TABLE A.—RESPONDENT AND HOUR BURDEN ESTIMATES FOR CHIS 2005 CANCER CONTROL TOPICAL MODULE

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Adult Individuals—Pilot CCM and Demographics	150	1	.17	25.50
Adult Individuals—CCM and Demographics	55,000	1	.17	9,350.00
Totals				9,375.50

The annualized cost to respondents is estimated at: $140,632.50. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Request For Comments: Written comments and/or suggestions from the public and affected agencies should address 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.

Direct Comments To OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Dr. Nancy Breen, Ph.D., Project Officer, National Cancer Institute, EPN 4005, 6130 Executive Boulevard MSC 7344. Bethesda, Maryland 20852–7344, or call non-toll free number (301) 496–8500 or e-mail your request, including your address to *breenn@mail.nih.gov.*

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

Dated: December 21, 2004.

Rachelle Ragland-Greene,

NCI Project Clearance Liaison, National Institutes of Health.

[FR Doc. 04–28687 Filed 12–30–04; 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 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.

Use of Anti-Parafibromin Antibodies to Diagnose Hyperparathyroidism-Jaw Tumor Syndrome (HPT–JT) and Parathyroid Cancer

William Simonds, Jian-hua Zhang, and Geoffrey Woodard (NIDDK) U.S. Provisional Application No. 60/531,875 filed 22 Dec 2003 (DHHS Reference No. E–032–2004/0–US–01)

Licensing Contact: Brenda Hefti; (301) 435–4632; *heftib@mail.nih.gov.*

This technology relates to methods of diagnosing cancer using antibodies that specifically bind to parafibromin. Parafibromin appears to be a tumor suppressor. Mutations in the coding sequence, specifically truncations or deletions, might be indicative of cancer or increased susceptibility to cancer. Antibodies targeting this tumor suppressor protein might have utility as a cancer diagnostic or prognostic, either alone, or as part of a kit.

This technology is described, in part, in GE Woodard *et al.*, ''Parafibromin, product of the hyperparathyroidism-jaw tumor syndrome gene HRPT2, regulates cyclin D1/PRAD1 expression.'' Oncogene 2004 Dec 06 (e-pub ahead of print).

Eosinophil-Derived Neurotoxin, an Antimicrobial Protein with Ribonuclease Activity, is an Immunostimulant

De Yang *et al.* (NCI)

U.S. Patent Application No. 10/834,733 filed 29 Apr 2004 (DHHS Reference No. E–191–2003/1–US–01)

Licensing Contact: Brenda Hefti; (301) 435–4632; *heftib@mail.nih.gov.*

Eosinophil-derived neurotoxin (EDN) has in vitro anti-viral activity that is dependent on its ribonuclease activity. This invention discloses that EDN is a selective chemoattractant and activator of dendritic cells, resulting in dendritic cell migration, maturation, and a production of a wide variety of cytokines. Based on these potent chemotactic and activating effects on dendritic cells, EDN might be useful as a clinical immunoadjuvant for the promotion of immune responses to specific antigens of tumors or pathogenic organisms.

Genes Expressed in Prostate Cancer and Methods of Use

Ira Pastan, Tapan Bera, and Byungkook Lee (NCI)

U.S. Provisional Patent Application No. 60/461,399 filed 08 Apr 2003 (DHHS Reference No. E–148–2003/0–US–01)

PCT Application No. PCT/US04/10588 filed 05 Apr 2004, which published as WO 2004/092213 on 28 Oct 2004

(DHHS Reference No. E–148–2003/0–PCT–02)

Licensing Contact: Brenda Hefti; (301) 435–4632; *heftib@mail.nih.gov.*

This invention is a novel gene, called New Gene Expressed in Prostate (NGEP). This gene appears to be expressed only in prostate. This gene has two known splice variants of significantly different size. The shorter splice variant encodes a cytoplasmic protein, while the longer splice variant encodes a plasma membrane protein.

This patent application contains claims to the polypeptide, NGEP, nucleotides encoding NGEP, antibodies that bind NGEP polypeptides, and methods of using these polypeptides, polynucleotides, and antibodies.

The presence of the protein on the cell surface and the selective expression in prostate and prostate cancer make this a potential target for prostate cancer diagnostics and therapeutics. Potential therapeutics could be gene-based, vaccines, antibodies, or immunoconjugates. Further information can be obtained by viewing a recent publication by the inventors (PNAS v. 104 no. 9, p. 3050–3064, March 2, 2004).

Immunogenic Peptides for the Treatment of Prostate and Breast Cancer

Jay Berzofsky, Sang-kon Oh, and Ira Pastan (NCI)

U.S. Provisional Patent Application 60/476,467 filed 05 Jun 2003 (DHHS Reference No. E–116–2003/0–US–01)

PCT Application No. PCT/US04/17574 filed 02 Jun 2004 (DHHS Reference No. E–116–2003/0–PCT–02)

Licensing Contact: Brenda Hefti; (301) 435–4632; *heftib@mail.nih.gov.*

This invention relates to antigenic sequences of the T cell receptor gamma alternate reading frame protein (TARP). TARP is expressed in breast cancer cells and prostate cancer cells. The patent application discloses immunogenic TARP polypeptides that generate an immune response to breast or prostate cancer cells that express TARP. These include sequences modified to make them more immunogenic. The application also discloses specific TARP nucleic acid sequences and host cells transfected with these nucleic acids. This invention may be useful as a therapeutic to treat breast or prostate cancer.

Detection of Antigen-Specific T Cells and Novel T Cell Epitopes by Acquisition of Peptide/HLA–GFP Complexes

Steven Jacobson, Utano Tomaru, and Yoshihisa Yamano (NINDS)

PCT Application No. PCT/US04/08960 filed 24 Mar 2004, which published as WO 2004/084838 on 07 Oct 2004 (DHHS Reference No. E–084–2003/2–PCT–01)

Licensing Contact: Brenda Hefti; (301) 435–4632; *heftib@mail.nih.gov.*

This invention relates to a method for identifying specific T cell epitopes and antigen-specific T cells through labeling with an HLA-GFP complex expressed on an antigen-presenting cell. The T cells acquired the peptide-HLA-GFP complex through T cell mediated endocytosis upon specific antigen stimulation. This basic method can be used for several purposes. First, it can be used to generate a T-cell immune response through the attachment of a reporter peptide to the antigen-presenting cell. It can also be used as a way to assay a population of cells to determine whether any T cells specific for a particular antigen are present. This might be useful in applications related to autoimmunity, infectious disease, or cancer. Third, it can be used as a therapeutic to eliminate antigen-specific T cells associated with disease, if coupled to a toxic moiety.

Use of Cripto-1 as a Biomarker for Neurodegenerative Disease and Method of Inhibiting Progression Thereof

David S. Salomon (NCI), Berman Nancy (EM), Edward B. Stephens (EM)

U.S. Provisional Application No. 60/508,750 filed 03 Oct 2003 (DHHS Reference No. E–075–2003/0–US–01)

PCT Application No. PCT/US04/32649 filed 01 Oct 2004 (DHHS Reference No. E–075–2003/0–PCT–02)

Licensing Contact: Brenda Hefti; (301) 435–4632; *heftib@mail.nih.gov.*

Cripto-1 is a gene that is currently thought to play an important role in several cancers, and is being developed in clinical trials as a cancer therapeutic.

The current invention relates to another use of Cripto-1 as a biomarker and possible therapeutic target for a variety of neurodegenerative diseases, including NeuroAids, Alzheimer's disease, MS, ALS, Parkinson's disease and encephalitis. Cripto-1 appears to be overexpressed by 20-fold or more in NeuroAids and as such may be enhanced in other inflammatory neurological diseases, and thus assist in the early detection of neurological changes associated with these diseases, as well as a possible therapeutic target for slowing progression.

Protein Kinase C Inhibitor, Related Composition, and Method of Use

Shaomeng Wang, Peter Blumberg (NCI), Nancy Lewin (NCI)

U.S. Provisional Patent Application No. 60/451,214 filed 28 Feb 2003 (DHHS Reference No. E–073–2003/0–US–01)

PCT Application No. PCT/US04/05855 filed 26 Feb 2004, which published as WO 2004/078118 on 16 Sep 2004 (DHHS Reference No. E–073–2003/0–PCT–02)

*Licensing Contact:*Brenda Hefti; (301) 435–4632; *heftib@mail.nih.gov.*

Protein kinase C is a critical component in cellular signaling, involved in cellular growth, differentiation, and apoptosis. It has been identified as a promising therapeutic target for cancer, diabetic retinopathy, and Alzheimer's disease, among other indications. This invention relates to lead compounds that can inhibit protein kinase C isoforms through disruption of their C1 domains. The inventors also found that these compounds possess isoform selectivity, an important feature for therapeutic specificity. Finally, although the disclosed compounds are previously known molecules, novel structures are described in the invention that have further improved specificity.

Recombinant Immunotoxin and Use in Treating Tumors

Ira Pastan (NCI), Masanori Onda (NCI), Nai-Kong Cheung (EM)

PCT Application No. PCT/US03/38227 filed 01 Dec 2003, which published as WO 2004/050849 on 17 Jun 2004 (DHHS Reference No. E–051–2003/0–PCT–02)

Licensing Contact: Brenda Hefti; (301) 435–4632; *heftib@mail.nih.gov.*

The current invention relates to the 8H9 monoclonal antibody (MAb), which is highly reactive with a cell surface glycoprotein expressed on human breast cancers, childhood sarcomas, and neuroblastomas but is not reactive with the cell surface of normal human tissues. This specific reactivity suggests that this antibody could be useful as a diagnostic, or as a therapeutic molecule to treat breast cancer, osteosarcoma, and neuroblastoma. The PCT application claims the 8H9 protein, 8H9 antibodies, 8H9 immunotoxins, pharmaceutical compositions, and methods of use.

More information can be found in a recent publication: M. Onda *et al.*, ''In vitro and in vivo cytotoxic activities of recombinant immunotoxin 8H9(Fv)-PE38 against breast cancer, osteosarcoma, and neuroblastoma,'' Cancer Res. 2004 Feb 15;64(4):1419–1424.

Activation of Recombinant Diphtheria Toxin Fusion Proteins by Specific Proteases Highly Expressed on the Surface of Tumor Cells

Stephen Leppla, Shi-Hui Liu, Manuel Osorio, and Jennifer Avallone (NIDCR)
U.S. Provisional Application No. 60/468,577 filed 06 May 2003 (DHHS Reference No. E–331–2002/0–US–01)
PCT Application No. PCT/US04/01430 filed 06 May 2004 (DHHS Reference No. E–331–2002/0–PCT–02)
Licensing Contact: Brenda Hefti; (301) 435–4632; *heftib@mail.nih.gov.*

This invention relates to diphtheria toxin fusion proteins comprising a diphtheria toxin (DT) cell-killing component and a cell-binding component such as granulocyte macrophage colony-stimulating factor (GM–CSF), interleukin 2 (IL–2), or epidermal growth factor (EGF). Receptors for the latter three materials are present on many types of cancer cells; therefore, these fusion proteins bind preferentially to these cancer cells. A key feature is that these toxins are altered so as to require activation by a cell-surface protease that is overexpressed on many types of cancers. Examples of such proteases include matrix metalloproteinases and urokinase plasminogen activator. Consequently, these novel cytotoxins kill tumors expressing receptors for either GM–CSF, IL–2, or EGF along with the cell-surface protease. Because killing requires the presence of both a receptor and a cancer-cell enriched protease, and few normal tissues contain both, there is less toxicity to normal cells. Thus, a larger amount of the agent may be used for cancer therapy without inducing side effects. In other words, these cytotoxins have a higher therapeutic index than toxins that are targeted to cells using a single strategy.

BASE, a New Cancer Gene, and Uses Thereof

Ira Pastan, Kristi Egland, James Vincent, Byungkook Lee, and Robert Strausberg (NCI)
PCT Application No. PCT/US03/39476 filed 10 Dec 2003 (DHHS Reference No. E–321–2002/0–PCT–02)
Licensing Contact: Brenda Hefti; (301) 435–4632; *heftib@mail.nih.gov*

The present invention identifies a new gene expressed in breast cancers. The gene undergoes alternative splicing, and is expressed as one of two polypeptides. Both splice variants appear to be secreted proteins, and therefore good potential therapeutic targets. The patent application claims BASE polypeptides, nucleic acids, gene therapy and vaccine uses, and antibodies. This novel gene target might be useful as a breast cancer marker for diagnostics, or as a target for breast cancer therapeutics.

Applications for the HMGN1 Pathway

Michael Bustin (NCI)
U.S. Provisional Patent Application No. 60/455,728 filed 17 Mar 2003 (DHHS Reference No. E–208–2002/0–US–01)
PCT Application No. PCT/US04/08060 filed 17 Mar 2004, which published as WO 2004/083398 on 30 Sep 2004 (DHHS Reference No. E–208–2002/0–PCT–02)
Licensing Contact: Brenda Hefti; (301) 435–4632; *heftib@mail.nih.gov*

HMGN1 is a protein that binds to nucleosomes, changes chromatin structure and affects transcription, and the expression of this protein changes during differentiation. Mice lacking this protein have increased growth capacity of several skin components, including epidermis, epidermal appendages, and dermis. Conceivably, this change could be related to an alteration of stem cell differentiation or to cell cycling events. The current invention relates to interference with this pathway, which might lead to increased stem cell differentiation and increased hair cycling and growth in humans as well. This invention might be useful to increase hair growth, enhance wound healing for epidermal and dermal wounds, and enhance stem cell populations for tissue regeneration, gene targeting, or gene therapeutic indications.

Dated: December 20, 2004.

Steven M. Ferguson,

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

[FR Doc. 04–28684 Filed 12–30–04; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive License: ''Vasostatin as Marrow Protectant'' and ''Use of Calreticulin and Calreticulin Fragments To Inhibit Endothelial Cell Growth and Angiogenesis and Suppress Tumor Growth''

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

ACTION: Notice.

SUMMARY: This notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR part 404.7(a)(1)(i), announces that the Department of Health and Human Services is contemplating the grant of an exclusive license to practice the inventions embodied in U.S. Patent No. 6,596,690 B2 entitled ''Vasostatin as Marrow Protectant'' (DHHS Reference E–230–2000/0); U.S. Patent Application No. 09/807,148 filed April 5, 2001, entitled ''Use of Calreticulin and Calreticulin fragments to inhibit endothelial cell growth and angiogenesis and suppress tumor growth'' (DHHS Reference E–082–1998/0–US–03); PCT Application No. PCT/US99/23240 filed October 5, 1999 entitled ''Use of Calreticulin and Calreticulin fragments to inhibit endothelial cell growth and angiogenesis and suppress tumor growth'' (DHHS Reference E–082–1998/0–PCT–02); to BioAccelerate, Inc., a venture capital group controlling the following twelve companies: Bioenvision, Enhance Biotech, Evolve Oncology, CNS Thera, Innova Lifestyle, Inncardio, Anvira, Neuro Bioscience, Biocardio, Oncbio, Innovative Oncology and Genar Oncology. The patent rights in these inventions have been assigned to the United States of America.

The prospective exclusive license territory may be worldwide and the field of use may be limited to development and sale of a pharmaceutical product useful in protecting bone marrow stem cells from the toxic effects of chemotherapy and radiotherapy.

DATES: Only written comments and/or license applications which are received by the National Institutes of Health on or before March 4, 2005 will be considered.

ADDRESSES: Requests for copies of the patent and/or patent applications, inquiries, comments and other materials relating to the contemplated exclusive license should be directed to: Mojdeh Bahar, J.D., Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804. Telephone: (301) 435–2950; Facsimile: (301) 402–0220; E-mail: *baharm@od.nih.gov*.

SUPPLEMENTARY INFORMATION: The technology claimed in the aforementioned patents is based on the discovery of the calreticulin N-domain (vasostatin) and the three previously uncharacterized properties of calreticulin. First, calreticulin N-domain is shown to stimulate the proliferation and survival in vitro of hematopoietic cells in the presence of previously identified growth factors. Second, Vasostatin is shown to protect