

[FR Doc. 04-1263 Filed 1-21-04; 8:45 am]  
BILLING CODE 4160-01-C

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Government-Owned Inventions; Availability for Licensing

**AGENCY:** National Institutes of Health, Public Health Service, DHHS.

**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.

#### Inhibitors of Formation of Protease Resistant Prion Protein

Bruce Chesebro, Byron Caughey, Joelle Chabry, Susette Priola (NIAID). U.S. Patent 6,211,149 issued on 03 Apr 2001 (DHHS Reference No. E-189-1998/0-US-02); U.S. Patent 6,355,610 issued on 12 Mar 2002 (DHHS Reference No. E-189-1998/0-US-03); U.S. Patent Application No. 10/096,080 filed 11 Mar 2002 (DHHS Reference No. E-189-1998/0-US-04).

*Licensing Contact:* Michael Ambrose; 301/594-6565; [ambrosem@mail.nih.gov](mailto:ambrosem@mail.nih.gov).

Protease-resistant prion proteins are actively associated with various transmissible spongiform encephalopathies (TSEs). These include Creutzfeldt-Jakob disease in humans and Bovine spongiform encephalopathy ("mad cow disease") in cattle.

The present invention discloses proprietary peptides and potential pharmaceutical compositions using such peptides that inhibit the formation of protease-resistant prion protein aggregates. These aggregates develop into amyloid deposits in the brain of affected patients, leading to the

development of the spongiform encephalopathy. The peptides, when used in vitro inhibit such aggregation. Furthermore, when used in pharmaceutical compositions and medically relevant dosages, may be used for therapies for TSEs.

#### Inhibitors of Amyloid Formation

Winslow S. Caughey, Byron Caughey, Lynne D. Raymond, Motohiro Horiuchi (NIAID). U.S. Patent 6,632,808 issued on 14 Oct 2003 (DHHS Reference No. E-205-1998/0-US-03).

*Licensing Contact:* Michael Ambrose; 301/594-6565; [ambrosem@mail.nih.gov](mailto:ambrosem@mail.nih.gov).

This invention discloses methods, compounds and compositions for therapeutic treatment of amyloidogenic diseases, like Alzheimer's disease, type 2 diabetes and, particularly, transmissible spongiform encephalopathies (prion diseases) such as CJD, Kuru in humans and BSE ("Mad Cow Disease") in cattle.

The invention is based on the findings that cyclic tetrapyrroles and derivatives inhibit the formation of protease-resistant prion protein (PrP-res) the pathologic, amyloidogenic protein aggregates of the prion diseases. These methods and compounds have the potential for the development of pharmaceutical therapies for the treatment and prevention of progression of such TSEs.

#### Inhibition of Diseases Associated With Amyloid Formation

Byron Caughey, Richard E. Race (NIAID).

U.S. Patent 5,276,059 issued on 04 Jan 1994 (DHHS Reference No. E-107-1992/0-US-01).

*Licensing Contact:* Michael Ambrose; 301/594-6565; [ambrosem@mail.nih.gov](mailto:ambrosem@mail.nih.gov).

Amyloid deposition in brain samples is diagnostic for several serious and fatal diseases. These include Alzheimer's disease as well as several transmissible spongiform encephalopathies (prion diseases) such as CJD and BSE ("Mad Cow Disease"). Together, these diseases having amyloid depositions are termed amyloidogenic diseases.

This invention covers and discloses the method and compositions of using Congo Red in the treatment of such amyloidogenic diseases. Congo Red is shown to inhibit the accumulation of PrP-res, the amyloidogenic and pathologic protein or the transmissible spongiform encephalopathies. The potential therapeutics covered by this invention includes Congo Red and its derivatives.

Dated: January 14, 2004.

**Steven M. Ferguson,**

*Director, Division of Technology Development and Transfer, Office of Technology Transfer, 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.

#### Codon-Optimization of the HIV-1 Vif Gene

Klaus Strebel, Stephan Bour, Kim-Lien Nguyen (NIAID); DHHS Reference No. E-041-2004/0—Research Tool/Biological Material; Licensing Contact: Michael Ambrose; 301/594-6565; [ambrosem@mail.nih.gov](mailto:ambrosem@mail.nih.gov).

Expression of the HIV-1 Vif protein in the absence of other viral factors such as Tat and Rev is extremely inefficient due to the presence of inhibitory sequences on its mRNA. This invention uses codon optimization to remove such inhibitory sequences without altering the amino acid sequence of the protein. The modified vif gene in the resulting pcDNA-hVIF vector is expressed under the control of the CMV promoter. In this, the protein functions as wild type and is more amenable to high-level expression in mammalian cells.

Currently this vector is used in ongoing studies of HIV infection and its

ability to overcome cellular restriction to replication. As such, the reagent will be valuable to other researchers in discovering mechanisms of replication, next generation therapeutics and potentially prevention of infection as well.

