

*Intellectual Property:* HHS Reference No. E-222-2010/0—U.S. Patent Application No. 61/407,842 filed 28 October 2010.

*Licensing Contact:* Cristina Thalhammer-Reyero, PhD, MBA; 301-435-4507; [thalhamc@mail.nih.gov](mailto:thalhamc@mail.nih.gov).

**Richard U. Rodriguez,**

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

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## 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.

#### Vaccine To Prevent BK Polyomavirus-associated Kidney and Bladder Infections in Organ Transplant Recipients

*Description of Technology:* Nearly all adults have chronic urinary tract infections with one or more strains of BK polyomavirus (BKV). In healthy persons, the infection is controlled by the immune system and no symptoms are apparent. However, immunosuppressed persons, such as organ transplant recipients, can suffer from bladder disease or kidney disease caused by uncontrolled BKV growth. BKV causes cancer in animals; it is unknown if the same is true in humans.

A significant need remains for a means of preventing BKV infection and associated pathologies.

Researchers at the National Cancer Institute, NIH, have developed compositions and therapeutic methods for pre-vaccination of organ transplant recipients against BKV and prognostic methods to identify patients that may benefit from the vaccination. Methods for producing a BKV vaccine against all four known BKV serotypes are in development.

*Potential Commercial Applications:*

- An effective multivalent BKV vaccine to prevent BKV-associated pathologies of the urinary tract and bladder.
  - A prognostic kit to determine clinical benefit.
  - Tests for identifying renal transplant donors and recipients.
- Competitive Advantages:*
- A successful proof-of-principle study in mice has been conducted.
  - The inventors have identified the major virulent BKV serotype.
  - No vaccine for BKV infection currently exists.
  - If BKV is linked to cancer, the technology might be relevant to vaccines applicable to the general public.

*Development Stage:*

- Early-stage.
- Pre-clinical.
- In vitro data available.
- In vivo data available (animal).

*Inventors:* Christopher Buck and Diana Pastrana (NCI).

*Publication:* In preparation.

*Intellectual Property:* HHS Reference No. E-168-2011/0—U.S. Patent Application No. 61/508,897 filed 18 July 2011.

*Licensing Contact:* Patrick McCue, PhD; 301-435-5560; [mccuepat@mail.nih.gov](mailto:mccuepat@mail.nih.gov).

*Collaborative Research Opportunity:*

The NCI Center for Cancer Research, Laboratory of Cellular Oncology, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize this technology. For collaboration opportunities, please contact John Hewes, PhD at [hewesj@mail.nih.gov](mailto:hewesj@mail.nih.gov).

#### Gas Permeable Flasks To Grow Tumor Infiltrating Lymphocytes (TIL) for More Effective Anti-Cancer Immunotherapy

*Description of Technology:* Scientists at NIH have developed a strategy to obtain large quantities of highly reactive tumor infiltrating lymphocytes (TIL) from patient tumor samples for anti-cancer immunotherapy by making use of gas permeable (GP) flasks. This

advancement in personalized anti-cancer immunotherapy involves culturing a tumor sample in a series of GP containers to isolate and rapidly expand TIL. The process provides suitable quantities of TIL for adoptive transfer into the cancer patient more reliably than previous approaches.

Culturing and growing TIL in the GP containers permits efficient gas exchange between TIL cells and the air to promote optimal respiration, growth, and viability of the patient's TIL throughout the process. Using GP flasks in the TIL expansion process provides for better circulation of the growth media and larger surface area so more TIL can grow per unit volume. Therefore, less reagents and fewer numbers of culture containers are need to generate the required number of TIL for adoptive immunotherapy protocols to treat cancer patients. NIH researchers have demonstrated the advantages of this GP TIL growth process in comparison to their more established TIL expansion protocols using human patient tumor samples. This new TIL production method should enable TIL therapy to become more GMP compliant and allow it to become more standardized for widespread utilization as a cancer treatment option outside of NIH.

*Potential Commercial Applications:*

- Adoptive cell transfer therapy (immunotherapy) for a variety of human cancers.
- Growing TIL in gas permeable cultureware has the potential to become the new standard for obtaining suitable quantities of TIL for use in adoptive immunotherapy.
- GMP grade TIL manufacture process to allow for regulatory approval of TIL therapy so that it can become a more widely available personalized cancer treatment option.

*Competitive Advantages:*

- Simpler, faster, less laborious, less reagent intensive, and less equipment intensive TIL growth process compared to methods of obtaining TIL without gas permeable cultureware.
  - Reduces risks of microbial contamination versus comparable methodologies.
  - More GMP-compliant than other TIL growing processes.
  - Capable of producing larger quantities of TIL more reliably than other TIL methodologies.
  - Potential to expand the number of patients and types of cancers treatable by TIL.
- Development Stage:*
- Pre-clinical.
  - In vitro data available.
  - In vivo data available (human).

*Inventors:* Steven A. Rosenberg (NCI), Mark E. Dudley (NCI), Robert P. Somerville (NCI), Jianjian Jin (CC), Marianna V. Sabatino (CC), David F. Stroncek (CC).

*Intellectual Property:* HHS Reference No. E-114-2011/0—U.S. Patent Application No. 61/466,200 filed 22 March 2011.

*Related Technologies:*

- HHS Reference No. E-275-2002/1—U.S. Patent Application No. 10/526,697 filed 5 May 2005 (and foreign counterparts).

- HHS Reference No. E-273-2009/0—U.S. Patent Application No. 12/869,390 filed 26 August 2010.

*Licensing Contact:* Samuel E. Bish, PhD; 301-435-5282; bishse@mail.nih.gov.

*Collaborative Research Opportunity:* The National Cancer Institute Surgery Branch is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize gas permeable flasks for cell and gene therapy applications and multicenter clinical trials. For collaboration opportunities, please contact John Hewes, PhD, at hewesj@mail.nih.gov.

**A Novel Optomechanical Module that Enables a Conventional Inverted Microscope To Provide Selective Plane Illumination Microscopy (iSPIM)**

*Description of Technology:* The invention describes an optomechanical module that, when engaged with a conventional inverted microscope, provides selective plane illumination microscopy (iSPIM). The module is coupled to the translational base of the microscope whereby a SPIM excitation objective is engaged to one portion of the mount body, and a SPIM detection objective (having a longitudinal axis perpendicular to that of the excitation objective) is engaged to another portion of the mount body. Such a system offers the advantages of SPIM (optically sectioned, high-speed volumetric interrogation of living samples, enabling, for example, the study of developmental or neuronal dynamics at high frame rates), while maintaining the flexibility and sample geometry of commercially available inverted microscopes (thus additionally allowing wide-field, TIRF, confocal, or 2 photon imaging of samples).

*Potential Commercial Applications:* The microscope can be used for:

- Imaging of live whole animals (e.g. worms) (demonstrated already).
- Superresolution (photoactivated localization microscopy) with minimal bleaching of dye molecules.

- High speed investigation of neuronal dynamics at high frame rates.

*Competitive Advantages:*

- The system offers the advantages of SPIM, while maintaining the flexibility and sample geometry of commercially available inverted microscopes.

- In this system the sample can be easily mounted on a rectangular coverslip and may be translated using an automated 3D mechanical stage and additionally imaged using the conventional light path built into the inverted microscope frame.

*Development Stage:*

- Prototype.
- In vivo data available (animal).

*Inventors:* Hari Shroff (NIBIB) *et al.*

*Publication:* A publication is under review at PNAS.

*Intellectual Property:* HHS Reference No. E-078-2011/0—U.S. Provisional Patent Application No. 61/449,422 filed 04 Mar 2011.

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

*Collaborative Research Opportunity:* The NIBIB is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize applications of the invention. For collaboration opportunities, please contact Hari Shroff at 301-435-1995 or hari.shroff@nih.gov.

**A Vaccine for *Shigella sonnei* for Both Children and Adults**

*Description of Technology:* There is currently no vaccine widely available for shigellosis, which affects over 150 million people worldwide and causes over 1 million deaths a year, mostly children. The present invention discloses a novel immunogen to be used in a vaccine for both children and adults. The immunogen, a low-molecular mass O-SP-core fragment, generates high antibody responses in animal studies, which means reduced number of vaccinations. The immunogen is easy to isolate for ease of manufacturing. Additionally, the methods of manufacturing vaccines and protocols of preventing and/or treating Shigellosis had been carried out in the present invention.

*Potential Commercial Applications:* *Shigella sonnei* vaccines and diagnostics.

*Competitive Advantages:*

- Vaccine can be used in both children and adults.
- Doses of vaccine are reduced.
- Immunogen is easy to isolate for easy vaccine production.

*Development Stage:*

- Prototype.

- Pilot.
- Early-stage.
- Pre-clinical.
- In vitro data available.
- In vivo data available (animal).

*Inventors:* John B. Robbins, Rachel Schneerson, Joanna Kubler-Kielb, Christopher P. Mocca (NICHD).

*Publications:*

1. Robbins JB, *et al.* Synthesis, characterization, and immunogenicity in mice of *Shigella sonnei* O-specific oligosaccharide-core-protein conjugates. *Proc Natl Acad Sci U S A.* 2009 May 12;106(19):7974-7978. [PMID 19346477]

2. Kubler-Kielb J, *et al.* The elucidation of the structure of the core part of the LPS from *Plesiomonas shigelloides* serotype O17 expressing O-polysaccharide chain identical to the *Shigella sonnei* O-chain. *Carbohydr Res.* 2008 Dec 8;343(18):3123-3127. [PMID 18954864].

*Intellectual Property:* HHS Reference No. E-308-2008/0—

- PCT Application No. PCT/US2009/053897 filed 14 Aug 2009.

- U.S. Application No. 13/059,051 filed 14 Feb 2011.

*Licensing Contact:* Susan Ano, PhD; 301-435-5515; anos@mail.nih.gov.

Dated: August 29, 2011.

**Richard U. Rodriguez,**

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