

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 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 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 contacting Catherine Joyce, Ph.D., J.D., at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3821; telephone: 301/496-7056 ext. 258; fax: 301/402-0220; e-mail: joycec@od.nih.gov. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Methods of Generating Human CD4+ Th1 Cells

Dr. Daniel H. Fowler et al. (NCI).

[DHHS Reference No. E-335-01/0 filed 31 Aug 2001]

This technology pertains to the identification of specific culture conditions that yield human CD4+ T cells highly enriched for Th1 cytokine production. Recently, techniques have been developed that enable the *in vitro* expansion of mixed populations of T cells (CD4+ T-cells and CD8+ T-cells) using magnetic microbeads to which monoclonal antibodies to CD3 and CD28 have been attached. This technology is being developed commercially as the Xcellerate™ technology by Xcyte Therapies, Inc., Seattle, Washington.

The instant invention is directed to the use of the 3/28 bead-stimulated expansion of CD4+ cells, under specific culture conditions, to yield highly pure populations of Th1 cells. The reported conditions permit the production of large numbers of pure Th1 CD4+ cells from human CD4+ cells. Autologous populations of pure Th1 CD4+ cells may be useful for anti-cancer therapy and/or

to enhance the immune response against infectious agents.

Methods of Generating Human CD4+ Th2 Cells

Dr. Daniel H. Fowler et al. (NCI).

[DHHS Reference No. E-114-01/0 filed 02 Jul 2001]

This technology pertains to the identification of specific culture conditions that yield a high purity of Th2 cells. Recently, techniques have been developed that enable the *in vitro* expansion of mixed populations of T cells (CD4+ T-cells and CD8+ T-cells) using magnetic microbeads to which monoclonal antibodies to CD3 and CD28 have been attached. This technology is being developed commercially as the Xcellerate™ technology by Xcyte Therapies, Inc., Seattle, Washington.

The instant invention is directed to the use of the 3/28 bead-stimulated expansion of CD4+ cells, under specific culture conditions, to yield highly pure populations of Th2 cells. The reported conditions permit the production of large numbers of pure Th2 CD4+ cells from human CD4+ cells. This technology is potentially applicable for the treatment of several medical conditions. Particularly, research regarding the clinical application of using pure Th2 cells for reducing graft-versus-host disease (GVHD) during allogeneic stem cell transplantation (used in the treatment of leukemia and lymphoma) has proceeded to the stage of Phase I clinical trials.

Transforming Growth Factor-Beta (TGF-Beta) Antagonist Selectively Neutralizes "Pathological" TGF-Beta

Drs. Lalage Wakefield and Yu-an Yang (NCI).

[DHHS Reference No. E-059-01/0 filed 21 Jun 2001]

This technology pertains to the use of a soluble transforming growth factor-beta (TGF-beta) antagonist (SR2F) for the suppression of metastasis. The SR2F antagonist is composed of the soluble extracellular domain of the type II TGF-beta receptor fused to the Fc domain of human IgG. In accordance with the invention, it has been discovered that overexpression of the SR2F antagonist in transgenic mice significantly protects against experimentally induced metastasis without inducing the negative effects associated with loss of TGF-beta function in the TGF-beta knock out mice. Lifetime exposure to the antagonist did not result in any increase in spontaneous or induced tumorigenesis, and there was no evidence for significant manifestations of autoimmune disease or increase in

inflammatory lesions. The inventors speculate that this apparent ability of SR2F to discriminate between "physiological" and "pathological" TGF-beta relates to the relative accessibility of the two forms of TGF-beta, with only pathological TGF-beta being accessible to the antagonist.

Dated: February 20, 2002.

Jack Spiegel,

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

[FR Doc. 02-4831 Filed 2-27-02; 8:45 am]

BILLING CODE 4140-01-P

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Production of Adeno-Associated Virus in Insect Cells

Robert M Kotin et al. (NHLBI)

Serial No. 09/986,618 filed 09 Nov 01

Licensing Contact: Susan Rucker; 301/496-7735 ext 245; e-mail: ruckers@od.nih.gov

The invention, described and claimed in this patent application, relates to the field of production of recombinant adeno-associated virus (rAAV). More particularly, the invention relates to systems for producing rAAV in a baculovirus-based system. The systems

for producing rAAV can use the AAV Rep protein and an AAV ITR or the insect counterpart thereof, NS-1 and a chimeric ITR derived from AAV but containing the NS-1 binding site and the NS1-nicking site. The invention provides for increased production of rAAV when compared to mammalian systems employing 293 cells which are typically used for rAAV production.

This work has been published in part in C Ding et al., *J. Virol.* 76(1): 338-45 (Jan. 2002).

Microbial Identification Databases

Jon G. Wilkes et al. (FDA)

Serial No. 09/975,530 filed 10 Oct 2001

Licensing Contact: Dale Berkley; 301/496-7735 ext. 223; e-mail: berkleyd@od.nih.gov

The invention is a method for assembling a coherent database containing an essentially unlimited number of pyrolysis mass spectra to enable rapid chemotaxonomy of unknown microbial samples. The invention corrects for short and long-term drift of microbial pyrolysis mass spectra by using spectra of similar microbes as internal standards. The invention provides for the first time a practical way to assemble a coherent database containing an essentially unlimited number of pyrolysis mass spectra or other instrumental "fingerprints", where one or more is representative of each relevant strain, and representative of additional strains as they are added to the pool of microbial agents. Microorganisms can be identified using the invention from their fingerprint spectra regardless of the growth medium used to culture the bacteria. This is a result of the discovery that corrections made to the fingerprint spectrum of one type of bacterium to compensate for changes in growth medium may be applied successfully to metabolically similar bacteria. Fingerprint spectra to which the method of the invention may be applied include pyrolysis MALDI or other types of mass spectra, infrared spectra, chromatograms, NMR spectra and ion-mobility spectra. The present invention is especially useful for the rapid identification of microorganisms, including human pathogens.

Dated: February 20, 2002.

Jack Spiegel,

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

[FR Doc. 02-4832 Filed 2-27-02; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

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 meeting.

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

Name of Committee: National Cancer Institute Special Emphasis Panel, Cancer Intervention and Surveillance Modeling Network (CISNET).

Date: March 21, 2002.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Ramada Inn, 1775 Rockville Pike, Rockville, MD 20852.

Contact Person: Joyce C. Pegues, PhD., Scientific Review Administrator, Special Review and Resources Branch, Division of Extramural Activities, National Cancer Institute, 6116 Executive Boulevard, Room 7149, Bethesda, MD 20892, 301/594-1286. (Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 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, National Institutes of Health, HHS)

Dated: February 22, 2002.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 02-4811 Filed 2-27-02; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

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 meeting.

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

Name of Committee: National Cancer Institute Special Emphasis Panel to evaluate and Review One T32 Application

Date: March 19, 2002.

Time: 1:15 PM to 2:15 PM.

Agenda: To review and evaluate grant applications.

Place: 6116 Executive Boulevard, Room 3068A, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: David E. Maslow, PhD, Scientific Review Administrator, Grants Review Branch, Division of Extramural Activities, National Cancer Institutes, National Institutes of Health, 6116 Executive Boulevard—Room 8117, Bethesda, MD 20892-7405. 301/496-2330.

(Catalog of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 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, National Institutes of Health, HHS)

Dated: February 22, 2002.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 02-4818 Filed 2-27-02; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

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 meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial