Proteins or other biologically active molecules are easily denatured, and once introduced into the body, rapidly cleared. These problems are circumvented by first incorporating the protein into the microbead. Microbeads with protein payloads are then introduced into the tissue of interest, where the microbeads remain while degrading into biologically innocuous materials while delivering the protein/drug payload for adjustable periods of time ranging from hours to weeks. This technology is an improvement of the microbead technology described in U.S. Patent No. 5,759,582.

Applications: This technology has two commercial applications. The first is a pharmaceutical drug delivery application. The bead allows the incorporated protein or drug to be delivered locally at high concentration, ensuring that therapeutic levels are reached at the target site while reducing side effects by keeping systemic concentration low. The microbead accomplishes this while protecting the biologically active protein from harsh conditions traditionally encountered during microbead formation/drug formulation.

The microbeads are inert, biodegradable, and allow a sustained release or multiple-release profile of treatment with various active agents without major side effects. In addition, the bead maintains functionality under physiological conditions.

Second, the microbeads and microparticles can be used in various research assays, such as isolation and separation assays, to bind target proteins from biological samples. A disadvantage of the conventional methods is that the proteins become denatured. The denaturation results in incorrect binding studies or inappropriate binding complexes being formed. The instant technology corrects this disadvantage by using a bead created in a more neutral pH environment. It is this same environment that is used for the binding of the protein of interest as well.

Inventor: Phillip F. Heller (NIA).

Patent Status:

U.S. Provisional Application No. 60/602,651 filed 19 Aug 2004 (HHS Reference No. E–116–2004/0–US–01)

PCT Application No. PCT/US2005/026257 filed 25 Jul 2005, which published as WO 2006/023207 on 02 Mar 2006 (HHS Reference No. E–116–2004/0–PCT–02)

U.S. Patent Application No. 11/659,976 filed 12 Feb 2007 (HHS Reference No. E–116–2004/0–US–03)

Licensing Status: Available for non-exclusive or exclusive licensing.

Licensing Contact: Susan O. Ano, PhD; 301/435–5515; *anos@mail.nih.gov*.

Dated: February 7, 2008.

Steven M. Ferguson,

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

[FR Doc. E8–2749 Filed 2–13–08; 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.

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.

New Inhibitors of Multidrug Resistant Proteins Such as ABCG2

Description of Technology: Drug resistance plays a significant role in the failure of cancer chemotherapy. Some proteins such as ABCG2, Pgp and MRP1 that belong to the superfamily of ATP-binding cassette transporters contribute to this process.

Two categories of ABCG2 protein inhibitors—botryllamides, isolated from a marine sponge, and naphthopyrones, isolated from marine sea stars—have been obtained by high-throughput screening of 89,000 natural product extracts from the Natural Products Repository at NCI.

These new compounds serve as potential therapeutic agents for cancer chemotherapy either exclusively or in combination with conventional regimens. The study of structure-activity relationships will help delineate features that would enhance activity and specificity to multiple drug resistant proteins.

Advantages: Increase bioavailability of orally administered drugs; Enhance drug delivery to certain tissues.

Applications: Cancer therapeutics; Cancer stem cell research; Study of structure, function and relevance of MDR in cancer.

Market: Cancer is the second leading cause of death in America, after heart disease. Multiple drug resistance is a significant impediment in the treatment of cancers resulting in poor prognosis. Some cancers with demonstrated high levels of MDR are leukemia, colon, renal, liver, adrenocortical, and pancreatic. Breast, ovarian, sarcoma and small-cell lung cancer show increased MDR on treatment.

This new technology has the potential to increase the effectiveness of conventional chemotherapy and prognosis of cancer.

Developmental Status: Early stage.

Inventors: Curtis J. Henrich *et al.* (NCI).

Patent Status: U.S. Provisional Application No. 60/018,758 filed 03 Jan 2008 (HHS Reference No. E–315–2007/0–US–01).

Licensing Status: Available for non-exclusive licensing.

Licensing Contact: John Stansberry, PhD; 301/435–5236; *stansbej@mail.nih.gov*.

TGF-β Gene Expression Signature in Cancer Prognosis

Description of Technology: Hepatocellular carcinoma (HCC) is the third leading cause of cancer death worldwide, and it is very heterogeneous in terms of its clinical presentation as well as genomic and transcriptomic patterns. This heterogeneity and the lack of appropriate biomarkers have hampered patient prognosis and treatment stratification.

Available for licensing is a novel temporal TGF-β gene expression signature that predicts HCC patient clinical outcomes. Patients with tumors expressing late TGF-β responsive genes had a malignant prognosis and an invasive tumor phenotype as evaluated by decreased survival time, increased tumor recurrence, and vascular invasion rate. Additionally, this signature may also be able to prognose other cancers, including lung cancer.

