Gmail

Claire Cassedy <clairepcassedy@gmail.com>

Re: Prospective Grant of Exclusive Patent License: Mutant IDH1 Inhibitors Useful for Treating Cancer to Apexx Oncology. Notice for comment published in 83 FR 29562.

Vepa, Sury (NIH/NCATS) [E] <sury.vepa@nih.gov> Wed, Aug 1, 2018 at 11:59 AM
To: James Love <james.love@keionline.org>
Cc: Luis Gil Abinader <luis.gil.abinader@keionline.org>, Claire Cassedy <claire.cassedy@keionline.org>, Manon Ress <manon.ress@keionline.org>, Thiru Balasubramaniam <thiru@keionline.org>

VIA E-MAIL ONLY

James Love

Knowledge Ecology International

1621 Connecticut Ave. NW, Suite 500

Washington, DC 20009

Re: Prospective Grant of Exclusive Patent License: Mutant IDH1 Inhibitors Useful for Treating Cancer to Apexx Oncology. Notice for comment published in 83 FR 29562.

Dear Mr. Love,

Thank you for your emails dated July 10, 2018 regarding the prospective grant of an exclusive license to Apexx Oncology, which was published on June 25, 2018 in the Federal Register (83 FR 29562). The notice period provides an opportunity for public comment and possible objection to the proposed license. We consider all comments prior to negotiating the proposed license.

Specifically, we have considered your comments and address them in the following:

1. With respect to your comments about the license applicant, Apexx Oncology, Inc. (f/k/a FBIO Acquisition Corp. VI) is a majority-owned subsidiary of Fortress Biotech, Inc., a biopharmaceutical company dedicated to acquiring, developing and commercializing novel pharmaceutical and biotechnology products, both at the Fortress level and within certain of its subsidiaries, also known as Fortress Companies (http://www.fortressbiotech.com). Regarding its corporate details and business plans etc., we are unable to provide that information as we have learnt that information solely from the license application and as such it is privileged and confidential and is not subject to disclosure under 5 USC §552.
2. Regarding your comment “did the NIH have no reasonable prospects for a license to an entity with more resources and a stronger track record than a company that seems to barely exist,” prior to posting this notice for a proposed grant of an exclusive license, the NCATS determined that the criteria set forth in 37 CFR 404.7(a)(1)(ii-iii) have been satisfied and that the company is qualified to be granted an exclusive license to the Government’s intellectual property in the fields of use as specified.
3. With respect to your recommendations regarding pricing of products made by the licensee, NIH has not included pricing provisions in its licenses for many years, for reasons that have been extensively discussed in the literature, which is readily and publicly available.

4. Regarding your recommendation that “the licensee 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 that uses the invention, including reporting separately and individually the outlays on each clinical trial,” we already require our license applicants/licensees to provide us with sufficient information to evaluate the viability of their commercial plans and to continuously monitor the progress of the development of the licensed technology towards practical application. To the extent that this information is not already publicly available, it is confidential business information and we carefully maintain the confidentiality of that information as required by 37 C.F.R. 404, 5 USC §552 and other applicable regulations and statutes.
5. Regarding your comments about limiting or reducing the exclusivity, those determinations were made prior to the advertisement of the proposed license and consistent with 37 CFR 404.7 and other applicable regulations.

Once again, we thank you for the comments and recommendations provided by the KEI. NCATS has carefully reviewed and given serious consideration to your comments and recommendations. We have determined that KEI’s comments fail to establish that the grant of the prospective license to the Apexx Oncology would be inconsistent with applicable regulatory and statutory requirements. Consistent with NIH licensing practices, NCATS will review and consider all the comments and any objections it has received. If none of these are found to warrant a change in our proposed license, NCATS will proceed with the negotiation of an exclusive license to the Apexx Oncology.

Sincerely,

Sury Vepa

Sury Vepa, Ph.D., J.D.

Senior Licensing and Patenting Manager

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NIH NCATS: Improving Health Through Smarter Science

Connect with us!: https://ncats.nih.gov/connect

From: James Love [mailto:james.love@keionline.org]
Sent: Tuesday, July 10, 2018 4:35 PM
To: Vepa, Sury (NIH/NCATS) [E] <sury.vepa@nih.gov>
Cc: Luis Gil Abinader <luis.gil.abinader@keionline.org>; Claire Cassedy <claire.cassedy@keionline.org>; Manon Ress <manon.ress@keionline.org>; Thiru Balasubramaniam <thiru@keionline.org>
Subject: Re: Prospective Grant of Exclusive Patent License: Mutant IDH1 Inhibitors Useful for Treating Cancer to Apexx Oncology. Notice for comment published in 83 FR 29562.

July 10, 2018

Sury Vepa, Ph.D., J.D.,
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National Center for Advancing Translational Sciences
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Email sury.vepa@nih.gov

Re: Prospective Grant of Exclusive Patent License: Mutant IDH1 Inhibitors Useful for Treating Cancer to Apexx Oncology. Notice for comment published in 83 FR 29562.

https://www.federalregister.gov/documents/2018/06/25/2018-13486/prospective-grant-of-exclusive-patent-license-mutant-idh1-inhibitors-useful-for-treating-cancer

Dear Dr. Vepa,

Knowledge Ecology International (KEI) offers the following comments on the, “Prospective Grant of Exclusive Patent License: Mutant IDH1 Inhibitors Useful for Treating Cancer,” to Apexx Oncology, which was noticed in the Federal Register (83 FR 29562).

As far as the public can determine, Apexx Oncology is a secretive startup company. The only information we could find using a Google search about the company was a contest for a logo of the company. There is no record of a registered trademark for Apexx Oncology with the USPTO. No web page has been located. It is not obvious if Apexx Oncology is a new name for GeneXion Oncology (as indicated today), or a new company entirely, and in any case, there is next to nothing generally known about the company under either name.

When the NIH proposes giving an exclusive license on a patent to a company for which almost nothing is known, it should provide at the very least some basic information about the company. In seeking to respond to the first FR notice in this case, we had asked if GeneXion was owned by a company in Switzerland, but the NIH declined to answer. We don’t know who is on the board of directors, who the key staff are or if

another company owns this company. We would like to know if any current or former NIH employees or contractors are part of the company.

We also seek to learn -- why this company was selected in the first place? Do they have people who have worked on this particular technology, or have some special expertise? And since the patents are fairly new, did the NIH have no reasonable prospects for a license to an entity with more resources and a stronger track record than a company that seems to barely exist?

Here are some general provisions that we recommend for an exclusive license by the NIH.

1. **No discrimination against US residents in pricing.**

Prices in the U.S. for any drug, vaccine, medical device or other health technology using the invention should not be higher than the median price charged in the seven countries with the largest gross domestic product (GDP), that also have a per capita income of at least 50 percent of the United States, as measured by the World Bank Atlas Method.

2. **Developing countries.**

The license should not be exclusive for countries with a per capita income that is less than 30 percent of the US.

3. **Transparency.**

The licensee 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 that uses the invention, including reporting separately and individually the outlays on each clinical trial. We will 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.

4. **Reduce term of exclusivity when revenues are large.**

The exclusivity of the license in the U.S. should be reduced by one year for every $500 million in revenue equivalents, earned after the first $1 billion, where revenue equivalent is defined as global cumulative sales plus market entry rewards as well as government grants or tax credits, for the product or products using the invention.

Sincerely,

James Love
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https://keionline.org

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