



October 20, 2016

Andrew Burke, Ph.D.,
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via email: andy.burke@nih.gov

Dear Dr. Burke:

I am writing on behalf of Knowledge Ecology International (KEI), a non-profit non-governmental organization based in Washington, DC, that advocates for access to knowledge and access to affordable medicines.

Specifically, I am writing with additional comments to the ones submitted earlier today by James Love of KEI, and also some follow-up questions related to the prospective grant of an exclusive license to Kite Pharma, Inc., a California-based biopharmaceutical company, on "Development of Anti-CD70 Chimeric Antigen Receptors for the Treatment of CD70 Expressing Cancers," 81 FR 69066.

I am also writing with comments and questions in regards to past grants of exclusive licenses to Kite from the National Cancer Institute (NCI) at the National Institutes of Health (NIH) and other technology transfer agreements.

I look forward to your response, but also request that you consider them more broadly as questions that NIH should routinely address when determining how it should conduct its technology transfer operations, address potential conflicts of interest, and ensure that public interest considerations are upheld in licensing and technology transfer deals.

Please also consider both the questions and comments as part of the record for the Anti-CD70 license, and please also make this entire document available in full under the FOIA should it fall within the scope of a request for records.

Comments and Context

The relationship between NIH and Kite raises concerns about the lack of consideration for ensuring the public benefits from taxpayer-funded inventions, and about the lack of oversight in how personal relationships between industry and NIH employees could lead to conflicts of interest.

In a recent exploration of Kite's relationship with the NIH, I found three CRADA agreements between Kite and the NCI, as well as six exclusive licensing agreements on at least 14 patent applications filed around the world.

(See here for additional information: <http://keionline.org/node/2640>. Please also incorporate this reference into the record.)

Under the CRADAs, NCI conducts clinical research on behalf of and with the financial support of Kite, with the understanding that Kite can then gain marketing approval for taxpayer-funded technologies. Some of the exclusive licensing agreements grant Kite control over technologies listed as "background inventions" in the CRADAs, which are technologies that would normally fall outside the scope of intellectual property that Kite would have special rights in through a CRADA.

Kite maintains an extremely close relationship with Dr. Steven Rosenberg at NCI, who oversees one of the CRADAs between NCI and Kite. Dr. Rosenberg mentored Kite CEO and co-founder Dr. Arie Belldegrun, and is also listed as a "special advisor" on Kite's website. As a named inventor on some of the patents the NIH has licensed to Kite in the past, Dr. Rosenberg appears to have a financial interest in potential future royalties on Kite products.

Questions

1. Has the NIH considered conducting its own clinical trials to fully develop CAR-T or other T-Cell Receptor therapies, outside of any Cooperative Research and Development Agreements (CRADAs), to bring any of its various patented inventions to market? If not, why? If so, what considerations led the NIH to decide to exclusively license its patents, rather than develop the inventions on its own or to grant non-exclusive licenses to manufacturers?
2. Have you searched for, requested, or conducted analysis to determine what the estimated sales price and revenues will be for the technology being licensed to Kite?
3. What analysis, if any, has NIH conducted to ensure that the grant of an exclusive license to Kite Pharma would comply with the requirements in 35 U.S.C. § 209(a)? Please note that we are not requesting NIH to disclose the commercialization plan submitted by Kite as part of the licensing process, but rather we request a description of the process and standards used to evaluate that the plan will ensure compliance with § 209(a). Specifically, we are interested in knowing how NIH determined, under § 209(a)(1), that the grant of an exclusive license is

necessary to either “(A) call forth the investment capital and expenditures needed to bring the invention to practical application; or (B) otherwise promote the invention’s utilization by the public.”

3.1. For what reasons, if any, did the NIH determine that the grant of a nonexclusive license would be insufficient to either induce investment or promote public utilization of the patented inventions?

4. Who are the principal investigators at Kite Pharma that have the necessary experience to bring the patented inventions to practical application? If you decline to provide this information, what policies, statutes, or regulations, if any, prevent the NIH from providing such basic information?

5. Please provide copies of all patent applications, granted patents, and other pertinent documents related to the patented inventions that would be subject to the prospective license. If you decline to provide this information, please explain why, and under what statutory or regulatory authority you are doing so.

6. Why does the NIH prefer Kite Pharma over its competitors in the grant of exclusive licenses on T-cell receptor therapies? For example, the current exclusive licensing agreement in question, on CD70 CAR-T technologies, was evidently not executed with Dedalus Pharma LLC (see 81 FR 23737), and is now being offered to Kite Pharma, with a broader field of use.

6a. Which pharmaceutical firms, if any, have filed objections, either in this case or past cases, to the grant of exclusive licenses to Kite Pharma? If any pharmaceutical firms have filed objections to the grant of exclusive licenses to Kite, what response, if any, has NIH provided?

7. Does NIH favor licensing “background inventions” listed in CRADAs to its CRADA partners over other companies? For example, at least two patent applications (PCT/US/2011/051537 and PCT/US2012/029861), which are listed in the 2012 CRADA between Kite and NIH as background inventions, were licensed to Kite in an Exclusive License Agreement dated April 11, 2013.

8. Without making specific allegations of wrongdoing, the relationship between Dr. Rosenberg and Dr. Beldegrun and Kite may give an appearance of a potential conflict of interest. Has the NIH undertaken any review of the potential conflict, and addressed any ethical concerns that could be raised as regards the decision to collaborate with or grant exclusive licenses to Kite, under the terms that have been offered?

9. Which policies does the NIH have regarding cases where employees serve in an official capacity with businesses that license inventions from the NIH or participate in NIH CRADAs?

Thank you for your time.

Sincerely Yours,

A handwritten signature in blue ink, appearing to read 'Zack Struver', with a long horizontal flourish extending to the right.

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cc: Karen Maurey, M.S., Director, National Cancer Institute Technology Transfer Center; Richard Rodriguez, MBA, Deputy Director, National Cancer Institute Technology Transfer Center