

September 11, 2020

Jasmine Yang, Ph.D.
Senior Licensing and Patenting Manager
NCI Technology Transfer Center
Tel.: (240)-276-5530
Via: jasmine.yang@nih.gov

RE: Prospective Grant of an Exclusive Patent License: Anti-CD56 as an Antibody-Drug Conjugate (“ADC”) or Non-ADC To Target Glioblastoma Either Alone or in Combination With Other Potential Immuno-Oncology Drugs, to Connectyx Technologies Holdings Group (“Connectyx”) located in Boca Raton, FL.

Dear Dr. Yang:

Knowledge Ecology International (KEI) and the Union for Affordable Cancer Treatment (UACT) offer the following comments on the proposed grant of an exclusive license on the patents and patent applications noticed in the Federal Register ([85 FR 53390](#)), for anti-CD56 as an antibody-drug conjugate (“ADC”) or non-ADC to target glioblastoma to Connectyx Technologies Holdings Group (“Connectyx”) located in Boca Raton, FL.

Connectyx Technologies Holdings Group

Connectyx Technologies Holdings Group (or any company named “Connectyx”) appears to have no FDA-regulated products. A Google search of the term on the FDA website returns no hits.¹

According to Reuters, as of this morning the shares of Connectyx Technologies Holdings Group Inc (CTYX.PK) were trading at less than 1 cent. *Microcap Daily* refers to the company as a “sub penny.”²

A disclosure statement pursuant to the Pink Basic Disclosure for Connectyx Technologies Holdings Group, Inc. for the period ending March 31, 2020, indicates the number of shares outstanding are 322,800,327, which, at the recent Reuters-quoted price of \$.008 per share, would be less than \$3 million. It appears that the company has operated under different names over the years, including:

¹ According to Google.com, a search returns the following message: “Your search - site:fda.gov connectyx - did not match any documents.”

²<https://microcapdaily.com/the-fascinating-story-of-connectyx-technologies-holdings-group-inc-otcmkts-ctyx/125404/>

- Storage Innovation Technologies, Inc. until October 2007;
- National Boston Medical, Inc. until May 2004;
- Fragrance Express, Inc. until October 1998; and
- Growth Industries, Inc. until July 1998.

The company was originally incorporated on June 29, 1995, in the State of Nevada. As of October 31, 2007, the company was reincorporated in the State of Florida.³

Three of the seven directors of Connectyx reside in Boca Raton, Florida, including Paul and Brandon Michaels and Bary Gingsberg. Three directors reside in Stuart, Florida. One director lists High Point, North Carolina as their residence. On LinkedIn, Paul Michaels lists his location as West Palm Beach.

The issuers facilities are described as follows:

“The Company utilizes virtual office space at a cost of \$99 per month.”⁴

Earlier SEC enforcement actions, with previous management of company

US Securities and Exchange Commission (SEC) documents for “Connectyx” indicate a previous enforcement action for fraud and kickbacks to a hedge fund manager, involving a previous CEO of a company named Connectyx Technologies Corp..⁵

These proceedings arise out of a fraudulent scheme in which insiders of publicly-traded penny stock companies paid secret kickbacks to a purported corrupt hedge fund manager, who was in fact an undercover agent with the Federal Bureau of Investigation (“Fund Manager”), in exchange for the Fund Manager’s purchase of restricted stock of the penny stock companies on behalf of his purported hedge fund (“the Fund”), which did not actually exist.

1. Respondent, age 59, of Palm City, Florida was the President and Chief Executive Officer of Connectyx Technologies Corp. (“Connectyx”), a publicly traded company. Respondent participated in an offering of Connectyx stock, which is a penny stock. Respondent was charged with one count of conspiracy to commit wire fraud on February 27, 2014 and pleaded guilty to that charge on May 20, 2014 in U.S. v. Schuman, 14-CR-10053-MLW (D. Mass.).

