May 4, 2016

Betty Tong, Ph.D.
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National Institute of Diabetes and Digestive and Kidney Diseases
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Via email: betty.tong@nih.gov

May 4, 2016

Dear Dr. Betty Tong,

I am writing to express our concern and objections to the potential grant of exclusive patent licenses to Vital Spark Inc. and Kalytera Therapeutics Inc. for CB1 receptor mediating compounds, as announced in Federal Register notices, titled “Prospective Grant of Exclusive License: The Development of MRI-1569, MRI-2213 and MRI-2214 as a Therapeutic To Treat Obesity, Diabetes, Fatty Liver Disease and Liver Fibrosis” (81 FR 22997) and “Prospective Grant of Exclusive License: Development of the CB1/iNOS Series of Compounds as a Therapeutic To Treat System Sclerosis, Scleroderma, and Other Skin Fibrotic Diseases in Humans” (81 FR 22995), respectively.

The grant of exclusive licenses for different fields of use for the same patented invention are being considered for two different companies. There is limited information available on Kalytera Therapeutics Inc., but virtually no information about Vital Spark Inc.

We found no public records on Vital Spark Inc. after a reasonable search. The NIH declined to provide additional information beyond the Federal Register notice, citing confidentiality rules.

We are especially concerned about the lack of transparency in the the licensing process.

Under 37 CFR 404.7(a), the NIH is required to make determinations regarding the necessity of the grant of an exclusive license:

> “(1) Exclusive, co-exclusive or partially exclusive domestic licenses may be granted on Government owned inventions, only if
> …

> (ii) After expiration of the period in § 404.7(a)(1)(i) and consideration of any written objections received during the period, the Federal agency has determined that;
>
> …
>
> (B) Exclusive, co-exclusive or partially exclusive licensing 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
>
> (C) 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[.]"

As far as we know, the NIH has not demonstrated why granting an exclusive license to either company is necessary, how the proposed scope of exclusivity is limited to that "reasonably necessary to provide the incentive for bringing the invention to practical application," or how the NIH will ensure that the inventions is available to the public on reasonable terms, including but not limited to a reasonable price.

Calling for public comment on the license, and then providing almost none of the relevant information, makes the public comment process ineffective, as regards the public's role in objecting to licenses that undermine their rights to obtain access to the benefits of the inventions on favorable terms, or address other public interest issues.

We object to the policy of only providing the patent applications for publicly funded and developed inventions to parties interested in licensing the technology.

The NIH has already invested considerable public resources in CB1 receptor research as it applies to obesity and its comorbidities; it is therefore unsettling how untransparent the licensing process is.

We ask that the following be made publicly available:

1. The justification that scope of the exclusivity is not greater than reasonably necessary;
2. The analysis of the applicants conducted by the NIH to clearly demonstrate the obligations under 37 CFR part 404.7 and 35 U.S.C. 209 would be met by grant of the license;
3. The text of the proposed licenses, and of the final licenses, if granted;
4. The cost of the drug development, and the royalties and the revenue from the licensed technology; and
5. Any patent applications for the government owned invention.

The technologies proposed for licensing regarding CB1 receptors have important applications to the American public. According to the CDC, over 70% of American adults are overweight or obese, and obesity-related diseases are the leading cause of death.[1,2] The economic costs of obesity are just as bleak as they were in 2008, when the health care costs for obese individuals were $1,429 higher than for non-obese persons.

Accordingly, we ask that this exclusive commercialization license regarding federally-owned patent applications include provisions that ensure that the product are (a) reasonable, (b) in no event priced higher than other high-income countries and (c) that the prices are affordable enough that the products do not face restrictions on access or reimbursements by insurers and government payors.

KEI opposes the grant of exclusive licenses for CB1 technologies unless:

1. The NIH conducts sufficient analysis, and limits the terms and scope of the license, as required under 404.7(a)(1)(ii-iii);
2. The license contains sufficient safeguards regarding the affordability of the products developed under the patent licenses; and
3. The license requires transparent reporting on drug development costs, royalties, and revenues, and other items.

We object to any license that is not made public.

All reports specified in the license, including those described in the license appendices, should be public. If the NIH insists on transparency (as was common practice and acceptable in earlier years), the company requesting the license would agree. The company is getting the license before making any significant investments, and the NIH's invention may be worth several billion dollars.

We also ask the NIH to create a requirement for annual reports on R&D outlays, including an obligation that the company reports the following for each clinical trial that tests products covered by the patents:

- ClinicalTrials.Gov identifier
- Phase
- Conditions:
- Interventions:
- Title Acronym/Titles:
- Outcome Measures:
- Sponsor/Collaborators:
- Other Study IDs:
- Expenditure: (for that year)

[1] http://www.cdc.gov/nchs/fastats/obesity-overweight.htm
[2] http://www.cdc.gov/obesity/data/adult.html

With regard to sales prices, we request an annual report that provide data on the following variables:

- Units of sales, by country
- Revenue for sales, by country

With regard to government subsidies for research, we request a report that provides data for the following, by year:

- 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 contact.
- Tax credits associated with R&D for the product, including the U.S. orphan drug tax credit, broken out by the type of credit and the expenditure the credit was associated with (such as a specific trial).
- Other government R&D subsidies.

Since the statute requires that the "scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application" we request a copy of any analysis, if any, that was done to consider how many years of exclusive rights were necessary to bring the invention to practical application. We also propose the following terms for the contract:

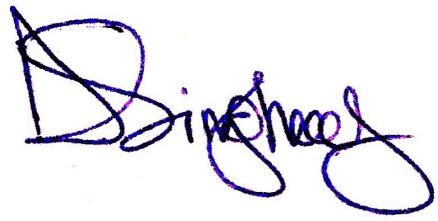
> The exclusive rights will extend to five years from the first sale of a product receiving approval by the U.S. FDA, or until the license holder recovers at least $1 billion in global sales from the product, whichever is shorter, and thereafter, the license will become non-exclusive. After the first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

KEI notes that the 5 year period, with possible extensions, follows NIH practice, prior to 1984, and other NIH licenses have had terms shorter than the life of patent. For example, in October 2001, the NIH exercised an option to make the licenses for the AIDS drug DDI non-exclusive, ten years after the initial FDA registration (see: Videx® Expanding Possibilities: A Case Study, NIH, National Institutes of Health Office of Technology Transfer, September 2003) in order to expand access to the drug, and to obtain lower cost supplies for federal programs.

The NIH could consider different time periods for exclusivity, but if the answer is always life of patent, no matter what the facts are, then the NIH is no longer meeting the requirements of 35 U.S.C. 209 to ensure that the "scope of exclusivity is not greater than reasonably necessary."

We hope the NIH will seriously consider these comments, and use its authority to advance affordable access to medical technologies that will benefit the overall health of the American public.

Regards,



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