November 6, 2020

Tedd Fenn
Senior Technology Transfer Manager
NCI Technology Transfer Center
National Institutes of Health
Via: Tedd.Fenn@nih.gov
Cc: Richard U. Rodriguez, richard.rodriguez@nih.gov

Re: Prospective Grant of an Exclusive Patent License: Development of a Direct Ocular Administered Formulation of Metformin for Use in Therapeutic Treatment of Retinal Degenerative Diseases in Humans to Connectyx.

Dear Tedd Fenn:

Knowledge Ecology International (KEI) provides the following comments on the proposed license to Connectyx Technologies Holdings Group ("Connectyx"), noticed in the Federal Register (85 FR 67360), for "Development of a Direct Ocular Administered Formulation of Metformin for Use in Therapeutic Treatment of Retinal Degenerative Diseases in Humans."

First, we object to the lack of transparency regarding the proposed license. Attached is an October 22, 2020 query we sent to Tedd Fenn, the designated contact for the prospective license, that did not receive a response. The public comment period is required by the Bayh-Dole Act,[1] and the National Institutes of Health (NIH) should be willing to provide basic information about the licenses so the public's comments can be informed by relevant facts about the proposed license.

In general, we do not understand how Connectyx would qualify for an exclusive license, given its lack of facilities and lack of a track record of bringing medical technologies to market. It seems as though the NIH is allowing this company to market NIH assets to third parties, without contributing meaningful investments in R&D. But if the NIH does provide the license, the license should include limits on prices and the period of exclusivity. At a minimum, the price should be no more than is charged in other high income countries, and the exclusivity should be no more than seven years following registration of the product, unless the NIH can produce an economic analysis to show that a lower period is actually needed to induce investments. In no case should the exclusivity be extended to any country with a per capita income of 30 percent or less than the U.S. per capita income, as measured by World Bank GNI per capita using the Atlas Method.

To provide for transparency, particularly in the case of a license to a firm like Connectyx, the NIH should publish the agreed upon license on its webpage, and require the company to report

[1] 35 U.S.C. § 209(e).

annually on the actual R&D outlays related to the licensed technology, as well as the average price for any resultant products by every country where the products are sold.

James Love
Knowledge Ecology International
james.love@keionline.org

Attachment

For the record, KEI sent the following message to Tedd Fenn on Oct 22, 2020, along with two follow-up notes asking if we could expect a response to our inquiries. As of submission of these comments, Fenn had not replied to any of our messages.

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to:    Tedd.Fenn@nih.gov
cc:    Kathryn Ardizzone <kathryn.ardizzone@keionline.org>, Luis Gil Abinader
<luis.gil.abinader@keionline.org>, Claire Cassedy <claire.cassedy@keionline.org>,
arianna.schouten@keionline.org
date:  Oct 22, 2020, 9:49 AM
Subject: Connectyx license

Tedd Fenn, Senior Technology Transfer Manager,NCI Technology Transfer Center
Via Email: Tedd.Fenn@nih.gov

Dear Tedd Fenn,
Tried to leave a message by phone, but the mailbox was full.

1.  I see that NIH granted Connectyx a license in the previous FR request, noticed
in 85 FR 53390. Does the company have any other NIH licenses?

2.  For the current case, is U.S. provisional patent application No. 62/899,899 and
entitled, "Druggable Targets to Treat Retinal Degeneration" filed September 13, 2019
(E-227-2017-US-01); International Patent Application No.: PCT/US2020/050540 and
entitled, "Druggable Targets to Treat Retinal Degeneration" filed September 11, 2020
(E-227-2017-PCT-02); and U.S. and foreign patent applications claiming priority to
the aforementioned applications, what is the development stage of the technology.
For example, have any human subject trials been done yet?

3.  Given it's a provisional patent application, just over a year old, have any
other companies expressed interest in a license, exclusive or non-exclusive?

4.  Do you know if there is any significant foreign beneficial ownership of this
company?

5.  Is the NIH negotiating a waiver of US manufacturing obligations for these
technologies?

6.  Does the company have a physical office, or only a web page?
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7. Has the White House communicated any preference for this company to obtain NIH licenses?

KEI would appreciate hearing from you before the end of the 15 day comment period, so we can reflect upon the answers when considering our comments.

Jamie