



This document is scheduled to be published in the Federal Register on 10/05/2015 and available online at <http://federalregister.gov/a/2015-25197>, and on FDsys.gov

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Invention; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S.

Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 209 and 37 CFR part 404 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Licensing information and copies of the U.S. patent applications listed below may be obtained by contacting Jasmine Yang, Ph.D., at the Technology Advancement Office, National Institute of Diabetes and Digestive and Kidney Diseases, Building 12A, Suite 3011 (MSC 5632), Bethesda MD 20892; Telephone: 301-451-7836; Email: jasmine.yang@nih.gov. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

SUPPLEMENTARY INFORMATION: Technology description follows.

Cannabinoid Receptor 1 (CB1) Inverse Agonists for the Treatment of Diabetes, Obesity and Their Complications

Description of Technology: Cannabinoid (CB1 and CB2) receptors recognize and mediate the effects of the active compound tetrahydrocannabinol found in marijuana. CB1 receptor activation plays a key role in appetitive behavior and metabolism.

Dr. Kunos and colleagues have designed a set of CB1 receptor inverse agonists that are effective at reducing obesity and its associated metabolic consequences while not causing the adverse neuropsychotropic side effects linked to earlier antagonists such as rimonabant. The CB1 receptor compounds were developed with the goals of 1) limiting their brain penetrance without losing their metabolic efficacy due to CB1 inverse agonism, and 2) generating compounds whose primary metabolite directly targets enzymes involved in inflammatory and fibrotic processes associated with metabolic disorders. The patent application of this technology are to the composition of matter and methods of use to the cannabinoid receptor (CB1) blocking compounds for the treatment of obesity, diabetes, fatty liver disease and a variety of obesity-related metabolic syndromes. The technology has the potential to be the next generation of safer CB1 receptor therapeutics for treating obesity.

Potential Commercial Applications:

- Treatment for obesity
- Treatment for metabolic syndrome
- Treatment of diabetes
- Treatment of fibrosis
- Treatment of Fatty Liver Disease such as Nonalcoholic steatohepatitis (NASH)

Competitive Advantages:

- Inhibits metabolic activity without causing psychiatric side effects
- Offers improved anti-inflammatory and anti-fibrotic efficacy

Development Stage:

- In vitro data available
- In vivo data available (animal)

Inventors: George Kunos (NIAAA), Malliga Iyer (NIAAA), Resat Cinar (NIAAA), Kenner Rice (NIDA)

Intellectual Property:

- HHS Reference No. E-282-2012/0-US-01 - US Provisional Patent Application No. 61/725,949 filed November 13, 2012
- HHS Reference No. E-282-2012/0-PCT-02 - PCT Application No. PCT/US2013/069686 filed November 12, 2013
- HHS Reference No. E-282-2012/0-US-03 - US Patent Application No. 14/442,383 filed May 12, 2015
- HHS Reference No. E-282-2012/0-CA-04 - Canadian Patent Application No. 2889697 filed April 27, 2015
- HHS Reference No. E-282-2012/0-EP-05 - European Patent Application No. 13802153.0 filed June 01, 2015
- HHS Reference No. E-282-2012/0-IN-06 - Indian Patent Application No. 3733/DELNP/2015 filed May 01, 2015
- HHS Reference No. E-282-2012/0-JP-07 - Japanese Patent Application No. 2015-542015 filed May 11, 2015

- HHS Reference No. E-282-2012/0-CN-08 - Chinese Patent Application No. 201380069389.9 filed July 3, 2015

- HHS Reference No. E-282-2012/1-US-01 - US Provisional Application No. 62/171, 179 filed June 04, 2015

Licensing Contact: Jasmine Yang, Ph.D.; 301-451-7836; jasmine.yang@nih.gov

Collaborative Research Opportunity: The National Institute on Alcohol Abuse and Alcoholism, Laboratory of Physiologic Studies, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize peripherally restricted CB1 receptor blockers with improved efficacy. For collaboration opportunities, please contact George Kunos, M.D., Ph.D. at George.Kunos@nih.gov or 301-443-2069.

Dated: September 29, 2015.

Richard U. Rodriguez,
*Acting Director,
Office of Technology Transfer,
National Institutes of Health.*

BILLING CODE 4140-01-P

[FR Doc. 2015-25197 Filed: 10/2/2015 08:45 am; Publication Date: 10/5/2015]