



DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive Patent License: Treatment and Prevention of Neuropathic Pain With P2Y14 Antagonists

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive, sublicensable patent license to Saint Louis University, (“SLU”), a non-profit university located in Missouri, in its rights to the inventions and patents listed in the Supplementary Information section of this notice.

DATES: Only written comments and/or applications for a license which are received by the NIDDK Technology Advancement Office [INSERT DATE 15 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER] will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, and comments relating to the contemplated exclusive patent license should be directed to: Betty B.

Tong, Ph.D., Senior Licensing and Patenting Manager, NIDDK Technology Advancement Office, Telephone: 301-451-7836; E-mail: tongb@mail.nih.gov.

SUPPLEMENTARY INFORMATION: The following and all continuing U.S. and foreign patents/patent applications thereof are the intellectual properties to be licensed under the prospective agreement to SLU:

1. U.S. Provisional Patent Application No. 62/877,385, filed July 23, 2019, entitled “Treatment And Prevention Of Neuropathic Pain With P2Y14 Antagonists” (HHS Ref. No. E-144-2019-0-US-01)
2. U.S. Provisional Patent Application No. 63/013,792, filed April 22, 2020, entitled

“Treatment And Prevention Of Neuropathic Pain With P2Y14 Antagonists” (HHS Ref. No. E-144-2019-1-US-01)

3. U.S. Patent Application 16/936,951, filed July 23, 2020, entitled “Treatment And Prevention Of Neuropathic Pain With P2Y14 Antagonists” [HHS Ref. No. E-144-2019-2-US-01].

The patent rights in these inventions have been assigned to the Government of the United States of America, and Saint Louis University. The prospective patent license will be for the purpose of consolidating the patent rights to SLU, co-owner of said rights, for commercial development and marketing. Consolidation of these co-owned rights is intended to expedite development of the invention, consistent with the goals of the Bayh-Dole Act codified as 35 USC §200-212. The prospective patent license will be worldwide, exclusive, and may be limited to those fields of use commensurate in scope with the patent rights. It will be sublicensable, and any sublicenses granted by SLU will be subject to the provisions of 37 CFR Part 401 and 404.

The invention pertains to methods for treating and preventing neuropathic pain by using selective antagonists for the P2Y14 receptor, a purinergic G protein-coupled receptor that is activated by extracellular UDP-glucose and related nucleotides. The technology provides a method of treating neuropathic pain by administering a P2Y14 receptor antagonist comprising a naphthalene or phenyl-triazolyl scaffold, potentially increase efficacy of treatments for neuropathic pain, and minimize risk of addiction.

This notice is made pursuant to 35 U.S.C. §209 and 37 CFR Part 404. The prospective exclusive patent license will include terms for the sharing of royalty income with NIDDK from commercial sublicenses of the patent rights and may be granted unless within fifteen (15) days from the date of this published notice the NIDDK receives written

evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. §209 and 37 CFR Part 404.

Complete applications for a license that are timely filed in response to this notice will be treated as objections to the grant of the contemplated exclusive patent license.

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available. License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information from these license applications will be made only as required and upon a request under the *Freedom of Information Act*, 5 U.S.C §552.

Dated: November 12, 2020.

Charles D. Niebylski,

Director,

Technology Advancement Office,

National Institute of Diabetes and Digestive and Kidney Diseases.

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