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.

DESCRIPTION: The inventions 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.

VORTEX COUNTER-CURRENT CHROMATOGRAPHY (CCC) SYSTEM

Description of Invention: Available for licensing and commercial development is a vortex counter-current chromatography system. The system has a rotary frame engaged to a vortex separation column for rotation in one direction through a vortex separation shaft engaged to a pulley system. The rotary frame is engaged to a central shaft that rotates the rotary frame in a direction opposite that of the vortex separation column such that planetary motion is imparted to the vortex separation column. The vortex separation column may be configured to receive a solvent system separable between two immiscible liquid phases introduced into the vortex separation column. A pulley system is operatively engaged to the separation column shaft and the central shaft for rotating the separation column shaft and the cortex separation column in a synchronous rotational direction opposite to the rotational direction of the rotary frame for imparting a type-I planetary motion to the vortex separation column. A counter-weight column is engaged at a symmetrical position opposite the vortex separation column along the rotary frame, wherein the two immiscible liquid phases undergo a vortex motion during rotation of the vortex separation column such that mixing of the two immiscible liquid phases takes place with a plane perpendicular to an axis of the vortex separation column.

Compared with conventional CCC systems, the vortex system has much higher partition efficiency in terms of height equivalent to a theoretical plate (only 2 cm compared with 20 cm that is required for the conventional system). The vortex system also provides an advantage of low column pressure which facilitates application of a large industrial-scale separation without a risk of leakage of solvent and column damage caused by high pressure.

Applications

- Drug Discovery.
- Chromatography.
- Natural Products Research.

Inventors: Yoichiro Ito (NHLBI).

Publications


Licensing Status: Available for licensing.

Licensing Contact: Shmulovm@mail.nih.gov.

MICROSCOPIC IMAGING TECHNIQUES

Description of Invention: The disclosed methods and apparatus of the technology can be used to provide radially or tangentially polarized beams (or both) to many applications. In particular, the technology can be effectively utilized in applications such as:

- Multi-photon microscopy.
- Microlithography.
- Ultrafine imaging in conjunction with the use of fluorophores.

Advantages: The technology provides higher optical resolution for certain applications as compared with currently used methodologies.

Development Status: The invention is fully developed.

Inventors: Jay R. Knutson (NHLBI).


Licensing Status: Available for licensing.

Licensing Contacts

- Uri Reichman, Ph.D., MBA; 301–435–4616; URT7@nih.gov.
- Michael Shmilovich, Esq.; 301–435–5019; shmilovm@mail.nih.gov.

Collaborative Research Opportunity: The NHLBI Laboratory of Molecular Biophysics is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact Brian Bailey at 301–394–4004 for more information.

MUCOSAL CYTOTOXIC T LYMPHOCYTE RESPONSES

Description of Invention: The invention offered for licensing provides methods and compositions for induction of an antigen-specific, mucosal cytotoxic T lymphocyte (CTL) response useful in preventing and treating infections with pathogens that gain entry via a mucosal surface. The methods of the invention involve administering either a soluble antigen itself, or a polynucleotide encoding the
soluble antigen, to a mucosal surface. The soluble antigens can be full length, naturally occurring polypeptides or fragments (i.e., peptides) derived from them. The soluble antigen is administered with an adjuvant at the mucosal site or without an adjuvant. Adjuvants can be, for example, Cholera toxin (CT), mutant CT (MCT), E. coli heat labile enterotoxin (LT) and others. Cytokines like IL–12 or IFNγ can also be administered to enhance the immunoreactivity. Mucosal routes of administration include intrarectal (IR), intranasal (IN), intragastric (IG), intravaginal (IVG) or intratracheal (IT). Soluble antigens can be derived from pathogenic viruses (e.g. HIV, influenza, or hepatitis virus), bacteria (e.g. Listeria monocytogenes), or prozoans. Furthermore, the soluble antigen can be tumor-associated antigen for cancer applications.

The utility of the technology has been extensively demonstrated when applied to HIV. Details about the HIV studies are provided in the eight (8) publications cited below.

Applications

- Immunization to treat infectious diseases,
- Possible applications in cancer therapy

Development Status: Proof of concept has been demonstrated, in particular as related to HIV.

Inventors: Jay A. Berzofsky (NCI) et al.

Relevant Publications


- Foreign patents issued in Australia (Application Number 93862/98 and Patent Number 757310) and in European countries (Application Number 89946065.5 and Patent Number 1011720): Germany, France, Ireland, United Kingdom, Italy, Portugal and Spain.

Licensing Status: Available for licensing and commercial development. Licensing Contacts: Uri Reichman, PhD, MBA; 301–435–4616; URT@nih.gov; or John Stansberry, PhD; 301–435–5236; js852e@nih.gov.

Collaborative Research Opportunity: The Center for Cancer Research, Vaccine Branch, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize Mucosal Cytotoxic T Lymphocyte Responses. Please contact John D. Hewes, PhD at 301–435–3121 or hjewes@mail.nih.gov for more information.


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

[FR Doc. 2010–22182 Filed 9–3–10; 8:45 am]
BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0426]

Draft Guidance for Industry: Bar Code Label Requirements—Questions and Answers (Question 12 Update); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled “Guidance for Industry: Bar Code Label Requirements—Questions and Answers (Question 12 Update)” dated August 2010. This draft guidance provides you, manufacturers of a licensed vaccine, with advice concerning compliance with the bar code label requirements. In this guidance, FDA is proposing to amend our response to question 12 (Q12) in the “Bar Code Label Requirements—Questions and Answers” guidance dated October 2006 (Bar Code Guidance), to provide recommendations to manufacturers of licensed vaccines in connection with the use of alternative coding technologies. When this guidance is finalized, we intend to incorporate the revised response to Q12 into the Bar Code Guidance, but otherwise continue with our recommendations for bar code label requirements as currently provided in the Bar Code Guidance.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comments on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments