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Re: KEI questions and initial comments on Prospective Grant of an Exclusive Patent License: Apparatus for Microarray Binding Sensors Having Biological Probe Materials Using Carbon Nanotube Transistors to Nanobernetics, LLC ("Nanobernetics") , as noticed in the Federal Register, 82 FR 41970.

Dear Jaime Greene,

Having seen a copy of the Federal Register notice on the proposed license to Nanobernetics, LLC, KEI has several questions and offers initial comments on the proposed license.

Questions.

1. Is this a start-up license?
2. What is the proposed term of the license?
3. What is the proposed royalty rate on the license?
4. Does the NIH have any other contracts, licenses, CRADAs or other agreements with the firm or any of its officers or founders?
5. LinkedIn lists a PhD student at the University of Maryland, College Park (UMCP) as the only employee for this firm, and the web page gives the names of just two persons, both graduate students at UMCP. Why does the NIH believe the firm can bring the invention to practical application, and does the NIH expect the firm will primarily market the patent rights to third parties, or develop the technology itself?
6. Will the license comply with the norms on pricing included in the directive in the U.S. Senate Armed Services Committee report for the National Defense Authorization Act for fiscal year 2018?

Initial Comments on the Proposed License

1. KEI suggests that the license include language to address the pricing norm proposed by the U.S. Senate Armed Services Committee report for the National Defense Authorization Act for fiscal year 2018.

One of the subject patents is U.S. Patent 8,017,938 (Application No. 11/723,369), filed 19 March 2007, titled "Apparatus for Microarray Binding Sensors Having Biological Probe Materials Using Carbon Nanotube Transistors." According to the published patent, "The work leading up to the present invention was funded, at least in part, by NSA under Grant H9823004C0470." We note the NSA is an agency of the Department of Defense.

On page 173 of Senate Report 115-125, titled "*National Defense Authorization Act for Fiscal Year 2018, Report to accompany S. 1519*," there is a directive on the "Licensing of federally owned medical inventions", which reads as follows:

> The committee directs the Department of Defense (DOD) to exercise its rights under sections 209(d)(1) or 203 of title 35, United States Code, to authorize third parties to use inventions that benefited from DOD funding whenever the price of a drug, vaccine, or other medical technology is higher in the United States than the median price charged in the seven largest economies that have a per capita income at least half the per capita income of the United States.

We suggest that the following language be included in the license:

> [The party obtaining the license] agrees to make the product available to the public in the U.S. at publicly disclosed prices no higher than the median price charged in Canada plus the seven countries with the largest GDP, which have per capita incomes of at least half that of the U.S.

2. Address and make more concrete the expectations regarding the obligation to technologies "available to the public on reasonable terms."

The company obtaining the license should disclose the steps it will undertake to make the benefits of the invention "available to the public on reasonable terms," as is required by the Bayh Dole Act per definition under 35 U.S.C. § 201(f). If this obligation is seen as global, then the following text would be appropriate:

> [The party obtaining the license] agrees to disclose the steps it will take to enable the registration and availability of the product at an affordable price in every country with a demonstrated need, 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.

3. Access to the technology in developing countries.

We oppose making the license exclusive worldwide. The NIH should reserve the right to issue licenses to third parties, including the Medicines Patent Pool, in countries that have a per capita income less than half that of the U.S.

Sincerely,

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