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**Comments Due Date:** Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

Dated: December 7, 2004.

**Peter Savage,**

*Director, DECA, NHLBI.*

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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, 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.

#### Human Monoclonal Antibodies Against Hendra and Nipah Viruses

Dimiter S. Dimitrov et al. (NCI). U.S. Provisional Application filed 1 Nov 2004 (DHHS Reference No. E-004-2005/0-US-01); Related to the Phage Display Library described in DHHS Reference No. E-005-2005/0.

**Licensing Contact:** Michael Shmilovich; 301/435-5019; [shmilovm@mail.nih.gov](mailto:shmilovm@mail.nih.gov).

Available for licensing are neutralizing human monoclonal antibodies against the envelope proteins (Envs) of Hendra virus (HeV) and Nipah virus (NiV) for uses in immunotherapy, vaccine development and as diagnostic or research reagents. Monoclonal antibody variable region fragments (Fabs and scFvs) have been isolated from screening a human phage display library against the Envs. The phage display library (DHHS Ref. No. E-005-2005) is useful for screening other viral or cancer antigens and can be licensed from DHHS under a biological materials license.

In addition to licensing, the technology is available for further development through collaborative research with the inventors via a Cooperative Research and Development Agreement (CRADA).

#### Human Antibody Phage Display Library

Dimiter S. Dimitrov et al. (NCI). DHHS Reference No. E-005-2005/0—Research Tool; Related to the Monoclonal Antibodies Against Hendra and Nipah Viruses described in U.S. Provisional Application filed 1 Nov 2004 (DHHS Reference No. E-004-2005/0-US-01).

**Licensing Contact:** Michael Shmilovich; 301/435-5019; [shmilovm@mail.nih.gov](mailto:shmilovm@mail.nih.gov).

Available for licensing as a biological material for either internal use or commercial distribution is a human F<sub>ab</sub> immunoglobulin/antibody fragment phage display library. The library contains 10<sup>10</sup> F<sub>abs</sub> derived from the peripheral blood of ten (10) healthy human donors. The high quality of the library was demonstrated in the successful selection of high affinity antibodies specific for Hendra and Nipah viruses; however, the library is useful for selecting a variety of antigen specific immunoglobulin/antibody F<sub>ab</sub> fragments especially for cancer or viruses.

In addition to licensing, the technology is available for further development through collaborative research with the inventors via a Cooperative Research and Development Agreement (CRADA).

#### Vaccines Against Crimean-Congo Hemorrhagic Fever

Dimiter Dimitrov and Xiadong Xiao (NCI). U.S. Provisional Patent Application filed 3 Nov 2004 (DHHS Reference Nos. E-299-2004/0-US-01 and E-299-2004/1-US-01).

**Licensing Contact:** Michael Shmilovich; 301/435-5019; [shmilovm@mail.nih.gov](mailto:shmilovm@mail.nih.gov).

Crimean-Congo hemorrhagic fever (CCHF) is a tick-borne public health concern in many regions of the world including Africa, the Middle East, Europe, and Western Asia. The disease is etiologically linked to Crimean-Congo hemorrhagic fever virus (CCHFV) from the *Nairovirus* genus of the *Bunyaviridae* family of viruses and is transmitted primarily through the bite of *Ixodid* ticks. Available for licensing and commercial development are antigens, immunogens, and nucleic acid constructs for the development of vaccines against CCHFV. The antigens and immunogens are peptides corresponding to the soluble ectodomains of CCHFV G1 (Gc) and G2 (Gn) glycoproteins. Also provided are coupled proteins that include soluble peptide fragments derived from the G1 (Gc) or G2 (Gn) ectodomains or portions thereof; peptidomimetics; vaccines; immunogenic compounds methods for vaccination and inhibitors of CCHFV cell entry. Expression vectors and DNA vaccines encoding these peptides are also within the scope of the invention as well as antibodies, aptamers and kits containing antibodies or aptamers that bind to these peptides. CCHFV has been implicated as a pathogen of biodefense significance.

#### Intracellular Contrast Agents for Magnetic Resonance Imaging

Mrinal K. Dewanjee (NIHCC). U.S. Provisional Patent Application filed 8 Oct 2004 (DHHS Reference No. E-291-2004/0-US-01).

**Licensing Contact:** Michael Shmilovich; 301/435-5019; [shmilovm@mail.nih.gov](mailto:shmilovm@mail.nih.gov).

Available for licensing and commercial development are contrast agents for magnetic resonance imaging (MRI). These agents are composed of charge neutral and lipid-soluble complexes of paramagnetic cations bound by chelators. Unlike conventional extra-cellular contrast agents, these agents of the present

invention penetrate into the cells and thus permit higher spatial resolution in MRI. The paramagnetic cation is preferably  $Gd^{+3}$ ,  $Dy^{+3}$  and  $Fe^{+3}$  with three equivalents of a charge neutralizing chelator that provides a neutral lipid-soluble complex of the paramagnetic cation. The complex is extracted rapidly and retained intracellularly, when mammalian cells are incubated in buffer or plasma media. Hence, they may be used in imaging vascular plaque after intra-arterial injection and tracking the distribution patterns of injected immune cells in localizing the inflammatory disease or implanted stem cells in regenerative medicine.

#### **Electromagnetically Tracked Tissue Ablation Device**

Bradford J. Wood (NIHCC). U.S. Provisional Patent Application filed 5 Nov 2004 (DHHS Reference No. E-278-2004/0-US-01).

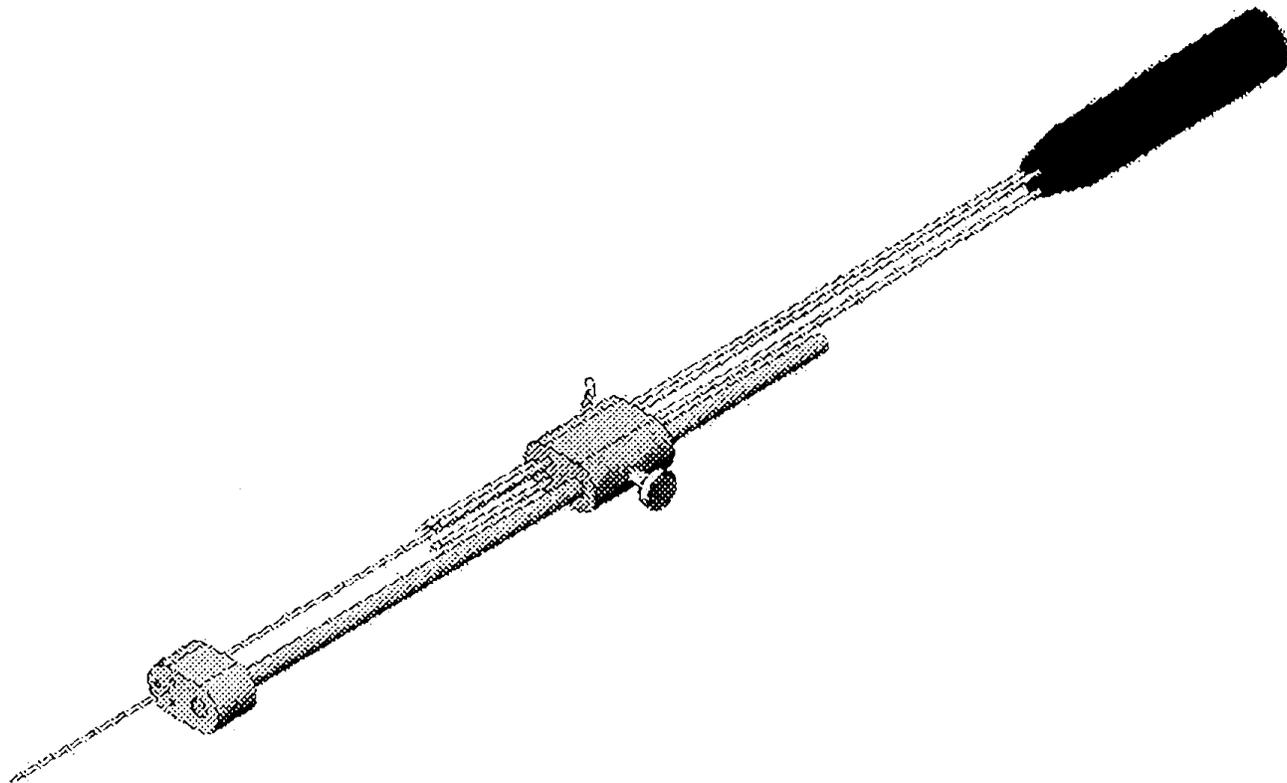
*Licensing Contact:* Michael Shmilovich; 301/435-5019; [shmilovm@mail.nih.gov](mailto:shmilovm@mail.nih.gov).

