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.

Protection Against Vertical Transmission of Pathogenic Infections

Drs. Gene Shearer and Maria T. Rugeles (NCI).

DHHS Reference No. E–225–2003/0–US–01 filed 22 May 2003.

Licensing Contact: Sally Hu; 301/435–5606; *hus@mail.nih.gov.*

This invention describes the treatment of pregnant women who are infected with HIV–1 (or other infectious agents that would be harmful to their fetuses and/or newborns) to reduce the risk of vertical transmission of the infectious agents. The treatment could potentially be accomplished by treating the pregnant women with recombinant ribonucleases (RNases), or by immunizing the women with allogeneic leukocytes that could stimulate the production of endogenous RNases. Since alloantigen stimulation of blood leukocytes from healthy individuals results in production of ribonucleases (RNases) that inhibit HIV–1 and HTLV–1 replication, alloimmunization of at risk or infected pregnant females would be protective for their newborns from infection of different pathogens, including HIV–1 and HTLV–1. Thus, this invention may provide a cost effective and a therapeutically effective means of preventing vertical transmission of pathogens, including HIV–1 and HTLV–1.

Inhibition of HIV–1 Replication by the Ribonuclease, Recombinant Angiogenin

Drs. Gene Shearer, Joost J. Oppenheim, Maria T. Rugeles, and Susanna M. Rybak (NCI).

DHHS Reference No. E–327–2002/0-US–01 filed 22 May 2003.

Licensing Contact: Sally Hu; 301/435–5606; *hus@mail.nih.gov.*

This invention describes the inhibition of human immunodeficiency virus-1 (HIV–1) replication by recombinant angiogenin, a ribonuclease (RNase). Ribonucleases have been shown to inhibit HIV–1 replication in chronically-infected cell lines. This invention has demonstrated that angiogenin is a potent inhibitor of HIV–1 replication. For example, angiogenin inhibits HIV–1 replication in primary activated T lymphocyte cultures as well as chronically infected cell lines. Since inhibition of HIV–1 replication in primary activated T lymphocytes would decrease the risk of HIV spreading to other T cells, angiogenin has several advantages over other known ribonucleases that are used to inhibit HIV replication. Furthermore, this invention raised the possibility that angiogenin could be used in lower doses for inhibiting HIV replication and would be less toxic as compared to other ribonucleases. Thus, angiogenin may be an RNase of choice for treating patients with AIDS and this invention would overcome some of the problems involved in current ribonucleolytic HIV treatments.

Dated: August 18, 2003.

Steven M. Ferguson,

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

[FR Doc. 03–21694 Filed 8–25–03; 8:45 am]

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Container for Drying Biological Samples, Method of Making Such Container, and Method of Using Same

Geoffrey L. Kidd (NEI).

U.S. Patent Application Serial No. 10/238,147 filed 09 Sep 2002 (DHHS Reference No. E–304–2003/0–US–01).

Licensing Contact: Marlene Astor, 301/435–4426, or David Sadowski, 301/435–5525.

Problem Addressed by This Invention: Many materials, such as drugs, growth factors, etc., must be kept sterile and must be aliquotted for storage. Usually, these aliquots are best stored lyophilized. When compared to freezing in solution, lyophilization offers more than twenty-fold longer shelf-lives for these labile compunds. Yet, researchers have never had a way to keep aliquots sterile through the lyophilization process. Consequently, each aliquot has had to be filter-sterilized when reconstituted for use. This process has the disadvantages of consuming: excessive filters, syringes, sterile receptacles, and time; and may result in serious loss of precious sample due to absorption by the filters—especially with small samples. Alternatively, researchers have had to forego lyophilization and store their sterile solutions in the less-stable frozen form.

Solution Offered by This Invention: The multi-well plates of this invention provide venting through a filter element thereby permitting a sterile solution to remain sterile throughout lyophilization, even after the vacuum is released and air reenters the multi-well plate. Thus, a starting solution is simply filter-sterilized while in a relatively large volume, using a single filter and therefore suffering minimal loss and consuming little time. It is then aliquotted into a multi-well plate and lyophilized. The plate may then be transferred directly to the freezer, if

desired. The compound is reconstituted when needed, and may then be used immediately without further filtration.

Potential Applications of This Invention: All researchers worldwide who utilize sterile, labile compounds will have an interest in this product, including governmental, university, institutional, and drug company laboratories. Most notably in need are investigators involved in drug-testing, which is normally done either in cell cultures, laboratory animals, or humans, and which requires sterility of many aliquots of many drugs. Additionally, this product will have a large market relating to basic research utilizing microbial, plant, or animal cell or organ cultures, to which sterile compounds such as growth factors are commonly added. Research in drugs, growth factors, etc., is expanding ever more rapidly, and generally requires a cell culture system in which to study such compounds. Most of these compounds are quite expensive. Loss of potency during storage and loss of material during filtration are widespread problems which may be overcome with this invention. Therefore, there exists a tremendous need and immense market for these multi-well plates.

