III. Opportunity to Submit Domestic Information

As required by section 201(d)(2)(A) of the CSA (21 U.S.C. 811(d)(2)(A)), FDA, on behalf of HHS, invites interested persons to submit comments regarding the nine named drugs. Any comments received will be considered by HHS when it prepares a scientific and medical evaluation of these drugs. HHS will forward a scientific and medical evaluation of these drugs to WHO, through the Secretary of State, for WHO's consideration in deciding whether to recommend international control/decontrol of any of these drugs. Such control could limit, among other things, the manufacture and distribution (import/export) of these drugs and could impose certain recordkeeping requirements on them.

HHS will not now make any recommendations to WHO regarding whether any of these drugs should be subjected to international controls. Instead, HHS will defer such consideration until WHO has made official recommendations to the Commission on Narcotic Drugs, which are expected to be made in early 2006. Any HHS position regarding international control of these drugs will be preceded by another **Federal Register** notice soliciting public comments as required by section 201(d)(2)(B) of the CSA.

IV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the drugs. The abbreviated comment period is necessary to allow sufficient time to prepare and submit the domestic information package by the deadline imposed by WHO. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 5, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–23958 Filed 12–12–05; 8:45 am]

BILLING CODE 4160–01–S

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.

Tri-Functional Nanospheres

Yun-bo Shi (NICHD) *et al.*

U.S. Patent Application No. 11/135,380 filed 24 May 2005 (HHS Reference No. E–145–2005/0–US–01).

Licensing Contact: Cristina Thalhammer-Reyero; 301/435–4507; *thalhamc@mail.nih.gov*.

Available for licensing and commercial development is an invention related to ''biofunctional'' tri-functional nanospheres (TFNs) or multi-functional nanospheres (MFNs) obtained by binding one or more biomaterials, such as folate, IgG, biotin or streptavidin, to fluorescent-magnetic bifunctional nanospheres (BFNs). Unlike other BFNs available, which are virtually all based on having a magnetic core, the present invention is based on mesoporous BFNs with hydrophobic inner cavities. The properties of the TFNs of the subject invention have superior qualities for use for the various applications that require aqueous solutions.

Nanospheres are becoming the materials of choice for a rapidly increasing number of pharmaceutical and biomedical applications, including the use of quantum dots (QDs) and magnetic nanoparticles. Materials with the combined function of fluorescent labeling and magnetic separation have many applications in biomedical science, including those resulting from the encapsulation of both particles in polymer microcapsules. However, these related prior technologies are predominantly dependent on core-shell type technologies. Typically, a magnetic material such as magnetite or a fluorescent particle such as a QD is used as a core. Such a core-shell structure is chemically unstable and disadvantageous for fluorescence applications because the shell tends to absorb either or both of the excitation and emission lights, thus dimming the fluorescent signal. The nanoparticles of this invention are composed of a mesoporous copolymer, a magnetic material embedded into the mesoporous copolymer, a fluorescent nanomaterial concurrently embedded into the mesoporous copolymer, and one or more biomaterials coupled to the mesoporous copolymer.

TFNs and MFNs have multiple uses. When the TFNs are labeled by a single biomaterial, the nanoparticles may specifically bind to a cell, or a protein or any other moiety that to which the biomaterial specifically binds. For instance, the biomaterial may be a small molecule ligand that is specifically bound by a cell surface receptor. MFNs in which two bioagents are coupled to single BFNs allow using one bioagent to target a macromolecule or a cell and using the second one to alter the function/properties of the macromolecule or cell, *e.g.*, using a protein to target a cell and using a toxin or cell death protein to kill the targeted cell, or using a chemical or protein to target a protein within a complex and another one to alter the function of a different component of the complex.

The technology is further described in ''Biofunctionalization of fluorescent-magnetic-biofunctional nanospheres and their applications,'' Guo-Ping Wang, Er-Qun Song, Hai-Yan Xie, Zhi-Ling Zhang, Zhi-Quan Tian, Chao Zuo, Dai-Wen Pang, Dao-Cheng Wu and Yun-Bo Shi; Chemical Communications, 2005, (34), 4276–4278; DOI: 10.1039/b508075d.

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

Efficient Growth of Wild-Type Hepatitis A Virus in Cell Culture for Development of Live Vaccines

Gerarado Kaplan and Krishnamurthy Konduru (FDA).

U.S. Provisional Application No. 60/684,526 filed 28 Jun 2005 (HHS Reference No. E–151–2004/0–US–01).
Licensing Contact: Chekesha S. Clingman; 301/435–5018; *clingmac@mail.nih.gov*.

This technology relates to the development of recombinant wild-type and attenuated Hepatitis A Virus (HAV) vectors capable of growing in cell culture and useful for development of a live HAV vaccine. This technology also encompasses HAV vectors coding for markers that allow the selection of cell lines that support the efficient growth of wild-type and attenuated HAV in culture for diagnostic and environmental monitoring purposes. The currently available killed HAV vaccines are expensive and require a two dose schedule to confer immunity for approximately two decades. Inability of wild-type (wt) HAV to grow efficiently in cell culture has been the major roadblock to developing a live HAV vaccine, which could confer lifelong immunity, be cost-effective and allow eradication of the virus. The inventors have developed recombinant infectious HAV coding for resistance genes against antibiotics that inhibits translation in mammalian cells and provides a selective phenotype that allows selection of cells expressing the phenotype within one week. Also, the inventors have created methods of selecting cells permissive for replication of wild-type and not overly attenuated HAV by utilizing selective or screened phenotypes and antibiotic resistant cell techniques.

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

Internal Control Nucleic Acid Molecule for Real-Time Polymerase Chain Reaction

Michael Vickery, Angelo DePaola, George Blackstone (FDA).
U.S. Provisional Application No. 60/471,121 filed 16 May 2003 (HHS Reference No. E–213–2003/0–US–01);
PCT Application No. PCT/US04/15175 filed 14 May 2004 (HHS Reference No. E–213–2003/0–PCT–02).
Licensing Contact: Michael Shmilovich; 301/435–5019; *shmilovm@mail.nih.gov*.

The invention provides a PCR internal control system for use in both real-time PCR (also known as kinetic or Q–PCR) and conventional PCR. This flexible system has a number of novel design qualities which make it universally adaptable for use in virtually any real-time or conventional PCR assay, including RT–PCR and multiplex PCR applications, regardless of the organism/gene/nucleic acid being targeted. It provides the user/assay developer a choice of control product sizes, fluorogenic probe reporting systems, and thermal cycling options, allowing ease of incorporation into various assay formats and instrument platforms. This unique internal control also can be readily incorporated into virtually any existing quantitative multiplex real-time PCR assay. The invention also provides methods of using the internal control system and kits of the invention.

Additional information may be found in Vickery *et al.*, ''Detection and Quantification of Total and Potentially Virulent Vibrio parahaemolyticus Using a 4-Channel Multiplex Real-Time PCR Targeting the tl, tdh, and trh Genes and a Novel PCR Internal Control,'' published abstract, 103rd General Meeting of the American Society for Microbiology, May 18–23, 2003, Washington, DC.

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

Bisubstrate Inhibitors of Acetyltransferases

Dr. David Klein *et al.* (NICHD).
HHS Reference No. E–205–1999/0–PCT–02 filed 08 Aug 2000.
Licensing Contact: Marlene Shinn-Astor; 301/435–4426; *shinnm@mail.nih.gov*.

The present invention provides methods of inhibiting acetyletransferase enzymes, such as arylalkylamine-N-acetyltransferase (AANAT), by producing a bisubstrate inhibitor in a cell. AANAT catalyzes the transfer of acetyl groups from Acetyl coenzyme A (AcCoA) to substrates such as serotonin. Bisubstrate inhibitors are compounds which share characteristics of AcCoA and of the specific acetyl group acceptors. A highly potent bisubstrate inhibitor of AANAT is CoA-S-N-acetyltryptamine. That inhibitor may be formed *in vitro* by the reaction of alkylating derivatives of the acetyl acceptor and AcCoA. However, the inhibitor thus formed does not cross the cell membranes and is expensive to produce using AcCoA.

The present invention is based on the surprising discovery that a bisubstrate inhibitor which is specific for a particular acetyltransferase can be formed in a cell by introducing into the cell an alkylating derivative of an acetyl acceptor. Formation of the bisubstrate inhibitor occurs efficiently at very low concentrations of introduced drug because the enzyme to be inhibited positions and catalyzes the reactants favorably to form the inhibitor. The bisubstrate inhibitor is likely to accumulate in the cell because it is stable, highly charged and thus will not pass through cell membranes. The targeted acetyltransferase will thus be inhibited and therapeutic actions realized.

The varied actions of acetyltransferases in biochemical processes offer many potential therapeutic targets. Acetylation inactivates drugs and endogenous ligands so inhibitors could, for example, enhance the effectiveness of antibiotics where antibiotic resistance is due to a high level of acetylation. In the case of AANAT, acetylation inactivates serotonin and is the rate limiting step in the formation of melatonin. Inhibition of AANAT will thus decrease melatonin production and increase serotonin levels. Melatonin is a pineal hormone that has endocrinological, neurophysiological, and behavioral functions. Since melatonin and serotonin are implicated in several types of mood disorders, inhibition of AANAT could have valuable therapeutic uses. Specific inhibitors of melatonin synthesis are not yet available and serotonin antagonists have unacceptable side effects in many patients.

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

Imaging With Positron-Emitting Taxanes, Camptothecins, and Other Drugs as a Guide to Antitumor Therapy

Jerry M. Collins, Raymond W. Klecker, Lawrence Anderson (FDA).
U.S. Patent Application No. 10/088,561 filed 19 Mar 2002 (HHS Reference No. E–263–1998/0–US–03);
U.S. Patent Application No. 10/319,812 filed 16 Dec 2002 (HHS Reference No. E–263–1998/1–US–01).
Licensing Contact: Michael Shmilovich; 301/435–5019; *shmilovm@mail.nih.gov*.

Available for licensing and commercial development is a method for using of positron-emitting compounds to label taxane type drugs. This invention also relates to the use, synthesis and structure of three radio-labeled probe molecules, ^{11}C–SN–38, ^{11}C-imatinib, and ^{11}C-mitoxantrone. SN–38 is a major active metabolite of Camptosar, a product marketed by Pharmacia for the treatment of colorectal cancer. Imatinib is a compound that is used to treat chronic myeloid leukemia (CML) and is

marketed under the tradename Gleevec. Mitoxantrone is also used to treat certain types of cancers and multiple sclerosis. For all of these compounds the FDA approved new and expanded uses and there is intense interest in determining whether and where each of the compounds actually collects in the body, and especially whether they are taken up by the targeted tumor. Traditional approaches to determine drug uptake and retention have been invasive. Advantages of using this technology include: (1) Avoidance of exposing patients to toxic drugs that have no potential for benefit; (2) ability to rapidly determine whether a given tumor will be likely to respond to a particular drug; and (3) the ability to monitor the impact of various dosages, schedules, and modulators for delivery, in situ, at the actual tumor under treatment conditions. Further, methods to guide treatment of solid tumors, with labeled taxanes, are also disclosed in the present application.

Additional information may be found in: Ravert *et al.*, ''Radiosynthesis of [11C]paclitaxel,'' J Label Compd and Radiopharm, 2002, 45(6):471–477.

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

Dated: December 1, 2005.

Steven M. Ferguson,

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

[FR Doc. E5–7249 Filed 12–12–05; 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.

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Quantitative Assay of the Angiogenic and Antiangiogenic Activity of a Test Molecule

Steven K. Libutti (NCI).

U.S. Patent Application No. 11/014,472 filed 16 Dec 2004 (HHS Reference No. E–152–2002/1–US–01).

Licensing Contact: Mojdeh Bahar; 301–435–2950; *baharm@mail.nih.gov.*

The invention provides a method of measuring the angiogenic or antiangiogenic activity of a test molecule. The method comprises obtaining an embryonated fowl egg, creating a window in the shell of the fowl egg, such that the CAM membrane is exposed, providing to a test region of interest on the CAM a substrate, administering to a vessel located in the CAM a test molecule, administering to a vessel located in the CAM a fluorescent-labeled particle, such that the fluorescent-labeled particle travels through each vessel contained in the test region of interest, removing the substrate and the test region of interest from the fowl egg, capturing a three-dimensional image of the test region of interest, wherein the three-dimensional image comprises a plurality of pixels, such that a fluorescent vascular density (FVD) value can be assigned to the test region of interest, and comparing the FVD value of the test region of interest with the FVD value of a control region of interest that was prepared in the same manner as the test region of interest but without the administration of a test molecule, such that the angiogenic or antiangiogenic activity of the test molecule is measured. A lower FVD value of the test region of interest as compared to the FVD value of the control region of interest is indicative of the test molecule being useful as an inhibitor of angiogenesis. Conversely, a higher FVD value of the test region of interest as compared to the FVD value of the control region of interest is indicative of the test molecule being useful as a stimulator of angiogenesis.

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

Autotaxin: Motility Simulating Protein Useful in Cancer Diagnosis and Therapy

Mary Stracke, Lance Liotta, Elliot Schiffman, Jerry Krutzch, and Jun Murata (NCI).

U.S. Patent Application filed 16 Feb 2005 (HHS Reference No. E–142–1990–2–US–05).

Licensing Contact: Mojdeh Bahar; 301–435–2950; *baharm@mail.nih.gov.*

Cell motility plays an important role in embryonic events, adult tissue remodeling, wound healing and metastasis of tumor cells. Some tumor cells produce proteins termed ''autocrine motility factors'' that stimulate motility in tumor cells. This invention describes a novel tumor protein called Autotaxin (''ATX'') that stimulates both random and directed migration of human A2058 melanoma cells. ATX is a member of the nucleotide phosphodiesterase and pyrophosphatase (NPP) family of proteins but is the only member of the family that stimulates motility. It is also the only member shown to possess lysophospholipase D activity.

This invention can provide a functional marker that can directly estimate the invasive potential of a particular human cancer. One could also use this invention as an assay for a particular secreted marker in body fluids, or in tissues. Other uses include the detection, diagnosis, and treatment of human malignancies, and other inflammatory, fibrotic, infectious and healing disorders.

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

Dated: December 1, 2005.

Steven M. Ferguson,

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

[FR Doc. E5–7250 Filed 12–12–05; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the