Available for licensing, development, manufacturing and commercial

distribution is an ablation device coupled with electromagnetic tracking for procedural navigation. Minimally invasive interventions exemplified by devices like this are rapidly increasing in popularity. This device improves accuracy and may improve outcomes by using pre-procedural imaging (like CT, MRI, PET) during procedures, to assist with guidance of ablation probes to a target that shows up on pre-procedural imaging. This allows use of exquisite diagnostic imaging during interventional procedures, that otherwise would not be available. This device is similar to having a miniaturized version of an automobile GPS (global positioning system) on the tip of a small needle. Image guided surgery is not truly "image guided" without being able to use all pre-operative imaging during the procedure. One example allows accurate identification and treatment of a tumor that is only briefly seen on CT scan, then disappears, or is only seen with PET. Tissue burns during thermal ablation, releasing gas that obscures the real-time ultrasound image. This device allows use of CT and other enhanced

imaging during repositioning of ablation needles, which is the most difficult part of the procedure.

One design can include a guidance needle and grid to direct the ablation needle. Another design includes a plate with an aperture and button coupled to the plate wherein the plate has a beveled surface and a slideable hub coupled to the plate by a rod. An added advantage is an inclusion of a plurality of guide apertures to focus the needle. The needle is inserted into and guided by one of the guide apertures of the grid as the needle is introduced into a body of a patient to a target site. The device is useful for therapy or for biopsy and includes a button defining an aperture, a hub defining an aperture being slideably coupled to the button by a rod, and a lock mechanism configured to lock the hub relative to the button on the rod. The system also includes a removable probe inserted through the hub and the button and a miniature magnetically trackable sensor coil that fits inside a 22 Gauge needle. A pictorial representation of the device is shown here.



In addition to licensing, the technology is available for further development through collaborative research with the inventors via a

Cooperative Research and Development Agreement (CRADA).

#### **Grid Etcher for Generating Defined Growth Areas**

Rea Ravin, James Sullivan, Daniel Hoepfner, David Munno, Ronald

McKay (NINDS). U.S. Patent Application filed 14 Oct 2004 (DHHS Reference No. E-125-2004/0-US-01).

*Licensing Contact:* Michael Shmilovich; 301/435-5019; [shmilovm@mail.nih.gov](mailto:shmilovm@mail.nih.gov).

Available for licensing and commercial development is a cell culture tool kit for etching confined growth areas on substrates coated with tissue culture growth matrix, such as fibronectin. The kit includes three components: an etching comb (etcher) with rectangular teats, a back plate, and an open chamber with guides to direct the etcher.

*Overview:* Cells are plated over a glass cover slide previously coated with growth matrix. Perpendicular channels are etched into the culture, removing both growth matrix and plated cells, resulting in rectangular growth areas containing only the cells plated originally to each growth area. This protocol allows high-density cultures to grow freely within a confined growth area. Specifically, this procedure prevents emigration out of the growth area and also prevents immigration from individual cells or sphere clusters into the growth area, common if cells are plated on pre-defined surfaces.

*Method:* A coated cover slide is plated with cells. The cover slide is then sandwiched between the back plate, and open chamber with etching guides, then secured in place. The chamber is filled with media and the etcher is drawn across the cover slip to generate a first set of channels. The etcher is then drawn across the cover slip in a perpendicular direction to generate a second set of channels, resulting in rectangular growth areas. The number of the teats on the etcher determines the number of squares in the grid, the width of each teat will determine the distance between the squares and the gap between the teats will determine the size of the squares.

This tool kit enables the production of a slide for monitoring dynamic cell processes especially for the proliferation and migration of stem cells or other migratory cells. Beside complexity, a significant problem with existing containment systems is the inability to keep cells within the field of observation and to keep out cells not present in the field of view at the onset of the experiment. The present invention provides a simple and flexible solution that enables long-term cell culture in a defined growth area.

