mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Ms. Shari Eason Ludlam, MPH, Project Officer, NIH, NHLBI, 6701 Rockledge Drive, MSC 7936, Bethesda, MD 20892–7934, or call non-toll-free number 301–402–2900 or E-mail your request, including your address to: *Ludlams@nhlbi.nih.gov*.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Dated: December 16, 2008.

Michael S. Lauer,

Director, Division of Prevention and Population Sciences, NHLBI, National Institutes of Health.

Dated: December 16, 2008.

Suzanne Freeman,

Chief, FOIA, NHLBI, National Institutes of Health.

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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, 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.

Doxycycline-Inducible B16 Melanoma Cell Lines Expressing CXCR4 or CCR10

Description of Technology: The chemokine receptor CXCR4 functions in normal cells, but has been shown to be the most common chemokine receptor expressed on cancer cells, including melanoma, colon, breast, and lung cancers. It plays roles in angiogenesis and cancer cell survival as well as metastasis. CCR10 has also been shown to be expressed by melanoma cells. Like CXCR4, expression of CCR10 can enhance cancer cell survival and block immune recognition of cancer cells. Antagonists of CXCR4 and CCR10, under various conditions, have decreased metastasis or prevented tumor formation after implantation of cancer cells in mice.

These cell lines are based on the widely used B16 murine melanoma cell line. The cell lines were transduced with retroviral vectors encoding cDNA for either CXCR4 or CCR10 under control of a TET-dependent promoter. Both lines achieve greater than 10 fold induction of the respective genes (proteins), which has been confirmed by surface antibody staining using flow cytometry. These cell lines are ideally suited for studying the effect of these chemokine receptors in tumor growth or metastasis. They are also useful for developing a mouse model for studying the effect of down-regulating these receptors specifically in melanoma cells. This would mimic the effect of antagonists without the confounding effects of systemically inhibiting CXCR4 or CCR10. By either adding or removing dietary administered doxycycline, receptor expression can be regulated to assess the role of these two receptors in a variety of cancer-related assays.

Applications:

- Study the effect of chemokine receptors in tumor growth or metastasis
- Test CXCR4 and CCR10 antagonists in preclinical studies
- Develop B16 melanoma mouse model mimicking the effect of chemokine receptor antagonists

Advantages:

- Ability to regulate *in vitro* and *in vivo* expression of the chemokine receptor
- Ability to investigate the *in vivo* role in cancer cells of doxycycline control of chemokine receptor expression

Market: Cancer is the second leading cause of death in the U.S. and it is estimated that more than 1 million Americans develop cancer in a year.

Development Status: The technology is currently in the preclinical stage of development.

Inventors: Sam T. Hwang (NCI) .

Publication: T Kakinuma, ST Hwang. Chemokines, chemokine receptors, and cancer metastasis. J Leukoc Biol. 2006 Apr;79(4):639–651.

Patent Status: HHS Reference No. E–345–2008/0—Research Material. Patent protection is not being sought for either technology.

Licensing Status: Available for non-exclusive licensing under a Biological Materials License Agreement.

Licensing Contact: Adaku Nwachukwu, J.D.; 301–435–5560; *madua@mail.nih.gov*.

Monoclonal Antibodies to the Tumor-Specific Antigen, Human ROR1

Description of Technology: B–cell chronic lymphocytic leukemia (B–CLL) is an incurable disease developed by more than 15,000 Americans each year and currently, there are no therapeutic monoclonal antibodies (mAbs) that specifically recognize B–CLL tumor cells. Receptor tyrosine kinase-like orphan receptor 1 (ROR1) is a constitutively expressed tumor-specific cell surface antigen and an ideal target for therapeutic antibodies.

Available for licensing are four mouse anti-human ROR1 mAbs (hybridomas designated 2A2, 2D11, 1A1, and 1A7). All four mAbs bind specifically to the extracellular domain of human ROR1 and have good potential for therapeutic development by either humanization, conversion to chimeric mouse/human antibodies, or conjugation to a radioisotope, chemical drug or bacterial toxin.

