case in which there is contemplated a disposal to any private interest of -
>
> (a) Real and related personal property that has an estimated fair market value of $3 million or more; or
>
> (b) Patents, processes, techniques, or inventions, irrespective of cost.

Furthermore, 40 U.S.C. § 113 provides for limitations on the reach of the FPASA by explicitly enumerating a list of departments, agencies, and heads of those departments and agencies that retain authority that cannot be impaired or affected by the FPASA. This list does not include the Department of Health and Human Services, the Secretary of Health and Human Services, the National Institutes of Health, or the Director of the National Institutes of Health. The omission of

these entities and offices evidences the fact that NIH licensing activities are not exempt from the requirements of the FPASA.

"Disposal" under the FPASA Includes Licensing, and the Bayh Dole Act does not Create an Exception to the FPASA Requirement Regarding Antitrust Advice..

Ms. Rogers's email errantly suggests that "disposal" under the FPASA does not touch licensing activities: "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."

While the Bayh-Dole Act and its attendant regulations govern the licensing of federally-owned and federally-funded patents by NIH, there is no exception within the Bayh-Dole Act that would exempt the agency from having to abide by the requirements of the FPASA. 35 U.S.C. § 209(a)(4) in fact creates an obligation that the licensing federal agency may only grant a license on a federally-owned invention if it, "will not tend to substantially lessen competition or create or maintain a violation of the Federal antitrust laws." Logically, this suggests that the FPASA requirement applies; the NIH has abundant expertise in developing new medical technologies but does not have the antitrust expertise of the Attorney General.

Furthermore, the term "disposal" is not a defined term under 40 U.S.C. § 102 of the FPASA, and is not limited to "assignment" or "sale." In fact, there are many examples of regulations and laws that include licensing amongst dispositions, either explicitly or by implication.

For example, in the State Department's Foreign Affairs Manual, licenses are included as a method of disposal along with sale, assignment, and lease.[16] The manual distinguishes between "permanent" disposals (e.g. sale) and licenses, which are "preferable because a license generally creates no enforceable rights for the licensee and does not diminish the U.S. Government's title rights. . . [and] require prior review and approval by OBO/PRE/RPL and the Office of the Legal Adviser (L/BA) for properties controlled by Department of State, or USAID/W-M/MS/OMD for properties controlled by USAID."[17]

Likewise, General Services Administration regulations in many places include licenses among the possible methods of disposal. *See, e.g.*, FMR §102-75.296 ("A landholding agency may be the disposal agency for real and related personal property when— …(c) The agency is disposing of —(1)...licenses…").

The Uniform Commercial Code defines "account" to include a right to payment for "property that has been or is to be sold, leased, licensed, assigned, or otherwise disposed of." Unif.Commercial Code § 9-102.

[16] 15 FAM 521.1.
[17] 15 FAM 521.5.

Conclusion

For all of the reasons stated above, KEI requests that the NIH reverse its determination to proceed with this license (1) unless it includes the public interest safeguards referred to in our submitted comments, and (2) until the NIH seeks and obtains antitrust advice from the Attorney General.

We request a hearing for this appeal.

Sincerely,

Andrew S. Goldman, Esq.
Counsel, Policy and Legal Affairs
Knowledge Ecology International
+1.202.332.2670
andrew.goldman@keionline.org

Attachments:

(1) Email from Dr. Lambertson to James Love, January 25, 2018.
(2) Objection of Knowledge Ecology International to Proposed Exclusive License to Gilead of Chimeric Antigen Receptors that Recognize the CLD30 Protein, Jan. 4, 2017.
(3) Email from Karen Rogers to Andrew Goldman and James Love, Feb. 15, 2018.
(4) Email from Andrew Goldman to Dr. Lambertson and Dr. Collins, Feb. 14, 2018.
(5) KEI Comments on Army Exclusive License on Zika Virus Vaccine Patents to Sanofi, March 10, 2017.