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Re: Prospective Grant of Exclusive License: Development of 5T4 Antibodies in Human Cancer Therapeutics and Diagnostics to Ovensa, Inc. ("Ovensa") located in Ontario, Canada.

Federal Register Citation: 81 FR 19211 Page: 19211 (1 page)
Document Number: 2016-07556
Shorter URL: https://federalregister.gov/a/2016-07556

Dear Dr. Freel,

I am writing to express our opposition to the grant on an exclusive license to Ovensa, Inc., ("Ovensa"), located in Ontario, Canada, of several patents related to the development of 5T4 antibodies for the treatment, prevention or diagnosis of cancer.

KEI opposes the grant of exclusive license in this case 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 affordability and reasonable pricing of the products developed under the patent licenses,

3. The license places restrictions on charging US residents higher prices than the median prices charged in countries with the seven largest GDP and per capita incomes of 50 percent or more than the United States per capita income,
4. The license quires products are affordable in developing countries, and explicitly allows the NIH to grant licenses to the patents to the Medicines Patent Pool (MPP) for use in developing countries;
5. The license requires transparent reporting on drug development costs, royalties and revenues.

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)

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 governing the grant of exclusive licenses 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, and without an analysis to determine the the "scope of exclusivity is not greater than reasonably necessary," the NIH would have failed to meet the requirements of 35 U.S.C. 209.

Sincerely,

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Annex: Intellectual Property to be licensed

From the Federal Register Notice:

- U.S. Provisional Patent Application No. 62/034,995 filed August 8, 2014 entitled "Human Monoclonal Antibodies Specific for 5T4 and Methods of Their Use" [HHS Ref. No. E-158-2014/0-US-01];
- PCT Application No. PCT/US2015/044253 filed August 8, 2015 entitled "Human Monoclonal Antibodies Specific for 5T4 and Methods of Their Use" [HHS Ref. No. E-158-2014/0-PCT-02].

The patent rights in these inventions have been assigned to the government of the United States of America. The prospective exclusive license territory may be worldwide and the field of use may be limited to "the use of the Licensed Patent Rights in combination with the Licensee's proprietary or exclusively in-licensed platforms and technologies for the treatment, prevention or diagnosis of cancer."

5T4 is an antigen expressed on many different types of cancers, especially solid tumors. Its expression is limited in normal tissue, but is prevalent in malignant tumors throughout their development making it an attractive target for cancer immunotherapy. 5T4 is often found in colorectal, ovarian, and gastric tumors and as a result, has been used as a prognostic aid for these cancers. The role of 5T4 in antibody-directed immunotherapy has been studied using murine monoclonal antibodies (mAbs). In addition, the cancer vaccine TroVax (currently in clinical trials for multiple solid tumors) targets 5T4. The present invention describes the identification and characterization of two fully human mAbs (m1001 and m1002) that bind to 5T4. Since the mAbs are fully human, they could have less immunogenicity and better safety profiles than the existing mouse and humanized antibodies. These mAbs have the potential to be cancer therapeutics as naked mAbs, chimeric antigen receptors (CARs) or antibody-drug conjugates (ADCs).