DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health
Prospective Grant of Exclusive License: Treatment of Proliferative Disorders Using an Unexpected mTOR Kinase Inhibitor

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.

This notice replaces a notice published in 71 FR 46496, August 14, 2006, to correct the heading and objection to the contemplated license.

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.

ADDITION: Requests for a copy of the patent applications, 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; telephone: (301) 435–4521; facsimile: (301) 402–0220; e-mail: carsonsu@od.nih.gov.

SUPPLEMENTARY INFORMATION: The subject PCT application is related to the field of vascular disease and biomarkers FOS and DUSP1 as expressed in peripheral blood or secreted into serum.

The prospective co-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 co-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.


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

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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 PI3K 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, by the date referenced above, 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.


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DEPARTMENT OF HOMELAND SECURITY

United States Secret Service

Submission For Review; Extension Of Currently Approved Information Collection Requests


ACTION: 30-day Notice and request for comments.

SUMMARY: The Department of Homeland Security (DHS) has submitted the following information collection requests (ICR) to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995: 1620–0002. The information collections were previously published in the Federal Register on June 15, 2006, at Vol. 71, No. 115, pages 34635 and 34636, allowing for OMB review and a 60-day public comment period. Comments received by DHS are being reviewed as applicable. This notice allows for an additional 30 days for public comments.

DATES: Comments are encouraged and will be accepted until September 22, 2006. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the items contained in this notice should be directed to the Office of Management and Budget, Attn: Desk Officer for Homeland Security, Office of Management and Budget Room 10235, Washington, DC 20503; telephone 202–395–7316.

The Office of Management and Budget is particularly interested in comments which:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form(s) and instructions should be directed to: United States Secret Service, Security Clearance Division, Attn: ATC/SAIC Lawrence Tucker, Clearance and Access Branch, 950 H Street, NW., Washington, DC 20373–5824. Telephone number: (202) 406–5979.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires each Federal agency to provide interested Federal agencies and the public an early opportunity to comment on information collection requests. The notice for this proposed information collection contains the following:

(1) The name of the component of the U.S. Department of Homeland Security;

(2) Type of review requested, e.g., new, revision, extension, existing or reinstatement;

(3) OMB Control Number, if applicable;

(4) Title;

(5) Summary of the collection;

(6) Description of the need for, and proposed use of, the information;

(7) Respondents and frequency of collection; and

(8) Reporting and/or Recordkeeping burden. The Department of Homeland Security invites public comment.

The Department of Homeland Security is especially interested in public comment addressing the following issues:

(1) Is this collection necessary to the proper performance of the Department, including whether the information will have practical utility;

(2) is the estimate of burden for this information collection accurate;

(3) how might the Department enhance the quality, utility, and clarity of the information to be collected; and

(4) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. All comments will become a matter of public record. In this document the U.S. Secretary Service is soliciting comments concerning the following information collection:

Title: Contractor Personnel Access Application.

OMB No.: 1620–0002.

Form Number: SSF 3237.

Abstract: Respondents are all Secret Service contractor personnel requiring access to Secret Service controlled facilities in performance of their contractual duties. These contractors, if approved for access, will require escorted, unescorted, and staff-like access to Secret Service controlled facilities. Responses to questions on the SSF 3237 yield information necessary for the adjudication of eligibility for these facilities.


Frequency: On occasion.

Type of Review: Extension.

Affected Public: Individuals.

Estimated Number of Respondents: 5,000 respondents.