

Licensing Status: This assay is available nonexclusively through a biological materials license.

Licensing Contact: Peter A. Soukas, J.D.; 301/435-4646; soukasp@mail.nih.gov.

Molecular Motors Powered by Proteins

Description of Technology: The technology available for licensing and commercial development relates to molecular motors powered by proteins. Some implementations describe a molecular motor in which multiple concentric cylinders or nested cones rotate around a common longitudinal axis. Opposing complementary surfaces of the cylinders or cones are coated with complementary motor protein pairs, such as actin and myosin. The actin and myosin interact with one another in the presence of ATP to rotate the cylinders or cones relative to one another, and this rotational energy is harnessed to produce work. Speed of movement is controlled by the concentration of ATP and the number of nested cylinders or cones. The length of the cylinders or cones can also be used to control the power generated by the motor.

Another configuration forms the motor out of a set of stacked disks, much like CDs on a spindle. The advantage of this form is extreme simplicity of construction compared to the nested cylinders or cones. In yet another configuration, which has aspects of both of the previous forms, the surfaces are broken into annular rings in order to overcome that the inner surfaces rotate at a different rate than the outer surfaces. This belt form may ultimately be used in molecular manufacturing.

Applications: Supplying power to prosthetic implants and other medical devices without external power sources.

Many other applications that could use a motor in other biotechnological areas, in addition to the medical applications.

The inventions can be implemented on either a microscopic or macroscopic scale.

Development Status: Very early stage of development.

Inventors: Thomas D. Schneider and Ilya G. Lyakhov (NCI).

Relevant Publications: "Molecular motor", Patent Publication Nos. WO 2001/009181 A1, published 02/08/2001; CA 2380611A1, published 02/08/2001; AU 6616600A, published 02/19/2001; EP 1204680A1, published 05/15/2002; and U.S. 20020083710, published 07/04/2002.

Patent Status: HHS Reference No. E-018-1999/0—International Application Number PCT/US 2000/20925 filed 07/

31/2000; granted Application AU 2002/18688 B2, and the corresponding European and Canadian applications being prosecuted, all entitled "Molecular Motor."

HHS Reference No. E-018-1999/1—allowed U.S. Application No. 10/061,377 filed 02/01/2002, entitled "Molecular Motor."

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

Licensing Contact: Cristina Thalhammer-Reyero, PhD, MBA; 301-435-4507; thalhamc@mail.nih.gov.

Collaborative Research Opportunity: The National Cancer Institute, Center for Cancer Research Nanobiology Program is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize the Molecular Rotation Engine. Please contact John D. Hewes, PhD at 301-435-3121 or hewesj@mail.nih.gov for more information.

Dated: January 16, 2008.

Steven M. Ferguson,

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

[FR Doc. E8-1247 Filed 1-24-08; 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.

ADDRESS: 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.

3D Imaging of Mammalian Cells Using Focused Ion Beam-Secondary Ion Mass Spectrometry (FIB-SIMS)

Description of Technology: Available for licensing and commercial development is a new automated approach to cellular imaging that allows 3D visualization of cellular organelles and protein expression at nanometer (nm) resolution using ion abrasion scanning electron microscopy (IA-SEM). The approach uses established technologies for 3D imaging [1, 2] by iterative use of a focused ion beam and scanning electron beam combined with established technologies for mass spectrometry. Strategies to explore the 3D distribution of cellular components are being developed with the goal of establishing rapid methods for determining protein, metabolite and drug localization in the subcellular space.

Applications: Cytology; Oncology; Cell biology; Drug development; Drug targeting.

Development Status: Pilot experiments are ongoing for the development and optimization of the technology using commercially available components. Clinical applications for the diagnosis of tissue specimens are also being explored.

Inventor: Sriram Subramaniam (NCI).

