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Via Email: david.lambertson@nih.gov

Re: Prospective Grant of an Exclusive Patent License: The Development of Bispecific Antibodies Targeting Glypican 1 (GPC1) for the Treatment of GPC1-Expressing Human Cancer

Dear Dr. Lambertson:

Knowledge Ecology International (KEI) and Union for Affordable Cancer Treatment (UACT) are writing to comment on the "Prospective Grant of an Exclusive Patent License: The Development of Bispecific Antibodies Targeting Glypican 1 (GPC1) for the Treatment of GPC1-Expressing Human Cancer" to NeoImmune Tech, Inc. ("NeoImmune").[1]

During the comment period, KEI asked the National Institutes of Health (NIH) several questions about the license. The NIH has not answered any of the questions submitted by KEI, thereby limiting our ability to comment on the license, a right that is provided in 35 U.S.C. § 209(e).

Because the license disposes of government-owned property, the NIH may not grant the license unless it first requests the antitrust advice of the U.S. Attorney General. 40 U.S.C. § 559.

If the NIH grants the license, we request that it incorporates a series of provisions designed to safeguard the public interest in the invention and promote the policy objectives of the Public Health Service (PHS) Technology Transfer Manual.

[1] 85 Fed. Reg. 18579, available at https://www.federalregister.gov/documents/2020/04/02/2020-06917/prospective-grant-of-an-exclusive-patent-license-the-development-of-bispecific-antibodies-targeting.

Background

The proposed license involves one invention, E-028-2019, "High Affinity Monoclonal Antibodies Targeting Glypican-1" (U.S. Patent Application No. 62/795,415).[2]

According to the Federal Register notice, the field of use for the license "[m]ay be limited to: The research, development and commercialization of a bispecific antibody or the treatment of GPC1-expressing human cancers."

The license opportunity notice for the invention states that it has "[p]otential therapeutic benefit for several cancer types with few treatment options – including uterine cervical cancer and pancreatic adenocarcinoma[.]"[3]

The prospective licensee, NeoImmune, is a biotech company based in Rockville, Maryland, with a location in Korea. NeoImmune's lead product is Hyleukin-7, a "T cell amplifier designed to reconstitute and enhance antitumoral T cell immunity."[4]

Discussion

1. The NIH was not transparent about the license, limiting the public's right to comment under 35 U.S.C. § 209(e).

A federal agency may not grant an exclusive license in government-owned technology without first notifying the public of the prospective license, allowing a minimum 15-day period for the public to comment, and considering all timely-submitted comments. 35 U.S.C. § 209(e).

For the public to meaningfully comment on a proposed license, it must have basic information about it. Our ability to comment on the license has been limited by the NIH's refusal to answer all of the questions that KEI submitted to the NIH.

On April 13, 2020, KEI emailed Dr. David Lambertson, the point of contact for the license, a list of nine questions about it. He did not respond prior to the close of the comment period.

With respect to past proposed patent licenses, the NIH has asserted two major reasons for declining to provide the information requested by KEI: that the information sought was irrelevant, or that it was confidential.

The questions KEI asked and Dr. Lambertson did not answer are not irrelevant. They relate to how the NIH had applied the criteria at 35 U.S.C. § 209 governing a federal agency's authority

[2] *Id.*
[3] https://www.ott.nih.gov/technology/e-028-2019.
[4] http://neoimmunetech.com/company/overview.html.

to grant an exclusive license. There can be no issue more relevant to a licensing decision than how the NCI determined that an exclusive license was a necessary incentive (35 U.S.C. § 209(a)(1)) and how it concluded that the scope of the license is not broader than necessary (35 U.S.C. § 209(a)(2)).

Likewise, the information Dr. Lambertson failed to provide was not confidential business information.

Federal law and regulations regarding government patent licenses do not make all aspects of license applications confidential. Rather, they establish the confidentiality only of a license applicant's commercialization plans and periodic utilization reports—items that KEI did not request.

The Bayh-Dole Act gives the public a role in licensing decisions concerning inventions that are funded and owned by the public. Because the questions KEI asked and Dr. Lambertson failed to answer were relevant and non-confidential, Dr. Lambertson had no basis for not answering them and the NIH's lack of transparency undermined our ability to comment on the license.

2. In the event that the NIH decides to grant the license, we recommend that the NIH includes a series of provisions designed to safeguard the public interest and ensure that the license implements the governing principles listed in the Public Health Service (PHS) technology transfer manual.

In the event that the NIH proceeds with the license, KEI requests that it includes the following provisions to protect the public's interest in the NIH-funded technology:

1. **Exclusivity.** If the NIH decides to grant exclusive rights to the subject invention, it should limit exclusivity to the European Union, Japan and other high-income countries, but not the United States, so that countries that did not fund the R&D underlying the invention would bear the costs of the exclusivity, while the U.S. residents would not. The NIH should also limit exclusivity in moderate and lower income countries, where the monopoly is likely to have an adverse impact on access with almost no benefit in terms of the incentives for the company.

1. **Price discrimination.** Any medical technology using the patented invention should be available in the United States at a price that does not exceed the median price in the seven largest economies by GDP that have at least 50 percent of the GNI per capita as the United States, using the World Bank Atlas method. This is a modest safeguard.

2. **Low and middle income countries.** The exclusive license should not extend to countries with a per capita income less than 30 percent of the United States, in order to ensure that the patents do not lead to restricted and unequal access in developing

countries. If the NIH rejects this suggestion, it needs to provide something that will give effect to the policy objective in the "United States Public Health Service Technology Transfer Policy Manual, Chapter No. 300, PHS Licensing Policy," which states the following: "PHS seeks to promote commercial development of inventions in a way that provides broad accessibility for developing countries."

3. **Global registration and affordability.** The license should require NeoImmune to disclose the steps it 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.

4. **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 developing countries, upon a finding by HHS or the WHO that people in these markets do not have sufficient access to the medical technology.

5. **Years of exclusivity.** We propose the license reduce the years of exclusivity when revenues are large. The NIH has many options, including by providing an option for non-exclusive licensing, such as was done in the ddI case. We propose that the exclusivity of the license be reduced when the global cumulative sales from products or services using the invention exceed certain benchmarks. For example, the period of exclusivity in the license could be reduced by one year for every $500 million in global cumulative revenue after the first one billion in global sales. This request is consistent with the statutory requirements of 35 U.S.C. § 209, which requires that "the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application."

6. **Transparency of R&D outlays.** NeoImmune should be required to file an annual report to the NIH, available to the public, on the R&D costs associated with the development of any product or service that uses the invention, including reporting separately and individually the outlays on each clinical trial. We will note that this is not a request to see a company business plan or license application. We are asking that going forward the company 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.

Conclusion

The NIH's failure to answer KEI's questions about this license has undermined our right, as members of the public, to comment on it. Because the license disposes of government-owned property, the NIH may not grant the license unless it first requests the antitrust advice of the U.S. Attorney General. 40 U.S.C. § 559. In the event that the NIH grants the license, we ask that it incorporates the provisions listed above, which are designed to protect the public interest in the licensed technologies and to accomplish the policies outlined in the PHS Technology Transfer Manual.

Sincerely,

Knowledge Ecology International
Union for Affordable Cancer Treatment