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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Use of Quaking-Induced Conversion (QUIC) for Detection of Prions

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR 404, that the National Institutes of Health (NIH), Department of Health and Human Services, is contemplating the grant of an exclusive license to practice the inventions embodied in US provisional Application 60/961,364 filed July 20, 2007 [E-109-2007/0-US-01], PCT/US2008/070656, filed July 21, 2008; [E-109-2007/1-PCT-01], EPC application No 08796382.3 filed July 21, 2008 [E-109-2007/1-EP-03], US Application No. 12/177,012, filed July 21, 2008 and issued as US patent 8,216,788 on July 10, 2012 [E-109-2007/1-US-02], and US Application No. 13/489,321, filed June 5, 2012 [E-109-2007/1-US-04]; Each entitled “*Detection of Infectious Prion Protein by Seeded Conversion of Recombinant Prion Protein*” By Byron Caughey et al. to Prionics AG having a place of business at Wagistrasse 27a CH-8952 Schlieren-Zurich, Switzerland. The patent rights in this invention have been assigned to the United States of America.

DATES: Only written comments and/or application for a license that are received by the NIH Office of Technology Transfer on or before [INSERT DATE 30 DAYS FROM DATE OF PUBLICATION OF NOTICE IN THE FEDERAL REGISTER] will be considered.

ADDRESSES: Requests for a copy of the patent application, inquiries, comments and other materials relating to the contemplated license should be directed to: Tedd Fenn, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Email: Tedd.Fenn@mail.nih.gov; Telephone: 301-435-5031; Facsimile: 301-402-0220.

SUPPLEMENTARY INFORMATION:

The prospective worldwide exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404. The prospective exclusive license may be granted unless, within thirty (30) days from the date of this published Notice, NIH 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 404.

The invention relates to methods and compositions for the detection of infectious proteins or prions and diagnosis of prion related diseases. Prion diseases are neurodegenerative diseases of great public concern because humans may be infected from hooved animals used as food, food products such as milk, or blood products. Currently available tests for disease-causing prions are either incapable of detecting low concentrations of prions and must be used post-mortem or are incapable of detecting low concentrations of prions economically or accurately. This technology enables rapid and economical detection of sub-lethal concentrations of prions by using recombinant, normal, prion protein (rPrP-sen) as a marker or indicator of infectious prions in a sample. Specifically, prions (contained in a sample) seed the polymerization of rPrP-sen, and polymerized rPrP-sen is detected as an amplified indicator of prions in the sample. This assay differs from the protein-misfolding cyclic amplification assay (PMCA) because it enables the effective use of rPrP-sen and does not require multiple amplification cycles unless a higher degree of sensitivity is required. It is anticipated that this technology can be combined with

additional prion-detection technologies to further improve the sensitivity of the assay. In its current embodiment, this assay has been used to detect prions in brain tissue or cerebral spinal fluid (CSF) from humans (variant CJD), sheep (scrapie), and hamsters (scrapie).

The proposed field of exclusivity may be limited to diagnostics requiring premarket approval by a US or a foreign regulatory agency.

Properly filed competing applications for a license filed in response to this notice will be treated as objections to the contemplated license. Comments and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: September 27, 2013.

Richard U. Rodriguez,
Director,
Division of Technology Development & Transfer,
Office of Technology Transfer,
National Institutes of Health.

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