Publications:

1. J Heymann, M Hayles, I Gestmann, L Giannuzzi, L Lich, S Subramaniam. Site-specific 3D imaging of cells and tissues with a dual beam microscope. *J. Struct. Biol.* 2006 Jul;155(1):63-73.

2. J Heymann, D Shi, S Kim, D Bliss, J Milne, S Subramaniam. 3D imaging of melanoma cells using automated "ion abrasion scanning electron microscopy". *Microsc Microanal.* 2007 Aug;13(Suppl 2):360-361, doi 10.1017/S1431927607079287.

Patent Status: U.S. Provisional Application No. 60/970,070 filed 05 Sep 2007 (HHS Reference No. E-313-2007/0-US-01); U.S. Provisional Application No. 60/974,686 filed 24 Sep 2007 (HHS Reference No. E-313-2007/1-US-01).

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

Licensing Contact: Michael A. Shmilovich, Esq.; 301/435-5019; shmilovm@mail.nih.gov.

Collaborative Research Opportunity: The National Cancer Institute is seeking statements of capability or interest from parties interested in collaborative research and/or partnership agreements to further develop and commercialize tools for 3D mapping cells and tissues at nanometer resolution. Please contact

John D. Hewes, Ph.D. at 301-435-3121 or hewesj@mail.nih.gov for more information.

A Drug Index to Quantify Harmful Drug Exposure in Older Adults

Description of Technology:

Polypharmacy is the simultaneous use of multiple drugs. It is prevalent in individuals ages 65 and older who carry a high burden of illness and take various medications for treatment. Reducing the incidence of polypharmacy in older people presents a major challenge for healthcare professionals. NIH scientists have discovered a novel method to assess polypharmacy for which physicians can use to evaluate drug response of patients more effectively and determine better therapeutic regimens for the patient. This method calculates the total drug burden (TDB) index associated with anticholinergic and sedative drugs, using the equation, $TDB = B_{AC} + B_S$. Further, this invention could be implemented into a portable computing device, such as personal digital assistant (PDA).

Applications: Useful for physicians to help reduce prescribing errors, lower the incidence of adverse drug reactions and improve medical outcomes in older patients.

Market:

Seven percent (7%) of the elderly are under polypharmacy and purchase over 30% of prescription drugs and 40% of over-the-counter (OTC) drugs.

Medication misuse costs the health care system over \$177 billion dollars and results in more than 200,000 deaths each year.

Development Status: Early stage.

Inventors: Darrell R. Abernethy (NIA), et al.

Patent Status: International Application No. PCT/US06/44718 filed 17 Nov 2006 (HHS Reference No. E-241-2006/0-PCT-01)

Licensing Status: Available for licensing.

Licensing Contact: Rung C. Tang, J.D.; 301/435-5031; tangrc@mail.nih.gov.

Recombinant Modified *Bacillus anthracis* Protective Antigen for Use in Vaccines

Description of Invention: This invention relates to improved methods of preparing *Bacillus anthracis* protective antigen (PA) for use in vaccines. PA is a secreted, non-toxic protein with a molecular weight of 83 KDa. PA is a major component of the currently licensed human vaccine (Anthrax Vaccine Adsorbed, AVA). Although the licensed human vaccine has been shown to be effective against cutaneous anthrax infection in animals

and humans and against inhalation anthrax in rhesus monkeys, the licensed vaccine has several limitations: (1) AVA elicits a relatively high degree of local and systemic adverse reactions, probably mediated by variable amounts of undefined bacterial products, making standardization difficult; (2) the immunization schedule requires administration of six doses within an eighteen (18) month period, followed by annual boosters; (3) there is no defined vaccine-induced protective level of antibody to PA by which to evaluate new lots of vaccines; and (4) AVA is comprised of a wild-type PA. It has been suggested that a vaccine comprising a modified purified recombinant PA would be effective, safe, allow precise standardization, and require fewer injections.

