

requirements, cost data, and coordination with Medicaid. Each quarterly report requests updates from programs on number of patients served, type of pharmaceuticals prescribed, and prices paid to provide medication. The first quarterly report of each ADAP

fiscal year (due in July of each year) also requests information that only changes annually (e.g., State funding, drug formulary, eligibility criteria for enrollment, and cost-saving strategies including coordinating with Medicaid).

The quarterly report represents the best method for HRSA to determine how ADAP grants are being expended and to provide answers to requests from Congress and other organizations.

The estimated annual burden is as follows:

Form	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
1st Quarterly Report .....	57	1	57	3	171
2nd, 3rd, & 4th Quarterly Reports .....	57	3	171	1.5	256.5
Total .....	57	.....	228	.....	427.5

Send comments to Susan G. Queen, PhD, 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: September 28, 2007.

**Alexandra Huttinger,**

*Acting Director, Division of Policy Review and Coordination.*

[FR Doc. E7-19599 Filed 10-3-07; 8:45 am]

**BILLING CODE 4165-15-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.

#### Hepatitis C Virus Cell Culture System

*Description of Technology:* Hepatitis C virus (HCV) infection causes chronic liver disease and is a major global health problem with an estimated 170 million people affected worldwide and 3-4 million new cases every year. Therapeutic advances will be greatly aided by the ability of researchers to successfully replicate and characterize the virus in vitro. The study of HCV replication has, however, been hindered by the lack of an efficient virus culture system. One approach, using cell culture adaptive mutations in the viral RNA has been found to significantly enhance HCV virus production, but it has been difficult to define which stage of the viral lifecycle is affected by a given adaptive mutation.

NIH researchers have now developed a single-cycle virus production system that allows the stage of the viral lifecycle affected by a specific adaptive mutation to be determined. They have isolated a unique subclone of Huh 7 Hepatoma cells, S29, that permits HCV replication and infectious virion release, but is resistant to infection by HCV. This permits the use of single cycle growth studies, and removes the confounding effects of virus re-infection allowing progress to be made on structure/function studies, or on studies of the effects of drugs on replication and virus assembly.

*Applications:* HCV drug discovery; HCV single-cycle virus studies; HCV structure/function studies.

*Market:* HCV research.

*Inventors:* Suzanne U. Emerson, Robert H. Purcell, Rodney Russell (NIAID).

*Patent Status:* HHS Reference No. E-324-2007/0—Research Tool. Patent protection is not being sought for this technology.

*Licensing Status:* Available for licensing.

*Licensing Contact:* Chekesha S. Clingman, Ph.D.; 301/435-5018; [clingmac@mail.nih.gov](mailto:clingmac@mail.nih.gov).

#### Use of CpG Oligodeoxynucleotides To Induce Epithelial Cell Growth

*Description of Invention:* Wound repair is the result of complex interactions and biologic processes. Three phases have been described in normal wound healing: acute inflammatory phase, extracellular matrix and collagen synthesis, and remodeling. The process involves the interaction of keratinocytes, fibroblasts and inflammatory cells at the wound site. The sequence of the healing process is initiated during an acute inflammatory phase with the deposition of provisional tissue. This is followed by re-epithelialization, collagen synthesis and deposition, fibroblast proliferation, and neovascularization, all of which ultimately define the remodeling phase. These events are influenced by growth factors and cytokines secreted by inflammatory cells or by the cells localized at the edges of the wound.

Tissue regeneration is believed to be controlled by specific peptide factors which regulate the migration and proliferation of cells involved in the repair process. Thus, it has been proposed that growth factors will be useful therapeutics in the treatment of wounds, burns and other skin disorders. However, there still remains a need for additional methods to accelerate wound healing and tissue repair.

This application claims methods of increasing epithelial cell growth. The methods include administering a therapeutically effective amount of a CpG oligodeoxynucleotide (ODN) to induce epithelial cell division. Also claimed are methods of inducing wound healing. The method includes treating the wound with a CpG oligonucleotide, thereby inducing wound healing. The wound can be any type of wound, including trauma or surgical wounds. The CpG ODN can be applied systemically or locally.

**Application:** Induction of wound healing through use of CpG oligodeoxynucleotides.

**Developmental Status:** CpG oligonucleotides have been synthesized and preclinical studies have been performed.

**Inventors:** Dennis Klinman and Takahashi Sato (NCI).

**Patent Status:** U.S. Provisional Application filed 06 Sep 2007 (HHS Reference No. E-242-2007/0-US-01).

**Licensing Status:** Available for exclusive or nonexclusive licensing.

**Licensing Contact:** Peter A. Soukas, J.D.; 301/435-4646; [soukasp@mail.nih.gov](mailto:soukasp@mail.nih.gov).

**Collaborative Research Opportunity:** The Laboratory of Experimental Immunology of the National Cancer Institute is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize methods of increasing epithelial cell growth. Please contact John D. Hewes, Ph.D. at 301-435-3121 or [hewesj@mail.nih.gov](mailto:hewesj@mail.nih.gov) for more information.

#### **Flexible, Polyvalent Antiviral Dendritic Conjugates for the Treatment of HIV/AIDS**

**Description of Technology:** This technology describes the design and synthesis of flexible, polyvalent, antiviral conjugates of less than 200 kDa for the treatment of HIV/AIDS. These conjugates are mimetic of D1D2-Ig $\alpha$ tp, a high-molecular-weight (1 MDa) CD4-immunoglobulin fusion construct with extreme HIV neutralizing potency. Cryo electron microscopy suggests that the extreme potency of D1D2-Ig $\alpha$ tp is due to polyvalent presentation of a gp120-binding ligand on a flexible scaffold. The current prototype for the technology is a conjugate comprising soluble, two-domain human CD4 covalently linked to a flexible poly(ethylene glycol)-PAMAM dendrimer scaffold. The construct is designed to retain a high degree of flexibility and polyvalence, and, at less than 200 kDa, is similar in size to successful antibody therapeutics currently on the market. Because it retains the key determinants of potency and the human CD4 moieties of D1D2-Ig $\alpha$ tp, this conjugate is expected to have the following unique set of HIV antiviral properties: (1) IC<sub>90</sub> infectivity neutralization values in the nanomolar range against HIV primary isolates; (2) lack of susceptibility to viable escape mutations, because the ligand is CD4, and because CD4-independence evolves concomitantly with constitutive exposure of neutralization-sensitive,

highly conserved coreceptor binding site epitopes; (3) indefinite control of HIV viral replication, without the need for combination therapy, arising from properties (1) and (2); (4) improved HIV viral replication control when used in combination with other Highly Active Antiretroviral Therapy (HAART); (5) improved prevention of seroconversion when used in combination with other HAART shortly following known exposure to HIV.

**Applications:** Novel therapeutics for the treatment and prevention of HIV infection.

**Development Status:** Synthesis and characterization in progress.

**Inventors:** Sriram Subramaniam and Adam Bennett (NCI).

**Publication:** AE Bennett *et al.* Cryo electron tomographic analysis of an HIV neutralizing protein and its complex with native viral gp 120. *J Biol Chem.*, in press; published online ahead of print June 28, 2007.

**Patent Status:** U.S. Provisional Application No. 60/932,464 filed 31 May 2007 (HHS Reference No. E-213-2007/0-US-01).

**Licensing Status:** Available for licensing.

**Licensing Contact:** Sally Hu, Ph.D.; 301/435-5606; [HuS@mail.nih.gov](mailto:HuS@mail.nih.gov).

**Collaborative Research Opportunity:** The Laboratory of Cell Biology of the National Cancer Institute is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize Flexible, Polyvalent Antiviral Dendritic Conjugates for the Treatment of HIV/AIDS. Please contact John D. Hewes, Ph.D. at 301-435-3121 or [hewesj@mail.nih.gov](mailto:hewesj@mail.nih.gov) for more information.

#### **Monoclonal Antibodies to Fusion-Active Conformations of GP41**

**Description of Technology:** This technology describes three novel monoclonal antibodies, 2F12, 9C5 and 11B8, which were derived against an HIV gp41 heptad-repeat entry inhibitor that mimics a structure of the HIV envelope protein fusion intermediate. These antibodies recognize the fusion-intermediate and six-helix conformations of gp41 and are useful tools for high-throughput screening assays (HTS) to identify novel HIV-1 inhibitors. Since the drugs identified in the assays using these monoclonal are expected to inhibit HIV infection in a different manner than current antiretroviral drugs, these antibodies may serve as valuable tools for screening for new drugs that may have activity against HIV strains that are

resistant to currently available antiretroviral drugs.

**Applications:** Research tool.

**Development Status:** *In vitro* data available.

**Inventors:** Carol D. Weiss and Russell A. Vassell (CBER/FDA).

**Related Publication:** S Jiang *et al.* A screening assay for antiviral compounds targeted to the HIV-1 gp41 core structure using a conformation-specific monoclonal antibody. *J Virol Methods*. 1999 Jun;80(1):85-96.

**Patent Status:** HHS Reference No. E-124-2007/0—Research Tool. Patent protection not being pursued for this technology.

**Licensing Status:** Available for non-exclusive licensing as biological material.

**Licensing Contact:** Sally Hu, Ph.D.; 301/435-5606; [HuS@mail.nih.gov](mailto:HuS@mail.nih.gov).

Dated: September 27, 2007.

**Steven M. Ferguson,**

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

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**BILLING CODE 4140-01-P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **National Institutes of Health**

#### **Office of Portfolio Analysis and Strategic Initiatives, Office of the Director, National Institutes of Health; Notice of Meeting**

Notice is hereby given of a planning meeting for the proposed Council of Councils, an external advisory panel to the NIH IC Directors and the Office of Portfolio Analysis and Strategic Initiatives (OPASI).

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

**Name of Committee:** Council of Councils Planning Group.

**Date:** November 8, 2007.

**Time:** 8:30 a.m. to 5:00 p.m.

**Agenda:** Among the topics proposed for discussion are: Role of the Council and timeline.

**Place:** National Institutes of Health, Building 31, Conference Room 6, 9000 Rockville Pike, Bethesda, MD 20892.

**Contact Person:** Robert D. Hammond, PhD, Consultant To OPASI, 301-977-9307, [bhammond@thehillgroup.com](mailto:bhammond@thehillgroup.com).

Any interested person may file written comments with the committee by forwarding