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Via email: [andy.burke@nih.gov](mailto:andy.burke@nih.gov)

June 8, 2021

**Re: Prospective Grant of an Exclusive Patent License: Methods and Compositions for Adoptive Cell Therapy ([86 FR 27852](#))**

Dear Dr. Burke:

Knowledge Ecology International (KEI) would like to offer the following comments regarding the “Prospective Grant of an Exclusive Patent License: Methods and Compositions for Adoptive Cell Therapy,” to Lyell Immunopharma, Inc. (Lyell), a firm based in San Francisco, CA.

KEI has commented on previous proposed licenses to Lyell, including in [September 2019](#) and again in [April 2020](#).

In the case of the September 2019 license, the NIH was supporting two clinical trials on the technologies (which are still ongoing). One of the trials was taking place on the NIH campus at the National Cancer Institute, while the other was being conducted at Stanford University and was supported by an NIH grant. Both trials were Phase 1 trials, so the NIH supporting and conducting these trials represented a significant de-risking of the technologies’ development.

The geographic scope of the license at hand is worldwide, and the field of use conveys the rights to the “[m]anufacture and commercialization of adoptive T cell therapy products generated from autologously-derived, induced pluripotent stem cells for the treatment of cancer in humans.”

The field of use for this license is the same broad scope as previous technologies exclusively licensed to Lyell, and in some cases are the exact same. This exclusive license appears to build upon and expand Lyell’s portfolio of exclusive technologies in the area of cell therapies for the treatment of cancers.

In light of this consolidation, it is critical that the NIH seek the advice of the Attorney General on whether the execution of the license would be consistent with antitrust law (40 U.S.C. § 559). Under the Federal Property and Administrative Services Act, 40 U.S.C. §§ 101 et seq., “[a]n executive agency shall not dispose of property to a private interest until the agency has received the advice of the Attorney General on whether the disposal to a private interest would tend to create or maintain a situation inconsistent with antitrust law.” 40 U.S.C. § 559(b)(1).

This includes when the NIH proposes to grant an exclusive license in federally-owned technology. “Property” is defined at 40 U.S.C. § 102 to mean “any interest in property.” The statute exempts personal property if the fair market value is less than \$3,000,000, but specifically excludes “a patent, process, technique, or invention” from that exception.

The regulation 41 C.F.R. § 102-75.270 also makes clear the inclusion of patents “irrespective of cost.”

In communications regarding previous licenses, the NIH has made clear to KEI that as a practice, it does not consult the Attorney General prior to issuing exclusive licenses. In the past, the NIH has asserted its position with respect to 40 U.S.C. § 559 as follows:

The statute you reference is directed to the disposal (assignment) of government property. It has little relevance to our patent licensing activities, which are principally government by the Bayh-Dole Act and its regulations.

KEI disagrees with the NIH’s assertion.

35 U.S.C. § 209(a)(4) allows a federal agency to grant an exclusive license only if the license “will not tend to substantially lessen competition or create or maintain a violation of the Federal antitrust laws.” 35 U.S.C. § 211 provides that “[n]othing in this chapter shall be deemed to convey to any person immunity from civil or criminal liability, or to create any defenses to actions, under any antitrust law[.]” The Bayh-Dole Act sets out the areas in which the statute “shall take precedence over any other Act which would require a disposition of rights in subject inventions[.]” 35 U.S.C. § 210, and mentions 21 separate statutes, but not the FPASA.

The term “disposal” is not a defined term under 40 U.S.C. § 102 of the FPASA, and is not limited to “assignment” or “sale.” In fact, there are many examples of regulations and laws that include licensing amongst dispositions, either explicitly or by implication.

If NIH grants an exclusive license in a federally-owned invention, it is disposing of a government property interest so as to trigger 40 U.S.C. § 559.

The consultation requirement at 40 U.S.C. § 559 is also consistent with the Bayh-Dole Act’s prohibition on the grant of an exclusive patent license that will “tend to substantially lessen

competition or create or maintain a violation of the Federal antitrust laws [.]” 35 U.S.C. § 209(a)(4).

KEI requests that the NIH only proceed with this license if it has consulted the Attorney General regarding the antitrust implications of its issuance, bearing in mind that the license is illegal if it will “tend to” “substantially lessen competition” -- not simply if it violates a federal antitrust law.

KEI also urges the NIH to include the following provisions in the terms of any license.

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 Lyell 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