This invention claims methods of producing and recovering PA from a cell or organism, particularly a recombinant cell or microorganism. The invention claims production and purification of modified PA from a non-sporogenic strain of *Bacillus anthracis*. In contrast to other previously described methods, greater quantities of PA are obtainable from these cells or microorganisms. Specifically, a scalable fermentation and purification process is claimed that is suitable for vaccine development, and that produces almost three times more product than earlier-reported processes. This is accomplished using a biologically inactive protease-resistant PA variant in a protease-deficient non-sporogenic avirulent strain of *B. anthracis* (BH445). One of the PA variants described in the patent application lacks the furin and chymotrypsin cleavage sites.

The invention relates to improved methods of producing and recovering sporulation-deficient *B. anthracis* mutant strains, and for producing and recovering recombinant *B. anthracis* protective antigen (PA), especially modified PA which is protease resistant, and to methods of using of these PAs or nucleic acids encoding these PAs for eliciting an immunogenic response in humans, including responses which provide protection against, or reduce the severity of, *B. anthracis* bacterial infections and which are useful to prevent and/or treat illnesses caused by *B. anthracis*, such as inhalation anthrax, cutaneous anthrax and gastrointestinal anthrax.

Application: Improved *B. anthracis* vaccines.

Developmental Status: Phase I clinical studies are being performed.

Inventors: Stephen Leppla (NIDCR), M. J. Rosovitz (NIDCR), John Robbins (NICHHD), Rachel Schneerson (NICHHD)

Patent Status:

U.S. Provisional Application No. 60/402,285 filed 09 Aug 2002 (HHS Reference No. E-268-2002/0-US-01).

U.S. Patent Application No. 10/638,006 filed 08 Aug 2003, now U.S. Patent 7,261,900 (HHS Reference No. E-268-2002/0-US-02).

U.S. Patent Application No. 11/831,860 filed 31 Jul 2007 (HHS Reference No. E-268-2002/0-US-03).

Licensing Status: Available for exclusive or nonexclusive licensing.

Licensing Contact: Peter A. Soukas, J.D.; 301/435-4646; soukasp@mail.nih.gov.

Methods for Preparing *Bacillus anthracis* Protective Antigen for Use in Vaccines

Description of Invention: This invention relates to improved methods of preparing *Bacillus anthracis* protective antigen (PA) from a cell or organism, particularly a recombinant cell or microorganism, for use in vaccines. Production and purification methods of modified PA from a non-sporogenic strain of *Bacillus anthracis* are described. Specifically, a scalable fermentation and purification process is claimed that is suitable for vaccine development, and that produces almost three times more product than earlier-reported processes. This is accomplished using a biologically inactive protease-resistant PA variant in a protease-deficient non-sporogenic avirulent strain of *B. anthracis* (BH445). One of the PA variants described in the patent application lacks the furin and chymotrypsin cleavage sites.

Advantages: *Bacillus anthracis* protective antigen is a major component of the currently licensed human vaccine (Anthrax Vaccine Adsorbed, AVA). Although the current human vaccine has been shown to be effective against cutaneous anthrax infection in animals and humans and against inhalation anthrax in rhesus monkeys, the licensed vaccine has several limitations: (1) AVA elicits a relatively high degree of local and systemic adverse reactions, probably mediated by variable amounts of undefined bacterial products, making standardization difficult; (2) the immunization schedule requires administration of six doses within an eighteen (18) month period, followed by annual boosters; (3) there is no defined vaccine-induced protective level of antibody to PA by which to evaluate new lots of vaccines; and (4) AVA is comprised of a wild-type PA. Thus a vaccine comprising a modified purified recombinant PA would be effective, safe, allow precise standardization, and require fewer injections.

The invention also relates to PA variants, and/or compositions thereof, which are useful for eliciting an immunogenic response in mammals, particularly humans, including responses that provide protection against, or reduce the severity of, infections caused by *B. anthracis*. The vaccines claimed in this application are intended for active immunization for prevention of *B. anthracis* infection, and for preparation of immune antibodies.

