waivers and reductions granted, FDA estimates that 2,225 products will qualify for product fees in FY 2004, after allowing for waivers and reductions, and will use this number for its FY 2005 estimate. Accordingly, the FY 2005 product fee rate is determined by dividing the adjusted total fee revenue to be derived from product fees ($92,803,650) by the estimated 2,225 products for a FY 2005 product fee of $41,710 (rounded to the nearest ten dollars).

VI. Fee Schedule for FY 2005

The fee rates for FY 2005 are set out in table 4 of this document:

TABLE 4.

Fee Category	Fee Rates for FY 2005
Applications	
Requiring clinical data	$672,000
Not requiring clinical data	$336,000
Supplements requiring clinical data	$336,000
Establishments	$262,200
Products	$41,710

VII. Implementation of Adjusted Fee Schedule

A. Application Fees

The appropriate application fee established in the new fee schedule must be paid for any application or supplement subject to fees under PDUFA that is received after September 30, 2004. Payment must be made in U.S. currency by check, bank draft, or U.S. postal money order payable to the Food and Drug Administration. Please include the user fee identification (ID) number on your check. Your payment can be mailed to: Food and Drug Administration, P.O. Box 360909, Pittsburgh, PA 15251–6909

If checks are to be sent by a courier that requests a street address, the courier can deliver the checks to: Food and Drug Administration (360909), Mellon Client Service Center, rm. 670, 500 Ross St., Pittsburgh, PA 15262–0001. (Note: This Mellon Bank address is for courier delivery only.)

Please make sure that the FDA post office box number (P.O. Box 360909) is written on the check. The tax ID number of the FDA is 530 19 6965.

B. Establishment and Product Fees

By August 31, 2004, FDA will issue invoices for establishment and product fees for FY 2005 under the new fee schedule. Payment will be due on October 1, 2004. FDA will issue invoices in October 2005 for any products and establishments subject to fees for FY 2005 that qualify for fees after the August 2004 billing.

Dated: July 27, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–17442 Filed 7–30–04; 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, 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.

Mouse Model of PRKAR1A Down-Regulation

Constantine Stratakis *et al.* (NICHD); DHHS Reference No. E–266–2004/0—Research Tool; Licensing Contact: Mojdeh Bahar; 301/435–2950; *baharm@mail.nih.gov.*

The invention represents the first animal model of cyclic AMP (cAMP)-induced tumorigenesis, and the first animal model of protein kinase A (PKA)-related tumorigenesis. The cAMP/PKA system is of seminal importance for cellular function and signaling, and is involved in many systems and diseases. This discovery is expected to facilitate the development of drugs useful in treating endocrine and other tumors.

Compositions and Methods for Diagnosis and Treatment of Chemotherapy-Resistant Neoplastic Disease

John Park (NINDS); U.S. Provisional Application No. 60/571,296 filed 15 May 2004 (DHHS Reference No. E–192–2004/0–US–01); Licensing Contact: Jesse S. Kindra; 301/435–5559; *kindraj@mail.nih.gov.*

The present invention relates to compositions and methods for the treatment of a neoplastic disease state (*i.e.,* tumors) using RNA interference-mediated down regulation of stathmin expression. This invention also discloses methods for determining the presence or predisposition to a neoplastic disease state.

Stathmin is a cytoplasmic protein that is highly expressed in many different types of tumors such as leukemias, lung cancers and brain tumors. Stathmin is believed to be involved in the regulation of the cell cycle via its interactions with microtubules. Lowering the expression of stathmin in tumor cells using RNA interference (RNAi) technology causes a decrease in tumor cell growth and also causes such cells to become more sensitive to the effects of standard chemotherapeutic agents.

Accordingly, the delivery of stathmin RNAi oligonucleotides either alone or in combination with standard chemotherapies may be used to treat patients with various tumors. For example, retroviruses or adeno-associated viruses containing stathmin RNAi oligonucleotides could be delivered to brain tumors in order to

decrease cell growth and increase sensitivity to standard chemotherapies.

Compositions of Matter and Methods of Use of Fluorescent Protein Kinases

Derek Braun and Peter Blumberg (NCI); U.S. Provisional Application filed 19 May 2004 (DHHS Reference No. E–093–2004/0–US–01); Licensing Contact: Mojdeh Bahar; 301/435–2950; *baharm@mail.nih.gov.*

The invention describes the development of fusion proteins, as well as polynucleotides encoding such fusion proteins, between protein kinase C (PKC) isoforms and variants of green fluorescent protein for the purpose of detecting protein kinase C activation within intact cells via fluorescence resonance energy transfer (FRET). Repeatable dose-dependent change of FRET with a number of PKC ligands, including phorbol esters and bryostatin, have been demonstrated. The invention is useful as a drug discovery tool for evaluating therapeutics that target PKCs.

