opportunity to provide information to the Selection Committee through their capability statements. The Capability Statement should not exceed 10 pages and should address the following selection criteria:

(1) The statement should provide specific details regarding the safety and efficacy of the proposed anti-obesity agency for long-term use in obese diabetic patients with a description how it might be utilized in SHOW.

(2) The statement should include a detailed plan demonstrating the ability of the Collaborator to provide sufficient quantities of the agent in a timely manner for the duration of the study.

(3) The statement should outline outcome measures proposed by the Collaborator which support the aims of SHOW. The specifies of the proposed outcome measures and the proposed support could include, but not be limited to the following: Specific funding commitment to support the advancement of scientific research, personnel, services, facilities, equipment, or other resources that would contribute to the conduct of the trail.

(4) The statement must address willingness to promptly publish research results and ability to be bound by PHS intellectual property policies (see CRADA: http://www.nih.gov/od/ott/crada198.htm).

Dated: May 26, 1999.

Jack Spiegel,

Director, Division of Technology Development and Transfer, Office of Technology Transfer.

[FR Doc. 99–14245 Filed 6–4–99; 8:45 am]

BILLING CODE 4140–01–M

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.

Acylated Oligopeptide Derivatives Having Cell Signal Inhibiting Activity

Terrence R. Burke, Jr. (NCI)

Serial No. 09/236,160 filed 22 Jan 99

Licensing Contact: Richard Rodriguez; 301/496–7056, ext. 287; e-mail: rr154z@nih.gov

The invention is directed to pharmaceutically active compounds comprising an N-oxalyl peptide structure. These compounds have the ability to disrupt the interaction between SH2 domain (e.g., Grb2) containing proteins, and proteins with phosphorylated moieties, especially phosphorylated tyrosine moieties on protein tyrosine kinase (PTK) receptors. The effect of inhibiting the association of SH2 domain-containing proteins with PTKs is to inhibit downstream signaling through one or more specifically targeted effector proteins. Examples of these SH2-containing proteins include, but are not limited to, Src, Lck, Fps, ras-GTPase activating protein, Fyn, Lyk, Fgr, Fes, Zap-70, Bcr-Abl, JAK1 and JAK2. These compounds could prove highly useful for the treatment of some cancers. In particular, Grb2 SH2 domains afford an ideal target because they provide a critical link between growth factor receptor PTKs and downstream signaling events involving ras-proteins which have been directly implicated with oncogenic processes. Examples of this include: members of the epidermal growth factor receptor PTK family (ErbB-2) which are found in many breast cancers; the hepatocytes growth factor/scatter factor (Met) PTK which is overexpressed in many human tumors; and the Bcr-Abl PTK which is necessary for Philadelphia chromosome positive leukemia. The development of this technology could therefore provide for the design and use of powerful therapeutics for disease states where signal transduction becomes deregulated.

Water-Insoluble Drug Delivery System

E Tabibi, E Ezennia, BR Vishnuvajjala, S Gupta (NCI)

Serial No. 60/113,423 filed 22 Dec 98

Licensing Contact: Girish Barua; 301/496–7056, ext. 263; e-mail: gb18t@nih.gov

This technology describes an improved, stable drug delivery system for water-soluble drugs, in particular 17-allylaminogeldanamycin (17–AAG) and a pharmaceutical composition comprising such a drug delivery system, as well as methods for preparing the drug delivery system. The water-insoluble drug is dissolved in a water miscible organic solvent that forms a continuous phase with water and a surface active agent. The application of this technology enables the more effective delivery of drugs such as geldanamycin and 17–AAG, with preparation of the system requiring less complex processing steps.

Nucleosides for Imaging and Treatment Applications

Jerry M. Collins, Raymond W. Klecker, Aspandiar G. Katki, Lawrence Anderson (FDA).

DHHS Reference No. E–058–97/1 filed 30 Oct 98; PCT/US98/23109

Licensing Contact: John Fahner-Vihtelic; 301/496–7735 ext. 270; e-mail: jf36z@nih. gov

The present application describes recently developed nucleosides that provide for (1) external imaging of tumor cell proliferation, (2) noninvasive determination of which tumors would be sensitive to drug therapy, and (3) potential utility as a novel antitumor treatment approach. No comparable procedures are available to determine, prior to treatment, which tumors are likely to respond to a given therapeutic approach. This invention also has the ability to rapidly evaluate the success or failure of treatment, during the course of therapy. As imaging agents, these nucleosides are directly targeted towards specific events, rather than broad measures of effect such as fluorodeoxyglucose. There is no currently available treatment for tumors with high levels of drug resistance, specifically due to overexpression of the key enzyme, thymidylate synthase. The utility of these inventions has been demonstrated in cultured human tumor cells, and preclinical toxicology studies have been conducted which permit entry into initial human testing.

Virally Mediated Gene Therapy for the Control of Chronic or Persistent Pain

MJ Iadarola, RM Caudle, AA Finegold, AJ Mannes (NIDCR)

DHHS Reference No. E–044–98/0 filed 23 Sep 98 Licensing Contact: Kai Chen; 301/496–7056 ext. 247; e-mail: kc169a@nih.gov

Current treatments for pain, especially chronic pain, are only partially effective and can eventually involve procedures that are invasive or associated with unacceptable side effects. In vivo gene transfer could be used to directly modulate pain and provide a long-term pain control. This invention describes a method of using an adenovirus or an adeno-associated virus that are genetically engineered to deliver DNA encoded peptides or proteins to neurons involved in the transmission of pain. The invention provides for a novel means to treat chronic pain by administering a beta-endorphin-expressing recombinant adenovirus into the subarachnoid space. The recombinant virus infects the pia mater connective tissue cells and the infected cells express the fusion protein, wherein the fusion protein is cleaved and the neuroactive product is secreted into spinal cord parenchymal tissue in an amount effective to treat the chronic pain but not significantly affecting basal nociceptive responses. The invention demonstrates a gene transfer approach to treatment of chronic pain disorders or cancer pain, and may be generalized to spinal cord injury or neurodegenerative disorders.

O^2-Arylated or O^2-Glycosylated 1-Substituted Diazen-1-ium-1,2-diolates and O^2-Substituted 1-[(2-Carboxylato) Pyrolidin-1-yl] Diazen-1-ium-1,2-diolates

JE Saavedra, LK Keefer, A Srinivasan, C Bogdan, WG Rice, X Ji, (NCI)

DHHS Reference No. E–093–96/3 filed 26 Sep 97 (U.S. Patent Application Serial No. 09/254,301 filed 03 Mar 99, based on Provisional U.S. Patent Applications No. 60/026,816 filed 27 Sep 96, No. 60/045,917 filed 07 May 97, and No. 60/051,696 filed 03 Jul 97)

Licensing Contact: Kai Chen; 301/496–7056 ext. 247; e-mail: kc169a@nih.gov

Diazeniumdiolates are compounds that contain, an N_2O_2 functional group. These compounds are potentially useful as prodrugs because they generate nitric oxide upon degradation. Nitric oxide (NO) plays a role in regulation of blood pressure, inflammation, neurotransmission, macrophage-induced cytostasis, and cytotoxicity. NO is also important in the protection of the gastric mucosa, relaxation of smooth muscle, and control of the aggregation state of blood cells. Derivatives of diazeniumdiolates have been produced that degrade under differing environmental conditions, allowing for selective delivery of nitric oxide in a manner dependent on environment. A new series of diazeniumdiolate derivatives has been synthesized that are stable in neutral to acidic environments and generate nitric oxide in basic or nucleophilic environments. These derivatives are potentially suited to the delivery of nitric oxide to basic or nucleophilic compartments within the body. They may be useful for inactivating proteins to prevent detoxification of chemotherapeutic agents or disruption of proteins active in tumor formation, infection, or regulatory activities. The compounds are stable in an aqueous environment but can be activated by enzymatic action to release nitric oxide that is believed to be useful in treating fulminant liver failure, respiratory problems, impotence, and a variety of cardiovascular/hematologic disorders. The diazeniumdiolates have also been derivatized by their incorporation into polymers. These compounds may allow for site specific delivery of nitric oxide. Overall, these compounds appear to be applicable toward the wide variety of processes involving nitric oxide.

Immunologically Active Peptides From the HIV Envelope Protein Eliciting Both Antibody and T Cell Responses

William R. Kenealy, Stephen R. Petteway and Paul J. Durda

U.S. Patent No. 5,562,905 issued 08 Oct 96

Licensing Contact: Robert Benson; 301/496–7056 ext. 267; e-mail rb20m@nih.gov

This invention is a series of chemically synthesized peptides of about 15 amino acids in length from the gp160 envelope protein of various isolates of HIV–1. Antibodies raised against the peptides block proliferation of HIV and block HIV-induced cell fusion in cell culture. The peptides are potential vaccines against HIV infection and monoclonal antibodies raised against the peptides are potentially useful as therapeutics. Foreign equivalent cases to USSN 07/148,692 (Berzofsky et al., PCT/US89/00712) are also available for licensing.

The NIH has many other patents and pending patent applications, most foreign filed, claiming various peptides from the HIV envelope protein that are T helper epitopes, CTL epitopes and neutralizing antibody epitopes discovered in the laboratory of Dr. Jay Berzofsky. Dr. Berzofsky has designed synthetic chimeric peptides (called ''multideterminant'' peptides) that combine a peptide containing several T helper epitopes which can activate many human HLA types (called a ''multicluster'' peptide, and claimed in USSN 08/455,685) with a peptide combining a CTL and neutralizing B cell epitope (called a ''p18'' peptide, and claimed in USSN 07/847,311 and U.S. patents 5,820,865 and 5,562,905). These multideterminant peptides contain only epitopes that lead to protection without containing epitopes that are detrimental to protection. Two of the multicluster chimeric peptides are in clinical trials. Multideterminant peptides are claimed in USSN 08/060,988 and 08/407,252.

Computational Analysis of Nucleic Acid Information Defines Binding Sites

Thomas D. Schneider (NCI), Peter K. Rogan

Serial No. 08/494,115 filed 23 Jun 95; U.S. Patent 5,867,402 issued 02 Feb 99

Licensing Contact: John Fahner-Vihtelic, 301/496–7735, ext. 270; e-mail: jf36z@nih.gov

Current approaches to determine whether a nucleotide change is a benign polymorphism or is associated with a genetic disease rely on sequence comparisons of a substantial number of individuals. This invention embodies a computational method that is able to predict whether a nucleotide change will have a deleterious effect. The claims of this invention relate to a computer program which has the novel feature in that it is designed to calculate the relative importance of a given nucleotide change. This program is unique in that it is capable of predicting the effect that a given nucleotide change would have on a particular sequence such as a known binding site. The method has been successfully applied to predicting the effects of changes at human splice junctions. Further information is available at ''http://www.lecb.ncifcrf.gov/~toms/walker/index.html''.

Dated: May 26, 1999.

Jack Spiegel,

Director, Division of Technology Development and Transfer, Office of Technology Transfer.

[FR Doc. 99–14244 Filed 6–4–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing: Cyanovirin-based Topical Microbicides for Prevention of Sexual Transmission of HIV

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.