Application: Improved *B. anthracis* vaccines.

Developmental Status: Phase I clinical studies are being performed.

Inventors: Joseph Shiloach (NIDDK), Stephen Leppla (NIDCR), Delia Ramirez (NIDDK), Rachel Schneerson (NICHD), John Robbins (NICHD).

Publication: DM Ramirez, *et al.* Production, recovery and immunogenicity of the protective antigen from a recombinant strain of *Bacillus anthracis*. J Ind Microbiol Biotechnol. 2002 Apr;28(4):232-238.

Patent Status: U.S. Provisional Application No. 60/344,505 filed 09 Nov 2001 (HHS Reference No. E-023-2002/0-US-01); U.S. Patent Application No. 10/290,712 filed 08 Nov 2002 (HHS Reference No. E-023-2002/0-US-02).

Licensing Status: Available for exclusive or nonexclusive licensing.

Licensing Contact: Peter A. Soukas, J.D.; 301/435-4646; soukasp@mail.nih.gov.

Collaborative Research Opportunity: The National Institutes of Health is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize methods of preparing *Bacillus anthracis* protective antigen (PA) from a cell or organism, particularly a recombinant cell or microorganism, for use in vaccines. Please contact Rochelle S. Blaustein, J.D., at 301/451-3636 or Rochelle.Blaustein@nih.gov for additional information.

Chimeric Gag Pseudovirions

Description of Technology: The human immunodeficiency virus (HIV) is the causative agent of acquired immunodeficiency syndrome (AIDS). The HIV virion basically consists of a viral core and envelope. The core consists predominantly of gag- and pol-encoded proteins and the viral RNA. Expression of recombinant Gag precursor proteins can lead to assembly and budding of virus-like particles (pseudovirions). The production of Gag-based pseudovirions in mammalian and insect cell systems using recombinant virus vectors provides a novel technology for engineering recombinant

protein-based particulate vaccines for HIV and other viruses. The incorporation of additional viral or cellular, peptides and polypeptides may be advantageous in vaccine preparations, since they may contain antigenic epitopes that may play a role in inducing protection from infection or disease.

The subject invention provides chimeric nucleic acids comprising a retroviral gag sequence, a target nucleic acid sequence derived from a nucleic acid encoding a fusion partner, and a frame shift site. Expression of the chimeric gene cassette results in packaging the fusion partner into the Gag pseudovirion. Suitable fusion partners can be derived from any protein of interest which has a biological activity or which elicits a cellular or humoral immune response.

Applications: HIV vaccines and/or therapeutics.

Development Status: Early stage.

Inventors: Gregory J. Tobin (NCI/SAIC), *et al.*

Patent Status: U.S. Patent No. 6,099,847 issued 08 Aug 2000 (HHS Reference No. E-105-1996/1-US-01).

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

Licensing Contact: Susan Ano, PhD; 301/435-5515; anos@mail.nih.gov.

Dated: January 14, 2008.

Steven M. Ferguson,

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

[FR Doc. E8-1259 Filed 1-24-08; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; 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 meetings.

The meetings 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: Oncological Sciences Integrated Review Group; Basic Mechanisms of Cancer Therapeutics Study Section.

Date: January 28-29, 2008.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road, NW., Washington, DC 20015.

Contact Person: Lambratu Rahman, PhD, Scientific Review Officer, Center for Scientific Review; National Institutes of Health, 6701 Rockledge Drive, Room 6214, MSC 7804, Bethesda, MD 20892, 301-451-3493, rahmanl@csr.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, (HHS)

Dated: January 16, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 08-275 Filed 1-24-08; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

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 meetings.

The meetings 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: Center for Scientific Review Special Emphasis Panel; Nutrition.

Date: January 31, 2008.

Time: 1 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Abubakar A. Shaikh, PhD, DVM, Scientific Review Administrator, Center for Scientific Review, National