

TABLE A.—ANNUALIZED BURDEN ESTIMATES FOR CHIS 2007 DATA COLLECTION

Data collection	Estimated number of respondents	Frequency of response	Average time per response	Annual hour burden
(1) Pilot Test Adult Demographics	150	1	.07	11
CCM	150	1	.03	5
(2) Full Survey Adult Demographics	55,000	1	.07	3,850
CCM	55,000	1	.03	1,650
Totals	55,150	1	.1	5,516

There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proposed performance of the functions of the agency, including whether the information shall have practical utility; (2) 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) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Nancy Breen, Ph.D., Project Officer, National Cancer Institute, EPN 4005, 6130 Executive Boulevard MSC 7344, Bethesda, Maryland 20852-7344, or call non-toll free number 301-496-8500 or FAX your request, including your address to breenn@mail.nih.gov.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of this publication.

Dated: August 24, 2006.

Rachelle Ragland-Greene,

NCI Project Clearance Liaison, National Institutes of Health.

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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.

Novel Acylthiol Compositions and Methods of Making and Using Them

Description of Technology: This invention provides a novel family of acylthiols and uses thereof. More specifically, this invention provides effective inhibitors of HIV that selectively target its highly conserved nucleocapsid protein (NCp7) by interacting with metal chelating structures of a zinc finger-containing protein. Because of the mutationally intolerant nature of NCp7, drug resistance is much less likely to occur with compounds attacking this target. In addition, these drugs should inactivate all types and strains of HIV and could also inactivate other retroviruses, since most retroviruses share one or two

highly conserved zinc fingers that have the CCHC motif of the HIV Ncp7. Finally, this invention could be very useful for the large-scale practical synthesis of HIV inhibitors, because these compounds can be prepared by using inexpensive starting materials and facile reactions. Thus, it opens the possibility that an effective drug treatment for HIV could be made available to much larger populations. These thioesters may also be used as an active component in topical applications that serve as a barrier to HIV infection.

Inventors: John K. Inman (NIAID), Atul Goel (NCI), Ettore Appella (NCI), James A. Turpin (NIAID), Marco Schito (NCI).

Publications:

1. ML Schito, A Goel, Y Song, JK Inman, RJ Fattah, WG Rice, JA Turpin, A Sher, E Appella. In vitro antiviral activity of novel human immunodeficiency virus type 1 nucleocapsid p7 zinc finger inhibitors in a transgenic murine model. *AIDS Res Hum Retroviruses*. 2003 Feb;19(2):91-101.

2. P Srivastava, M Schito, RJ Fattah, T Hara, T Hartman, RW Buckheit Jr, JA Turpin, JK Inman, E Appella. Optimization of unique, uncharged thioesters as inhibitors of HIV replication. *Bioorg Med Chem*. 2004 Dec 15;12(24):6437-6450.

3. LM Jenkins, JC Byrd, T Hara, P Srivastava, SJ Mazu, SJ Stahl, JK Inman, E Appella, JG Omichinski, P Legault. Studies on the mechanism of inactivation of the HIV-1 nucleocapsid protein NCp7 with 2-mercaptobenzamide thioesters. *J Med Chem*. 2005 Apr 21;48(8):2847-2858.

4. V Basrur, Y Song, SJ Mazur, Y Higashimoto, JA Turpin, WG Rice, JK Inman, E Appella. Inactivation of HIV-1 nucleocapsid protein P7 by pyridinioalkanoyl thioesters. Characterization of reaction products and proposed mechanism of action. *J Biol Chem*. 2000 May 19;275(20):14890-14897.

5. JA Turpin, Y Song, JK Inman, M Huang, A Wallqvist, A Maynard, DG

Covell, WG Rice, E Appella. Synthesis and biological properties of novel pyridinioalkanoyl thioesters (PATE) as anti-HIV-1 agents that target the viral nucleocapsid protein zinc fingers. *J Med Chem.* 1999 Jan 14;42(1):67-86.

Patent Status: U.S. Patent Application No. 10/485,165 filed 28 Jan 2004, claiming priority to 03 Aug 2001 (HHS Reference No. E-329-2000/0-US-06).

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

Licensing Contact: Sally H. Hu, Ph.D., M.B.A.; 301/435-5605; hus@mail.nih.gov.

Novel Thioesters and Uses Thereof

Description of Technology: The human immunodeficiency virus (HIV) is the causative agent of acquired immunodeficiency syndrome (AIDS). Drug-resistance is a critical factor contributing to the gradual loss of clinical benefit to treatments for HIV infection. Accordingly, combination therapies have further evolved to address the mutating resistance of HIV. However, there has been great concern regarding the apparent growing resistance of HIV strains to current therapies.

The present invention provides for a novel family of thioesters and uses thereof. These thioesters are capable of inactivating viruses by a variety of mechanisms, particularly by complexing with metal ion-complexing zinc fingers. The invention further provides for methods for inactivating a virus, such as the human immunodeficiency virus (HIV), using these compounds, and thereby also inhibiting transmission of the virus.

Inventors: James A. Turpin (NCI), Yongsheng Song (NCI), John K. Inman (NIAID), Mingjun Huang (NCI), Anders Wallqvist (NCI), David G. Covell (NCI), William G. Rice (NCI), Ettore Appella (NCI), *et al.*

Patent Status: U.S. Patent No. 6,706,729 issued 16 Mar 2004 (HHS Reference No. E-136-1998/0-US-10); U.S. Patent Application No. 10/738,062 filed 16 Dec 2003 (HHS Reference No. E-136-1998/0-US-11).

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

Licensing Contact: Sally H. Hu, Ph.D., M.B.A.; 301/435-5605; hus@mail.nih.gov.

Dated: August 25, 2006.

Steven M. Ferguson,

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

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A Novel Small Protein Antibiotic

Description of Technology: Due to the increase in drug resistance among bacteria, continued progress in the development of new antibiotic treatments is needed. Available for licensing and commercial development is the small protein SrgT, its analogs and related peptides. SrgT is a 43 amino acid protein that effectively inhibits bacterial growth. This protein likely exerts its antibiotic action by inhibiting the metabolism of glucose in these microorganisms. The claimed invention includes methods for SrgT synthesis and suggested modifications for production of SrgT analogs and related peptides, which may remain effective against potential SrgT resistant bacteria. Thus, the current technology provides a novel approach to the treatment and prevention of bacterial infections.

Application: Novel therapeutics and prophylactics for bacterial infections.

Development Status: Preclinical data is available at this time.

Inventors: Carin K. Vanderpool and Susan Gottesman (NCI).

Selected Publication: CK Vanderpool, S Gottesman. Involvement of a novel transcriptional activator and small RNA in post-transcriptional regulation of the

glucose phosphoenolpyruvate phosphotransferase system. *Mol Microbiol.* 2004 Nov; 54(4):1076-1089.

Patent Status: U.S. Provisional Application No. 60/799,830 filed 11 May 2006 (HHS Reference No. E-166-2006/0-US-01).

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

Licensing Contact: Cristina Thalhammer-Reyero, Ph.D., M.B.A.; 301/435-4507; thalhamc@mail.nih.gov.

Methods and Compositions for the Production of Highly Effective Vaccines Against Cancers and Infectious Diseases

Description of Technology: Because cancers and infectious diseases remain prominent causes of death among adults and children worldwide, the availability of vaccines targeting these conditions is a global health priority. With the current vaccine development state-of-the-art, there are limitless combinations of enhancing molecules that can be used with antigen vaccines targeting these diseases. The technology offered for licensing and commercial development combines effective aspects of antigen-vaccines, including peptides and other forms of vaccination, with enhancing molecules, including co-stimulation of T cell immunity for efficient vaccine development.

The claimed invention includes a non-viral polynucleotide vector encoding immune enhancing molecules, such as the T cell co-stimulatory molecule B7.1 (CD80), which significantly enhance cellular immune responses when combined with antigen stimulation. Delivery of this co-stimulatory molecule as non-replicating DNA with any antigenic form, peptides in this case, overcomes the problems of combining enhancing molecules with the antigen in the same DNA vector, co-infecting or transfecting these molecules in the same antigen presenting or tumor cell, or manufacturing enhancing molecules in the same format as the antigens. Furthermore, the use of this chimeric vaccine with the enhancing molecule expressed as polynucleotide vector overcomes the low antigenicity and safety considerations of viral vectors, as well as the instability and conformational maintenance challenges associated with the use of full-length protein delivery. Furthermore, polynucleotide's constructs encoding enhancing molecules are inexpensive to produce and can potentially be used along with any form of antigen vaccine delivery system, including peptides, full-length proteins and naked DNA antigens.