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December 9, 2016

Barry Datlof
via email: barry.m.datlof.civ@mail.mil

Dear Barry:

Thank you for taking the time to speak with me earlier today. Per our conversation, I am providing you with a written request on behalf of Knowledge Ecology International (KEI) for information related to the Federal Register notice of the U.S. Army's intent to grant an exclusive license on patents related to a vaccine for Zika virus to Sanofi Pasteur. Intent to Grant an Exclusive License of U.S. Government-Owned Patents, 81 Fed. Reg 89,087 (Dec. 9, 2016).

Before KEI submits written comments on the license, KEI would like to review the following documents and information:

- The intellectual property that the Army intends to license to Sanofi Pasteur, including (1) United States Provisional Patent Application 62/343,315, entitled, "Zika Virus Vaccine and Methods of Production" filed May 31, 2016, and (2) United States Provisional Patent Application 62/370,260, entitled, "Zika Vaccine and Methods of Preparation" filed August 3, 2016.
- The amount that the government spent on research and development that contributed to the patent applications for the inventions, including through direct funding of clinical trials and subsidies, such as grants and tax credits to private pharmaceutical companies or non-profit research institutions. Please describe the research that was undertaken by the Army relevant to the development of the vaccine, such as animal or human tests. Please identify any clinical trials using the patented inventions, including the trial name, ClinicalTrials.gov identification number, the number of patients enrolled, and the trial phase.
- A copy of the proposed licensing agreement.

If the Army declines to provide a copy of the full agreement, describe or provide any provisions related to:

- pricing of the vaccine in the United States;
- affordable access in developing countries;
- the field of use;
- the term of the license; and
- the royalty rates.

If the Army declines to provide copies of the patent application, please provide the names of the inventors listed on the applications and the claims in the patents.

As I noted in our conversation, when commenting on exclusive licenses, we prefer to have as much information about the inventions and the license as possible. We would therefore appreciate if you could provide the above information and answers to our questions within the next week, to enable us to review the documents prior to drafting and submitting our comments.

If the Army decides to treat this as a request under the Freedom of Information Act — as you indicated might be possible during our conversation — we would be happy to provide additional information in support of a fee waiver.

I am happy to speak with you on the phone again to clarify any of the above.

Sincerely Yours,



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