SunMed Advisors LLC

³ <https://backend.otcmartets.com/otcapi/company/financial-report/246431/content>

⁴ <https://backend.otcmartets.com/otcapi/company/financial-report/246431/content>

⁵ <https://www.sec.gov/litigation/admin/2015/34-75082.pdf>

According to the Pink Basic Disclosure document, the principal investors in Connectyx Holdings appear to be SunMed Advisors LLC., which controls 63.6 percent of the stock, and is represented by Paul Michaels, the current CEO and a director, and Barry Ginsberg, a director. SunMed claims to have “a direct presence in Japan.” Paul Michaels, Alexander Michaels and Barry Ginsberg are listed as the “team” for SunMed. According to the SunMed webpage, Paul Michael “provided financial leadership for almost 18 years to Inabata & Co. Ltd., one of Japan’s largest trading companies,” and “founded Nobelpharma, Ltd. Japan, an affiliate of Inabata & Co. Ltd., which is now one of Japan’s most profitable orphan drug companies.”⁶

KEI has asked Paul Michael and Dr. Yang at the NIH if Connectyx has any significant foreign investment, but has not received a response from either.

The company seeking the license seems to have modest financial assets, a thin resume for drug development, and appears to be almost a Michaels family operation, with Paul, Brandon and Alexander Michaels among the key figures. The LinkedIn profile for Paul Michaels states that he became acting CEO of Connectyx in March 2020 and CEO in July 2020.

It does seem odd that the NIH would provide an exclusive license to this company for an important cancer treatment, including the U.S. Patent No. 10,548,987 issued on February 02, 2020, and one US and one PCT patent application.

Safeguards

KEI always wants the NIH to include safeguards to protect the public’s interest in the licensed technology, and particularly when there is little known about a company, or if it appears likely that the company is merely speculating on the assets.

Some of our comments are designed to protect the public from the actions of whatever company subsequently acquires the rights to the inventions, when and if Connectyx executes an exit strategy.

US Manufacturing

KEI has asked the NIH if it has, or is intending to negotiate a waiver for US manufacturing. Dr. Yang has not responded.

The 35 U.S.C. § 209 analysis

No exclusive license should be granted until the NIH conducts an economic analysis to determine if exclusivity can be limited to less than the life of the patent.

⁶ <https://sunmedadvisors.com/our-team#alexander>

Any exclusive license should limit the number of years of exclusivity to that which is “reasonably necessary to provide the incentive for bringing the invention to practical application” and this requires an evaluation of the risks and costs of trials and other R&D necessary to advance a product to regulatory approval, as well as of the potential market for a product upon such approval.

We ask that the NIH provide a mechanism to shorten the term of exclusivity when sales targets are met, such as by reducing exclusivity for one year for every half billion dollars in sales after the first billion dollars of sales.

Price discrimination

Any medical technology using the patented invention should be available in the United States at a price that does not exceed the median price in the seven largest economies by GDP that have at least 50 percent of the GNI per capita as the United States, using the World Bank Atlas method. This is a modest safeguard.

Low and middle income countries

The exclusive licenses should not extend to countries with a per capita income less than 30 percent of the United States, in order to ensure that the patents do not lead to restricted and unequal access in countries with significantly lower incomes.

Global registration and affordability

Even if the rights in the patent do not apply to low and middle income countries (we have yet to determine the actual geographic scope of the patent rights), the license should require the licensee to disclose the steps that each will take to enable the timely registration and availability of the medical technology at an affordable price in the United States and in every country with a demonstrated need, according to the Centers for Disease Control and Prevention (CDC) and/or the World Health Organization (WHO), 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.

Medicines Patent Pool

In the event that patent rights extend to foreign countries, the NIH should retain a right to grant the WHO, the Medicines Patent Pool or other governments the rights to use the patent rights to procure the medical technology from competitive suppliers, including technology transfer, in developing countries, upon a finding by HHS or the WHO that people in these markets do not have sufficient access to the medical technology.

Transparency of R&D outlays

The licensees 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 or service that uses the inventions, including reporting separately and individually the outlays on each clinical trial. We 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.

Acknowledgement of federal funding - publication and publicity

The licensee should be required to clearly state, when issuing statements, press releases, and other documents describing the development of any product that includes the licensed inventions, a statement that describes the role of the licensed inventions and federal funding of the research and development.

Additional transparency issues

The license should have provisions that give effect to the transparency norms set out in WHA72.8 “Improving the transparency of markets for medicines, vaccines, and other health products”, a resolution enthusiastically supported by HHS last year.

Please notify us if a license is actually granted, so we can request a copy under the FOIA.

Sincerely,

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

Manon Ress
UACT
manon.ress@cancerunion.org