#### **Chlorine Dioxide Gas Decontamination Apparatus**

Deborah E. Wilson, D.Ph. (ORS). U.S. Provisional Application 60/620,095

filed 18 Oct 2004 (DHHS Reference No. E-190-2004/0-US-01).

*Licensing Contact:* Michael Shmilovich; 301/435-5019; [shmilovm@mail.nih.gov](mailto:shmilovm@mail.nih.gov).

Available for licensing and commercial development is an apparatus for decontaminating articles and areas contaminated with one or more biosafety level 2, 3, or 4 pathogens. Particularly, the focus of decontamination is a piece of laboratory equipment, such as a biological safety cabinet. The apparatus is portable, and includes a moveable cart, a source of chlorine dioxide gas, a humidification means, an inlet conduit for introducing a flow of chlorine dioxide gas from the source of chlorine dioxide gas into the environment and for simultaneously humidifying the environment, and an outlet conduit for withdrawing gas from the environment. The apparatus further includes a blower for circulating gas between the environment to the humidifier and vice versa. Of particular advantage, the moveable cart weighs less than 200 pounds. The patent application covering this apparatus can be reviewed under a confidentiality nondisclosure agreement.

Dated: December 9, 2004.

**Steven M. Ferguson,**

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

[FR Doc. 04-27723 Filed 12-17-04; 8:45 am]

**BILLING CODE 4140-01-P**

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#### **Methods and Compositions for Protecting Cells From Ultrasound-Mediated Cytolysis**

Joe Z. Sostaric (NCI), Norio Miyoshi (EM), Peter Riesz (NCI). U.S. Provisional Application No. 60/620,258 filed 19 Oct 2004 (DHHS Reference No. E-311-2004/0-US-01). *Licensing Contact:* Michael Shmilovich; 301/435-5019; [shmilovm@mail.nih.gov](mailto:shmilovm@mail.nih.gov).

Available for licensing and commercial development are methods for protecting cells from ultrasound-mediated cytotoxicity. Therapeutic uses of ultrasound (*e.g.*, sonoporation, thrombolysis, HIFU, sonophoresis, acoustic hemostasis) may induce changes in tissue state, including apoptosis and cytotoxicity, through thermal effects (*e.g.*, hyperthermia), mechanical effects (*e.g.*, acoustic cavitation or through radiation force, acoustic streaming and other ultrasound induced forces), and chemical effects (via sonochemistry or by the activation of solutes by sonoluminescence). Furthermore, ultrasound exposure conditions in biological processes, *e.g.* ultrasound bioreactors, are limited by the need to decrease cytotoxicity of microbes or animal and plant cells. Accordingly, the protecting molecules used to carry out the methods of the invention possess the ability to protect cells against ultrasound mediated cytotoxicity, without hindering ultrasound induced physical effects that could be utilized to create beneficial effects. The protecting solutes are surface active and possess at least one "carbohydrate unit" as described. The solutes include, but are not limited to: alkyl- $\beta$ -D-thioglucopyranoside, alkyl- $\beta$ -D-thiomaltopyranoside, alkyl- $\beta$ -D-galactopyranoside, alkyl- $\beta$ -D-thiogalactopyranoside, or alkyl- $\beta$ -D-maltotriose, hexyl- $\beta$ -D-glucopyranoside, heptyl- $\beta$ -D-glucopyranoside, octyl- $\beta$ -D-glucopyranoside, nonyl- $\beta$ -D-glucopyranoside, hexyl- $\beta$ -D-maltopyranoside, n-octyl- $\beta$ -D-maltopyranoside, n-octyl- $\beta$ -D-thioglucopyranoside, 2-propyl-1-pentyl- $\beta$ -D-maltopyranoside, methyl-6-O-(N-heptylcarbamoyl)- $\alpha$ -D-glucopyranoside, 3-cyclohexyl-1-propyl- $\beta$ -D-glucoside, 6-O-methyl-n-heptylcarboxyl- $\alpha$ -D-glucopyranoside.

In addition to licensing, the technology is available for further