

Dated: July 28, 2006.

Steven Ferguson,

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

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BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Treatment of Cardiovascular Conditions With Nitrite Therapy

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. § 209(c)(1) and 37 CFR § (a)(1)(I), that the National Institutes of Health (NIH), Department of Health and Human Services (HHS), is contemplating the grant of an exclusive license to practice the invention embodied in: PCT patent application PCT/US2004/041256 filed December 9, 2004, entitled: "Methods for Suppressing an Immune Response or Treating a Proliferative Disorder" [HHS Reference Number: E-259-2003/0-PCT-02], to Sahajanand Medical Technologies Pvt. Ltd., registered as a private limited company in accordance with the Companies Act of India, having a principle place of business in Surat, India and U.S. headquarters in Gaithersburg, Maryland. The field of use may be limited to the use of 2-(4-piperazinyl)-8-phenyl-4H-1-benzopyran-4-one (LY303511), for the treatment and prevention of stenosis and restenosis and/or other proliferative disorders. The United States of America is an assignee of the patent rights in these inventions.

DATES: Only written comments and/or application for a license, which are received by the NIH Office of Technology Transfer on or before October 13, 2006 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: Susan Carson, D. Phil, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; E-mail: carsonsu@od.nih.gov; Telephone: (301) 435-5020; Facsimile: (301) 402-0220.

SUPPLEMENTARY INFORMATION: The search for specific kinase inhibitors is an active area of drug development as there is a continued need for effective

anti-proliferative therapeutics with acceptable toxicities. The core invention is a novel method of use of one of the 4H-1-benzopyran-4-one derivatives (LY303511) which has been shown to target mTOR and casein kinase 2 (CK2) without affecting P13K activity (JPET, May 26, 2005, doi: 10.1124/jpet.105.083550). Proof of concept data is available in an in vivo human xenograft PC-3 prostate tumor model, without observed toxicity. In vitro data suggests that 2-(4-piperazinyl)-8-phenyl-4H-1 benzopyran-4-one and derivatives may be effective in treating inflammatory, autoimmune and other proliferative disorders including restenosis and a variety of cancers. Method of use claims are directed to derivatives of 2-(4-piperazinyl)-substituted 4H-1-benzopyran-4-one compounds as anti-proliferative, immunosuppressive, anti-inflammatory, anti-restenosis and anti-neoplastic agents.

The prospective 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 60 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.

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: July 24, 2006

Steven M. Ferguson,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Privacy Act of 1974; Proposed Altered System of Records

AGENCY: National Institutes of Health (NIH), Department of Health and Human Services (DHHS).

ACTION: Notification of Proposed Altered System of Records.

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, as amended (Privacy Act), the National Institutes of Health (NIH) hereby publishes a notice of a proposal to alter System of Records, No. 09-25-0168, "Invention, Patent, and Licensing Documents Submitted to the Public Health Service by its Employees, Grantees, Fellowship Recipients, and Contractors, HHS/NIH/OD." NIH proposes a new legal authority for the maintenance of the System to read: 15 U.S.C. 3710, 3710a, 3710c & 3710d and 35 U.S.C. 200 *et seq.* provide authority to maintain the records; 37 CFR part 401 "Rights to Inventions Made by Nonprofit Organizations and Small Business Firms under Government Grants, Contracts, and Cooperative Agreements;" 37 CFR part 404 "Licensing of Government Owned Inventions;" and 45 CFR part 7 "Employee Inventions." NIH is also proposing new routine uses for this System.

These records will be maintained by the Office of Technology Transfer (OTT), OIR/OD; Office of Financial Management (OFM), OD; Office of Reports and Analysis (ORA), OER/OD; Health and Human Services Technology Development Coordinators and HHS Contract Attorneys who retain files supplemental to the records maintained by the Office of Technology Transfer; and the Extramural Inventions and Technology Resources Branch, OPERA/OER/OD.

DATES: The NIH invites interested parties to submit comments on or before September 13, 2006. The NIH will send a Report of the Proposed Altered System to the Congress and to the Office of Management and Budget (OMB). The proposed altered System of Records will be effective 40 days from the date submitted to the OMB, unless NIH receives comments that would result in a contrary determination.

ADDRESSES: You may submit comments, identified by the Privacy Act System of Records Number 09-25-0168, by any of the following methods:

- *Federal eRulemaking Portal:* <http://regulations.gov>. Follow the instructions for submitting comments.

- *E-mail:* [nihprivacyactofficer@mail.nih.gov](mailto:.nihprivacyactofficer@mail.nih.gov) and include PA SOR number 09-25-0168 in the subject line of the message.

- *Phone:* (301) 496-2832 (not a toll-free number).

- *Fax:* (301) 402-0169.

- *Mail:* NIH Privacy Act Officer, Office of Management Assessment, National Institutes of Health, 6011 Executive Boulevard, Suite 601, MSC 7669, Rockville, Maryland 20892.