may be responsible for causing mutations that ultimately lead to human cancer formation.

The polymerase could be useful as a target for chemotherapeutic agents that block the polymerase's enzyme activity. This in turn could lead to an increase in the cure rate of cancer patients. In addition, a diagnostic assay could be developed to identify enzyme expression patterns and their mutations, so as to recognize humans with an increased risk of cancers. Therefore, the polymerase could be used as a research tool, or with more development, into a kit that could be used in both research and clinical labs.

TMC1 and TMC2 and Applications to Hereditary Deafness

Dr. Andrew Griffith et al. (NIDCD)
DHHS Reference No. E–168–01/0 filed 19 Sep 2001

Hearing loss is a common communication disorder effecting nearly 1 in 1,000 children in the United States alone, and nearly 50% of adults by the age of eighty. Deafness can be caused by both environmental and disease-related factors, however, in at least 50% of the cases, deafness is an inherited trait.

The NIH announces the isolation and purification of two novel genes termed TMC1 and TMC2 that may encode the mammalian hair cell mechanotransduction channel. It is known that the mechanotransduction channel is the critical molecule within the hearing pathway, which detects sound within the inner ear. Our investigators have discovered that dominant and recessive mutations in TMC1 underlie two forms of hereditary deafness known as DFNA36 and DFNB7/11, respectively. This technology would be useful to a company interested in finding new therapies to treat or prevent hearing loss as well as identifying persons at increased risk of developing aminoglycoside-induced hearing loss. This technology is also available for collaboration with a partner under a Cooperative Research and Development Award.

Gene Involved in Dietary Sterol Absorption and Excretion and Uses Therefor

Drs. Michael Dean and Shailendra Patel (NCI)
DHHS Reference No. E–295–99/1 filed 25 Sep 2001 (PCT/US01/29859)

The ATP binding cassette proteins are involved in cholesterol regulation. Cholesterol absorption from the diet is an important mechanism for regulating serum cholesterol levels. It is well known that high serum cholesterol levels are found in several diseases such as diabetes, atherosclerosis, and cardiovascular disease.

The NIH announces the identification and characterization of the ABCG5 gene. The gene maps to human chromosome 2, which has been identified as playing a role in the genetic disorder sitosterolemia. Patients with sitosterolemia display an abnormally high level of blood sterol debri from plants and fish, which can lead to coronary artery disease, atherosclerosis, and arthritis, as well as other diseases. The inventors believe that mutations in the ABCG5 gene interfere with sterol transport thereby causing sitosterolemia. Companies working in this area would find this technology useful in searching for agents that can treat or prevent any disease or condition that has associated with it high cholesterol levels.

Dated: January 11, 2002.

Jack Spiegel,

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

[FR Doc. 02–1439 Filed 1–18–02; 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, DHHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by agencies 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.

Efficient Inhibition of HIV–1 Viral Entry Through a Novel Fusion Protein Including CD4

James Arthos, Claudia Cicala, Anthony Fauci (NIAID)
DHHS Reference No. E–337–01/0 filed 25 Oct 2001
Licensing Contact: Peter Soukas; 301/496–7056 ext. 268; e-mail: *soukasp@od.nih.gov*

This invention relates to CD4 fusion proteins for use in the treatment of an immunodeficiency virus infection such as human immunodeficiency virus (HIV). These polypeptides have been shown by the inventors to inhibit the entry of primary isolates of HIV–1 into CD4+ T cells by targeting the gp120 subunit of the HIV–1 envelope. The invention claims recombinant polypeptides comprising a CD4 polypeptide ligated at its C-terminus with a portion of a human immunoglobulin comprising a hinge region and two constant domains of an immunoglobulin heavy chain. The portion of the IgG is fused at its C-terminus with a polypeptide comprising a tailpiece from the C terminus of the heavy chain of an IgA antibody. This protein is very large (greater than 800 kilodaltons), which may contribute to its ability to inhibit entry of primary isolates of HIV–1 into T cells. It presents twelve gp120 binding domains (D1D2) and can bind at least ten gp120s simultaneously. The inventors have shown that the construct efficiently neutralizes primary isolates from different HIV subgroups. Also claimed are use of the construct as a component of a vaccine and as a diagnostic.

Methods and Compositions for Production and Purification of Recombinant Staphylococcal Enterotoxin B (rSEB)

Daniel Coffman, Steven Giardina, Jianwei Zhu (NCI)
DHHS Reference No. E–075–01/0 filed 09 Oct 2001
Licensing Contact: Peter Soukas; 301/496–7056 ext. 268; e-mail:*soukasp@od.nih.gov*

This invention claims processes and compositions for fermentation, recovery, and purification of recombinant bacterial superantigens (rSAgs), exemplified by a recombinant staphylococcal enterotoxin B SEB (rSEB) protein mutated for use in administration to a mammalian recipient. This process generates an economically viable quantity of rSEB vaccine protein meeting FDA parenteral drug specifications. The purification methods generally involve multiple steps including hydrophobic interaction

chromatography (HIC), buffer exchange (desalting), and cation exchange. The final product of the purification is a highly purified rSAg composition satisfying clinical safety criteria and is immunogenic and protective against lethal aerosol challenge in a murine model. The methods and compositions claimed in the patent application provide possible therapeutics and prophylactics for diseases caused by bacterial SAgs, such as food poisoning, bacterial arthritis and other autoimmune disorders, toxic shock syndrome, and the potential use of SAg biowarfare agents.

Novel Peptides to a Melanoma Antigen and Their Use in Diagnostic and Therapeutic Methods

P. Hwu, R. LaPointe, S.A. Rosenberg (NCI)

DHHS Reference No. E–086–01/0 filed 22 Aug 2001

Licensing Contact: Kai Chen; 301/496–7736 ext. 247; e-mail: *chenk@od.nih.gov*

Various tumor-associated antigens are recognized by T cells, thereby eliciting an immune response. Among these tumor-associated antigens is gp100, which along with several other tumor antigens identified to date is associated with malignant melanoma. Most of the gp100 peptide epitopes identified to date are HLA–A2 (MHC Class I) restricted.

The current invention embodies the identification of a novel HLA–DRB1*0701 (MHC Class II) restricted epitope of gp100. As 16–28% of the population is HLA–DRB1*0701 positive, this peptide could represent a potential immunotherapeutic vaccine for use against melanoma in a significant percentage of the patient population. In addition, the current invention represents only the second gp100 peptide identified to date that is capable of eliciting a CD4+ helper T cell response. It is believed that administration of a peptide capable of eliciting a CD4+ T cell response may be required in order to upregulate a CD8+ T cell response against a Class I-restricted peptide. The identification of an immunogenic Class II-restricted epitope therefore could be of particular importance not only as an immunotherapeutic vaccine in and of itself, but also for use in a vaccination protocol in combination with an immunogenic Class I-restricted peptide.

Tumor Antigen Homologous to Poly(A) Polymerase

S. Topalian (NCI), M. Gonzales (NCI), J. Manley, and S. Kaneko

DHHS Reference No. E–002–01/0 filed 16 May 2001

Licensing Contact: Kai Chen; 301/496–7736 ext. 247; e-mail: *chenk@od.nih.gov*

Poly(A) polymerase (PAP) activity has long been linked to cancer, and several forms of PAP have been identified to date by various researchers. PAP is an enzyme that is required for the processing and stability of nascent RNA transcripts. The current invention embodies the identification of a new human tumor associated antigen, neo-poly(A) polymerase (neo-PAP), which shares approximately 70% amino acid and 61% nucleic acid sequence similarity with classic PAP.

Neo-PAP is overexpressed in all tumor cell lines tested, including human prostate cancers, colon cancers, and melanomas. It is expressed at low levels in normal human testis tissue as well, but is expressed only at very low levels or not at all in other normal human tissues. Thus, neo-PAP appears to be a ''cancer-testis'' antigen, which is a category of tumor-associated antigens that are recognized by cytotoxic and helper T lymphocytes as well as serum immunoglobulins. Members of this tumor antigen category, including NY–ESO–1 and MAGE–3, and currently in clinical testing as cancer vaccines. Neo-PAP therefore could represent a potential immunotherapeutic vaccine for use against cancers of various types, and could also be useful in the diagnosis/prognosis of cancer.

Dated: January 14, 2002.

Jack Spiegel,

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

[FR Doc. 02–1440 Filed 1–18–02; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary & Alternative Medicine; Notice of 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 National Advisory Council for Complementary and Alternative Medicine (NACCAM).

The meeting will be open to the public as indicated below, 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.

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/or contract proposals and the discussion could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Council for Complementary and Alternative Medicine.

Date: January 28, 2002.

Open: 8:30 am to 2:45 pm.

Agenda: The agenda includes the Opening Remarks by Director, NCCAM, Reports on FIC Activities, International Health Research Strategic Plan, New Initiatives, and other business of the Council.

Closed: 2:45 pm to adjournment.

Agenda: To review and evaluate grant applications and/or proposals.

Place: Neuroscience Conference Center, 6001 Executive Boulevard, Rockville, MD 20852.

Contact Person: Jane F. Kinsel, Ph.D. Executive Secretary, National Center for Complementary and Alternative Medicine, National Institutes of Health, 6707 Democracy Blvd., Suite 200, Bethesda, MD 20892, 301/402–7269.

The public comments session is scheduled from 1:15–1:45 pm. Each speaker will be permitted 5 minutes for their presentation. Interested individuals and representatives of organizations are requested to notify Dr. Jane Kinsel, National Center for Complementary and Alternative Medicine, NIH, 6707 Democracy Boulevard, Suite 200, Bethesda, Maryland 20892, 301–402–7269, Fax: 301–480–3519. Letters of intent to present comments, along with a brief description of the organization represented, should be received no later than 5 pm on January 18, 2002. Only one representative of an organization may present oral comments. Any person attending the meeting who does not request an opportunity to speak in advance of the meeting may be considered for oral presentation, if time permits, and at the discretion of the Chairperson. In addition, written comments may be submitted to Dr. Jane Kinsel at the address listed above up to ten calendar days (February 7, 2001) following the meeting.

Copies of the meeting agenda and the roster of members will be furnished upon request by Dr. Jane Kinsel, Executive Secretary, NACCAM, National Institutes of Health, 6707 Democracy Boulevard, Suite 200, Bethesda, Maryland 20892, 301–402–7269, Fax 301–480–3519.