1621 Connecticut Ave NW, Suite 500
Washington, D.C. 20009
+1 (202) 332-2670
http://keionline.org

9 December 2016

Knowledge Ecology International Comments RE NIST Docket No: 160311229-6229-01: Rights to Federally Funded Inventions and Licensing of Government Owned Inventions, 81 Fed. Reg. 78,090 (Nov. 7, 2016) (proposed rule to amend 37 C.F.R. §§ 401 and 404)

https://www.regulations.gov/comment?D=NIST-2016-0002-0001

Knowledge Ecology International (KEI) is a not for profit non governmental organization that searches for better outcomes, including new solutions, to the management of knowledge resources. KEI is focused on social justice, particularly for the most vulnerable populations, including low-income persons and marginalized groups.

Our comments will focus on the first question posed in the Federal Register notice: “Are there any changes to these regulations, consistent with current law, that you or your organization think would accelerate the transfer of federally funded research and technology to entrepreneurs, or otherwise strengthen the Nation's innovation system?”

1. Transparency of licensing should be improved.

Today we contacted the Army response to a notice in the Federal Register (81 FR 89087) about a potential exclusive license to patents on a vaccine for the Zika virus, to Sanofi, a French pharmaceutical and vaccine company. There are 15 days to respond. The Army was reluctant to provide any details about the terms in the proposed license, including such as items as any description of the technology to be licensed (the patent applications are not public), the royalty rate or any provisions on pricing. We have had similar experiences at the NIH, where the NIH has refused to give out the the address, phone number of names of principles of companies seeking exclusive license to potentially very important medical technologies, let alone the basics on what the companies would pay for the licenses, or how the products would be available to the public on “reasonable terms” (a requirement of 35 USC 201.f). See, for example: http://keionline.org/nih-licenses.

The reports on how patents are worked are generally secret, as are the royalty payments made.

All of this makes a mockery of the public's right to comment on proposed licenses (35 USC 209.e), and makes it difficult to evaluate the licensing practices of federal agencies.

2. We believe agencies do not do adequate evaluations of the scope of exclusivity necessary as required by 35 USC 209.

Under the statute, a federal agency "may grant an exclusive or partially exclusive license on a federally owned invention . . . only if granting the license is a reasonable and necessary incentive to call forth the investment capital and expenditures needed to bring the invention to practical application or otherwise promote the invention's utilization by the public, and even then, the proposed scope of exclusivity should be "not greater than reasonably necessary to provide the incentive for bringing the invention to practical application . . . or otherwise to promote the invention's utilization by the public."

In previous years, agencies seem to have made some effort to implement this restriction on exclusive rights, for example, by limiting the term of exclusivity for the license on the patents on the HIV/AIDS drug ddI. However, in recent years, as far as we can tell, agencies license for the entire term of the patent even when a shorter period would be sufficient to get a product into the market.

3. We believe agencies systematically ignore the requirement in 35 USC 201(f) that the benefits of inventions be "available to the public on reasonable terms."

Based upon our conversations with NIH and the US Army licensing officials, we believe there is ZERO interest in addressing the issue of what constitutes "reasonable terms". Indeed, the NIH has indicated that by simply making a product available for sale, at any price, the condition of practical application in the statute is satisfied. This was true in the case of Ritonavir, when the US price was 5 to 10 times higher than ANY other high income industrialized country, and for the prostate cancer drug Xtandi, when the price of $129,000 per year was 2 to 4 times higher than ANY other high income industrialized country.

We are concerned that the NIH is licensing patents to a vaccine for the Attenuated Respiratory Syncytial Virus (RSV) Vaccines[1], and the US Army is licensing patents to a vaccine for the Zika virus, without any obligations to make the products available on reason terms to US consumers. Both vaccines are being or have been licensed to the French vaccine and drug manufacturer Sanofi. If the vaccines are successful, we may be faced with very high costs to buy products based upon our own taxpayer funded research.

[1] http://keionline.org/node/2445.

A few other examples of where KEI has unsuccessfully sought reasonable pricing include:

- An NIH license for an entire class of Hepatitis C Virus (HCV) medicines to a small biopharmaceutical firm in California, in a case where the NIH declined to disclose the names of the principals in the business or their expertise in bringing HCV medicines to commercialization;[2]

- An NIH license on a class of Chimeric Antigen Receptor T-Cell Receptor (CAR-T) therapies, a form of cancer immunotherapy that will reportedly command high prices (upwards of $200,000 per patient per year) and a large share of the cancer treatment market, to Kite Pharma.[3]

4. Before giving a firm an exclusive right to patents on a drug, vaccine or other key medical invention, the federal government should publish an analysis that estimates the cost the federal government would have incurred in funding clinical trials and other development costs, without granting exclusive rights, and compare those costs of the expected costs of buy the invention from the license holder, when the manufacturer has obtained a legal monopoly.

5. In order to develop more useful evidence to evaluate licensing policies, licenses could and should require transparency of the costs of research and development. For medical inventions, this should include an annual report for R&D outlays, with the company reporting the following information for each clinical trial that it conducts on the patented invention:

a. ClinicalTrials.Gov identifier;
b. Phase;
c. Conditions;
d. Interventions;
e. Title Acronym/Titles;
f. Outcome Measures;
g. Sponsor/Collaborators;
h. Other Study IDs;
i. Expenditures (for that year);

The patent holder should also be required to report:

j. the sales prices, units of sales, and revenues, by country;
k. government subsidies related to the research, reported by year, including:

[2] http://keionline.org/node/2219

[3] "Kite Pharma Uses CRADAs to Conduct Important Clinical Research on New Cancer Treatments," http://keionline.org/node/2640; "KEI Comments on NIH Proposed Exclusive License to Kite Pharma for Cancer Treatment," http://keionline.org/node/2648; and "Kite Pharma Press Releases & News Stories Related to Relationship with National Cancer Institute," http://keionline.org/node/2644.

i. grants and research contracts from government agencies, with data on the funding agency, the identifier of the grant or contract, and the amount of the grant or contract;
ii. tax credits associated with R&D for the product, including the orphan drug tax credit, broken out by the type of credit and the expenditure the credit was associated with (such as a specific trial); and
iii. other government R&D subsidies;

6.. For medical inventions, agencies should be required to consider including provisions that would limit the length of exclusivity, when life of patent exclusivity is and excessive and costly incentive. For example, for some drugs or vaccines, where significant development costs are already paid for by the government, licenses could including provisions such as the following:

> The exclusive rights will extend to five years from the first sale of a product receiving approval by the U.S. FDA, or until the license holder recovers at least $1 billion in cumulative global sales from the product, whichever is shorter, and thereafter, the license will become non-exclusive. After the first five years of exclusivity, the NIH can extend the exclusivity by another 3 years, upon a showing that such extension is reasonable in light of the risk adjusted R&D costs to bring the product market, and the net revenues from sales.

7. To ensure that prices for products are “reasonable” -- the standard in 35 USC 201(f) -- and do not discriminate against US residents, licenses should limit the price of the product to no more than the median price of other high income countries. For example, using language such as:

> The [agency] will normally expect the licensee to make products available to the public in the United States at prices no higher than the median price charged in the seven countries with the largest GDP, that have per capita incomes of at least half that of the United States.

8. In some cases, it will be appropriate to include other standards for the reasonableness of prices, including to ensure that products are reasonably affordable.

For example, for drugs, health insurance plans often impose co-payments as high as 20 percent of the sale price of the drug. For such a co-payment to be affordable, the co-payment should be reasonable compared to the wages of a worker, after paying for taxes, food, shelter and other living expenses. The IRS considers medical expenses extraordinary if they exceed 10 percent of your adjusted gross income, or 7.5 percent for persons 65 or over. One could set a ceiling on prices for a single drug at 37.5 percent of the adjusted gross income (so that 20 percent of the drug was equal to 7.5 percent of the workers adjusted gross income), using the median wage for all employees (less than $36,000 per year), or a lower figure, such as the minimum wage

(less than $15,000 per year) or some multiple of the federal poverty level ($11,880 per year in 2016 for a single person), to make medicines more universally affordable.

37.5 percent of twice the federal poverty level would result in a cap in prices of $8,910 per year.

9. Licenses on medicines, vaccines and other health related inventions should require that products are available and affordable in developing countries, especially those with per capita incomes of less than one third of the U.S. per capita income.

We believe that the above provisions are consistent with the intent of the Bayh-Dole Act, which has as its "policy and objective" to promote innovation while protecting "the public against nonuse or unreasonable use of inventions." 35 U.S.C. § 200.

Sincerely,

James Love
Knowledge Ecology International
james.love@keionline.org
+1.202.332.2670
http://keionline.org