

Knowledge Ecology International
1621 Connecticut Avenue NW
Suite 500
Washington, DC 20009
Tel.: (202)332-2670
claire.cassedy@keionline.org
james.love@keionline.org

TO: FOIA Officer
Freedom of Information Office, NIH
Building 31, Room 5B35
31 Center Drive, MSC 2107
Bethesda, MD 20892-2107

DATE: June 29, 2018

RE: Request for Expedited Processing of Attached FOIA Request

Dear FOIA Officer:

Pursuant to 5 U.S.C. § 552(a)(6)(E)(i) and 5 U.S.C. § 552(a)(6)(E)(v)(II) and 45 CFR 5.27¹, Knowledge Ecology International (KEI) requests expedited processing of the attached FOIA request based upon the compelling need to obtain and disseminate more detailed information about the CAR T technology at issue in the proposed exclusive license as noticed in 83 FR 30448. This information is critical in order to allow the public to make informed comments on a potentially valuable and medically significant cancer treatment.

Under the above statutes and regulations, “compelling need” is defined to include:

- (I) that a failure to obtain requested records on an expedited basis under this paragraph could reasonably be expected to pose an imminent threat to the life or physical safety of an individual; or
- (II) with respect to a request made by a person primarily engaged in disseminating information, urgency to inform the public concerning actual or alleged Federal Government activity.

¹ NIH does not seem to have promulgated its own regulations for expedited processing, in spite of the statutory requirement at 5 U.S.C. § 552(a)(6)(E)(i) that “each agency shall promulgate regulations, pursuant to notice and receipt of public comment, providing for expedited processing of requests for records.” (Emphasis added). “Agency” is defined at 5 U.S.C. § 551(1) to mean “each authority of the Government of the United States, whether or not it is within or subject to review by another agency.” In the absence of NIH regulations, we cite the HHS regulations on expedited FOIA processing.

We describe how KEI meets the requirements of subparagraph II as a person primarily engaged in disseminating information, where there is urgency to inform the public concerning actual Federal Government activity as specified in 83 FR 30448.

KEI is a person² under FOIA that is primarily engaged in disseminating information.

Under KEI's Articles of Incorporation, Article III explicitly provides that education of the public and other constituencies is among the core purposes of the organization, and that the very mission of KEI itself is inextricably intertwined with the availability of knowledge and information:

“The Corporation is organized and will be operated exclusively for charitable, educational, and scientific purposes. Specifically, the Corporation will perform research, educate the public and other constituencies, and contribute to policy discourse and debate on issues relating to intellectual property, innovation, economics, international trade, consumer protection, law, and access to knowledge and the fruits of knowledge, including without limitation issues related to the public domain, freely licensed knowledge resources, knowledge resources that are available by custom, access to medical inventions including essential medicines, technologies and business or social systems that are used to manage knowledge resources, modes of stimulating and financing knowledge resources, and related technological, legal and social aspects of the management of knowledge.”

As explained within the attached FOIA request, KEI disseminates information through its website (<https://keionline.org>) which hosts an extensive archive that is regularly consulted by advocates, academics, and the press. KEI reviews FOIA responses to produce clear and concise analysis of those records, and additionally uses social media and listservs to distribute that analysis to the broad audience of persons interested in the subject of the request. As stated within the attached FOIA request:

KEI regularly publishes and analyzes records requested under the FOIA on its website, including recently on various government operations and activities at parts of DHHS:

- 28 February 2017, “CDC FOIA shows US, WHO opposed request to discuss UNSG's High-Level Panel on Access to Medicines Report at EB,” <https://keionline.org/node/2727>
- 18 October 2016, “Kite Pharma Uses CRADAs to Conduct Important Clinical Research on New Cancer Treatments,” <https://keionline.org/node/2640>
- 19 September 2016, “500+ Pages of Documents on NFL Attempts to Influence NIH Funding of Concussion Studies,” <https://keionline.org/node/2630>

² “Person” is defined at 5 U.S.C. § 551(2) to include “an individual, partnership, corporation, association, or public or private organization other than an agency.” KEI is a 501c3 nonprofit corporation incorporated in the District of Columbia in 2006.