Dated: August 14, 2003.

Steven M. Ferguson,

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

[FR Doc. 03–21695 Filed 8–25–03; 8:45 am]

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LMNA Gene and Its Involvement in Hutchinson-Gilford Progeria Syndrome (HGPS) and Arteriosclerosis

B. Maria H. Eriksson and Francis S. Collins (NHGRI). Serial No. 60/419,541 filed 18 Oct 2002 (DHHS Reference No. E–020–2003/0–US–01) and Serial No. 60/463,084 filed 14 Apr 2003 (DHHS Reference No. E–131–2003/0–US–01).

Licensing Contact: Fatima Sayyid; 301/435–4521; *sayyidf@mail.nih.gov.*

Hutchinson-Gilford Progeria Syndrome (HGPS) is a very rare progressive childhood disorder characterized by premature aging (progeria). The most common cause of death is from arteriosclerosis and few children affected by HGPS live beyond their teens. The invention identifies point mutations in the LMNA gene, a gene which encodes a nuclear lamin protein, as the cause of HGPS. These mutations activate a cryptic splice site within the LMNA gene which leads to the excision of a portion of an exon and the subsequent generation of a Lamin A protein with an internal deletion of fifty (50) amino acids. The identification of mutations associated with HGPS could lead to breakthroughs in detection, diagnosis, and treatment of HGPS and related or similar conditions, including arteriosclerosis and aging. See also Eriksson, M. et al ''Recurrent de novo point mutations in lamin A cause Hutchinson-Gilford progeria syndrome'' Nature 423, 293–298 (2003).

Synthesis of Proteins by Cell-Free Protein Expression

Deb K. Chatterjee (NCI). DHHS Reference No. E–328–2002/0–US–01 filed 11 Mar 2003.

Licensing Contact: Fatima Sayyid; 301/435–4521; *sayyidf@mail.nih.gov.*

Cell-free protein expression is becoming a valuable tool for rapid and economical production of recombinant proteins. In conventional cell-free protein synthesis systems, the ATP (high energy) supply is accomplished by secondary energy regenerating sources containing high-energy phosphate bonds. The sources include glucose (G), glucose-6-phosphate (G–6P), phosphoenolpyruvate (PEP), acetyl phosphate (AP), creatine phosphate (CP) or pyruvate. However, for some of these systems (G, G–6P and pyruvate) require the addition of exogenous enzymatic cofactors such as NAD/NADH, adding considerable expense to the system. In addition, the conventional systems (PEP, AP or CP) are also mired by unproductive enzymatic degradation of energy sources and unproductive consumption of ATP resulting in lower yields of protein.

The present invention offers a new ATP regeneration system for cell-free protein expression, using one of the early intermediates of the glycolytic pathway as the secondary energy source. The new energy source, costs only a fraction of the conventional substrates, provides chemical energy for protein synthesis without the addition of an exogenous enzymatic cofactor, thereby reducing the costs of the system. Moreover, the present system improves efficiency of protein synthesis by several folds by providing an improved energy regeneration system and protein-folding machinery.

Cycloxygenase Inhibition With Nitroxyl

David A. Wink *et al.* (NCI). Serial No. 60/470,320 filed 13 May 2003 (DHHS Reference No. E–301–2002/0–US–01).

Licensing Contact: Fatima Sayyid; 301/435–4521; *sayyidf@mail.nih.gov.*

Inflammation is initiated and maintained by the overproduction of prostaglandins in injured cells. Cyclooxygenase (COX) regulates the production of prostaglandins. As the rate-limiting step for prostaglandin synthesis, the COX pathway is the primary target for anti-inflammatory drugs. Inhibition of COX accounts for the activity of the non-steroidal anti-inflammatory drugs (NSAIDs), such as aspirin, acetaminophen, ibuprofen, naproxen, indomethacin. However, these drugs are nonselective COX inhibitors. While they inhibit the activity of COX–2 in inflammation, they also interfere with the activity of COX–1 in non-inflamed cells. The inhibition of COX–1 produces undesirable side effects, such as gastrointestinal bleeding and renal failure. Therefore, agents that selectively inhibit COX–2 over COX–1 are desirable for the treatment of inflammation. Moreover, COX–2 inhibiting compounds have been reported to be useful in treating a variety of conditions, such as general pain, osteoarthritis, rheumatoid arthritis, menstrual pain associated with primary dysmenorrhea, cancers, Alzheimer's disease and diabetes.

The present invention relates to methods of using nitroxyl to selectively inhibit COX–2 activity. Also disclosed are methods of using nitroxyl to treat conditions that respond favorably to COX–2 inhibition. Nitroxyl-donating compounds include nitroxyl-donating