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.

A Transgenic Model of Human Basal Triple Negative Breast Cancer [C3(l)-tag mice]

Description of Invention: Basal triple-negative breast cancer (TNBC) is a common form of human breast cancer for which there are no specific, targeted therapies, unlike hormone-responsive or Her2+ breast cancers. TNBC has a much worse prognosis than hormone receptor + cancer and is disproportionately high in the African-American population. NIH scientists have created and characterized a transgenic model that is currently an excellent mouse model for TNBC that shares important molecular characteristics of human TNBC, making it highly useful for preclinical testing of drugs and novel therapies. This model may provide a valuable means of identifying new drugs and therapies that could be translated to human clinical trials. The mouse model also develops prostate intraepithelial neoplasia and prostate cancer, therefore has also been used for studies of prostate cancer. The studies using the mouse model may fill important public health service needs.

Inventor: Jeffrey E. Green (NCI).

Patent Status: HHS Reference No. E–191–2010/0—Research Tool. Patent protection is not being pursued for this technology.

Licensing Status: Available for licensing under a Biological Materials License Agreement.

Licensing Contact: Betty Tong, Ph.D.; 301–594–6565; *tongb@mail.nih.gov*.

Collaborative Research Opportunity: The Transgenic Oncogenesis and Genomics Section of the Laboratory of Cancer Biology and Genetics, Center for Cancer Research, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this mouse model of TNBC to study cancer biology and for preclinical testing. Please contact John Hewes, Ph.D. at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Improved Pepper Spray for Repellency and Incapacitation

Description of Invention: Non-lethal means of temporarily incapacitating a person are greatly needed for law enforcement and for personal protection. A common approach is to use pepper spray. Although current pepper sprays are effective, they cause pain for excessively long periods, and could be life threatening for people who suffer from asthma and have hypersensitive airways. This technology describes a composition for use in an aerosol or spray, that when administered, causes a painful stimulation and incapacitates a person for only a brief period. This technology may improve safety over currently available pepper sprays.

Application: Incapacitating pepper spray with reduced toxicity.

Development Status: Early stage.

Inventors: Peter M. Blumberg and Larry V. Pearce (NCI).

Patent Status: U.S. Provisional Application No. 61/340,063 filed 12 Mar 2010 (HHS Reference No. E–048–2010/0–US–01).

Licensing Status: Available for licensing.

Licensing Contact: Charlene Sydnor, Ph.D.; 301–435–4689; *sydnorc@mail.nih.gov*.

Dated: July 12, 2010.

Richard U. Rodriguez,

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

[FR Doc. 2010–17430 Filed 7–15–10; 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.

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Novel Antigen for Use as Vaccine Against Nematode Infection

Description of Invention: This invention describes a new vaccine against *Strongyoides stercoralis*, which establishes a parasitic infection that affects an estimated 100–200 million people worldwide. The potential for fatal disease associated with S. stercoralis infection and the difficulty in treating hyperinfection underscores the need for prophylactic vaccines against the disease. This vaccine uses *S. stercoralis* immunoreactive antigen (SsIR); a novel antigen capable of providing 70–90% protection for mice immunized with the antigen. In addition, sera from immunized mice have also been used to effectively protect naïve mice from infection.

The invention may also have potential use in diminishing allergic responses, as *Strongyoides stercoralis* infection has been shown to reduce the murine response to allergens. Consequently, SsIR may be used to immunize individuals and reduce the allergic response. The antigen may also be used to identify homologous antigens from other parasitic nematodes that may be important for vaccine development.

Applications:

• Vaccines against *S. stercoralis* infection.

• Discovery and use of other anti-parasitic antigens for vaccines.

• Potential for allergy therapy.

Development Status: Early stage.

Market: 100–200 million worldwide.

Inventors: Thomas B. Nutman (NIAID) and David Abraham (Thomas Jefferson University).

Related Publication: Kerepesi LA, Keiser PB, Nolan TJ, Schad GA, Abraham D, Nutman TB. DNA immunization with Na+-K+ ATPase (Sseat-6) induces protective immunity to larval *Strongyloides stercoralis* in mice. Infect Immun. 2005 Apr;73(4):2298–2305. [PubMed: 15784574].

Patent Status: U.S. Provisional Application No. 61/301,426 filed 04 Feb 2010 (HHS Reference No. E–084–2010/0–US–01).

Licensing Status: Available for licensing.

Licensing Contact: Susan Ano, Ph.D.; 301–435–5515; *anos@mail.nih.gov*; or Eric Odom; 301–435–5009; *odome@mail.nih.gov.*

Collaborative Research Opportunity: The Laboratory of Parasitic Diseases at NIAID is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact Thomas Nutman, Ph.D at *tnutman@niaid.nih.gov* or Johanna Schneider, Ph.D at *schneiderjs@niaid.nih.gov* for more information.

Mouse Model of Individual Unresponsive to Interferon

Description of Invention: NIAID has developed a mouse model that produces very high levels of Interferon-alpha-receptor 2 (IFNAR2), both in liver cells and free-floating in serum.