Methods for the Identification and Use of Compounds Suitable for the Treatment of Drug Resistant Cells

Gergely Szakacs *et al.* (NCI); DHHS Reference No. E–075–2004/0–US–01 filed 18 June 2004; Licensing Contact: Jesse S. Kindra; 301–435–5559; *kindraj@mail.nih.gov.*

There is an important need to overcome cancer multiple drug resistance (MDR). ATP-binding cassette (ABC) transporters are a family of transporter proteins that contribute to drug resistance via ATP-dependent drug efflux pumps. Accordingly, based on the expression profile of 48 ABC transporters in sixty (60) cell lines, the present invention provides a method to identify (1) drugs that retain action in cells expressing MDR proteins, (2) compounds that reduce MDR by interfering with the efflux pumps. In addition, the invention describes a method to identify compounds whose antiproliferative effect is potentiated by the ABCB1/MDR1 transporter. These compounds might avoid the well-documented side-effects observed in clinical trials of ''classical'' MDR1 inhibitors and may serve as leads for development of novel anti-cancer agents to treat resistant disease.

Methods and Devices for Molecular Diagnosis and Prognosis of Lymphoid Malignancies

Louis M. Staudt *et al.* (NCI); U.S. Provisional Application No. 60/506,377 filed 03 Sep. 2003 (DHHS Reference No. E–234–2003/0–US–01); Licensing Contact: Jeffrey Walenta; 301/435–4633; *walentaj@mail.nih.gov.*

Human lymphomas and leukemias are a diverse set of cancers. Many of these cancers, while expressing a similar phenotype between different individuals, have a diverse underlying genetic basis for the disease. This diverse genetic basis has implications on the effective treatment of the various phenotypes of lymphoma. For example, a drug that was effective against one individual's phenotype of lymphoma will not be effective against a similar lymphoma in another individual. An invention that helps clinicians classify a lymphoproliferative disorder would provide the basis for a ''pharmacogenomic'' method for treating such cancers.

The patent application listed in this abstract describes the preliminary results of an ongoing effort to establish a molecular basis for classifying all lymphoproliferative disorders. Gene expression profiles, using a gene set of over 27,000 genes, have been established from a large population of lymphoproliferative tumor samples collected from patients at numerous healthcare institutions worldwide. Clinical outcomes were correlated to the gene expression profile data representing a plurality of lymphoid malignancy subtypes of previously known or unknown lymphoproliferative disorders. Finally, an analysis procedure was developed to predict the clinical outcomes based on a patients specific lymphoid tumor gene expression profile.

This patent application describes a method to predict the survival of patient with a lymphoproliferative disorder.

Dated: July 23, 2004.

Steven M. Ferguson,

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

[FR Doc. 04–17466 Filed 7–30–04; 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, 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.

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Griffithsin, Glycosylation-Resistant Griffithsin, and Related Conjugates, Compositions, Nucleic Acids, Vectors, Host Cells, Methods of Production and Methods of Using

Drs. Barry O'Keefe, Michael Boyd, and Toshiyuki Mori (NCI); U.S. Provisional Application No. 60/576,056 filed 01 Jun 2004 (DHHS Reference No. E–106–2003/0–US–01); Licensing Contact: Sally Hu; 301/435–5606; *hus@mail.nih.gov.*

This invention provides: (1) Isolated and purified antiviral peptides or antiviral proteins named griffithsin; (2) purified nucleic acid encoding griffithsin or a fragment thereof; (3) vectors comprising such a nucleic acid; a host cell comprising such a nucleic acid or vector; (4) a conjugate comprising all or part (such as an antiviral part) of the griffithsin; (5) antibodies that bind griffithsin; (6) methods of producing griffithsin and a conjugate thereof; (7) methods of inhibiting prophylactically and therapeutically a viral infection *e.g.*, HIV, influenza; and, (8) vaccine development and screening assays. Since picomolar concentrations of griffithsin irreversibly inactivate human clinical isolates of HIV and the griffithsin protein can also target other retroviruses (*e.g.* FIV, SIV and HTLV) and non-retroviruses (influenza, measles, ebola) having envelope constituents similar to HIV, this invention may represent potential new therapeutic or prophylactic applications against viruses, including the causative agent for AIDS.

Activation of Nerve Growth Factor Receptor Trophic Functions

Lino Tessarollo *et al.* (NCI); U.S. Provisional Application No. 60/509,158 filed 07 Oct 2003 (DHHS Reference No. E–013–2003/0–US–01); Licensing Contact: Norbert Pontzer; 301/435–5502, *pontzern@mail.nih.gov.*