- 16 September 2016, “NIH Waivers for U.S. Manufacturing Requirements for Federally-Funded Drugs,” <https://keionline.org/node/2629>

Additionally, KEI works closely with journalists to provide analysis for documents requested by KEI under the FOIA. KEI does not merely distribute documents to journalists, but provides in-depth analysis that later becomes the basis for stories:

- 3 March 2017, Vidya Krishnan, “U.S. nixed India’s plea on reforms in medicine,” The Hindu,
<http://www.thehindu.com/news/national/us-nixed-indias-plea-on-reforms-in-medicine/article17403526.ece>
- 31 December 2016, Dan Vergano, “If Taxpayers Invent A Drug, Should The Government Just Give It Away?,” Buzzfeed News,
<https://www.buzzfeed.com/danvergano/nih-drug-giveaway>
- 20 December 2016, “Front page New York Times story explores Kite Pharma’s profitable relationship with NIH regarding expensive cancer drug,”
<https://keionline.org/node/2703>

KEI additionally has done specific work in disseminating information particular to CAR T cancer treatments — the subject of the attached FOIA request and the relevant Federal Register notice in this instance — on issues pertaining to prices and patent and antitrust issues, including the question of whether CAR T should be considered a drug or a procedure, and the ramifications for both under U.S. and international patent laws. For example:

- 31 August 2017, James Love, “2017: Kymriah, the Novartis \$475,000 CAR T treatment, received 50 percent Orphan Drug tax credit on trials,” <https://www.keionline.org/23433>
- 18 October 2017, KEI Staff, “Penn ‘Certificates of Correction’ on Federal Funding for 5 CAR T Patents,” <https://www.keionline.org/23454>
- 5 January 2018, James Love, “2018: Briefing note on NIH proposed license to Gilead for CD-30 CAR T technology,” <https://www.keionline.org/24068>
- 24 January 2018, Thiru Balasubramaniam, “EB142: KEI statement on Preparation for the third High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases,” <https://www.keionline.org/23832>
- 14 February 2018, Andrew Goldman, “NIH Declines Request for the Budget for Clinical Trials Involving CAR T technology to be licensed to Kite/Gilead,”
<https://www.keionline.org/25808>
- 16 February 2018, James Love, “KEI asks FTC to block Celgene Acquisition of Juno Therapeutics, over BCMA-targeted CAR T treatment for Multiple Myeloma,”
<https://www.keionline.org/26089>
- 21 February 2018, James Love, “FTC approves Celgene acquisition of Juno without requiring divestitures,” <https://www.keionline.org/26456>

There is an Urgent Need to Inform the Public Concerning Actual Federal Government Activity As Noticed in 83 FR 30448, Regarding the Exclusive License of CAR T Patents to A Private Entity.

There is thus an urgent need to inform the public concerning the actual Federal Government Activity regarding the exclusive license of the CAR T patents at issue here, as noticed in 83 FR 30448. There is a very short fifteen day window for public comment on this proposed exclusive license, closing on July 13, 2018, and yet at present there is a wholly insufficient amount of information known about the details of the license and the underlying technology that would allow the public to make informed comment.

While the lifesaving promise of CAR T immunotherapy cancer treatment has been well documented, the high prices make the stakes high for consumers, patients, and payors. We note that two of the only CAR T technologies approved by the FDA have extremely high prices — Gilead's Yescarta, priced at nearly \$400,000 with a co-pay of \$79,0076; and Novartis's Kymriah, priced at \$475,000 per treatment.

In order to comment in a meaningful and non-perfunctory way, the public needs basic facts about the underlying technology to be licensed, the company to which it will be licensed to, and the relationships between the NIH and that company. This is why KEI has asked, in the attached FOIA, for (1) the enrollments and costs of specific clinical trials related to CAR T and mesothelin cancers; (2) documents related to the NIH analysis to determine whether a term of exclusivity less than the life of a patent would be appropriate and sufficient; and (3) and the NIH request for antitrust advice from the Attorney General, under 40 U.S.C. § 559.

The information regarding the clinical trials is important in order for the public to understand the extent to which the federal government and taxpayer funds have already subsidized the development of the patented technology. The request for the costs of clinical trials goes to the question of the magnitude of cost for conducting the trials required by the FDA to market services based upon the patented invention. Novartis has asserted that there are high costs for commercializing CAR T treatments, but we are skeptical, and note that the NIH has objective evidence regarding the costs of conducting relevant trials that would shed light on this issue for the public.

Understanding what the costs are for conducting trials is important for determining if any exclusivity is required, and if so, what the term of exclusivity should be, as is required by 35 U.S.C. § 209, and to what extent the NIH could insist on measures to protect the public from high prices, as required by 35 U.S.C. § 201(f).³

³ 35 U.S.C. § 201(f) defines practical application to include “that the invention is … available to the public on reasonable terms.” (Emphasis added.)

The NIH request for antitrust advice is important for the public to understand whether the NIH has abided by its black letter obligations under the law, under 40 U.S.C. § 559.

Under 5 U.S.C. § 552(a)(6)(E)(ii) and 45 CFR 5.27(c), the determination regarding the request for expedited processing is to be made within 10 calendar days of the request.

Pursuant to 5 U.S.C. § 552(a)(6)(E)(vi) and 45 CFR 5.27(a), I, James Packard Love, certify that the information described above as the basis for expedited processing of the attached FOIA request is true and correct to the best of my knowledge and belief.

A handwritten signature in blue ink that reads "James Packard Love".

James Packard Love
Director, Knowledge Ecology International