Chronic co-infection of HIV and hepatitis C virus (HCV) is associated with increased overall morbidity and mortality compared to those infected with just one virus. Recent data further suggests that co-infection is also associated with a more rapid progression of liver disease, higher HCV RNA viral levels, decreased cure rate of HCV, and increased toxicities of anti-HCV therapy. Finally, clinical trials have shown that many patients infected with both viruses do not respond to Interferon-based therapy. Research strongly suggests that non-responding patients have an increased level of a free-floating form of IFNAR2, which could block Interferon activity.

Resistance to Interferon therapy also occurs in other diseases, such as autoimmune diseases (e.g., lupus, scleroderma, psoriasis, vasculitis) and certain forms of cancer (e.g., Kaposi's sarcoma, follicular lymphoma). The various means by which resistance arises is currently being researched.

Applications:

• Study of mechanisms of resistance to Interferon therapy in selected diseases, such as HCV/HIV co-infection and certain cancers.

• Study of Interferon-alpha in auto-immune diseases such as lupus, scleroderma, psoriasis, and vasculitis.

• Drug design and screening.

Advantages:

• A model to screen, develop, and test drugs for HCV among HCV/HIV co-infected patients not responding to Interferon.

• A model for basic research, to study the biology and role of IFNAR2 and its function, along with the role of the Interferon receptor in the development of disease resulting from activation of the immune system.

Development Status: Proof-of-principle studies showing that the mice represent HCV/HIV co-infected individuals not responding to Interferon treatment.

Market: HIV/HCV co-infection is documented in one-third of all HIV-infected persons in the United States, an estimated 250,000 people. Moreover, certain cancers (*e.g.*, Kaposi's sarcoma, follicular lymphoma) normally treated with Interferon-alpha either show initial resistance or develop resistance during therapy, but the mechanism of resistance is highly complex; this mouse model will be useful in learning the paths through which resistance develops, and perhaps in designing strategies to overcome resistance. Finally, autoimmune diseases known to be caused (in whole or in part) by Interferon-alpha include lupus, scleroderma, psoriasis, and vasculitis.

Inventors: Shyamasundaran Kottilil (NIAID), Howard Young (NCI), Michael Polis (NIAID), Anthony Suffredini (NIHCC).

Patent Status: HHS Reference No. E–106–2009/0—Research Tool. Patent protection is not being pursued for this technology.

Licensing Status: Available for non-exclusive Biological Materials Licensing.

Licensing Contact: Susan Ano, Ph.D. 301–435–5515; *anos@mail.nih.gov.*

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases, Laboratory of Immunoregulation, is interested in collaborative research directed toward molecular strategies for vaccine and antiviral development, and animal models of viral hepatitis C. Please contact William Ronnenberg at 301–451–3522 or *wronnenberg@niaid.nih.gov* for more information.

Microwave-Assisted Freeze Substitution of Biological and Biomedical Samples

Description of Invention: Freeze substitution fixation (FS) of hydrated samples frozen in vitreous ice provides exceptional preservation of structure for light and electron microscopy, and enables immunological detection of thermo-labile antigens that otherwise are damaged/destroyed by processing at ambient or elevated temperatures. Its use as a research tool or in clinical pathology has, however, been limited by the relatively lengthy periods required for passive diffusion of fixatives and organic solvents into the frozen hydrated material.

The invention utilizes controlled microwave (MW) irradiation to accelerate the FS process; and comprises systems, devices and methods for microwave-assisted processing of samples under cryo-conditions. The entire MWFS procedure has been accomplished in less than 4 hours as compared to the approximately 2–5 days required for FS.

Applications:

• Provides superior preservation and rapid turnaround in research and high throughput clinical laboratory settings.

• Applicable to a broad range of biological samples, hydrogels, and other hydrated materials.

• Processing for light and electron microscopy.

• Low-temperature synthetic and analytical chemistry.

Advantages:

• Reduces processing periods from days to hours.

• Improves preservation, approaching native state.

• Enables uncomplicated, programmable operation.

• Provides excellent reproducibility.

Development Status:

• Proof of concept with varied biological samples.

• Adaptation of existing equipment with manual processing.

• Proposed designs for instrumentation and automation.

Inventors: David W. Dorward, Vinod Nair, Elizabeth R. Fischer, Bryan Hansen (NIAID).

Patent Status: Filed PCT, Publication Number WO 2010/028164; Priority Date: 2008–09–05 (HHS Reference No. E–238–2008/2–PCT–01).

Licensing Status: Available for licensing.

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

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases, Research Technologies Branch, Electron Microscopy Unit, is interested in collaborative research to further develop, evaluate, or commercialize potential applications of this invention, including design and development of instrumentation for conducting MWFS. Please contact Barry U. Buchbinder, Ph.D., NIAID/OTD, at 301–594–1696 or *bbuchbinder@niaid.nih.gov*, for more information.

Treatments for Smith-Lemli-Opitz Syndrome and Other Disorders of Cholesterol Biosynthesis

Description of Invention: This technology provides methods for treating Smith-Lemli-Opitz Syndrome and other disorders of cholesterol biosynthesis.

