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Via email: tongb@mail.nih.gov

June 8, 2021

Re: Prospective Grant of an Exclusive Patent License: P2Y14 Receptor Antagonists To Treat Kidney and Lung Inflammation (86 FR 27858)

Dear Dr. Tong:

Knowledge Ecology International (KEI) would like to offer the following comments regarding the "Prospective Grant of an Exclusive Patent License: P2Y14 Receptor Antagonists To Treat Kidney and Lung Inflammation" to Kantum Pharma Inc. (Kantum), located in Boston, Massachusetts.

The geographic scope of the license is worldwide, and the field of use conveys the rights to: "Commercial development of P2Y14 receptor antagonists for the prevention and treatment of conditions or diseases associated with inflammation in the kidney and lung in humans."

On May 27, 2021, Kantum announced new research on beneficial effects of P2Y14 antagonist in acute kidney injury via an article published by Kantum scientific founder Dr. Sylvie Breton in the Journal of Clinical Investigation. Does Kantum have a Cooperative Research and Development Agreement (CRADA) with the National Institutes of Health (NIH) for this technology?

The May 27, 2021 article acknowledges funding from several sources including the Netherlands Organisation for Scientific Research, the Netherlands Organisation for Health Research and Development, the Foundation Fighting Blindness, the Swiss National Foundation, other charitable and/or government funding sources, and at least three NIH grants: U54HD083091, F32 HD095599, and U54HG006493.

These are important aspects to consider as the NIH negotiates this license and considers the breadth of the terms of the license. An exclusive license by the NIH to a private company should

only provide the incentives needed to bring a technology to market. If the NIH has provided financial support or has otherwise de-risked aspects of the research and development of this technology, the license terms should reflect this with reduced scope of duration, geographic applicability, or other terms.

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.

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 Kantum 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