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.

SARS Coronavirus MVA Vaccines and Therapy

Bernard Moss (NIAID).
U.S. Provisional Application No. 60/558,995 filed 05 Apr 2004 (DHHS Reference No. E–165–2004/0–US–01).
Licensing Contact: Michael Shmilovich; 301/435–5019; *shmilovm@mail.nih.gov.*

Intranasal or intramuscular inoculations of BALB/c mice with modified vaccinia Ankara (MVA) vector encoding SARS–CoV Spike protein produced serum antibodies that recognized SARS S in ELISA and elicited protective immunity as shown by reduced titers of SARS–CoV in the upper and lower respiratory tracts of mice following challenge. Passive transfer of serum from mice immunized with MVA/S to naive mice also reduced the replication of SARS–CoV in the respiratory tract following challenge, demonstrating the role of antibody to S in protection.

Enhanced Sensitivity ELISA for SARS Diagnostic

Gary J. Nabel *et al.* (NIAID).
U.S. Provisional Application No. 60/503,508 filed 15 Sep 2003 (DHHS Reference No. E–334–2003/0–US–01).
U.S. Provisional Application No. 60/550,317 filed 08 Mar 2004 (DHHS Reference No. E–334–2003/1–US–01).
Licensing Contact: Michael Shmilovich; 301/435–5019; *shmilovm@mail.nih.gov.*

Reagents and protocols for extremely sensitive ELISA for use as a SARS diagnostic are described. The ELISA uses recombinant-expressed nucleoprotein (N) or spike (S) glycoprotein from the SARS coronavirus as capture antigens. As little as five (5) days after onset, detection of antibody response is possible. The ELISA described herein is more sensitive than existing technology because of the N and S proteins; existing ELISAs use formalin-inactivated whole virus or peptides.

E–334–2003/1–US–01 also describes DNA Vaccines (CMV/R–SARS–S plasmid) including a nucleic acid encoding the peptide of SARS Spike glycoprotein, the RSV enhancer, the mouse ubiquitin enhancer (mUBB), and the CMV enhancer (Xu *et al.* 1998 Nature Med. 4: 37–42). Optionally the HTLV–1 R region (Takebe *et al.* 1988 Mol Cell Biol 8: 466–472) is also included.

Interferon-Alpha SARS Treatment

Kathryn C. Zoon, Renqui Hu, Joseph B. Bekisz (NCI).

U.S. Provisional Application filed 30 Apr 2004 (DHHS Reference No. E–278–2003/0–US–01).

Licensing Contact: Michael Shmilovich; 301/435–5019; *shmilovm@mail.nih.gov.*

The Public Health Service seeks a licensee to commercialize protein engineered human interferon alphas for treating and/or preventing a SARS-associated coronaviral infection in humans and other relevant mammalian species.

Soluble SARS Coronavirus Spike Protein (S Protein)

Dimiter S. Dimitrov, Xiadong Xiao (NCI).

U.S. Provisional Application No. 60/489,166 filed 21 Jul 2003 (DHHS Reference No. E–228–2003/0–US–01).

Licensing Contact: Michael Shmilovich; 301/435–5019; *shmilovm@mail.nih.gov.*

The SARS coronavirus is etiologically linked to severe acute respiratory syndrome. Soluble forms of the SARS coronavirus spike protein have been cloned, expressed and characterized, and are available for licensing for use as research reagents, in the development of vaccines and inhibitors of the viral infection, for selection of monoclonal antibodies, and development of kits containing antibodies that bind to the spike protein. The filed patent application additionally claims the associated spike protein polypeptides, peptide fragments, and conserved variants thereof; nucleic acid segments and constructs that encode the spike protein, polypeptides and peptide fragments of the spike protein, and conserved variants thereof and coupled proteins that include the spike protein or a portion thereof and peptidomimetics.

Dated: June 20, 2004.

Steven M. Ferguson,

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

[FR Doc. 04–14750 Filed 6–29–04; 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.

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.

Antibody (Anti-Allergen) Microarray

Jay E. Slater, William J. Finlay, Nicolette DeVore (FDA)
DHHS Reference No. E–044–2004/0—Research Tool
Licensing Contact: Michael Shmilovich; 301/435–5019; *shmilovm@mail.nih.gov*

Available for licensing as a biological material or by material transfer is a microarray with immobilized antibodies specific to particular allergens or allergen epitopes and specifically allergens from an allergen vaccine or extract. Allergen extracts are manufactured and sold worldwide for the diagnosis and treatment of IgE-mediated allergic disease. Each extract contains a variety of active allergenic components (*e.g.*, proteins, carbohydrates and other small molecules) in varying concentrations and immugenicities. Most allergen extracts are non-standardized. These extracts have been labeled either with a designation of extraction ratio (w/v) or with a protein unit designation determined using the Kjeldahl method (protein nitrogen units/mL). There appears to be little correlation between these two designations and biological measures of allergen potency. At

