ANDA No.	Drug	Applicant
89–616	Isoetharine Inhalation Solution USP, 0.167%.	Do.
89–617	Isoetharine Inhalation Solution USP, 0.2%.	Do.
89–618	Isoetharine Inhalation Solution USP, 0.25%.	Do.

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Drug Evaluation and Research (21 CFR 5.82), approval of the applications listed in the table in this document, and all amendments and supplements thereto, is hereby withdrawn, effective October 10, 2000.

Dated: September 12, 2000.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 00–24844 Filed 9–29–00; 8:45 am]

BILLING CODE 4160–01–F

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 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.

Method and Device for Analysis of Biological Specimens

M. Emmert-Buck (NCI), C. Englert (NCI), R. Bonner (NICHD), and L. Liotta (NCI)

DHHS Reference No. E–197–00/0 filed 26 Jul 2000

Licensing Contact: Uri Reichman; 301/496–7736 ext. 240; e-mail: reichmau@od.nih.gov

The invention discloses methods for selective analysis of cellular samples, and more particularly it provides methods for selective analysis of tissue samples, such as tumors. The methods include placing the tissue on a surface such as membrane for example, and activating the surface at selected sites adjacent to the cells of interest. The activated sites become permeable and thus transferable to fluids. The cells adjacent to the permeable sites can than be selectively extracted and their content analyzed by standard biochemical procedures or by applying the extract to microarray devices, such as cDNA arrays, for analysis of gene expression etc. The technique presents a convenient alternative to existing methods of tissue microdissection. For further convenience, the technique can be readily combined with a variety of analytical devices such as microarrays biochips or other devices which include multiple regions carrying multiple capture molecules.

Hepatitis A Virus Clones Adapted for Growth in African Green Monkey Kidney (AGMK) Cells and Vaccines Comprising said Clones

Robert H. Purcell *et al.* (NIAID)

DHHS Reference No. E–008–95/0 filed 06 Aug 1999

Licensing Specialist: Carol Salata; 301/496–7735 ext. 232; e-mail: salatac@od.nih.gov

The present invention relates to hepatitis A virus clones adapted to growth in African Green Monkey Kidney Cells intended to be used as a live attenuated vaccine. Several cell culture-adapted strains of hepatitis A virus (HAV) are currently being used as inactivated vaccines. However, the inactivated vaccines have the limitation that multiple doses are required for effective immunization. Thus, a live vaccine could have the advantage of inducing life-long immunity following administration of only a single dose.

Preclinical studies have been done using virus isolates of this invention. Preliminary observations suggest that some of the HM–175 P39 virus isolates analyzed may be promising candidates for use as a live attenuated vaccine. HM–175 P39 clone 15 appears to have the growth and attenuation properties that are desirable in a live vaccine for HAV as it is partially attenuated for tamarins and fully attenuated for chimpanzees. HM–175 P39 clone 13 may also be a potential vaccine candidate as it replicates efficiently in tamarins, resulting in moderate increases in serum liver enzyme and early seroconversion to anti-HAV positivity but is still fully attenuated for chimpanzees.

Method of Predicting Susceptibility to HIV Infection or Progression of HIV Disease

Michael W. Smith, Hyoung Doo Shin, Stephen J. O'Brien (NCI)

DHHS Reference No. E–066–99/0 filed 09 Apr 1999 and DHHS Reference No. E–066–99/1 filed 06 Apr 2000

Licensing Contact: J. P. Kim; 301/496–7056 ext. 264; e-mail: kimj@od.nih.gov

This invention identifies the importance of a variant in the IL 10 gene (–592–5′A) that is commonly found in the population with HIV–1/AIDS. Individuals that inherit one or two copies of this form of IL 10 are at a greater risk for progression from HIV–1 infection to the development of clinical AIDS or death. The effects of IL 10–592 are particularly evident 5 years after infection. The gene variant and its product may be of diagnostic value in testing to determine treatment regimens for patients and mimicking the effect of the IL 10–5′A gene variant may be useful in developing therapies for HIV infection. The polymorphism of the present invention can be used in association with other alleles, such as CCR5–D32, CCR2–64I, CCR5– +.P1.+, HLA–B35 and HLA homozygosity, to determine an individual's susceptibility to HIV infection, and provide a prognosis for disease progression in those who have been infected. The potential therapies derived from the IL 10–592 genetic variant may be particularly applicable to patients on triple drug therapy since these patients have generally been infected for a number of years prior to treatment.

