July 9, 2018

Dear Rose M. Freel, Ph.D.,
Licensing and Patenting Manager,
NCI Technology Transfer Center,
8490 Progress Drive, Suite 400, Frederick, MD 21701;
rose.freel@nih.gov.

RE: Prospective Grant of an Exclusive Patent License: Development of an Anti-Mesothelin Chimeric Antigen Receptor (CAR) for the Treatment of Human Cancer (83 FR 30448)

Dear Dr. Freel,

On June 29, 2018, KEI submitted a FOIA request for information regarding the enrollment and costs of NIH-funded clinical trials involving mesothelin expressing cancers, and trials involving chimeric antigen receptor modified T-cells (CAR T), as well as other documents that would be relevant to the patents proposed to be licensed under 83 FR 30448.[1] These other requested documents specifically included the analysis done under 35 U.S.C. § 209, and the request for antitrust advice from the Attorney General under 40 U.S.C. § 559.

KEI requested expedited processing of this FOIA request on the grounds that there is a compelling need to obtain and disseminate the information in advance of the deadline for public comments on 83 FR 30448, because the information is critical in order for the public to make informed comment.[2] The request for expedited processing was warranted under 5 U.S.C. § 552(a)(6)(E)(i) and 5 U.S.C. § 552(a)(6)(E)(v)(II) and 45 CFR 5.27, as explained in further detail in the request itself.

Today KEI received a rejection of its request for expedited processing of the request.[3]

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1 https://www.keionline.org/wp-content/uploads/2018/06/KEI-NIH-FOIA-Prospective-License-Notice-83-FR-30448.pdf

2 https://www.keionline.org/wp-content/uploads/2018/06/Expedited-Processing-Request-KEI-NIH-FOIA-Prospective-License-Notice-83-FR-30448.pdf

3 https://www.keionline.org/wp-content/uploads/2018/06/NIH-Rejection-Expedited-Processing-9July2018.pdf

As you know, on June 28, 2011, KEI Director James Love emailed Dr. Rose Freel to ask if the technology at issue in 83 FR 30448 had been subject to any clinical trials (1) funded by the NIH, or (2) funded by any other party, noting that this information would be useful for the formulation of comments. Dr. Freel first responded on July 2, 2018, to say that she was unaware of any such trials, but then followed up on Friday July 6, 2018 to say that in fact there are two trials in recruitment phase at Memorial Sloan Kettering.

KEI believes it is important to have information about the costs of the trials, in order to evaluate the need for an exclusive license, and also to determine the scope of rights, including the term of the patent license, that are required to commercialize the patented inventions.

Since receiving the NIH rejection of expedited treatment of a FOIA for information on the costs of NIH funded trials, KEI has reached out to the contract persons for several trails listed in the ClinicalTrials.Gov database that indicated NIH funding, asking for enrollment and budget numbers for the trials.

The high price that Novartis set for tisagenlecleucel (TN Kymriah) was justified to the public on the completely unverifiable claim that Novartis spent $1 billion on the development of the procedure. KEI believes the R&D costs are important, but also important enough to be verified. In this case, the fact that the NIH is sponsoring many CAR T trials means the NIH itself is in possession of information that can be used to understand the actual R&D costs required to commercialize the licensed CAR T invention. We would like the comment period extended long enough for the NIH to provide KEI and others with the information about the budgets for its CAR T trials.

Understanding the extent to which federal funds have subsidized the development of a patented inventions, and knowing how expensive it is to make the additional investments needed for FDA approval, is critical to the determination of the scope of exclusivity that would be warranted under 35 U.S.C. § 209, as well as the leverage that the federal government has to demand access and affordability in any license to be executed.

As such, KEI requests that the deadline for comments on 83 FR 30448 be extended until the information requested has been made publicly available.

Sincerely,

Luis Gil Abinader
Knowledge Ecology International (KEI)
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