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March 4, 2016

Dear Nancy Weiss,

I am writing today to raise the ongoing issue of a lack of responsiveness on the part of the National Institutes of Health (NIH) to Knowledge Ecology International (KEI) regarding requests for information relevant to the licensing of NIH owned patents.

Over the course of the last year, KEI has made multiple requests for information to the NIH and been confronted with a sustained unwillingness to provide basic information to KEI, in our role providing public comments on proposals for grant exclusive rights in specific patents the NIH owns. I will illustrate two recent cases to illustrate the problem.

***HCV patents, licensed to Virotas Biopharmaceuticals***

In March 2015, KEI sought to respond to a public comments notice issued by NIH in the Federal Register regarding the prospective grant of an exclusive license for small molecule therapeutics against hepatitis C virus infection, based upon this Federal Register notice.

Title: Prospective Grant of Exclusive License: Small Molecule Therapeutics Against Hepatitis C Virus Infection  
Friday, March 27, 2015, Comments Close: 04/13/2015  
Agencies: Department of Health and Human Services, National Institutes of Health  
Document Citation: 80 FR 16389  
Page: 16389 -16390 (2 pages)

Document Number: 2015-06974

Shorter URL: <https://federalregister.gov/a/2015-06974>

The NIH was considering granting a commercial patent license agreement to “Virotas Biopharmaceuticals, LLC, a company having a place of business in California.” KEI tried to find more information about Virotas Biopharmaceuticals, and found that the company had no website, and the only web presence from a Good search was the name of the registered agent in Delaware.

The patents in question appeared to be for an entire new class of treatments for the hepatitis C virus (HCV). The patents were offered for license at the same time the pricing of sofosbuvir, a drug to treat HCV, was the major drug pricing controversy in the United States, and at a time when HCV drug costs are breaking the budgets of Medicare and the public.

All the NIH was willing to reveal about the company was its name.

KEI attempted to contact the NIH on this issue and initially received no response. KEI then found a publication related to the small molecule in question and directly contacted the authors for more information. Shortly after contacting the authors, KEI was contacted by the NIH/NIDDK Media Relations and Public Liaison team and told that the public liaison would provide answers to some of KEI’s questions. When asked if they could provide any information about the pharmaceutical company that is seeking the exclusive license in the federal register notice, such as names, addresses or titles in the company (board of directors or shareholders), the public liaison replied, “Virotas Biopharmaceuticals, LLC is a privately held start-up company with founders experienced in drug development and commercialization.” The NIH would not even inform us of the address of the company to which they were considering licensing a molecule developed with taxpayer funding.

Furthermore, when KEI asked to find out more information about the licensing deal to be made with Virotas Biopharmaceuticals, the NIH informed us that in order to learn more about the deal, we would be required to sign a nondisclosure agreement, barring us from speaking about this issue with any sort of effectiveness.

***Patents on Production of Attenuated Respiratory Syncytial Virus Vaccines,  
licensed to Sanofi***

Right now KEI is seeking to respond to a request for written comments in the Federal Register concerning the prospective grant of an exclusive license for the production of attenuated respiratory syncytial virus vaccines.

Title: Prospective Grant of Exclusive License: Production of Attenuated Respiratory Syncytial Virus Vaccines

February 22, 2016, Comments Close: 03/08/2016

Agencies: Department of Health and Human Services, National Institutes of Health  
Document Citation: 81 FR 8728  
Page: 8728 -8729 (2 pages)  
Document Number: 2016-03486  
Shorter URL: <https://federalregister.gov/a/2016-03486>

On the day that the Federal Register notice was published, February 22, 2016, KEI sent an email with a five questions regarding the vaccines to the licensing specialist listed on the Register notice as the contact for inquiries. The licensing specialist replied almost two weeks later, March 3, 2016, only three business days before the deadline, and offered to schedule a phone call for Friday, March 4, 2016 at 3PM (the next day) to answer the questions. After we confirmed the call, the licensing specialist wrote back and informed us he was advised that “the matter is now out of my jurisdiction,” all inquiries will now have to go through the NIH/NIAID Office of Communications and Government Relations (OCGR), and our previously scheduled call was now canceled.

The NIH has spent decades developing the technology covered by the patents for the Attenuated Respiratory Syncytial Virus Vaccines. The vaccine will be used primarily by children under 2 years old. According to the NIH notice in the *Federal Register*:

“Respiratory syncytial virus (RSV) is the most important cause of viral acute lower respiratory infection (ALRI) in infants and children worldwide and is responsible for over 30 million new ALRI episodes worldwide and up to 199,000 deaths in children under five (5) years old. In the United States, the virus infects nearly all children at least once by the age of two (2) and is the most common cause of bronchiolitis and infant pneumonia, causing up to 125,000 hospitalizations of children each year. RSV disease burden is less understood in the developing world, but available data indicates that the virus causes a significant proportion of childhood ALRI in these parts of the world, particularly in the first months of life.”

KEI is now faced with commenting on the decision to give the French-owned company Sanofi a monopoly on this vaccine, without any cooperation from the NIH that would help the public understand if a better option would be for the NIH to develop the vaccine itself, or if there is sufficient leverage to introduce clauses in the licenses that protect the public on issues of pricing and affordability of the vaccine.

The repeated actions and behaviors of the taxpayer-funded NIH have been appalling. The NIH is asking for public comment on these exclusive licenses, which they required to do by law, but the public any practical means to provide informed commentary or feedback. This is unacceptable, and reflects a surprising degree of arrogance by the NIH toward taxpayers.

We ask the Administration to review the NIH policies as regards the transparency of its licensing decisions, and to develop guidelines to ensure that in the future the public will have broader rights to knowledge about the patents it owns and the licensing of those patents.

If needed, I am happy to provide documentation of our correspondences with the NIH on these issues. Thank you in advance for your attention to this troubling pattern of behavior on the part of the NIH.

Sincerely,  
Claire Cassedy