Applications: Method to diagnose cancer; Method to monitor cancer progression and aid clinicians to choose appropriate therapies; Commercial kits to prognose cancer.

Advantages: Early diagnostic tool to stratify HCC patients to chose more effective treatment.

Development Status: The technology is currently in the pre-clinical stage of development.

Market:

An estimated 1,444,920 new cancer diagnoses in the U.S. in 2007.

Cancer is the second leading cause of death in United States.

It is estimated that the cancer therapeutic market would double to $50 billion a year in 2010 from $25 billion in 2006.

Inventors: Snorri Thorgeirsson (NCI) and Cedric Coulouaran (NCI).

Relevant Publication: Manuscript in press Hepatology 2008.

Patent Status: U.S. Provisional Application No. 60/981,661 filed 22 Oct 2007 (HHS Reference No. E–282–2007/0–US–01).

Licensing Status: Available for exclusive or non-exclusive licensing.

Licensing Contact: Jennifer Wong; 301–435–4633; *wongje@mail.nih.gov*.

Collaborative Research Opportunity: The National Cancer Institute, Center for Cancer Research, Laboratory of Experimental Carcinogenesis is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize a novel temporal TGF-β gene expression signature that predicts HCC patient clinical outcomes. Please contact John D. Hewes, PhD at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

A Fold-Back Diabody Format for Diphtheria Toxin-Based Immunotoxins That Can Increase Binding and Potency

Description of Technology: NIH inventors, in collaboration with Scott and White Memorial Hospital inventors, have developed new immunotoxins comprising a mutant diphtheria toxin linked to an anti-prostate specific membrane antigen (PSMA) fold-back diabody. The fold-back diabody construct has a shortened linker region between the heavy and light chains of the antibody variable domain. This construct allows interactions between the longer-linked variable domains while preventing interactions between the shorter-linked variable domains. This results in increased efficiency of epitope recognition and delivery to the appropriate target cells. These immunotoxins can be used for the treatment of cancers that overexpress PMSA, with specific application against prostate cancer.

Applications:

Treatment of primary prostate tumors.

Treatment of metastatic prostate tumors, for which no currently effective treatment exists.

Application against other tumors expressing the PSMA epitope on the tumor neovasculature such as breast cancer.

Advantages:

Increased potency of 10–40-fold resulting from the use of the fold-back diabody construct.

First treatment with applications to metastatic prostate cancer.

Pichia pastoris production process of the fold-back immunotoxin can be used to scale up for GMP production.

Benefits:

Significant social benefit for successfully treating the second leading cause of cancer-related deaths among males in the United States.

Approximately 8 billion USD per year are spent on prostate cancer treatment; a new treatment could procure a significant financial position.

Opportunity to occupy a strong market position through the development of the first treatment of metastatic prostate cancer.

Inventors: David Neville (NIMH) *et al.*

Patent Status: U.S. Patent Application No. 60/953,416 filed 01 Aug 2007 (HHS Reference No. E–268–2007/0–US–01).

Licensing Status: Available for licensing.

Licensing Contact: David A. Lambertson, PhD; 301–435–4632; *lambertsond@mail.nih.gov*.

Collaborative Research Opportunity: The National Institute of Mental Health, Laboratory of Molecular Biology, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize anti-PSMA fold-back immunotoxins. Please contact David Neville by phone at 301–496–6807 or e-mail *davidn@mail.nih.gov* for more information.

Ribosomal Protein S3 (RPS3), an Essential Component of NF-kB is a Novel and Selective Drug Target

Description of Technology: NF-kB, represented by the p50-p65 heterodimer, is a DNA binding protein complex that has well documented functions in inflammatory or autoimmune diseases. Its potential as a drug target is currently being explored by the pharmaceutical industry.

The present invention describes that ribosomal protein S3 (RPS3) is a novel component of the p65 homodimer and p65-p50 heterodimer DNA binding complex. Experiments confirmed that RPS3 is essential for normal expression of specific NF-kB target genes, including key physiological events that require p65.

Advantages and Applications: A novel and selective target for drug candidates targeting the NF-kB pathway.

Development Status: The technology is currently in the pre-clinical stage of development.

Inventors: Michael J. Lenardo and Fengyi Wan (NIAID).

Patent Status: U.S. Provisional Application No. 60/913,336 filed 23 Apr 2007 (HHS Reference No. E–162–2007/0–US–01).

Licensing Status: Available for exclusive and non-exclusive licensing.

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

Collaborative Research Opportunity: The NIAID Laboratory of Immunology is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact Dr. Michael Lenardo at 301–496–6754 for more information.

A New Technology for Identification of Genes Expressed in Hypoxia Conditions

Description of Technology: Low concentrations of oxygen (hypoxia) are a major pathophysiological condition conducive for angiogenesis, necessary for tumor growth and metastasis of cancer cells.

A new technology comprising of a vector DNA (pGL2-TK-HRE) that expresses the luciferase gene under the influence of a hypoxia inducible promoter sequence from the nitric oxide synthase gene has been used to transform various human tumor cell lines such as U251–HRE and PC3–HRE. These cells express little to no luciferase under normal oxygen levels, but stably express significantly higher levels under low oxygen levels.

The transformed cell lines can be used to screen and develop drugs and small molecules that inhibit angiogenesis, an attractive target for cancer therapy. The technology can also be used in gene therapy where the therapeutic gene is being expressed under a hypoxia inducible promoter.

Advantages: Quantitative; Robust, stably express luciferase; Can be used in vivo.

Applications: Early detection of angiogenesis; Cancer therapeutics; Gene therapy.

Market: Cancer is the second leading cause of death in America, after heart disease. Every year, more than a million people are diagnosed with cancer. Over 50% of the cases reported in the U.S. affect the lung, breast, prostate and colorectal. Although the number of

deaths reported is declining 553,888 cancer deaths in 2004 compared to 556,902 in 2003, the total number of all cancer deaths among women is rising.

With the help of the new technology early detection, therapy and monitoring of cancer combating efforts would be possible.

Development Status: Developed.

Inventor: Giovanni Melillo (NCI)

Patent Status: HHS Reference No. E–220–2003/0—Research Tool. Patent protection is not being sought for this technology.

Licensing Status: Available for non-exclusive licensing.

Licensing Contact: John Stansberry, PhD; 301/435–5236; *stansbej@mail.nih.gov*.

Date: February 6, 2008.

Steven M. Ferguson,

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

[FR Doc. E8–2752 Filed 2–13–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Center for Substance Abuse Prevention; Notice of Meeting

Pursuant to Public Law 92–463, notice is hereby given of the meeting of the Center for Substance Abuse Prevention (CSAP) National Advisory Council on March 6, 2008.

The meeting is open and will include discussion of the Center's policy issues, and current administrative, legislative and program developments.

Attendance by the public will be limited to space available. Public comments are welcome. Please communicate with the CSAP Council's Designated Federal Official, Ms. Tia Haynes (see contact information below), to make arrangements to attend, comment or to request special accommodations for persons with disabilities.

Substantive program information, a summary of the meeting, and a roster of Council members may be obtained as soon as possible after the meeting, either by accessing the SAMHSA Committee Web site, *http://www.samhsa.gov/council/csap/csapnac.aspx,* or by contacting Ms. Haynes. The transcript for the open session will also be available on the SAMHSA Council Web site within three weeks after the meeting.

Committee Name: Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Prevention National Advisory Council.

Date/Time/Type: March 6, 2008. From 9 a.m.–4:30 p.m.: Open.

Place: 1 Choke Cherry Road, Sugarloaf and Seneca Conference Rooms, Rockville, Maryland 20857.

Contact: Tia Haynes, Designated Federal Official, SAMHSA/CSAP National Advisory Council, 1 Choke Cherry Road, Room 4–1066, Rockville, MD 20857, Telephone: (240) 276–2436, Fax: (240) 276–2430, E-mail: *tia.haynes@samhsa.hhs.gov*.

Toian Vaughn,

Committee Management Officer, Substance Abuse and Mental Health Services Administration.

[FR Doc. E8–2715 Filed 2–13–08; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of Amspec Services LLC, as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of Amspec Services LLC, as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given that, pursuant to 19 CFR 151.12 and 19 CFR 151.13, Amspec Services LLC, 1818 A Federal Road, Galena Park, TX 77015, has been approved to gauge and accredited to test petroleum and petroleum products, organic chemicals and vegetable oils for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *cbp.labhq@dhs.gov*. Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories. *http://cbp.gov/xp/cgov/import/operations_support/labs_scientific_svcs/commercial_gaugers/*.

DATES: The accreditation and approval of Amspec Services LLC, as commercial gauger and laboratory became effective on April 10, 2007. The next triennial inspection date will be scheduled for April 2010.

FOR FURTHER INFORMATION CONTACT: Commercial Gauger Laboratory Program Manager, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Suite 1500N, Washington, DC 20229, 202–344–1060.

Dated: January 31, 2008.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. 08–678 Filed 2–13–08; 8:45 am]

BILLING CODE 9111–14–M

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of Robinson International (USA) Inc., as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of Robinson International (USA) Inc., as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given that, pursuant to 19 CFR 151.12 and 19 CFR 151.13, Robinson International (USA) Inc., 4400 S. Wayside Drive, Suite 107, Houston, TX 77207, has been approved to gauge and accredited to test petroleum and petroleum products, organic chemicals and vegetable oils for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquires regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *cbp.labhq@dhs.gov*. Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories.

http://cbp.gov/xp/cgov/import/operations_support/labs_scientific_svcs/commercial_gaugers/.