agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Gail Dapolito at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/oc/advisory/default.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 12, 2009.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E9–3786 Filed 2–20–09; 8:45 am]

BILLING CODE 4160–01–S

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.

Quantitative Real-Time RT–PCR Array for Detection of Human Herpesvirus 6A Gene Expression

Description of Technology: This invention describes an RT–PCR array that allows for the simultaneous transcriptional profiling of the human herpesvirus HHV6A genome. It may be used to determine the contribution of HHV6A to the development of lymphomas, other types of cancer or diseases where an infectious agent is suspected. Primer pairs are designed to amplify under identical reaction conditions and are rigorously tested to ensure specificity for the HHV6A ORFs to the exclusion of all other human herpesviruses including HHV6B and HHV7.

Recent findings of the association of active viral genes with cancer cells have led to new proposed targets for cancer vaccines and therapeutics. The ability to distinguish HHV6A from other related herpesviruses, and to independently assay viral gene activity, may lead to the identification of new viral targets for the treatment of cancers and other diseases where HHV6A transcription is active.

Applications:

- Analysis of whole HHV6A genome expression.
- Identification of HHV6A gene expression and its association with disease states.

Development Status: Late stage.

Inventors: Rachel K. Bagni (NCI/SAIC), Francis W. Ruscetti (NCI), *et al.*

Patent Status: U.S. Provisional Application No. 61/114,753 filed 14 Nov 2008 (HHS Reference No. E–019–2009/0–US–01).

Licensing Status: Available for licensing.

Licensing Contact: Jeffrey A. James, PhD; 301–435–5474; *jeffreyja@mail.nih.gov*.

Collaborative Research Opportunity: The National Cancer Institute, Advanced Technology Program, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize virus specific quantitative real-time RT–PCR arrays. Please contact John D. Hewes, PhD at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

In Vivo Quantitative Tissue Oxygen Imaging Using Pulsed Time-Domain Electron Paramagnetic Resonance—Echo-Based Single Point Imaging (ESPI)

Description of Technology: Available for licensing and commercial development are patent rights covering an EPR image formation strategy for *in vivo* imaging of physiological function. It emphasizes image resolution and quantitative assessment of *in vivo* tissue oxygen that are important in planning radiation and chemotherapeutic treatments for patients with cancers. The method pertains exclusively to time-domain Fourier Transform EPR imaging (FT–EPRT) with emphasis on spatial and temporal resolution, since physiological processes are generally rapid and require accurate and rapid time-course information.

Two most important existing methods are Spin Echo Fourier (SEF) and Single Point Imaging (SPI). ESPI (Echo-based Single Point Imaging) enables the combination of the advantages of the quantitative T_2 contrast of SEF strategy and the super high resolution of the SPI methodology, leading to reliable EPR imaging for tissue physiological function *in vivo*.

Applications:

- EPR (Electron Paramagnetic Resonance).
- *In vivo* imaging.
- Tissue oxygen.

Inventors: Sankaran Subramanian, Nallathamby Devasahayam, Shingo Matsumoto, James Mitchell, Murali Cheruki, John Cook (NCI).

Patent Status: U.S. Provisional Application No. 61/200,579 filed 29 Nov 2008 (HHS Reference No. E–250–2008/0–US–01), entitled ''Pulsed Time-Domain Electron Paramagnetic Resonance In Vivo Tissue Oxygen Imaging Via Cooperative ESE/ESPI''.

Licensing Status: Available for licensing.

Licensing Contact: Michael A. Shmilovich, Esq.; 301–435–5019; *shmilovm@mail.nih.gov*.

Collaborative Research Opportunity: The National Cancer Institute Radiation Biology Branch is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize Echo-based Single Point Imaging. Please contact John D. Hewes, PhD at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Microwave-Assisted Freeze Substitution of Biological and Biomedical Samples (MWFS)

Description of Technology: Freeze substitution fixation (FS) of hydrated samples frozen in vitreous ice provides exceptional preservation of structure for light and electron microscopy, and enables immunological detection of thermo-labile antigens that otherwise are damaged/destroyed by processing at ambient or elevated temperatures. Its use as a research tool or in clinical pathology has, however, been limited by the relatively lengthy periods required for passive diffusion of fixatives and organic solvents into the frozen hydrated material.

The instant invention utilizes controlled microwave (MW) irradiation to accelerate the FS process; and comprises systems, devices and methods for microwave-assisted processing of samples under cryo-conditions. The entire MWFS procedure has been accomplished in less than 4 hours as compared to the approximately 2–5 days required for FS.

Applications:

• Provides superior preservation and rapid turnaround in research and high throughput clinical laboratory settings.

• Applicable to a broad range of biological samples, hydrogels, and other hydrated materials.

• Processing for light and electron microscopy.

• Low-temperature synthetic and analytical chemistry.

Advantages:

• Reduces processing periods from days to hours.

• Improves preservation, approaching native state.

• Enables uncomplicated, programmable operation.

• Provides excellent reproducibility.

Development Status:

• Proof of concept with varied biological samples.

• Adaptation of existing equipment with manual processing.

• Proposed designs for instrumentation and automation.

Market:

• Commercial and clinical histology laboratories.

• Pathology and forensic laboratories.

• Biomedical and biological research laboratories.

• Hydrogel and hydrated material research and quality control laboratories.

• Pharmaceutical and other synthetic and analytical chemistry laboratories.

Inventors: David Dorward, Vinod Nair, and Elizabeth Fischer (NIAID).

Publications: Manuscripts in preparation.

Patent Status:

• U.S. Provisional Application No. 61/094,848 filed 05 Sep 2008 (HHS Reference No. E–238–2008/0–US–01).

• U.S. Provisional Application No. 61/112,575 filed 07 Nov 2008 (HHS Reference No. E–238–2008/1–US–01).

• No foreign rights available at the present.

Licensing Status: Available for licensing.

Licensing Contact: RC Tang, JD, LLM; 301–435–5031; *tangrc@mail.nih.gov*.

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases, Research Technologies Branch, Electron Microscopy Unit, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize potential applications of the above mentioned invention, including design and development of instrumentation for conducting microwave-assisted freeze (cryo) substitution. Please contact Jason (Christopher) Freeman, J.D., NIAID/OTD, at 301–451–5054 or *freemanch@niaid.nih.gov* for more information.

Compositions and Methods for Vaccine and Virus Production

Description of Technology: This technology relates to compositions and methods for improving the growth characteristics of cells engineered to produce live viruses such as the Influenza virus. Featured is a method that uses the gene candidate, siat7e, or its expressed or inhibited products in Madin Darby Canine Kidney (MDCK) cells. The gene expression modulates anchorage-dependence of the cell line thereby allowing scale-up on bioreactor platforms without the use of microcarrier beads and reducing production costs. More specifically, this technology claims use of the methods embodied in the patent application for production of the Influenza viruses (human, avian and canine).

Applications: This technology may be used to improve the production of prophylactic compounds against the seasonal flu. Influenza viruses are traditionally isolated and propagated in chicken embryonated eggs. Egg-derived viruses are the source of Influenza vaccine preparation. Issues associated with this current Influenza virus production strategy are prolonged planning of egg supplies and cultivation periods, variants in antigenic properties of egg-derived viruses, sterility and hypersensitivity to egg compounds in a fractional population of potential vaccine recipients. Defined cell substrates are currently being investigated. MDCK cells have been shown to produce sufficient viral titers. However, these cells are anchorage-dependent and thus limited in scale-up even with the use of microcarrier beads. This technology provides a method for converting the MDCK cells into suspension culture and thus a promising alternative for Influenza virus production.

Advantages: This technology offers the ability to improve yields and reduce the cost associated with the production of the Influenza virus through the genetic modification of the MDCK cell line having:

• Altered growth characteristics.

• Altered adhesion characteristics.

• Altered rate of proliferation.

• Improvement in cell density growth in suspension.

• Improvement in hemagglutinin production.

Development Status: Late Stage—Ready for Production.

Market: Based on the marketing data collected during the late 1990s and early 2000s, growth of pharmaceutical companies' investments in vaccine have generated sales just slightly below $10 billion in 2004 and this statistic is expected to at least triple by the mid-2010s. It has also been reported that egg-based Influenza vaccines account for approximately 14% of the total vaccine sales and will approach a market size of $4 billion at the end of the decade. However, the belief of an impending Influenza pandemic has also spurred the search for a defined cell line that can serve as an alternative to the current egg-based production. Discovery and characterization of a suitable cell line for Influenza virus would be extremely valuable.

Mammalian cells such as Vero, PER.C6, and especially MDCK cells have been under investigation by both academic and industrial groups for their suitability to produce commercially viable viral titers. This technology details the genetic modification of the MDCK cell line with a human gene and consequently the isolation of an anchorage-independent MDCK cell line that has consistently produced a higher hemagglutinin titer.

This technology is ready for use in drug/vaccine discovery, production and development. The technology provides methods for altering the adhesion properties of the MDCK cell line to improve growth and production properties. Companies that are actively seeking production platforms based on mammalian cell lines that offer high efficiency, high throughput systems for Influenza virus production and ease of scale-up would be potential licensees of this technology.

Inventors: Joseph Shiloach, Pratik Jaluria, Michael Betenbaugh and Chia Chu (NIDDK).

Patent Status: U.S. Provisional Application No. 61/124,077 filed 11 Apr 2008 (HHS Reference No. E–173–2008/0–US–01).

Licensing Status: Available for licensing.

Licensing Contact: Peter A. Soukas, J.D.; 301–435–4646; *soukasp@mail.nih.gov*.

Collaborative Research Opportunity: The Biotechnology Core laboratory will consider collaborative research to further develop, evaluate, or

commercialize the above invention. Please contact Dr. Joseph Shiloach at *joseph.shiloach@nih.gov* or 301–496–9719 for more information.