present, there are nineteen standardized allergen extracts available from U.S. manufacturers. Each extract is assigned a potency value for sale to the public. Potency value is an arbitrary measurement based on quantitation of the total protein content and specific allergen content within the allergen extracts (as measured with hyperimmune sheep sera), or by the inhibition of the binding of IgE from pooled allergic sera to reference allergen. These methods are generally crude and provide only integral averages. These averages are non-characteristics of the concentration of individual allergens in the extract and their respective immunoglobulin binding affinities. By contrast, this microarray uses large numbers of engineered antibodies to ''fingerprint'' the test extract. The present invention provides 10–100 allergen specific scFV or F_{ab} immunoglobulins imprinted on a solid matrix in multiple concentrations. The allergen mixture is applied to the array and the pattern of protein binding to each spot is analyzed quantitatively and qualitatively. Thus, large numbers of component allergenic proteins can be assayed quickly and simultaneously.

Epitopes of Ebola Virus Glycoproteins Useful for Vaccine Development

Carolyn A. Wilson et al. (FDA)
U.S. Provisional Application No. 60/532,677 filed 23 Dec 2003 (DHHS Reference No. E–271–2003/0–US–01)
Licensing Contact: Susan Ano; 301/435–5515; *anos@mail.nih.gov*

The current technology describes the identification of amino acid residues on Ebola glycoprotein (GP) critical for virus infection through mutation of residues in the glycoprotein-1 (GP1) of Ebola virus (Zaire strain). The amino acid residues identified through mutational analysis are conserved and can be found in all published sequences of strains of Ebola and Marburg viruses, making them a good target for development into a cross-protective vaccine or antiviral therapy. The mutations could be used to generate non-infectious Ebola viral particles for use in vaccines. These residues in wild-type filoviruses could also be targeted by compounds to prevent viral entry into cells or could potentially represent an epitope (or part of an epitope) for use as an immunogen in a vaccine. Vaccines utilizing these non-infectious particles may be safer than vaccines that use other common approaches, *e.g.* live-attenuated virus vaccines. In addition to the non-infectious particles, this technology describes the polypeptides that form them, the polynucleotide sequences encoding the polypeptides, and vectors comprising the polynucleotides. These additional materials could also form the basis of an Ebola vaccine or antiviral therapy. Also claimed are kits for detection of antibodies to Ebola involving contacting the sample containing antibodies to the polypeptides described in the invention.

Haplotypes of Human Bitter Taste Receptor Genes

Dennis Drayna, Un-Kyung Kim (NIDCD)
U.S. Provisional Application No. 60/480,035 filed 11 Jul 2003 (DHHS Reference No. E–222–2003/0–US–01); PCT Application filed 18 Jun 2004 (DHHS Reference No. E–222–2003/1–PCT–01)
Licensing Contact: Susan Carson; 301/435–5020; *carsonsu@mail.nih.gov*

Bitter taste has evolved in mammals as a crucial, important warning signal against ingestion of poisonous or toxic compounds. However, many beneficial compounds are also bitter and taste masking of bitter tasting pharmaceutical compounds is a billion dollar industry. The diversity of compounds that elicit bitter-taste sensations is very large and more than two dozen members of the T2R bitter taste receptor gene family have been identified. How individuals are genetically predisposed to respond or not to respond to the bitter taste of substances like nicotine and certain foods like broccoli may have broad implications for nutritional status and tobacco use. Large individual differences in the perception of bitterness of these compounds have been well documented, and common allelic variants of a member of the T2R bitter taste receptor gene family have been shown to underlie variation in the ability to taste the bitter compound phenylthiocarbamide (PTC) [DHHS Ref. No. E–169–2001/0–PCT–02].

Scientists at the NIDCD have extended these results to other bitter taste receptors and have sequenced 22 of the 24 known T2R genes in a series of populations worldwide, including Hungarians, Japanese, Cameroonians, Pygmies and South American Indians, and the present invention includes these isolated sequences and their variants. This includes a total of 127 SNPs and 109 different protein coding haplotypes, including those defined for the PTC Receptor (T2R38) [E–169–2001/0]. The inventors showed that 77% of the SNPs identified caused an amino acid substitution in the encoded receptor protein, giving rise to a high degree of receptor protein variation in the population. The frequencies of these different haplotypes have been shown to differ in different populations which will aid in population-specific studies, such as those targeting differences in taste perception between Europeans and Asians, for example.

The invention available for licensing includes these novel SNPs and haplotypes and methods of use, which can be used to better identify and characterize different groups of individuals within and between populations that vary in the their bitter taste abilities. This is important to the food and flavoring industry, for example, where these variants can be used to aid in the development of a variety of taste improvements in foods and orally administered medications.

A related technology also available for licensing is DHHS Ref. No. E–169–2001/0–PCT–02, Phenylthiocarbamide Taste Receptor, International Publication No. WO 03/008627.

Dated: June 24, 2004.

Mark L. Rohrbaugh,

Director, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 04–14777 Filed 6–29–04; 8:45 am]
BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

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Maleiimide Anti-Tumor Phosphatase Inhibitors

Christophe Michejda *et al.* (NCI).