Smith-Lemli-Opitz Syndrome (SLOS) is an autosomal recessive disorder caused by an inborn error of cholesterol biosynthesis. It affects an estimated one in 20,000 to 60,000 newborns, and is most prevalent in Caucasians of Central European ancestry. It is characterized by distinctive facial features, microcephaly, mental retardation or learning disabilities, and behavioral problems, as well as malformations in many parts of the body, such as the heart, lungs, kidneys, gastrointestinal tract, and genitalia. However, the clinical manifestations of this disease can vary widely, ranging from relatively moderate symptoms to profoundly severe and life-threatening symptoms. At least 95% of SLOS patients present with some degree of mental retardation and learning disability.

Biochemically, SLOS is caused by disruption of the DHCR7 gene, which is responsible for the final step in the production of cholesterol; this results in low cholesterol levels and an accumulation of toxic byproducts of cholesterol biosynthesis in the blood, nervous system, and other tissues. Supplementary dietary cholesterol is provided to SLOS patients, but is often of limited clinical benefit; because levels of byproducts remain high, they may interfere with the uptake of free cholesterol.

Although some of the behavioral and learning problems are due to developmental problems, a portion of these symptoms are likely due to a biochemical disturbance. That biochemical disturbance is potentially treatable.

In their recent work, the inventors have discovered that the accumulation in SLOS cells of the cholesterol precursor 7–DHC causes abnormal sphingolipid storage and transport, resulting in a cellular phenotype similar to that observed in the lysosomal storage disease Niemann-Pick type C (NPC). They have also discovered that treatment with inhibitors of sphingolipid biosynthesis corrects these abnormalities, and thus such inhibitors are of potential therapeutic benefit for the treatment of SLOS, as well as for other diseases exhibiting similar defects in sphingolipid trafficking.

This technology claims compounds that inhibit sphingolipid biosynthesis for use in treating diseases which have a secondary Niemann-Pick type C disease-like cellular phenotype, including SLOS, as well as methods of treatment and pharmaceutical compositions.

Applications: Development of therapeutics for Smith-Lemli-Opitz Syndrome and other diseases which have a secondary Niemann-Pick type C disease-like cellular phenotype, which includes inborn errors of cholesterol biosynthesis, Huntington's disease, cystic fibrosis, and autism.

Development Status: In vitro studies have been performed using a sphingolipid biosynthesis inhibitor.

Inventors: Forbes D. Porter *et al.* (NICHD).

Related Publications:

1. FD Porter. Malformation syndromes due to inborn errors of cholesterol synthesis. J Clin Invest. 2002 Sep 15; 110(6):715–724. [PubMed: 12235098]

2. XS Jiang *et al.* Quantitative proteomic analysis of inborn errors of cholesterol synthesis: Identification of altered metabolic pathways in DHCR7 and SC5D deficiency. Mol Cell Proteomics. 2010 Mar 19; Epub ahead of print. [PubMed: 20305089]

3. XS Jiang *et al.* Activation of Rho GTPases in Smith-Lemli-Opitz syndrome: pathophysiological and clinical implications. Hum Mol Genet. 2010 Apr 1;19(7):1347–1357. [PubMed: 20067919]

4. Tierney *et al.* Analysis of short-term behavioral effects of dietary cholesterol supplementation in Smith-Lemli-Opitz syndrome. Am J Med Genet A. 2010 Jan;152A(1):91–95. [PubMed: 20014133]

Patent Status:

- U.S. Patent Application No. 12/666,279 filed 19 Jan 2010 (HHS Reference No. E–206–2007/0–US–06).
- Related International patent applications.

Licensing Status: Available for licensing.

Licensing Contact: Tara Kirby, Ph.D.; 301–435–4426; *tarak@mail.nih.gov.*

Collaborative Research Opportunity: The National Institute of Child Health and Human Development, Section on Molecular Dysmorphology, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact Alan Hubbs, Ph.D. at 301–594–4263 or *hubbsa@mail.nih.gov* for more information.

Dated: July 12, 2010.

Richard U. Rodriguez,

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

[FR Doc. 2010–17428 Filed 7–15–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–2900–FN2]

Medicare and Medicaid Programs; Approval of the Community Health Accreditation Program for Continued Deeming Authority for Hospices

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final notice of Removal of Conditional Probationary Status.

SUMMARY: Based on our review and observations, we have determined that the standards and processes used by the Community Health Accreditation Program (CHAP) hospice accreditation program meet or exceed our requirements. This final notice announces our decision to approve without condition CHAP's request for continued recognition as a national accreditation program for hospices seeking to participate in the Medicare or Medicaid programs.

DATES: *Effective Date:* This final notice is effective November 20, 2009 through November 20, 2012.

FOR FURTHER INFORMATION CONTACT:

Cindy Melanson, (410) 786–0310.
Patricia Chmielewski (410) 786–6899.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services in a hospice, provided certain requirements are met. Section 1861(dd)(1) of the Social Security Act (the Act) establishes distinct criteria for entities seeking designation as a hospice