

The authorizing statute is Section 330 of the Public Health Service Act, as amended.

HRSA collects data in the UDS which is used to ensure compliance with

legislative mandates and to report to Congress and policy makers on program accomplishments. To meet these objectives, BPHC requires a core set of data collected annually that is

appropriate for monitoring and evaluating performance and reporting on annual trends.

Estimates of annualized reporting burden are as follows:

Type of report	Number of respondents	Responses per respondent	Total responses	Hours per responses	Total burden hours
Universal Report	1,002	1	1002	27	27,054
Grant Report	234	1	234	18	4,212
Total	1,002		1,326		31,266

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 10-33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: February 2, 2007.

Caroline Lewis,

Acting Associate Administrator for Administration and Financial Management.

[FR Doc. E7-2553 Filed 2-13-07; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Field of Use: Development of a Live Microbicide for Preventing Sexual Transmission of HIV

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 404.7(a)(1)(i), that the National Institutes of Health (NIH), Department of Health and Human Services, is contemplating the grant of an exclusive license to practice the invention embodied in:

(1) U.S. Patent No. 5,821,081, filed April 26, 1996, issued Oct. 13, 1998, entitled "Nucleic Acids Encoding Antiviral Proteins and Peptides, Vectors and Host Cells Comprising Same, and Methods of Producing the Antiviral Proteins and Peptides" (E-117-1995/1-US-01) (Inventors: Michael R. Boyd, Kirk R. Gustafson, Robert H. Shoemaker, and James B. McMahon) (NCI);

(2) U.S. Patent No. 5,843,882, filed April 27, 1995, issued Dec. 01, 1998, entitled "Antiviral Proteins and Peptides, DNA, DNA-coding Sequences Therefore, and Uses thereof" (E-117-1995/0-US-01) (Inventors: Michael R. Boyd, Kirk R. Gustafson, Robert H. Shoemaker, and James B. McMahon) (NCI);

(3) U.S. Patent No. 5,998,587, filed Nov. 13, 1997, issued Dec. 7, 1999, entitled "Anti-cyanovirin Antibody" (E-117-1995/1-US-02) (Inventors: Michael R. Boyd, Kirk R. Gustafson, Robert H. Shoemaker, and James B. McMahon) (NCI);

(4) U.S. Patent No. 6,015,876, filed Oct. 27, 1999, issued Jan. 18, 2000, entitled "Method of Using Cyanovirins" (E-117-1995/0-US-02) (Inventor: Michael R. Boyd, Kirk R. Gustafson, Robert H. Shoemaker, and James B. McMahon) (NCI);

(5) U.S. Patent No. 6,780,847, filed March 22, 2001, issued August 24, 2004, entitled "Glycosylation-Resistant Cyanovirins and Related Conjugates, Compositions, Nucleic Acids, Vectors, Host Cells, Methods of Production and Methods of Using Nonglycosylated Cyanovirins" (E-074-1999/3-US-01) (Inventors: Michael R. Boyd, Barry O'Keefe, Toshiyuki Mori (NCI) and Angela Gronenborn (NIDDK));

(6) U.S. Patent No. 7,048,935, filed July 1, 2002, issued May 23, 2006, entitled "Cyanovirin Conjugates and Matrix-Anchored Cyanovirin and Related Compositions and Methods of Use" (E-074-1999/1-US-03) (Inventor: Michael R. Boyd (NCI);

(7) U.S. Patent No. 7,105,169, filed September 12, 2001, issued September 12, 2006, entitled "Cyanovirins Conjugates and Matrix-Anchored Cyanovirins and Methods of Use" (E-074-1999/1-US-02) (Inventor: Michael R. Boyd (NCI);

(8) U.S. Patent No. 6,743,577, filed October 27, 1999, issued June 1, 2004, entitled "Methods of Using Cyanovirins to Inhibit Viral Infection" (E-074-1999/0-US-03) (Inventor: Michael R. Boyd (NCI);

(9) U.S. Patent No. 6,420,336, filed October 27, 1999, issued July 16, 2002, entitled "Methods Of Using Cyanovirins Topically To Inhibit Viral Infection" (E-074-1999/3-US-01) (Inventor: Michael R. Boyd (NCI) to Osel, Inc. (Hereafter Osel), having a place of business in Santa Clara of California. The patent rights in these

inventions have been assigned to the United States of America.

DATES: Only written comments and/or application for a license, which are received by the NIH Office of Technology Transfer on or before April 16, 2007 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: Sally Hu, Ph.D., M.B.A., Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; E-mail: huss@od.nih.gov; Telephone: (301) 435-5606; Facsimile: (301) 402-0220.

SUPPLEMENTARY INFORMATION: 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.

Cyanovirin-N (CV-N) is a novel, naturally occurring anti-HIV protein that was originally isolated from *Nastoc ellipsosporum*, a blue-green algae. Cyanovirin is a protein with potent neutralizing activity against HIV1 and 2 by blocking the fusion reaction between HIV and CD4 target cells. Cyanovirin is in the pre-IND development phase with several animal toxicology and irritation studies completed; initial chemical purification processes developed; and no human data to date. Dr. Boyd and his colleagues have demonstrated that a simple aqueous gel formulation of CV-N completely protected macaques against intravaginally or intarectally transmitted SHIV 89-9P (a chimeric simian/human immunodeficiency virus that causes "AIDS" in simians). Also importantly, there was no indication of any toxicity or other adverse effects of the CV-N to the macaques in these

preclinical microbicide evaluation studies. CV-N has the potential to become a microbicide useful in preventing sexual transmission of HIV. An effective anti-HIV microbicide could slow down the spread of the virus in the population, especially in the developing world, before an effective vaccine is available.

The field of use may be limited to the topical use of commensal bacteria that express cyanovirin-N.

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: February 2, 2007.

Steven M. Ferguson,

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

[FR Doc. E7-2486 Filed 2-13-07; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

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

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; *telephone:* 301/496-7057; *fax:* 301/402-0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Integrase Inhibitors for the Treatment of Retroviral Infection Including Human Immunodeficiency Virus-1

Description of Technology: Available for licensing and commercial development are stilbenedisulfonic acid derivatives for treatment of human immunodeficiency virus-1 (HIV-1) and other retroviral infections. Current HIV-1 therapeutic treatments target the viral protease and reverse transcriptase enzymes, which are essential for retroviral infection. However, these drugs often have limitations due to drug resistant variants, which render drugs ineffective. Additionally, such drugs are often toxic when administered in combination therapies. Thus, efficacious inhibitors of retroviral infection that are devoid of toxicity are presently needed.

The subject invention describes stilbenedisulfonic acid derivatives, which target the integrase enzyme of retroviruses. Similar to protease and reverse transcriptase activity, integrase function is essential for retroviral infection. Integrase catalyzes integration of reverse transcribed viral DNA into a host cell's genome. For this reason, integrase is considered a rational therapeutic target for HIV-1 infection. Further, integrase is a favorable target because the enzyme has no human cellular counterpart, which could interact with a potential integrase inhibitor and cause harmful side effects. Recent clinical data with an integrase inhibitor from Merck shows impressive clinical activity. The Merck compound is different from the current invention and is projected for FDA approval mid 2007. Thus, the subject invention is valuable for safe and effective treatment of HIV-1 and other retroviral infections.

Application: Treatment of HIV infection.

Development Status: The technology is ready for use in drug discovery and development.

Inventors: Yves Pommier (NCI), Elena Semenova (NCI), Christophe Marchand (NCI).

Patent Status: U.S. Provisional Application No. 60/849,718 filed 04 Oct 2006 (HHS Reference No. E-264-2006/0-US-01).

Licensing Status: Available for exclusive or non-exclusive licensing.

Licensing Contact: Sally Hu, Ph.D.; 301/435-5606; HuS@mail.nih.gov.

Broadly Cross-Reactive Neutralizing Antibodies Against Human Immunodeficiency Virus Selected by ENV-CD4-CO-Receptor Complexes

Description of Technology: This invention provides a novel anti-HIV human monoclonal antibody named X5.

This antibody demonstrates promise over conventional anti-HIV antibodies because the X5 antibody exhibits a unique binding activity compared to its counterparts. It has been established that the initial stage of HIV-1 entry into cells is mediated by a complex between the viral envelope glycoprotein (Env) such as gp120-gp41, a receptor CD4 and a co-receptor CCR5. The X5 antibody binds to an epitope on gp120 that is induced by interaction between gp120 and the receptor CD4 and enhanced by the co-receptor CCR5. The X5 antibody also shows strong activity at very low levels (in the range from 0.0001-0.1 Mg/ml concentration is dependent on the isolate). Because it is a human antibody, it can be administered directly into patients so that it is an ideal candidate for clinical trials. It also can be easily produced because it was obtained by screening of phage display libraries and its sequence is known. Finally, since it has neutralized all virus envelope glycoproteins, including those from primary isolates of different clades, the epitope is highly conserved and resistance is unlikely to develop. Therefore, this antibody and/or its derivatives including fusion proteins with CD4 are good candidates for clinical development.

Additional information on the current research in Dr. Dimitrov's laboratory may be found at <http://www-lecb.ncicrf.gov/dimitrov/dimitrov.html>.

Applications: Antibody for HIV research, diagnostics and therapeutic development.

Development Status: Preclinical data is available at this time.

Inventors: Dimitar Dimitrov (NCI), Xiadong Xiao (NCI), Yuuei Shu (NCI), Sanjay Phogat (NIAID), *et al.*

Patent Status: Patent Cooperation Treaty Serial No. PCT/US02/33165 filed 16 Oct 2002; National Stage Filing in United States, India, Canada, Australia, Europe (HHS Reference No. E-130-2001/0).

Availability: Available for licensing and commercial development, excluding the field of use of the development of the PEGylated X5, PEGylated X5 derivatives, mutants of PEGylated X5 or a derivative.

Licensing Contact: Sally Hu, Ph.D.; 301/435-5606; HuS@mail.nih.gov.

Collaborative Research Opportunity: The NCI Center for Cancer Research Nanobiology Program (CCRNBP) is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize antibodies for HIV research, diagnostics and therapeutic development. Please contact John D. Hewes, Ph.D. at (301