TABLE 1.—ANNUALIZED ESTIMATE OF HOUR BURDEN

Type of respondents	Number of respondents	Frequency of response	Average time for response (hr)	Total hour burden *
GRIP Awardees	101	1	0.50	50.5
Total	101	1	0.50	50.5

* Total Burden = N Respondents × Response Frequency × minutes to complete/60.

TABLE 2.—ANNUALIZED COST TO RESPONDENTS

Type of respondents	Number of respondents	Frequency of response	Approximate hourly wage rate/hr	Total respondent cost *
GRIP Awardees	101	1	$13	656.50
Total	101	1	13	656.50

* Total Respondent Cost = N Respondents × Response Frequency × minutes to complete/60 × hourly rate.

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Dr. Linda Kupfer, Fogarty International Center, National Institutes of Health, 16 Center Drive, Bethesda, MD 20892, or call non-toll-free number 301–496–3288, or e-mail your request, including your address to: *kupferl@mail.nih.gov.*

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Dated: November 20, 2007.

Timothy Tosten,

Executive Officer, FIC, National Institutes of Health.

[FR Doc. E7–23235 Filed 11–29–07; 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.

A Family of Small Molecules for Selective Inhibition of Wip1 Phosphatase

Description of Technology: The Wip1 phosphatase acts on proteins containing a particular phosphorylated amino acid sequence. Studies have shown that Wip1 is overexpressed in a number of human cancers, including breast cancer, neuroblastoma and ovarian cancer. Wip1 activity has also been shown to have a suppressive effect on the tumor suppressor p53. This suggested that inhibition of Wip1 could be of therapeutic value in the treatment of cancer.

NIH inventors have developed small molecules that simulate the structure of the amino acid sequence that Wip1 recognizes. The structure of the small molecules allows for specific targeting to Wip1. These small molecules have the ability to significantly inhibit Wip1 phosphatase activity at the micromolar level. As a result, these small molecules can be used in the design of therapeutics for cancers that overexpress Wip1.

Applications: Treatment of cancer, including but not limited to breast cancer, ovarian cancer and neuroblastoma.

Can be used either alone or in combination with other known anti-cancer therapeutics.

Advantages: Structure of the inhibitor allows targeting of Wip1 without inhibition of related phosphatases and their biological processes, possibly leading to fewer undesired effects during treatment.

Small molecules are stable and have the ability to effectively penetrate cells.

Can be applied to many different types of cancer.

Benefits: The current lack of Wip1 inhibitors means that development of the small molecules could lead to the occupation of a significant position in the cancer therapeutic market.

The successful inhibition of a new target in cancer therapy could provide far-reaching social benefit in the treatment of multiple cancers.

Inventors: Ettore Appella *et al.* (NCI).

U.S. Patent Status: U.S. Patent Application No. 60/969,258 (HHS Reference No. E–302–2007/0–US–01).

Licensing Contact: David A. Lambertson, Ph.D.; Phone: (301) 435–4632; Fax: (301) 042–0220; E-mail: *lambertsond@mail.nih.gov*.

Collaborative Research Opportunity: The National Cancer Institute's Laboratory of Cell Biology is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize therapeutics for cancers that overexpress Wip1. Please contact John D. Hewes, Ph.D. at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Selenocysteine Mediated Hybrid Antibody Molecules

Description of Technology: Available for licensing is a new class of hybrid molecules composed of an antibody, or antibody fragment, and a small synthetic molecule (such as a small molecule inhibitor, or cytotoxic compound). These biological and chemical components are covalently linked at an engineered selenocysteine near the C-terminus of the antibody, or antibody fragment. Through this covalent linkage, the chemical and the biological component can acquire properties of one another. For example, the synthetic molecule acquires antibody properties such as circulatory half-life, effector functions, and ability to interfere with protein interactions whereas the antibody, or antibody fragment, acquires properties of the small synthetic molecule such as specificity, affinity, and stability to bind to targets that are sterically inaccessible to immunoglobulins. The technology can also be used to equip an antibody, or antibody fragment, with a small synthetic molecule that enhances target destruction or imaging capabilities through site-selective biotinylation, PEGylation, addition of an imaging agent, or addition of a cytotoxic agent such as a chemotherapeutic drug or a chelate for radioisotope labeling. The hybrid antibody molecules can be engineered with a variety of small synthetic molecules, and the combination of immunogenic properties and those of the small synthetic molecules results in compounds with powerful target destruction or imaging capabilities. This technology could be applied towards the targeted delivery of small synthetic molecules to various cell surface receptors, and may have applicability as a prevention, diagnosis, or therapy for numerous disease states.

Applications: Potent novel compositions that retain immunogenic properties and those of small synthetic molecules that can be produced at a large scale; Method to prevent, diagnose, and treat cancer, infectious diseases and autoimmune diseases.

Market: Monoclonal antibody market is projected to exceed $30 billion by 2010; Revenue from antibodies for therapeutics and diagnostic uses are expected to grow at an average annual growth rate of 11.5%.

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

Inventors: Christoph Rader *et al.* (NCI).

Patent Status: U.S. Provisional Application No. 60/909,665 filed 02 Apr 2007 (HHS Reference No. E–146–2007/0–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, Experimental Transplantation and Immunology Branch, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize Selenocysteine Mediated Hybrid Antibody Molecules. Please contact Dr. Christoph Rader at (301) 451–2235 or *raderc@mail.nih.gov* for more information.

SLCO1B3 Genotyping to Predict a Survival Prognosis of Prostate Cancer

Description of Technology: Steroid hormones have been implicated in playing a fundamental role in the pathogenesis of prostate cancer. Polymorphisms in the genes that code for enzymes or hormones involved in androgen regulatory pathway are proposed to influence an individual's risk for developing prostate cancer. Since many membrane transporters are modulators of steroid hormones absorption and tissue distribution, genetic polymorphisms in genes encoding these transporters may account for the risk of prostate cancer and the predicting of survival. The OATP1B3 (formerly OATP8) steroid uptake transporter is overexpressed in prostate cancer, and polymorphisms in *SLCO1B3* have been associated with altered testosterone uptake, and also an increased prostate cancer risk.

This invention identifies two polymorphic genetic markers in the *SLCO1B3* (formerly *SLC21A8*) gene, called 334T>G and 699G>A, that can be measured in genomic DNA obtained from a blood sample to predict survival from diagnosis of prostate cancer in that individual patient. This genetic profiling result has profound clinical applications in diagnosis for each individual patient and ultimate treatment regimen. Specifically, the inventors have provided a correlation between clinical outcome of SLCO1B3 genotype with median survival of androgen independent prostate cancer. They have also shown that the genotype is predictive of testosterone uptake through the OATP1B3 transporter, and this information is useful to inform clinical decisions regarding antiandrogen therapy.

Advantages and Applications: *SLCO1B3* genotyping can be used in combination on a gene chip with several polymorphisms known to predict survival of prostate cancer patients. Thus the OATP1B3 polymorphism would be one genetic marker in a series of other markers that would be used to inform clinical decisions.

SLCO1B3 upregulation can be used as a prognostic tool.

Development Status: Initial experiments have been performed with clinical samples from patients with prostate cancer.

Inventors: William D. Figg et al. (NCI).

Patent Status: U.S. Provisional Application No. 60/879,503 filed 08 Jan 2007 (HHS Reference No. E–083–2007/0–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 National Cancer Institute's Medical Oncology Branch is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize the use of the *SLCO1B3* genotyping to inform clinical decisions regarding drug treatment, or prognosis of prostate cancer. Please contact John D. Hewes, Ph.D. at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

A New Method for Determining Level of Immunosuppression in Humans

Description of Technology: These inventions describe a method of determining the level of immunosuppression in a human subject by determining the level of expression of at least one selected T-Cell Receptor subunit protein, or protein in the T lymphocyte signal transduction pathway, and comparing the level to that found in healthy individuals.

Applications: The method can be used to identify candidates for autologous adoptive immunotherapy

and for identification of agents which cause or reverse immunosuppression.

Development Status: Pre-clinical stage.

Inventors: Augusto C. Ochoa et al. (NCI).

Patent Status: U.S. Patent No. 5,583,002 issued 10 Dec 1996 (HHS Reference No. E–231–1995/1–US–01);

U.S. Patent No. 5,556,763 issued 17 Sep 1996 (HHS Reference No. E–231–1995/3–US–01);

U.S. Patent No. 5,889,143 issued 10 Dec 1996 (HHS Reference No. E–231–1995/3–US–02);

U.S. Patent Application No. 09/280,655 filed 29 Mar 1999 (HHS Reference No. E–231–1995/3–US–03);

U.S. Patent No. 5,658,744 issued 19 Aug 1997 (HHS Reference No. E–232–1995/0–US–01);

U.S. Patent No. 5,965,366 issued 12 Dec 1999 (HHS Reference No. E–232–1995/1–US–01); and any foreign equivalent patents and patent applications.

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

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

Dated: November 14, 2007.

Steven M. Ferguson,

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

[FR Doc. E7–23193 Filed 11–29–07; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

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Monoclonal Antibody to a Specific Peptide–MHC Class II Complex

Description of Invention: T lymphocytes play an important role in the immune system by recognizing foreign protein motifs on cells. T lymphocytes are stimulated to recognize these motifs through their interactions with peptide-MHC complexes (pMHC). Thus, studying pMHC is an important aspect of understanding how the immune system works, particularly with regard to the development of vaccines. Unfortunately, the detection of pMHC is largely dependent on indirect assays, due to the difficulty of producing antibodies for specific pMHC.

This invention regards the development of hybridomas (C4H3) for the production of antibodies that are highly specific for a particular pMHC complex consisting of hen egg lysozyme peptide 46-61 (HEL) and the I-A^k MHC class II molecule. These antibodies can be used for a myriad of purposes which include studying how cells form pMHC.

Applications: Discovery of methods for antigen delivery in the development of vaccines.

Quantitation and distribution of pMHC complexes on cells.

Study antigen processing in experimental immunological research systems.

Advantages: High specificity for the pMHC complex of HEL-I-A^k MHC class II molecule.

HEL-I-A^k is widely used in experimental immunological research systems, giving the hybridoma and antibodies great applicability.

Inventors: Ronald N. Germain *et al.* (NIAID).

Publications: 1. G Zhong *et al.* Production, specificity, and functionality of monoclonal antibodies to specific peptide-major histocompatibility complex class II complexes formed by processing of exogenous protein. Proc Natl Acad Sci U S A. 1997 Dec 9; 94(25):13856–13861.

2. A Porgador *et al.* Localization, quantitation, and in situ detection of specific peptide-MHC class I complexes using a monoclonal antibody. Immunity. 1997 Jun; 6(6):715–726.

Patent Status: HHS Reference No. E–021–2008/0–Research Tool. Patent protection is not being pursued for this technology.

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

Collaborative Research Opportunity: The NIAID Lymphocyte Biology Section, Laboratory of Immunology is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize monoclonal antibody C4H3, specific for HEL (46-61) bound to the MHC class II molecule I-A^k. Please contact Ronald N. Germain, M.D., Ph.D., at *rgermain@nih.gov* for more information.

Bifunctional Compounds that Bind to Hormone Receptors

Description of Technology: The development and progression of prostate cancer is dependent on the androgen receptor (AR), a ligand-dependent transcription factor. In the inactive form AR resides in the cytosolic region of the cell and when activated, AR is imported into the nucleus. Initial hormonal therapy for prostate cancer involves lowering serum levels of testosterone to shut down AR activity. Despite initial patient responses to testosterone-depleting therapies, prostate cancer becomes refractory to hormonal therapy. Notably, AR is reactivated in hormone-refractory prostate cancer and reinstates its proliferative and survival activity.

Available for licensing is a novel chemical compound which is bifunctional and binds to AR. This compound is comprised of tubulin-binding and steroid receptor-binding moieties. This compound is designed to antagonize AR function in a nonclassical manner by several mechanisms and kills hormone-refractory prostate cells better than both functional moieties. This compound is a first-in-class of bifunctional steroid receptor binding agents that can antagonize steroid receptors in a variety of hormone-dependent diseases, such as breast and prostate cancer.

Applications: Therapeutic compounds that selectively target steroid receptor-expressing cancer cells resulting in decreased toxicity.

Method to treat hormone resistant prostate cancer and potentially other steroid receptor dependent diseases such as breast cancer.

Market: Prostate cancer is the second most common type of cancer among men, wherein one in six men will be diagnosed with prostate cancer.

An estimated 218,890 new cases of prostate cancer and 27,050 deaths due to prostate cancer in the United States in 2007.