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21 December 2016

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

Re: Intent To Grant an Exclusive License of U.S. Government-Owned Patents for patents on Zika Virus Vaccine and Methods of Production to Sanofi Pasteur, Inc.

Dear Sir or Madam,

KEI registers the following objections and comments on the public notice regarding the:

> "intent to grant an exclusive, royalty-bearing, revocable license to pending United States Provisional Patent Application 62/343,315, entitled, "Zika Virus Vaccine and Methods of Production" filed May 31, 2016 and an exclusive, royalty-bearing, revocable license to pending United States Provisional Patent Application 62/370,260, entitled, "Zika Vaccine and Methods of Preparation" filed August 3, 2016 to Sanofi Pasteur, Inc.,"
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> Document Citation: 81 FR 89087, Page: 89087-89088 (2 pages)
> Document Number: 2016-29514
>
> For licensing issues, Mr. Barry Datlof, Office of Research & Technology Assessment, (301) 619-0033. For patent issues, Ms. Elizabeth Arwine, Patent Attorney, (301) 619-7808, both at telefax (301) 619-5034.

The day the public notice appeared in the Federal Register, we contacted Barry Datlof, asking the following questions about the proposed license:

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 subsides, 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.

The Army has refused to release any of this information. This forces us to guess about every salient detail about the license that is relevant to whether or not the Army has addressed the statutory requirements of 35 U.S.C. § 209 and § 201(f).

KEI objects to the lack of transparency for this proposed license, and request that the deadline for public comment be extended for an additional 30 days, during which time we ask the Department of the Army to make available to the public the information requested, as well as the analysis used to address the statutory objections of 35 U.S.C. § 209.

In particular, we request the Army to explain why

> "granting the license is a reasonable and necessary incentive to call forth the investment capital and expenditures needed to bring the invention to practical application"

and importantly, why

> "the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application."

KEI also requests the Army to share its analysis that the license will ensure that the "benefits" of the invention will be "available to the public on reasonable terms," a requirement of 35 U.S.C. § 201(f).

In the meantime, and in case the Army does not grant our request for the public to have additional time and information to evaluate the proposed license, we offer the following objections, suggestions for the terms and additional comments.

1. To ensure that prices for products are "reasonable" -- the standard in 35 U.S.C. § 201(f) -- and do not discriminate against U.S. residents, licenses should limit the price of the product to no more than the median price of other high income countries. For example, by using language such as: The [agency] will normally expect the licensee to make products available to the public in the United States at prices no higher than the median price charged in the seven countries with the largest GDP, that have per capita incomes of at least half that of the United States.

2. Limit the length of exclusivity, as the life of patent exclusivity is an excessive and costly incentive. Because significant development costs are already paid for by the government, the license should include a provision that the exclusive rights will extend to five years from the first sale of a product receiving approval by the U.S. FDA, or until the license holder recovers at least $300 million (or a different number) in cumulative global sales from the product, whichever is shorter, and thereafter, the license will become non-exclusive. After the first five years of exclusivity, the NIH can extend the exclusivity by another 3 years, upon a showing that such extension is reasonable in light of the risk adjusted R&D costs to bring the product market, and the net revenues from sales.

3. In order to develop more useful evidence to evaluate licensing policies, the licenses can and should require transparency of the costs of research and development. This should

include an annual report for R&D outlays, with the company reporting the following information for each clinical trial that it conducts on the patented invention:

a. ClinicalTrials.Gov identifier;
b. Phase;
c. Conditions;
d. Interventions;
e. Title Acronym/Titles;
f. Outcome Measures;
g. Sponsor/Collaborators;
h. Other Study IDs;
i. Expenditures (for that year);

The patent holder should also be required to report:

j. the sales prices, units of sales, and revenues, by country;
k. government subsidies related to the research, reported by year, including:
    i. grants and research contracts from government agencies, with data on the funding agency, the identifier of the grant or contract, and the amount of the grant or contract;
    ii. tax credits associated with R&D for the product, including the orphan drug tax credit, broken out by the type of credit and the expenditure the credit was associated with (such as a specific trial); and
    iii. other government R&D subsidies;

4. The licenses should require that products are available and affordable in developing countries, especially those with per capita incomes of less than one third of the U.S. per capita income, and/or where the health threats are particularly acute.

In addition to the measures above, and in the absence of any useful information from the Army on the invention, we ask that the reasonableness of U.S. prices for the vaccine (required by statute to be "available to the public reasonable terms") be determined by an independent evaluation by the Office of Budget and Management (OMB), following a public hearing, and after receiving inputs from all stakeholders, including entities expected to reimburse or otherwise bear the vaccine cost, and informed by useful disclosures of the public investment in the vaccine, the expected costs to the vaccine manufacturer, and the anticipated market demand.

Sincerely,

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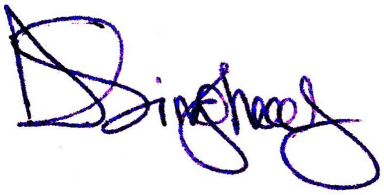

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35 U.S.C.
United States Code, 2011 Edition
Title 35 - PATENTS

§201. Definitions

As used in this chapter—

(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.

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35 U.S.C.
United States Code, 2011 Edition
Title 35 - PATENTS
PART II - PATENTABILITY OF INVENTIONS AND GRANT OF PATENTS
CHAPTER 18 - PATENT RIGHTS IN INVENTIONS MADE WITH FEDERAL ASSISTANCE
Sec. 209 - Licensing federally owned inventions

§209. Licensing federally owned inventions

(a) Authority.—A Federal agency may grant an exclusive or partially exclusive license on a federally owned invention under section 207(a)(2) only if—

(1) granting the license is a reasonable and necessary incentive to—

(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;

(2) the Federal agency finds that the public will be served by the granting of the license, as indicated by the applicant's intentions, plans, and ability to bring the invention to practical application or otherwise promote the invention's utilization by the public, and that the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application, as proposed by the applicant, or otherwise to promote the invention's utilization by the public;

(3) the applicant makes a commitment to achieve practical application of the invention within a reasonable time, which time may be extended by the agency upon the applicant's request and the applicant's demonstration that the refusal of such extension would be unreasonable;

(4) granting the license will not tend to substantially lessen competition or create or maintain a violation of the Federal antitrust laws; and

(5) in the case of an invention covered by a foreign patent application or patent, the interests of the Federal Government or United States industry in foreign commerce will be enhanced.

Selected articles and other information:

Donald McNeil, Jr. and Pam Belluck, Extensive Brain Defects Seen in Babies of Mothers With Zika, New York Times, December 13, 2016.

From the CDC Zika page: