Subject city, state	Effective date
Robinson, Cynane Ann Yetta ... Southfield, MI	12/20/2001
Rodebaugh, Cheryl Lynn ..... Denver, CO	12/20/2001
Rose, Keith D ..... Big Rapids, MI	12/20/2001
Roudebush, Mark D ..... Cordova, TN	12/20/2001
Rouselle, Dionne Marie ..... Memphis, TN	12/20/2001
Rubinstein, David M ..... Tamarac, FL	12/20/2001
Schwirian, Jay A ..... White Oak, PA	12/20/2001
Smith, Terrance Herbert ..... Sioux Falls, SD	12/20/2001
Smith, William H III ..... Philadelphia, PA	12/20/2001
Sparks, Darlene V ..... Annandale, VA	12/20/2001
Stevens, Joanne K ..... Broadview Hgts, OH	12/20/2001
Strasser, Robert T ..... Lake Zurich, IL	12/20/2001
Thompson, Emma R ..... Lithonia, GA	12/20/2001
Van Brookhoven, Gloria ..... Atlanta, GA	12/20/2001
Vodvarka, James M ..... Steubenville, OH	12/20/2001
Webb, James R ..... Shawnee Mission, KS	12/20/2001
Wohlschlaeger, Michael Alan ... Panama City Bch, FL	12/20/2001
Wolf, Jacob M ..... Akron, OH	12/20/2001
Wright, Bill G ..... Lincoln, NE	12/20/2001
Yoder, Patricia L ..... Ocklawaha, FL	12/20/2001
Young-Cheney, Joan E ..... Creswell, OR	12/20/2001
Peer Review Organization Cases	
Hinkley, Bruce Stanton ..... Dallas, TX	11/14/2001

Dated: December 3, 2001.

Calvin Anderson, Jr.,

Director, Health Care Administrative Sanctions, Office of Inspector General.

[FR Doc. 01–32156 Filed 12–31–01; 8:45 am]

BILLING CODE 4150–04–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 contacting Peter A. Soukas, J.D., at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7056 ext. 268; fax: 301/402–0220; e-mail: *soukasp@od.nih.gov.* A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

LL–37 is an Immunostimulant

Oleg Chertov (NCI), Joost Oppenheim (NCI), De Yang (NCI), Qian Chen (NCI), Ji Wang (NCI), Mark Anderson (EM), Joseph Wooters (EM)

Serial No. 09/960,876 filed 21 Sep 2001

This invention relates to use of an antimicrobial peptide as a vaccine adjuvant. LL–37 is the cleaved antimicrobial 37-residue C-terminal peptide of hCAP18, the only identified member in humans of a family of proteins called cathelicidins. LL–37/hCAP18 is produced by neutrophils and various epithelial cells. LL–37 is well known as an antimicrobial peptide. However, although antimicrobial peptides have generally been considered to contribute to host innate antimicrobial defense, some of them may also contribute to adaptive immunity against microbial infection. The inventors have shown that LL–37 utilizes formyl peptide receptor-like 1 (FPLR1) as a receptor to activate human neutrophils, monocytes, and T cells. Since leukocytes participate in both innate and adaptive immunity, the fact that LL–37 can chemoattract human leukocytes may provide one additional mechanism by which LL–37 can contribute to host defense against microbial invasion, by participating in the recruitment of leukocytes to sites of infection. The invention claims methods of enhancing immune responses through the administration of LL–37 alone, in conjunction with a vaccine, and methods of treating autoimmune diseases. The invention is further described in Chertov et. al., ''LL–37, the neutrophil granule- and epithelial cell-derived cathelicidin, utilizes formyl peptide receptor-like 1 (FPRL1) as a receptor to chemoattract human peripheral blood neutrophils, monocytes, and T cells,'' J Exp. Med. 2000 Oct 2;192(7):1069–74.

A Method for Bioconjugation Using Diels-Alder Cycloaddition

Vince Pozsgay (NICHD)

Serial Number 09/919,637 filed 01 Aug 2001

This invention relates to a new method for the synthesis of conjugate vaccines using the Diels-Alder cycloaddition reaction to covalently attach a carbohydrate antigen from a pathogen to a protein carrier. The Diels-Alder reaction has not been extended to conjugation involving biopolymers or other types of polymeric materials. Advantages of this method are that cross-linking during conjugation is entirely avoided in addition to the mild chemical conditions under which this synthesis method proceeds. Diels-Alder reactions commonly take place in high-temperature environments; the method contemplated by this invention takes place at much lower temperatures. In addition to claiming methods of synthesis for conjugate vaccines using the Diels-Alder cycloaddition, the patent application claims vaccines produced utilizing the method, and methods of inducing antibodies which react with the polysaccharides contemplated by the invention.

Identification of New Small RNAs and ORFs

Susan Gottesman (NCI), Gisela Storz (NICHD), Karen Wassarman (NICHD), Francis Repoila (NCI), Carsten Rosenow (EM)

Serial No. 60/266,402 filed 01 Feb 2001

The inventors have isolated a number of previously unknown sRNAs found in E. coli. Previous scientific publications by the inventors and others regarding sRNAs have shown these sRNAs to serve important regulatory roles in the cell, such as regulators of virulence and survival in host cells. Prediction of the presence of genes encoding sRNAs was accomplished by combining sequence information from highly conserved intergenic regions with information about the expected transcription of neighboring genes. Microarray analysis also was used to identify likely candidates. Northern blot analyses were then carried out to demonstrate the presence of the sRNAs. Three of the sRNAs claimed in the invention regulate (candidates 12 and 14, negatively and candidate 31, positively) expression of RpoS, a major transcription factor in bacteria that is important in many pathogens because it regulates (amongst other things) virulence. The inventors' data show that these sRNAs are highly

conserved among closely related bacterial species, including Salmonella and Klebsiella, presenting a unique opportunity to develop both specific and broad-based antibiotic therapeutics. The invention contemplates a number of uses for the sRNAs, including, but not limited to, inhibition by antisense, manipulation of gene expression, and possible vaccine candidates.

Peptides that Stabilize Protein Antigens and Enhance Presentation to CD8+ T Cells

Roger Kurlander, Elizabeth Chao, Janet Fields (CC)

DHHS Reference No. E–172–99/1 filed 12 Dec 2000 (PCT/US00/33027, published as WO 01/40275), with priority to 06 Dec 1999

This invention relates to compositions and methods for stabilizing an antigen against proteolytic degradation and enhancing its presentation to CD8+ cells. The invention claims ''fusion agents,'' isolated molecules comprising a hydrophobic peptide joined to an epitope to which a CD8+ T cell response is desired. Also claimed in the invention are the nucleic acid sequences that encode the fusion agents. Recently, there has been great interest in developing vaccines to induce protective CD8+ T cell responses, however, there are practical obstacles to this goal. Although purified antigenic peptides are effectively presented in vitro, introduced in a purified form they often do not stimulate effective T cell responses in vivo because the antigens are insufficiently immunogenic and too easily degraded. Adjuvants or infectious ''carriers'' often can enhance these immune responses, however, these added agents can cause unacceptable local or systemic side effects. The present invention increases antigen stability and promotes in vivo responses in the absence of an adjuvant or active infection.

The invention describes three variants of lemA, an antigen recognized by CD8+ cells in mice infected with Listeria monocytogenes. The antigenic and stabilizing properties of lemA can be accounted for by the covalent association of the immunogenic aminoterminal hexapeptide with the protease resistant scaffolding provided by amino acids 7 to 33 of the lemA sequence (lemA(7–33)). Variants t-lemA, and s-lemA bearing an antigenic sequence immediately preceding lemA(7–33), and lemS containing an immunogenic sequence immediately after lemA(7–33), each induce a CD8+ T cell response and protect the crucial immunogenic oligopeptide from protease degradation. The site of antigen insertion relative to lemA(7–33) can influence antigen processing by preferentially promoting processing either in the cytoplasm or endosomal compartment. Therefore, several embodiments of the invention involve the construction of antigen processing protein molecules and their methods of use. Alternatively, a DNA sequence coding lemA(7–33) may be inserted at an appropriate site to enhance the immunogenicity of the antigenic element coded by a DNA vaccine. In sum, this invention is an attractive, nontoxic alternative to protein/adjuvant combinations in eliciting CD8 responses in vivo and a useful element for enhancing the efficiency with which products coded by DNA vaccines are processed and presented in vivo. Because lemA(7–33) is particularly effective in protecting oligopeptides from proteases, this invention may have particular usefulness in enhancing local T cell at sites such as mucosal surfaces where there may be high proteolytic activity.

For more specific information about the invention or to request a copy of the patent application, please contact Peter Soukas at the telephone number or e-mail listed above. Additionally, please see a related article published in the Journal of Immunology at: 1999;163:6741–6747.

Vibrio cholerae O139 Conjugate Vaccines

Shousun Szu, Zuzana Kossaczka, John Robbins (NICHD)

DHHS Reference No. E–274–00/0 filed 01 Sep 2000 (PCT/US00/24119)

Cholera remains an important public health problem. Epidemic cholera is caused by two Vibrio cholerae serotypes O1 and O139. The disease is spread through contaminated water. According to information reported to the World Health Organization in 1999, nearly 8,500 people died and another 223,000 were sickened with cholera worldwide. This invention is a polysaccharide-protein conjugate vaccine to prevent and treat infection by Vibrio cholerae O139 comprising the capsular polysaccharide (CPS) of V. cholerae O139 conjugated through a dicarboxylic acid dihydrazide linker to a mutant diphtheria toxin carrier. In addition to the conjugation methods, also claimed in the invention are methods of immunization against V. cholerae O139 using the conjugates of the invention. The inventors have shown that the conjugates of the invention elicited in mice high levels of serum antibodies to CPS, a surface antigen of Vibrio cholerae O139, that have vibriocidal activity. Clinical trials of the two most immunogenic conjugates have been planned by the inventors. This invention is further described in Infection and Immunity 68(9), 5037–5043, Sept. 2000.

Dated: December 19, 2001.

Jack Spiegel,

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

[FR Doc. 01–32170 Filed 12–31–01; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases; 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 552(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 Institute of Arthritis and Musculoskeletal and Skin Diseases Special Emphasis Panel.

Date: December 21, 2001.

Time: 8:30 am to 3:00 pm.

Agenda: To review and evaluate grant applications.

Place: Natcher Building, 45 Center Drive, Conference Rooms E1/E2, Bethesda, MD 20892. (Telephone Conference Call)

Contact Person: Tracy A. Shahan, PhD, Scientific Review Administrator, National Institute of Arthritis and Musculoskeletal and Skin Diseases, Natcher Building, MSC 6500, 45 Center Drive, 5AS–25H, Bethesda, MD 20892, (301) 594–4952.

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.

Name of Committee: National Institute of Arthritis and Musculoskeletal and Skin Diseases Special Emphasis Panel.

Date: December 21, 2001.

Time: 3:30 pm to 4:30 pm.

Agenda: To review and evaluate grant applications.

Place: Natcher Building, 45 Center Drive, Conference Rooms E1/E2, Bethesda, MD 20892. (Telephone Conference Call)