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The Kite CAR CD19 and CD 20 license

James Love <james.love@keionline.org> Tue, Jul 16, 2019 at 12:20 PM
To: "Lambertson, David (NIH/NCI) [E]" <david.lambertson@nih.gov>
Cc: Claire Cassedy <claire.cassedy@keionline.org>, Kathryn Ardizzone <kathryn.ardizzone@keionline.org>, Luis Gil Abinader <luis.gil.abinader@keionline.org>, Manon Ress <MANON.RESS@cancerunion.org>

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Dear Dr. Lambertson,

In failing to address Claire Cassedy's questions 1-5, from her July 12 email, you state: "The other questions either have been answered previously or are not related to the criteria set forth in 37 CFR 404.7(a)(1)(ii-iii) regarding a decision by a federal agency to grant an exclusive license."

Her 1-4 questions were:

1. At what stage of development are the inventions listed?
2. Has the government funded any clinical trials relevant to these technologies?
3. If the government has provided funding, how much has been spent by the government on these trials? Can you provide NCT numbers?
4. Is the term in the proposed licenses to be life of patent or less than life of patent?

Her question 5 was:

5. In working towards executing this license, has the NIH sought advice from the Attorney General (as is required under 40 USC § 559) to determine if the “disposal to a private interest would tend to create or maintain a situation inconsistent with antitrust law”?

37 CFR 404.7(a)(1)(ii) states:

> (ii) After expiration of the period in §404.7(a)(1)(i) and consideration of any written objections received during the period, the Federal agency has determined that;
> (A) The interests of the Federal Government and the public will best be served by the proposed license, in view of the applicant’s intentions, plans, and ability to bring the invention to practical application or otherwise promote the invention’s utilization by the public;
> (B) The desired practical application has not been achieved, or is not likely expeditiously to be achieved, under any nonexclusive license which has been granted, or which may be granted, on the invention;
> (C) Exclusive or partially exclusive licensing is a reasonable and necessary incentive to call forth the investment of risk capital and expenditures to bring the invention to practical application or otherwise promote the invention’s utilization by the public; and
> (D) The proposed terms and scope of exclusivity are not greater than reasonably necessary to provide the incentive for bringing the invention to practical application or otherwise promote the invention’s utilization by the public;

(C) and (D) of (ii) go to issues that are directly related to questions 1-4. Obviously, if a company is licensing technologies in very early stages of development where no trials have been funded or subsidized, they will need more robust incentives than when a technology is already further along, and the government is funding trials. Failing to respond to Claire's questions is withholding information that we need to comment on the proposed license.

As regards Claire's question 5, regarding advice from the Attorney General, this is directly relating to due diligence for 37 CFR 404.7(a)(1)(iii), which states:

> (iii) The Federal agency has not determined that the grant of such license will tend substantially to lessen competition or result in undue concentration in any section of the country in any line of commerce to which the technology to be licensed relates, or to create or maintain other situations inconsistent with the antitrust laws; and

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