

28 August 2020

Michael Shmilovich, Esq.  
Senior Licensing and Patent Manager  
National Institutes of Health  
Tel.: 301-435-5019  
Via: shmilovm@nih.gov

**Re: Prospective Grant of an Exclusive Start-Up Patent License for Evaluation:  
Immunotherapy for Relapsed/Refractory Diffuse Large B Cell Lymphoma to ONK  
Therapeutics of Ireland**

Dear Mr. Shmilovich:

Knowledge Ecology International (KEI) and the Union for Affordable Cancer Treatment (UACT) offer the following comments on the “Prospective Grant of an Exclusive Start-Up Patent License for Evaluation: Immunotherapy for Relapsed/Refractory Diffuse Large B Cell Lymphoma” to ONK Therapeutics of Ireland, as noticed in [85 FR 49387](#).

ONK Therapeutics is a company in Ireland. Since the company is not based in the United States, it is even more compelling for the National Institutes of Health (NIH) to protect U.S. residents from paying prices greater than other high income countries.

This is technology financed by U.S. taxpayers, and the company to receive the license is foreign-owned and operated. The terms of any license should reflect the obligation, in 35 U.S.C. § 209, to limit exclusivity to that which is necessary, and in 35 U.S.C. § 201(f), to ensure that inventions are made “available to the public on reasonable terms.”

How will the NIH address and enforce the Bayh-Dole U.S. manufacturing requirement in the case of this license? You stated that this issue is yet to be negotiated, but since U.S. manufacture preference is required under law (35 U.S.C. § 204), and companies seeking an exception must apply for a waiver, isn't this something the NIH should be transparent about, during the public comment period, when the license is to an Irish start up company?

**The 35 U.S.C. § 209 analysis**

35 U.S.C. § 209 has several restrictions on the grant of an exclusive license. In Section 209(a)(1), the agency has to determine if exclusivity is a reasonable and necessary incentive to induce the investments to bring an invention to practical application.

(a) Authority.—A Federal agency may grant an exclusive or partially exclusive license on a federally owned invention under section 207(a)(2) only if—

- (1) granting the license is a reasonable and necessary incentive to—  
(A) call forth the investment capital and expenditures needed to bring the invention to practical application; or (B) otherwise promote the invention's utilization by the public;

Additionally, if some exclusivity is warranted, the agency still has to determine the scope of exclusivity, and is required to ensure that that the proposed scope of exclusivity is not greater than reasonably necessary:

(a) Authority.—A Federal agency may grant an exclusive or partially exclusive license on a federally owned invention under section 207(a)(2) only if—

...

- (2) the Federal agency finds that the public will be served by the granting of the license, as indicated by the applicant's intentions, plans, and ability to bring the invention to practical application or otherwise promote the invention's utilization by the public, and that the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application, as proposed by the applicant, or otherwise to promote the invention's utilization by the public;

No exclusive license should be granted until the NIH conducts an economic analysis to determine if exclusivity can be limited to less than the life of the patent, as was the case, for example, for all extramural-funded patents when the Bayh-Dole Act was passed in 1980, and under previous NIH Directors, as in the case of the ddl license for an HIV drug.

Videx® Expanding Possibilities: A Case Study, National Institutes of Health Office of Technology Transfer, September 2003.

<https://www.ott.nih.gov/sites/default/files/documents/pdfs/VidexCS.pdf>

“The technology transfer challenge was to negotiate a license that would provide a strong incentive for a drug company to make the significant investment necessary for the rapid development of a new drug while ensuring the long-term public health benefits. This balance was struck by offering a license that was initially exclusive, but which could become non-exclusive early, prior to the expiration of the NIH patents. Several companies competed for the license.”

### **Limits on the term of exclusivity**

Any exclusive license should limit the number of years of exclusivity to that which is “reasonably necessary to provide the incentive for bringing the invention to practical application” and this requires an evaluation of the risks and costs of trials and other R&D necessary to advance a

product to regulatory approval, as well as of the potential market for a product upon such approval.

We note that the prospective license limits the initial term of exclusivity, with an option to extend the license after the initial period of exclusivity expires if ONK provides the NIH “with a commercial development plan supporting such a conversion.”

It is appropriate and consistent with the Bayh-Dole Act for the NIH to limit the initial term of exclusivity and condition extensions of the license on the licensee performing actions that are beneficial to the public. However, the NIH can and should go further in limiting the terms of exclusivity for its licenses than it is proposing to do here.

The NIH should consider how the license with Bristol Myers Squibb over the cancer drug cisplatin was structured, where the NIH allowed the limited term of exclusivity and BMS’s desire for an extension to extract valuable concessions for the U.S. government, including BMS contributing tens of millions of dollars to NIH directed cancer research, and lowering the price of the product after the initial period of exclusivity (shorter than the patent life) had run its course.

In this case, we ask that the NIH provide a mechanism to shorten the term of exclusivity when sales targets are met, such as by reducing exclusivity for one year for every half billion dollars in sales after the first billion dollars of sales.

### **Limit on US exclusivity**

We ask that if exclusive rights are granted, that this only be in high income countries, but not in the United States. Or at a minimum, have the U.S. exclusivity shorter than the exclusivity in other high income countries, perhaps after global revenue targets are reached.

### **40 U.S.C. § 559 - Advice of Attorney General with respect to antitrust law**

We insist that the NIH seek the advice of the U.S. Attorney General, as is required by 40 U.S.C. § 559(b)(1).

### **Additional issues if an exclusive license is granted**

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

**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.

**Low and middle income countries.** The exclusive licenses 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.

**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 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.

#### **Acknowledgement of federal funding - publication and publicity**

The licensee should be required to clearly state, 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 federal funding of the research and development.

#### **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 last year.

Please notify us if a license is actually granted, so we can request a copy under the FOIA.

Sincerely,

James Love, on behalf of Knowledge Ecology International  
james.love@keionline.org

Manon Ress, Union for Affordable Cancer Treatment  
manon.ress@cancerunion.org