Teniae Coli Guided Navigation and Registration for Virtual Colonoscopy

Description of Technology: This invention describes a more sensitive and efficient method for colon cancer screening using the *teniae coli* as an anatomical reference. Most computed tomographic colonography (CTC) protocols for colon cancer screening require that a patient is scanned in both the supine and prone positions for increased sensitivity; as a result, a reference system between scans is necessary for lesion matching. The *teniae coli* are three equal-distanced bands of longitudinal smooth muscle on the surface of the colon between the appendix and the sigmoid colon. These muscles can be used as anatomical landmarks to derive a coordinate system to better localize and register the corresponding supine and prone positions of a CTC study. The inventors have devised a semi-automated system for extracting data from the *teniae coli* and defining coordinate systems based on them.

The invention allows for more detailed detection of anatomical features for surgical planning, better camera orientation and virtual protocols, more efficient lesion registration, and precise record keeping. The algorithm has been used successfully to correctly localize several polyps to the same circumferential position in both supine and prone scans of a CTC study.

Applications:

• Positioning virtual cameras for navigating a single dataset.

• Synchronizing virtual cameras for virtual colonoscopic navigation.

• Predicting lesion candidates in a bound region for both 2D and 3D reading paradigms.

• Automatic polyp matching between scans for CAD applications.

Development Status: Late stage.

Inventors: Hui-Yang Huang (CC), Ronald M. Summers (CC), Dave R. Roy (OD).

Publication: A Huang, DA Roy, RM Summers, M Franaszek, N Petrick, JR Choi, PJ Pickhardt. *Teniae coli*-based circumferential localization system for CT colonography: feasibility study. *Radiology* 2007 May;243(2):551–560.

Patent Status:

• U.S. Patent Application No. 11/436,889 filed May 17, 2006 (HHS Reference No. E–084–2006/0–US–01).

• No foreign rights available.

Licensing Status: Available for licensing.

Licensing Contact: Jeffrey A. James, PhD; 301–435–5474; *jeffreyja@mail.nih.gov*.

Method and Apparatus for Performing Multiple Simultaneous Manipulations of Biomolecules in a Two-Dimensional Array

Description of Technology: This technology concerns a method and apparatus for accomplishing and/or facilitating the analysis of multiple biomolecules separated in a two-dimensional array, such as gel, membrane, tissue biopsy, etc. The invention employs a separator, termed an External Movement Inhibitor Device, that allows biomolecules to be transferred from an array such as those listed above to another support system while maintaining the two-dimensional spatial relationship of the biomolecules as in the array. The biomolecules can subsequently be subjected to various manipulations such as amplification, reverse transcription, labeling, cloning, etc., after which multiple well-established methods for quantitative and qualitative analysis can be used.

Applications:

• Two dimensional nucleic acid analysis.

• Two dimensional proteomic analysis.

• Histology/Pathology.

Advantages: Allows for simultaneous 2D analysis of nucleic acids and proteins.

Development Status: In vitro data can be provided upon request.

Market:

• Histology/Pathology of tissue samples.

• Tissue arrays.

• Nucleic acid and proteomic analysis.

Inventors: Michael R. Emmert-Buck *et al.* (NCI).

Patent Status:

• International Patent Application No. PCT/US03/37208 filed 20 Nov 2003 (HHS Ref. No. E–339–2002/0–PCT–02).

• U.S. Patent Application No. 10/535,521 filed 18 May 2005 (HHS Reference No. E–339–2002/0–US–03).

Licensing Status: Available for licensing.

Licensing Contact: Kevin W. Chang, PhD; 301–435–5018, *changke@mail.nih.gov*.

Collaborative Research Opportunity: The National Cancer Institute Laboratory of Pathology and Urologic Oncology Branch, Center for Cancer Research is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize an external movement inhibitor device for spatially restricted PCR amplification of nucleic acids. Please contact John D. Hewes, PhD at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Dated: February 10, 2009.

Richard U. Rodriguez,

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

[FR Doc. E9–3811 Filed 2–20–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meetings

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 meetings.

The meetings 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 Institute on Drug Abuse Special Emphasis Panel; NIDA–K Conflicts—SEP.

Date: March 17, 2009.

Time: 4:30 p.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Ritz Carlton Hotel, 1150 22nd Street, N.W., Washington, DC 20037.

Contact Person: Kristen V. Huntley, PhD, Scientific Review Administrator, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, Room 220, MSC 8401, 6101 Executive Boulevard, Bethesda, MD 20892–8401, 301–435–1433, *huntleyk@mail.nih.gov*.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; Medications Development Centers.

Date: March 19–20, 2009.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Sofitel Hotel, 806 15th Street, Washington, DC 20005.

Contact Person: Scott Chen, PhD, Scientific Review Officer, Office of Extramural Affairs, National Institute on Drug Abuse, National Institutes of Health, DHHS, 6101 Executive Boulevard, Room 220, MSC 8401, Bethesda, MD 20892, 301–443–9511, *chensc@mail.nih.gov*.