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**Re: Prospective Grant of an Exclusive Patent License: Development and Commercialization of Certain Fusion Proteins and Their Use for the Treatment of Humans With Short Stature ([86 FR 6892](#))**

Dear Mr. Girards:

The following are comments offered by Knowledge Ecology International (KEI) regarding the “Prospective Grant of an Exclusive Patent License: Development and Commercialization of Certain Fusion Proteins and Their Use for the Treatment of Humans With Short Stature,” to EpifiZa Inc. located in Montreal, Canada.

The proposed exclusive license territory is worldwide and the field of use includes, “the development, manufacture, distribution, sale and use of one or more fusion proteins for the treatment of humans with short stature associated with one or more genetic conditions.”

Considering that the company set to receive this exclusive license is a foreign firm, how will the National Institutes of Health (NIH) address and enforce the U.S. manufacturing requirement (35 U.S.C. § 204) in the case of this license? One of the requirements on the grant of exclusive licenses of federally-funded inventions outlined in the Bayh-Dole Act is that it requires the licensee to “substantially” manufacture the invention in the United States. Licensees can obtain a waiver of the requirement to manufacture in the US. Has the licensee sought a waiver from the NIH, and will the NIH grant a waiver of the requirement?

The NIH has proposed to license, on an exclusive basis, this US taxpayer-funded technology to EpifiZa, a Canadian company. Since the company is not based in the United States, it is even more critical that the NIH ensure terms that will protect U.S. residents from paying prices greater than other high income countries, among other protections.

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.

KEI notes that the US government has recently incorporated similar terms in agreements related to COVID-19 vaccines and other technology contracts. For example, in the contract with Sanofi Pasteur (Sanofi) for a COVID-19 vaccine, the federal government included a term that stated that Sanofi will not sell the vaccine to any member of the G7 or Switzerland at a price lower than what the U.S. government paid. The NIH should apply this standard to its exclusive licensing practices, and prevent licensees from charging U.S. residents a higher price for products embodying the licensed invention than they charge residents of these high-income countries.

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

### ***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 EpifiZa 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***

We further request that the NIH includes the following additional provisions to protect the public's interest in this NIH-funded technology:

**Years of exclusivity.** We propose the license include terms that 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 ddl case. We propose that the terms stipulate that in any sublicense that the exclusivity of the license be reduced when the global cumulative sales from products or services using the inventions exceed certain benchmarks. For example, the period of exclusivity in the sublicense 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.”

**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 countries with significantly lower incomes.

**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 developing countries, 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. KEI therefore requests that the license 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,

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