

Knowledge Ecology International
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Re: Prospective Grant of Exclusive Patent License: Chimeric Antigen Receptors Targeting CD56 ([86 FR 16602](#))

Dear Dr. Freel:

Knowledge Ecology International (KEI) would like to offer the following comments regarding the “Prospective Grant of Exclusive Patent License: Chimeric Antigen Receptors Targeting CD56,” to Memorial Sloan Kettering Cancer Center (MSKCC), based in New York City.

The exclusive license is to be sublicensable, with the explicit intent of consolidating the patent rights with MSKCC towards further development and commercialization of the invention. The Federal Register notice states that any sublicense by MSKCC will be subject to the provisions of 37 CFR part 401 and 404.

The geographic scope of the license is worldwide, and the field of use is commensurate with the scope of the patent rights to be licensed. The inventions relate to,

“novel antibody binders and chimeric antigen receptors (CARs) that target CD56 or NCAM, a glycoprotein that is highly expressed in a variety of cancerous cells. Based on current available data, the intended use for the invention is anti-CD56 CARs for the treatment of CD56 positive cancers such as multiple myeloma.”

KEI submitted eight questions to Dr. Freel regarding the technology and the proposed license, and she provided replies to each question in a timely manner. While we had further questions based on her responses, we appreciated her attention and individual responses to our questions.

In response to our question regarding the term of the exclusive license (whether life of patent or less), Dr. Freel stated that “[t]he terms of the license have not yet been negotiated.” While KEI can appreciate that the license terms are not yet fully negotiated, knowing some of the relevant terms of the proposed exclusive license is essential for the public to exercise its rights to

comment or even appeal later. In the Federal Register notices concerning the licenses, the NIH already uses its discretion to reveal such information as the field of use or the geographic area. What is the basis for not addressing the term of the license?

Since the explicit purpose of this exclusive license is the further sublicensing and commercialization of the inventions, it is critical that the NIH incorporate terms that safeguard the public's interest in these inventions.

Below KEI has outlined terms that should be included to ensure transparency, protect against price discrimination, and ensure availability of any treatment in low- and middle-income countries (at affordable prices). KEI urges the NIH to include the following provisions in the terms of this license, and any sublicense entered into by MSKCC.

Prohibition against prices that discriminate against US residents

Any license should ensure that U.S. residents are not asked to pay prices that exceed the median price from the seven economies of the largest GDP and at least 50 percent of U.S. per capita income. The per capita income can be based upon the World Bank's Atlas method.

Transparency

Transparency of R&D outlays. The licensees should be required to file an annual report to the NIH, available to the public, on the research and development (R&D) costs associated with the development of any product or service that uses the inventions, including reporting separately and individually the outlays on each clinical trial. We note that this is not a request to see a company business plan or license application. We are asking that going forward MSKCC be required to report on actual R&D outlays to develop the subject inventions. Reporting on actual R&D outlays is important for determining if the NIH is meeting the requirements of 35 U.S.C. § 209, that "the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application[.]" Specifically, having data on actual R&D outlays on each clinical trial used to obtain FDA approval provides evidence that is highly relevant to estimating the risk adjusted costs of bringing NIH licensed inventions to practical application.

Acknowledgement of federal funding - publication and publicity. The licensee should be required to include, when issuing statements, press releases, and other documents describing the development of any product that includes the licensed inventions, a statement that describes the role of the licensed inventions and the total and proportionate contribution of federal funding to the research and development performed to bring the inventions to market.

Additional transparency issues. The license should have provisions that give effect to the transparency norms set out in WHA72.8 "Improving the transparency of markets for medicines, vaccines, and other health products", a resolution enthusiastically supported by HHS in 2019.

Additional Provisions to Protect the Public Interest

Global registration and affordability. The licenses should require the licensee to disclose the steps that each will take to enable the timely registration and availability of the medical technology at an affordable price in the United States and in every country with a demonstrated need, according to the Centers for Disease Control and Prevention (CDC) and/or the World Health Organization (WHO), either by supplying a country directly at an affordable, publicly disclosed price and with sufficient quantities, or by providing technology transfer and rights to all intellectual property necessary for third parties to do so.

Medicines Patent Pool. The NIH should retain a right to grant the WHO, the Medicines Patent Pool or other governments the rights to use the patent rights to procure the medical technology from competitive suppliers, including technology transfer, in LMICs, upon a finding by HHS or the WHO that people in these markets do not have sufficient access to the medical technology.

Conclusion

It is critical that the NIH ensure that the terms of this license promote the public interest in the invention and protect patients' equitable access to the technology, should it come to market. In the event that the NIH grants the license, KEI asks that it incorporates the provisions listed above in order to achieve those goals.

Please notify us if and when a license is granted, so we can request a copy under the Freedom of Information Act.

Sincerely,

Claire Cassedy

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Knowledge Ecology International