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.

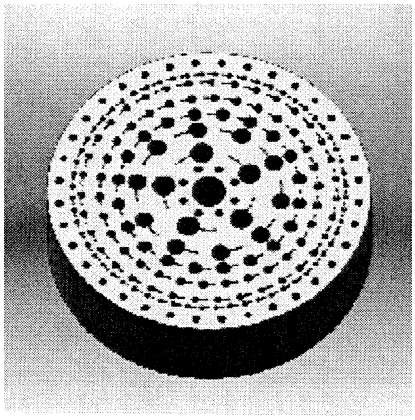
SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of Federally-funded research and development. Foreign patent applications are filed on selected 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.

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

1. Ito Y, Bowman RL. Countercurrent chromatography with flow-through coil planet centrifuge. Science 1971;173:420–422. [PubMed: 5557320]

2. Ito Y, Bowman RL. Countercurrent chromatography with flow-through coil planet centrifuge. J Chromatogr Sci. 1973;11:284–291.

Patent Status: U.S. Provisional Application No. 61/368,157 filed 27 Jul 2010 (HHS Reference No. E–196–2010/0–US–01).

Licensing Status: Available for licensing.

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

Superresolution Microscopy via Azicon Beam Polarization Devices

Description of Invention: The technology offered for licensing pertains to novel polarizers that produce tangentially and radially polarized beams. The polarizers and polarizing beam splitter of the technology include one or more pairs of axicons (also known as conical lenses) that are configured to separate an input beam into a radially polarized component and a tangentially (or azimuthally) polarized component. A second axicon pair can be positioned to recombine the tangentially polarized component so as to provide a more uniform beam intensity. The radial polarized component can be reflected or otherwise directed so that one or both the radial and tangential components are available for use.

Applications

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).

Patent Status: U.S. Provisional Application No. 61/308,202 filed 25 Feb 2010 (HHS Reference No. E–251–2009/0–US–01).

Licensing Status: Available for licensing.

Licensing Contacts

- Uri Reichman, Ph.D., MBA; 301–435–4616; *UR7a@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 301–594–4094 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 intratratracheal (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

1. Belyakov IM, Derby MA, Ahlers JD, Kelsall BL, Earl P, Moss B, Strober W, Berzofsky JA. Mucosal immunization with HIV–1 peptide vaccine induces mucosal and systemic cytotoxic T lymphocytes and protective immunity in mice against intrarectal recombinant HIV-vaccinia challenge. Proc Natl Acad Sci USA. 1998 Feb 17;95(4):1709–1714. [PubMed: 9465081]

2. Belyakov IM, Ahlers, JD, Brandwein BY, Earl P, Kelsall B, Moss B, Strober W, Berzofsky JA. The importance of local mucosal HIV-specific CD8+ cytotoxic T lymphocytes for resistance to mucosal viral transmission in mice and enhancement of resistance by local administration of IL–12. J Clin Invest. 1998 Dec 15;102(12):2072–2081. [PubMed: 9854042]

3. Belyakov IM, Ahlers JD, Clements JD, Strober W, Berzofsky JA. Interplay of cytokines and adjuvants in the regulation of mucosal and systemic HIV-specific CTL. J Immunol. 2000 Dec 1;165(11):6454–6462. [PubMed: 11086085]

4. Belyakov IM, Hel Z, Kelsall B, Kuznetsov VA, Ahlers JD, Nacsa J, Watkins DI, Allen TM, Sette A, Altman J, Woodward R, Markham PD, Clements JD, Franchini G, Strober W, Berzofsky JA. Mucosal AIDS vaccine reduces disease and viral load in gut reservoir and blood after mucosal infection of macaques. Nat Med. 2001 Dec;7(12):1320–1326. [PubMed: 11726972]

5. Belyakov IM, Kuznetsov VA, Kelsall B, Klinman D, Moniuszko M, Lemon M, Markham PD, Pal R, Clements JD, Lewis MG, Strober W, Franchini G, Berzofsky JA. Impact of vaccine-induced mucosal high avidity CD8+ CTLs in delay of AIDS-viral dissemination from mucosa. Blood 2006 Apr 15;107(8):3258–3264. [PubMed: 16373659]

6. Belyakov IM, Isakov DV, Zhu Q, Dzutsev A, Berzofsky JA. A novel functional CTL avidity/activity compartmentalization to the site of mucosal immunization contributes to protection of macaques against simian/human immunodeficiency viral depletion of mucosal CD4+ T cells. J Immunol. 2007 Jun 1;178(11):7211–7221. [PubMed: 17513770]

7. Belyakov IM, Ahlers JD, Nabel GJ, Moss B, Berzofsky JA. Generation of functionally active HIV–1 specific CD8+ CTL in intestinal mucosa following mucosal, systemic, or mixed prime-boost immunization. Virology 2008 Nov 10;381(1):106–115. [PubMed: 18793787]

8. Sui Y, Zhu Q, Gagnon S, Dzutsev A, Terabe M, Vaccari M, Venzon D, Klinman D, Strober W, Kelsall B, Franchini G, Belyakov IM, Berzofsky JA. Innate and adaptive immune correlates of vaccine and adjuvant-induced control of mucosal transmission of SIV in macaques. Proc Natl Acad Sci USA. 2010 May 25;107(21):9843–9848. [PubMed: 20457926]

Patent Status: HHS Reference No. E–268–1997/2—

- U.S. Patent Application No. 09/508,552, which issued as U.S. Patent No. 6,749,856 on 15 Jun 2004.
- Foreign patents issued in Australia (Application Number 93862/98 and Patent Number 757310) and in European countries (Application Number 98946965.5 and Patent Number 1011720): Germany, France, Ireland, United Kingdom, Italy, Portugal and Spain.
- Divisional U.S. Patent Application No. 10/815,340 filed 30 Mar 2004.

Licensing Status: Available for licensing and commercial development.

Licensing Contacts: Uri Reichman, PhD, MBA; 301–435–4616; *UR7a@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 *hewesj@mail.nih.gov* for more information.

Dated: August 31, 2010.

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 comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments