Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Annualized Totals	17,315			2,862

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) 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) 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) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to 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, D.C. 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: Chris Thomsen, Acting Chief, Cancer Information Service, RIB, OCC, OD, NCI, Building 31, Room 10A16, 9000 Rockville Pike, Bethesda, MD 20892, or call non-toll-free number (301) 496–5583 ext. 239 or E-mail your request, including your address to: thomsenc@occ.nci.nih.gov

COMMENTS DUE DATE: Comments regarding this information collection are best assured of having their full effect if received on or before February 27, 1997.

Dated: December 12, 1996.

Nancie L. Bliss,

OMB Project Clearance Liaison.

[FR Doc. 97–1982 Filed 1–27–97; 8:45 am]

BILLING CODE 4140–01–M

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health.

ACTION: Notice.

The inventions listed below are owned by agencies 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 U.S. 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). An signed Confidential Disclosure Agreement (CDA) will be required to receive copies of the patent applications.

Immunotoxin (MAB–RICIN), for the Treatment of Focal Movement Disorders

J Hott, R Youle, M Hallet, M Dalakas (NINDS)
Serial No. 60/027,458 filed 19 Sep 96
Licensing Contact: Stephen Finley, 301/496–7735 ext 215

This invention describes the use of an immunotoxin designed to treat focal dystonias that are currently being treated by injections of botulinum toxin (BTX) or by surgical myectomy. The immunotoxin (ITX) is prepared from a monoclonal antibody (MoAb35), specific to the nicotinic acetylcholine receptor in skeletal muscle, and is covalently linked to the toxin, ricin. ITX utilizes ricin's alpha chain and beta chain for its improved potency. ITX's potency was demonstrated by intramuscular injections into a rat model. The effects of intermuscular injections of ITX were compared to that of BTX. Even lower doses of ITX proved more effective and longer lasting than BTX in weakening muscle. The ITX selectively removed muscle fiber at the injection sites. It is believed that ITX may have clinical applications to those patients who have become refractory to BTX, or when used in combination or in place of BTX. In addition to the use of ITX in the treatment of all focal muscular spasms, ITX may prove useful in the treatment of other disorders of muscular spasms such as blepharospasms, cervical dystonia, hand dystonia, limb dystonia, hemifacial spasm, bruxism, strabismus, VI nerve palsy, for spasmodic, dysphonia, and oromandibular dystonia. (portfolios: Central Nervious System—Therapeutics, neurological, other; Central Nervous System—Therapeutics, neurological, muscle relaxants; Internal Medicine—Therapeutics, other)

Methods and Compositions for p300/CBP-Associated Transcriptional Co-Factor (P/CAF)

Y Nakatani, B Howard (NICHD)
Serial No. 60/022,273 filed 23 Jul 96
Licensing Contact: Ken Hemby, 301/496–7735 ext 265

The adenoviral oncoprotein E1A induces cell transformation by binding to various cellular components, such as the products of the retinoblastoma and p300/CBP gene families. This invention provides a transcriptional co-factor, p300/CBP-associated factor (P/CAF), which has intrinsic histone acetylase activity and also competes with E1A for binding to cellular targets. Also provided are methods of screening for compounds that affect P/CAF activity. Methods for directed gene therapy to provide functional wild-type or mutant P/CAF to cells producing varying levels of P/CAF protein are also provided. (portfolios: Cancer—Diagnostics; Cancer—Therapeutics, biological response modifiers; Devices—Research Tools and Materials, biologicals and chemicals)

Conformationally Locked Nucleoside Analogs

VE Marquez, JB Rodriquez, MC Nicklaus, JJ Barchi Jr, MA Siddiqui (NCI)
Serial Number 08/311,425 filed 23 Sep 94 (with priority to 24 Sep 93) and

Conformationally Locked Nucleoside Analogs as Antiherpetic Agents

VE Marquez, MC Nicklaus, JJ Barchi Jr, JB Rodriguez, MA Siddiqui (NCI)
Serial Number 60/023,565 filed 07 Aug 96
Licensing Contact: Robert Benson, 301/496–7056 ext 267

These inventions concern novel nucleoside analogs comprising carbocyclic-4′, 6′-cyclopropane-fused-2′, 3′-derivatives of ribo, deoxyribo and dideoxyribo purines and pyrimidines, and the corresponding nucleotides. The first patent application describes an anti-HIV utility. It has been foreign filed as PCT/US94/10794. The second application describes a new utility of the deoxyribo derivatives of the first application, namely as anti-Herpes Virus agents. The thymidine analog, in particular, showed good activity against Herpes Simplex Type 1 and Herpes Simplex Type 2 viruses, and Epstein-Barr virus as shown in an in vitro assay. It showed better antiherpes activity than acyclovir in a plaque reduction assay. Descriptions of the invention are to be found in Rodriguez et al., Tetrahedron Letters 34: 6233–6236, 1993; Rodriguez et al., J. Medicinal Chemistry 37: 3389–3399, 1994; Siddiqui et al., Nucleosides Nucleotides 15: 235–250, 1996 and Marquez et al., J. Medicinal Chemistry 39: 3739–3747, 1996. (portfolio: Infectious Diseases—Therapeutics, anti-viralsa, AIDS)

Long Distance Sequencer Method: A Novel Strategy for Large DNA Sequencing Projects

K Hagiwara, CC Harris (NCI)
Serial No. 60/017,569 filed 15 May 96
Licensing Contact: Leopold J. Luberecki, Jr., 301/496–7735 ext 223

The current invention represents an improvement over existing technologies used in sequencing long fragments of DNA. Existing technologies allow for the sequencing of a 10 kb fragment of DNA in two to three months; the present invention allows for such sequences to be obtained in two to three weeks. Specifically, the method consists of the cloning of a long (5 kb or longer) fragment of DNA into an appropriate vector, followed by the generation of a series of shorter fragments by a number of restriction digests. A ''vectorette unit'' is then ligated to each restriction fragment. This vectorette unit is an oligonucleotide 53 bases in length, and has a unique sequence which is not found in the human genome. Through use of the vectorette as a ''known end,'' together with a specific primer, the DNA is amplified via PCR and directly sequenced using current technologies. The investors have successfully used this method to sequence a 35 kb fragment of DNA.

This method appears to represent four key advantages over existing sequencing methods. First, the sequence of a long fragment of DNA can be obtained far more rapidly than is currently possible. Second, as multiple cloning steps are not necessary, it is easier to perform. Third, a much smaller amount of DNA is needed for this method than is necessary when using currently available sequencing techniques. Fourth, because of its organized way of sequencing, one can clearly identify the region being sequenced. (portfolio: Devices/Instrumentation—Research Tools and Materials)

Hepatitis B Core Antigen Fusion Proteins as Tumor Vaccines

LW Kwak, A Biragyn (NCI)
Serial No. 60/013,839 filed 21 Mar 96
Licensing Contact: Joseph Contrera, 301/496–7056 ext 244

Hepatitis B Core Antigen (HBcAg) represents a potentially potent carrier of vaccines. Embodied in this invention are a number of fusion proteins of HBcAg. It has been shown that HBcAg elicits a strong immune response, and it was thought that if one were to attach other weakly antigenic peptides of choice to the HBcAg protein in order to form a fusion protein, the antigenicity of the attached peptide of choice would be considerably enhanced. The fusion proteins embodied in this invention, which contain specific H-ras or MUC–1 (human epithelial cell mucin) peptides, have been shown to elicit protective anti-tumor immunity in vivo. This immunity is, in fact, superior to that elicited through immunizing with tumor antigen alone. These HBcAg fusion proteins, therefore, are believed to represent powerful new vaccines to be used toward the prevention and treatment of a wide variety of cancers. (portfolio: Cancer—Therapeutics, immunoconjugates Mab; Cancer—Therapeutics, immunoconjugates, conjugate chemistry; Cancer—Therapeutics, immunomodulators and immunostimulants)

Substantially Pure Non-IL-2 T-Cell Growth Factors

TA Waldmann, R Bamford, E Roessler, CK Goldman, G Szakiel, JD Burton, C Peters, AJ Grant, J Brennan, M Moos (NCI)
Serial No. 08/572,423 filed 14 Dec 95
Licensing Contact: Jaconda Wagner, 301/496–7735 ext 284

The invention provides isolated interleukin-T in human form, along with the methods for isolating the interleukin, and its respective non-IL–2 T-Cell growth factor and antibodies.

T cells play both regulatory and effector functions in human immune responses that are often mediated by interleukins. Interleukins are highly redundant and pleitrophic, controlling a wide range of functions. Abnormalities of interleukin and interleukin receptor systems are observed with a broad array of human diseases, including the forms of leukemia and autoimmune diseases such as rheumatoid arthritis that are caused by human T-cell lymphotropic virus-I. Thus, the invention could be used to treat a disorder associated with immune function, such as cancer, AIDS or other immunodeficiencies, by enhancing the immune system or, in treating an immune disorder, such as graft-versus-host disease, leukemia, lymphoma or an allograft rejection, by suppressing the immune system. (portfolio: Internal Medicine—Therapeutics, anti-inflammatory; Cancer—Therapeutics, biological response modifiers, growth factors)

Method of Preventing or Treating Disease Characterized by Neoplastic Cells Expressing CD40

RJ Armitag (Immunex), WC Fanslow (Immunex), DL Longo (NCI), WJ Murphy (NCI)
Serial No. 08/172,664 filed 23 Dec 93 and Serial No. 08/360,923 filed 21 Dec 94 (CIP)
Licensing Contact: Joseph Contrera, 301/496–7056, ext 244

The subject invention proposes a method for treating a mammal afflicted with a neoplastic disease caused by cells that express CD40. CD40 is a receptor protein present on B cells, monocytes, endothelial cells, and various carcinomas. The ligand for CD40 (CD40L) is present on activated T cells. CD40 has been shown to play a critical stimulatory role in normal B cell development. It has been previously demonstrated that signals that activate normal cells can lead to inhibition of neoplastic cells by inducing activation-induced cell death. Therefore, inhibition of neoplactic cell growth can be achieved through the use of CD40 stimulation. The invention discloses monoclonal antibodies to CD40, CD40 ligands, and combinations thereof. Oligomeric forms of CD40 ligands and fusion protein ligands are also disclosed. This invention is jointly owned by the National Institutes of Health and Immunex Corporation. All fields of use are available for licensing. (portfolio: Cancer—Therapeutics, immunoconjugates, Mab)

Recombinant DNA Clone Encoding Laminin Receptor

ME Sobel, LA Liotta, UM Wewer, MC Jaye, WN Drohan (NCI)
Serial No. 06/911,863 filed 26 Sep 86, which issued as U.S. Patent No. 4,861,710 on 29 Aug 89
Licensing Contact: Raphe Kantor, 301/496–7735 ext 247

A recombinant DNA clone that encodes high-affinity cell surface receptors for laminin, a glycoprotein component of basement membranes, offers an important tool for studying a variety of normal and abnormal cell processes including tumor metastases. These laminin receptors have been shown to inhibit metastases. These recombinant receptors can be used in diagnostic methods, to assess the content of laminin receptor mRNA, and to determine the pattern of laminin receptor genes in different tissue and tumor cell populations. (portfolio: Cancer—Research Materials; Cancer—Diagnostics, Mab based)

Dated: January 17, 1997.

Barbara M. McGarey,

Deputy Director, Office of Technology Transfer.

[FR Doc. 97–2062 Filed 1–27–97; 8:45 am]

BILLING CODE 4140–01–M

National Cancer Institute; Notice of Closed Meeting

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 National Cancer Institute Special Emphasis Panel (SEP) meeting:

Name of SEP: Geographical and Statistical Modeling of Exposure to OCCs/DAHs in LI and Breast Cancer and the Environment on Long Island.

Date: January 31, 1997.

Time: 2:30 p.m.

Place: Teleconference, Executive Plaza North, Room 643B, 6130 Executive Boulevard, Bethesda, MD 20892.

Contact Person: Robert Browning, Ph.D., Scientific Review Administrator, National Cancer Institute, NIH, Executive Plaza North, Room 643B, 6130 Executive Boulevard, MSC 7405, Bethesda, MD 20892–7405, Telephone: 301/496–7929.

Purpose/Agenda: To evaluate and review grant applications.

This notice is being published less than 15 days prior to the meeting due to the urgent need to meet timing limitations imposed by the review and funding cycle.

The meeting will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program Numbers: 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control.)

Dated: January 21, 1997.

Paula N. Hayes,

Acting Committee Management Officer, NIH.

[FR Doc. 97–1979 Filed 1–27–97; 8:45 am]

BILLING CODE 4140–01–M

National Cancer Institute; Notice of Planning Group Meeting

Notice is hereby given that the National Cancer Institute will hold a public meeting of a Planning Group which will assist NCI in establishing a Director's Consumer Liaison Group (DCLG). The Planning Group meeting will begin at 8:30 a.m. on March 13, 1997 and will end at 1:00 p.m. on March 14, 1997 at the Holiday Inn (Bethesda, MD). All sessions of the Planning Group meeting are open to the public. However, seating is limited and will be on a first-come, first served basis.

A temporary DCLG Planning Group of NCI staff and consumer-advocates was formed to help in establishing the DCLG. The purpose of the DCLG is to: (1) Help develop and establish processes, mechanisms, and criteria for identifying appropriate consumer-advocates to serve on a variety of program and policy advisory committees responsible for advancing the mission of the NCI; (2) serve as a primary forum for discussing issues and concerns and exchanging viewpoints that are important to the broad development of NCI programmatic and research priorities, e.g., the development of the annual Bypass Budget; and (3) establish and maintain strong collaborations between NCI and the cancer advocacy community to reach common goals. The DCLG, consisting of approximately 15 consumer-advocates who are involved in cancer advocacy and/or voluntary organizations, will meet several times a year. NCI anticipates that the activities and initiatives developed by NCI, in conjunction with the DCLG, will serve as models for consumer participation. Nominations for the members of the DCLG will be solicited from the cancer advocacy community. The first meeting of the DCLG is planned for late June 1997. A notice of the date and location of this meeting will be published in the Federal Register at a later date.

The objectives of the Planning Group are to: (1) define the initial role of the DCLG; and (2) define the DCLG membership solicitation process, as well as the criteria, categories, and rating system to identify and rank potential members of the DCLG. Development of criteria for membership on the DCLG will include identification of categories of members needed to ensure balance and diversity of representation. To identify DCLG members, the process selected by the Planning Group to announce and invite submission of names of consumer-advocates to serve on the DCLG will be followed. Nominees will be screened for eligibility according to a set of criteria and categories developed by the DCLG Planning Group. Consumer-advocates who are on the Planning Group will be unable to serve as members of the DCLG in its first year of operation, but their organizations may be represented by another individual.

To provide input to the Planning Group, members of advocacy or voluntary organizations related to cancer are invited to submit eligibility criteria and categories that could be used to identify individuals who could serve on the DCLG. These criteria and categories will be used to help the Planning Group to develop the process for identifying DCLG members. Submissions on criteria and categories should be mailed to Ms. Fran Oscar at Palladian Partners, 7315 Wisconsin Avenue, Suite 440W, Bethesda, MD 20814, or sent to her by FAX to (301) 986–5047 or by E-mail to palladianp@.aol.com. They must be received no later than 5:00 p.m. (EST) on February 15, 1997 to be included in the materials provided to the Planning Group prior to the meeting. Submissions received after that date and time will be accepted, but may not be included in the materials considered by the Planning Group members at the March 13–14 meeting. All submission must be accompanied by the following information: (1) Name and address of individual making the submission; and (2) name and address of cancer advocacy or voluntary organization with which they are affiliated.

Individuals who plan to attend the meeting and need special assistance, such as sign language interpretation or other special accommodations, should call Ms. Elaine Lee, Office of Liaison Activities, NCI at (301) 496–0644 or contract her by FAX (301) 402–2594 or E-mail (leee@od.nci.nih.gov) in advance of the meeting, by February 15, 1997. For additional information, contact Ms. Lee.