

8 June 2017

James Love
Knowledge Ecology International
1621 Connecticut Ave. NW, Suite 500
Washington, DC 20009

IN RE: 82 FR 23013, Prospective Grant of an Exclusive License: The Development of Monospecific and Bispecific Antibodies to GPC3 for the Treatment of Human Liver Cancers (NCI License Application A-301-2017)

Dear Mr. Love:

Thank you for providing us with your comments regarding the notice of the proposed license to AbPro by the National Cancer Institute (NCI). Prior to posting a notice for a proposed grant of an exclusive license, the NCI determines that the criteria set forth in 37 CFR 404.7(a)(1)(ii-iii) have been satisfied and that the company is qualified both technically and financially to be granted an exclusive license to the Government's intellectual property in the fields of use as specified. The notice period provides an opportunity for public comment and possible objection to the proposed license. We consider all comments prior to negotiating the proposed license.

While your comments have been given full consideration, they do not persuade us that the grant of an exclusive license to AbPro for NCI technology E-136-2012/0 would inconsistent with the regulations and, furthermore, advance public health. The reasons for this determination are set forth below:

- 1) With respect to your recommendations regarding pricing of products made by the licensee, NIH has not included pricing provisions in its licenses for many years, for reasons that have been extensively discussed in the literature, which is readily and publicly available.
- 2) With respect to the suggestion in your letter, NCI does not have the authority to require a licensee to publicly disclose financial or business confidential information, and this would be inconsistent with the licensing regulations. We respectfully refer you to 37 C.F.R. 404.14.

In conclusion, NCI has determined that your objection did not raise an issue that would preclude the grant of the proposed exclusive license, and the NCI intends to proceed with the negotiation of the proposed exclusive license. If I can be of any further assistance, please let me know.

Sincerely,
David A. Lambertson, Ph.D.
Senior Technology Transfer Manager
National Cancer Institute, TTC
david.lambertson@nih.gov