Isolation of Cellular Material Under Microscopic Visualization

Liotta *et al.* (NCI)
Serial No. 08/203,780 filed 01 Mar 1994, issued as U.S. Patent No. 5,843,644; Serial No. 08/544,388 filed 10 Oct 1995, issued as U.S. Patent No. 5,843,657; Serial No. 08/882,699 filed 25 Jun 1997; Serial No. 08/925,894 filed 08 Sep 1997, issued as U.S. Patent No. 6,010,888; Serial No. 09/388,805 filed 02 Sep 1999
Licensing Contact: J. P. Kim; 301/496–7056 ext. 264; e-mail: kimj@od.nih.gov

The present technology provides methods and devices for the isolation and analysis of cellular samples on a molecular or genetic level. More particularly, the invention relates to methods and devices for the microdissection, for example, utilizing laser capture microdissection (LCM), and the diagnosis and analysis of cellular samples which may be used in combination with a number of different technologies that allow for analysis of enzymes, antigens, mRNA, DNA, and the like from pure populations or subpopulations of particular cell types.

Nucleic Acid Constructs Containing HIV Genes with Mutated Inhibitory/Instability Regions and Methods of Using Same

George N. Pavlakis, Barbara K. Felber (NCI)
Serial No. 07/858,747 filed 27 Mar 1992; U.S. Patent 5,972,596 issued 26 Oct 1999; U.S. Patent 5,965,726 issued 12 Oct 1999; Serial No. 09/414,117 filed 08 Oct 1999; PCT/US93/02908
Licensing Contact: Carol Salata; 301/496–7735 ext. 232; e-mail: salatac@od.nih.gov

This invention describes methodology for modifying the inhibitory/instability sequences (INS) of mRNA by making multiple nucleotide substitutions without altering the coding capacity of the mRNA of interest. Mutating INS allows for or increases the expression of genes that would otherwise have not been expressed or would have been poorly expressed because of the INS normally present on the mRNA transcript. This novel approach also improves the stability of the mRNA. These methods can be used to increase the production of protein from many genes producing, for example, growth hormone, interferons, interleukins, and HIV Gag and env. DNA constructs are described which encode Gag protein which is highly expressed and does not require HIV rev for production. Thus it is a potentially useful HIV DNA vaccine. Assays have also been developed to facilitate detection of the boundaries of INS sequences of any mRNA.

Dated: September 20, 2000.

Jack Spiegel,

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

[FR Doc. 00–25175 Filed 9–29–00; 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, DHHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is 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.

ADDRESS: Licensing information and copies of the U.S. patent application listed below may be obtained by contacting Susan S. Rucker, J.D., at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7056 ext. 245; fax: 301/402–0220; e-mail: ruckers@od.nih.gov. A signed Confidential Disclosure Agreement will be required to receive a copy of the patent application.

HGF–SF Monoclonal Antibody Combinations

B Cao, S Koochekpou, M Oskarsson, D Bjurickovic, M Fivash, R Fisher and GR Vande Woude (NCI)
Serial No. 60/164,173 filed 09 Nov 1999

The invention described and claimed in this application relates to a composition which comprises a combination of two or more antibodies which specifically bind one or more epitopes of the growth factor known as hepatocyte growth factor/scatter factor (HGF/SF) which is able to inhibit HGF/SF signaling. In particular, the antibodies which specifically bind to HGF/SF are monoclonal antibodies. Hepatocyte Growth Factor (HGF) activates migration and proliferation of endothelial cells and is angiogenic, acting through the tyrosine kinase receptor encoded by the Met protooncogene. In addition, HGF/SF displays a unique feature in inducing ''branching morphogenesis'', a complex program of proliferation and motogenesis in a number of different cell types. Moreover, HGF is involved in the invasive behavior of several tumor cells both in vivo and in vitro. This combination of antibodies may be useful in drug screening assays, detection of HGF/SF expression or activity or in treating HGF/SF related diseases such as cancer.

Dated: September 21, 2000.

Jack Spiegel,

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

[FR Doc. 00–25176 Filed 9–29–00; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of Meeting: Chronic Fatigue Syndrome Coordinating Committee

In accordance with section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C., Appendix 2), notice is hereby given of a meeting of the Chronic Fatigue Syndrome Coordinating Committee.

Name: Chronic Fatigue Syndrome Coordinating Committee

Time and Date: Wednesday, October 25, 2000, from 9 a.m. to 4:30 p.m.

Place: Hubert H. Humphrey Building, Room 800, 200 Independence Avenue, SW., Washington, DC 20201.

Status: Open to the public, limited only by the space available. The meeting room will accommodate approximately 100 people. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Notice: In the interest of security, the Department has instituted stringent procedures for entrance to the Hubert H. Humphrey Building by non-government employees. Thus, persons without a government identification card will need to provide a photo ID and must know the subject and room number of the meeting in order to be admitted into the building. Visitors must use the Independence Avenue entrance.

Purpose: The Committee is charged with providing advice to the Secretary, the Assistant Secretary for Health, and the Commissioner, Social Security Administration (SSA), to assure interagency coordination and communication regarding chronic fatigue syndrome (CFS) research and