[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Start-Up Exclusive License: 1. Catalytic Domains of Beta (1,4)-Galactosyltransferase I Having Altered Donor and Acceptor Specificities Domains, that promote in vitro protein folding and methods for their use; 2. Targeted Delivery System for Bioactive Agents

AGENCY: National Institutes of Health, HHS

ACTION: Notice

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR Part 404.7(a)(1)(i), that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of a start-up exclusive patent license to practice the inventions embodied in:

1. US Patent 7,482,133 and AU Patent 2004204463, HHS Ref. E-230-2002/2-US-03 and E-230-2002/2-AU-07; Title: Catalytic Domains of Beta (1,4)-Galactosyltransferase I Having Altered Donor And Acceptor Specificities Domains, That Promote In Vitro Protein Folding And Methods For Their Use; Inventors: Pradman K. Qasba and Boopathy Ramakrishnan (NCI).

2. US Patent Application 10/580,108, HHS Ref E-037-2004/0-US-03; Title: Efficient Tagging of The Modified Galactose to the Free N-acetylglucosamine Moieties Of Glycoproteins With Tyr289Leu-Gal-T1 Mutant; Inventors: Pradman K. Qasba and Boopathy Ramakrishnan (NCI).

to SynAffix B.V., which is located in The Netherlands. The exclusive license is one which qualifies under the Start-Up License Agreement program which is in place from October 1, 2011

through September 30, 2013. The patent rights in these inventions have been assigned to the United States of America.

DATE: Only written comments and/or application for a license that are received by the NIH Office of Technology Transfer on or before [Insert date 15 days from date of publication of notice in the FEDERAL REGISTER] will be considered.

ADDRESS: Requests for a copy of the patent application, inquiries, comments and other materials relating to the contemplated license should be directed to: John Stansberry, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Email: stansbej@mail.nih.gov; Telephone: 301-435-5236; Facsimile: 301-402-0220.

SUPPLEMENTARY INFORMATION:

The prospective worldwide start-up exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless, within fifteen (15) 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 404.7.

E-230-2002/0, /1, /2 — The present invention is based on the discovery that the enzymatic activity of β-(1,4)-galactosyltransferase can be altered such that the enzyme can make chemical bonds that are very difficult to make by other methods. The ability to synthesize these types of bonds has many applications in research and medicine and maybe helpful in developing pharmaceutical agents and improved vaccines that can be used to treat diseases.

E-037-2004/0 — This invention describes the synthesis by the genetically engineered enzyme, Y289L-Gal-T1, of a unique disaccharide linkage of a glycoprotein, a modified UDP-α-galactose, that contains a chemically reactive ketone group (-$CH_2C(=O)$-CH3) at the C2 position of galactose. In Y289L-Gal-Tl, the binding pocket for DOP-α-galactose has been enlarged to accommodate modifications at the C_2 position of galactose, like the ketone moiety above, that can serve as a neutral, yet versatile chemical handle. Glycoproteins containing a reactive ketone, such as monoclonal antibodies, could be then labeled with other agents useful for imaging or therapy.

The field of use may be limited to conjugated glycoproteins for pharmaceuticals made using Licensed Patent Rights in combination with Licensee's proprietary or exclusively in-licensed Intellectual Property rights. For the avoidance of doubt, this Licensed Field of Use excludes use of Licensed Patent Rights solely.

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.

April 29, 2013
Date

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

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