### **Streptococcus Lipoprotein Antigens**

James M. Musser and Benfang Lei (NIAID); U.S. Provisional Application filed 10 Nov 2003 (DHHS Reference No. E-324-2003/0-US-01); Licensing Contact: Susan Ano; 301/435-5515; [anos@mail.nih.gov](mailto:anos@mail.nih.gov).

The current technology describes sixteen isolated and purified Spy polypeptides that are conserved across many Group A *Streptococcus* serotypes and that are expressed during infection. The polypeptides are from the polypeptide portion of a lipoprotein of a Group A *Streptococcus*. Infection with Group A *Streptococcus* bacteria can result in mild illness such as strep throat, or more severe illnesses such as necrotizing fasciitis and streptococcal toxic shock syndrome. Currently such infections are treated with antibiotics, but trends indicate an increasing resistance to *e.g.*, erythromycin. There is currently no licensed vaccine for Group A *Streptococcus*. The M protein, a main focus of studies directed toward vaccine development, elicits antibodies that are either serospecific or may induce harmful cross-reacting antibodies. This technology identified individual polypeptides that were promising vaccine candidates and various combinations thereof. Additionally, antibodies to these polypeptides are discussed, which could be used therapeutically or in diagnostic assays.

### **A Simple Method and Apparatus To Produce a Closed, Transverse Bone Fracture in a Mouse or Other Skeletal Creature**

Arabella Leet (NIDCR); DHHS Reference No. E-309-2003/0-US-01 filed 27 Oct 2003; Licensing Contact: Michael Shmilovich; 301/435-5019; [shmilovm@mail.nih.gov](mailto:shmilovm@mail.nih.gov).

A standard pair of pliers was modified to create a device that applies three-point bending forces across the leg of a mouse directly over the tibia bone. With this device, a reproducible transverse fracture can be fashioned quickly and easily, producing an animal model for fracture healing.

Although surgical fixation can be applied to the fracture, short-term splinting allows abundant bridging callus formation. This device does not require a platform for stabilizing the animals; instead the jaws are placed directly onto the limb, allowing

production of many fractures within minutes. By using three-point fixation, there is no crush type injury, as when using a guillotine-type device to drop a weight onto a pre-rodged bone.

Scientists studying fracture healing will find this simple device useful because no special surgical skills are required to produce and stabilize a fracture in a mouse model of fracture healing.

Dated: January 14, 2004.

**Steven M. Ferguson,**

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

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

### **National Institutes of Health**

#### **Notice of Meeting: Secretary's Advisory Committee on Genetics, Health, and Society**

Pursuant to Pub. L. 92-463, notice is hereby given of a meeting of the Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS), U.S. Public Health Service. The meeting will be held from 8:30 a.m. to 5:30 p.m. on March 1, 2004 and 8 a.m. to 5 p.m. on March 2, 2004, at the Marriott Hotel Bethesda on 5151 Pooks Hill Road in Bethesda, Maryland. The meeting will be open to the public with attendance limited to space available. The meeting also will be webcast.

The first half of the first day will be devoted to a presentation on and discussion of the work of the Committee's Inter-Meeting Task Force and priority setting process. The second half of the first day will consist of presentations on the issue of coverage and reimbursement, a possible priority area for the Committee. The second day will be entirely devoted to discussions around the top priorities and Committee action in these areas. Time will be provided each day for public comment.

Under authority of 42 U.S.C. 217a, section 222 of the Public Health Service Act, as amended, the Department of Health and Human Services established SACGHS to serve as a public forum for deliberations on the broad range of human health and societal issues raised by the development and use of genetic technologies and, as warranted, to provide advice on these issues.

The draft meeting agenda and other information about SACGHS, including information about access to the webcast, will be available at the following Web

site: <http://www4.od.nih.gov/oba/sacghs.htm>. Individuals who wish to provide public comment or who plan to attend the meeting and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the SACGHS Executive Secretary, Ms. Sarah Carr, by telephone at 301-496-9838 or e-mail at [sc112c@nih.gov](mailto:sc112c@nih.gov). The SACGHS office is located at 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892.

Dated: January 14, 2004.

**Anna Snouffer,**

*Acting Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 04-1257 Filed 1-21-04; 8:45 am]

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

### **National Institutes of Health**

#### **National Cancer Institute; Notice of Closed Meeting**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Cancer Institute Special Emphasis Panel, Biology of the Prostate Cancer Prevention Trial (PCPT).

*Date:* February 18-20, 2004.

*Time:* 7 p.m. to 1 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hilton Houston Plaza at Medical Center, 6633 Travis Street, Houston, TX 77030.

*Contact Person:* Shakeel Ahmad, PhD, Scientific Review Administrator, Research Programs Review Branch, National Cancer Institute, Division of Extramural Activities, 6116 Executive Blvd., Bethesda, MD 20892. (301) 594-0114; [amads@mail.nih.gov](mailto:amads@mail.nih.gov).

(Catalogue of Federal Domestic Assistant Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399,