Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: August 7, 2006.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06–6877 Filed 8–11–06; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Statement of Organization, Functions, and Delegations of Authority

Part N, National Institutes of Health, of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (HHS) (40 FR 22859, May 27, 1975, as amended most recently at 70 FR 61146, October 20, 2005, and redesignated from Part HN as Part N at 60 FR 56606, November 9, 1995), is amended as set forth below to reflect the reorganization of the NIH Ethics Office.

Section N–B, Organization and Functions, is amended by replacing the current section *NAT (formerly HNAT)* with the following:

NIH Ethics Office (NAT, formerly HNAT). (1) Provides oversight and strategic direction of NIH activities relating to ethics policy, oversight, and operational activities; (2) develops and administers the NIH policies and procedures for implementing the Government-wide conflict of interest statutes and regulations, the HHS supplemental conflict of interest regulations, and HHS policies; (3) implements a program for trans-NIH ethics oversight that includes information technology (IT) support systems, periodic reviews, audits, delegations of authority, training, and records management; and (4) determines real or potential conflicts of interest and assesses ethical considerations in scientific reporting, clinical trials, and scientific conferences and workshops.

Division of IC Operations and Liaison (NAT2, formerly HNAT2). (1) Provides centralized operational services to ICs in the review and processing of: (a) Individual ethics actions and (b) ethics actions having IC-wide impact such as preapproval of awards, and blanket approval of widely attended gatherings (WAGs); (2) provides advisory services in the management of IC ethics reviews; and (3) provides ethics services for the Office of the Director, NIH.

Division of Policy and Management Review (NAT3, formerly HNAT3). (1) Provides technical review of NIH and IC Ethics Programs and conducts risk assessment; (2) develops NIH-wide policies and procedures to ensure a rigorous NIH Ethics Program; (3) manages ethics delegations of authority; (4) develops and manages content for the NIH Ethics Web site; and (5) provides NIH-wide ethics training to staff.

Delegations of Authority: All delegations and redelegations of authority to officers and employees of NIH that were in effect immediately prior to the effective date of this amendment and are consistent with this amendment shall continue in effect, pending further redelegation.

Dated: August 4, 2006.

Elias A. Zerhouni,

Director, National Institutes of Health.

[FR Doc. E6–13305 Filed 8–11–06; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Recombinant Antibodies and Immunoconjugates Targeted to CD–22 Bearing Cells and Tumors

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 Part 404.7(a)(1)(i), that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to practice the inventions embodied in U.S. Patent Application No. 09/381,497, filed September 20, 1999, entitled ''Recombinant Antibodies and Immunoconjugates Targeted to CD–22 Bearing Cells and Tumors'' [E–059–1997/0–US–07]; European Patent Application No. 98912977.0, filed October 13, 1999, entitled ''Recombinant Antibodies and Immunoconjugates Targeted to CD–22 Bearing Cells and Tumors'' [E–059–1997/0–EP–05]; Japanese Patent Application No. 10–540812, filed March 19, 1998, entitled ''Recombinant Antibodies and Immunoconjugates Targeted to CD–22 Bearing Cells and Tumors'' [E–059–1997/0–JP–06]; Australian Patent No. 740904, issued on February 28, 2002, entitled ''Recombinant Antibodies and Immunoconjugates Targeted to CD–22 Bearing Cells and Tumors'' [E–059–1997/0–AU–03]; and Canadian Patent Application No. 2284665, filed March 19, 1998, entitled ''Recombinant Antibodies and Immunoconjugates Targeted to CD–22 Bearing Cells and Tumors'' [E–059–1997/0–CA–04]; to Cambridge Antibody Technology, Ltd., which has offices in Cambridge, United Kingdom. The patent rights in these inventions have been assigned to the United States of America.

The prospective exclusive license territory may be worldwide, and the field of use may be limited to the use of the BL22 and HA22 and variants thereof as claimed in the licensed patent rights for the treatment of hematologic malignancies.

DATES: Only written comments and/or applications 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 copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive license should be directed to: Jesse S. Kindra, J.D., M.S., Technology Licensing Specialist, Office of Technology Transfer, National Institutes of health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone (301) 435–5559; Facsimile: (301) 402–0220; E-mail: *kindraj@mail.nih.gov.*

SUPPLEMENTARY INFORMATION: This technology is a family of two (2) immunoconjugates, each consisting of an anti-CD–22 antibody coupled to a killing moiety, specifically pseudomonas exotoxin (PE38). The immunotoxins are both targeted towards CD–22, and may be useful as therapeutic agents for the treatment of leukemias, lymphomas and autoimmune diseases. Further, BL22 has shown success in early clinical trials.

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 sixty (60) days from the date of this published notice, the 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.

Applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive license. Comments and objections submitted 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 28, 2006.

Steven Ferguson,

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

[FR Doc. 06–6871 Filed 8–11–06; 8:45 am]

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 restenois 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 zenograft PC-3 prostate tumor model, without observed toxicity. In vitro data suggests that (2-(4-piperazinyl)-8-pheynl-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.

[FR Doc. 06–6880 Filed 8–11–06; 8:45am]

BILLING CODE 4140–01–M

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* 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.