Applications:

- Therapeutic antibodies against ROR1-expressing cancers like B–CLL and possibly other hematologic and solid malignancies
- Research tools for the study of ROR1 in cancer biology

Advantages:

- Hybridomas provide a continuous source of mAb
- Target extracellular domain of ROR1

Market:

- Currently, mAbs alemtuzumab® and rituximab®, which are not tumor cell-specific, are used for treating B–CLL. Rituximab® generated sales of 5.2 billion U.S. dollars in 2007.
- MAb market is estimated to be worth $30.3 billion in 2010 and it is one of the fastest growing sectors of the pharmaceutical industry with a 48.1% growth rate between 2003 and 2004.

Inventors: Christoph Rader and Sivasubramanian Baskar (NCI).

Publication: S Baskar et al. Unique cell surface expression of receptor tyrosine kinase ROR1 in human B-cell

chronic lymphocytic leukemia. Clin Cancer Res. 2008 Jan 15;14(2):396–404.

Patent Status: HHS Reference No. E–274–2008/0—Research Tool. Patent protection is not being pursued for this technology.

Licensing Status: This technology is available as a research tool under a Biological Materials License.

Licensing Contact: Jennifer Wong; 301–435–4633.; *wongje@mail.nih.gov*.

Collaborative Research Opportunity: The National Cancer Institute, Experimental Transplantation and Immunology Branch, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize diagnostic or therapeutic mAbs against ROR1. Please contact John D. Hewes, Ph.D. at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

A Novel and Efficient Technology for Targeted Delivery of siRNA

Description of Technology: The biological phenomenon of RNA interference (RNAi) has much promise for developing therapeutics to a variety of diseases. However, development of RNAi therapies remains mainly in preclinical stages largely because of difficulties in delivering small inhibitory RNAs (siRNA) and short hairpin RNAs (shRNA) into target cells. Although viral vector-based siRNA delivery systems have been widely used, their specificity and safety remains significant issue. Without a solution to this delivery problem, RNAi cannot fulfill its therapeutic promise.

Investigators at the National Institutes of Health have developed novel compositions and methods for delivering inhibitory oligonucleotides to cells in a targeted and efficient manner. The compositions and methods are based on utilizing a cell surface receptor targeting ligand, such as cytokine or chemokine, and a domain that binds an inhibitory oligonucleotide, to efficiently deliver the inhibitory oligonucleotide to the cell that expresses the cell surface receptor targeting ligand. Chemokine receptors are differentially expressed on various cells, including tumors; hence this technology allows targeting siRNA to aberrant cells. Gene silencing can also be achieved in variety of immune cells by targeting cytokine receptors. This technology has great potential for developing into a safe and effective means of delivering therapeutic siRNAs.

Applications:

• Treatment of cancers and autoimmune diseases by delivery of siRNA to tumor cells or various aberrantly functioning immune cells.

• This technology can be used to boost vaccine responses against cancers and chronic infectious diseases.

• Targeted delivery of fluorochrome-labeled RNA both *in vitro* and *in vivo* for diagnostic purposes, for example, to trace or localize various cells and to determine tumor metastasis and aberrant proliferation or homing of immune cells.

Advantages:

• Simple method for linking siRNA to polypeptides to create non-covalent or covalent complexes.

• *In vivo* targeted delivery of inhibitory RNAs into cells rather than systemically.

• Delivery of multiple inhibitory RNAs to target multiple genes.

• Long term repression of target gene expression through RNAi phenomenon.

Development Status: Currently animal model studies planned.

Inventors: Arya Biragyn, Purevdorj Olkhanud and Juan Espinoza (NIA).

Publications: None directly related to the invention.

Patent Status: U.S. Provisional Application No. 61/045,088 filed 15 Apr 2008 (HHS Reference No. E–051–2008/0–US–01).

Licensing Status: Available for exclusive or non-exclusive licensing.

Licensing Contact: Surekha Vathyam, Ph.D.; 301–435–4076; *vathyams@mail.nih.gov*.

Collaborative Research Opportunity: The National Institute on Aging, Immunotherapeutics Unit, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize chemokine-based siRNA/shRNA technology for treatment of cancers and autoimmune diseases, i.e. to control expression of immunomodulatory cytokines and other factors that facilitate tumor escape, activity of regulatory T cells or Th2 type of cells. This technology can be also utilized to boost vaccine responses against cancers and chronic infectious diseases. Please contact John D. Hewes, Ph.D. at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Method of Promoting Hematopoietic Stem Cell Engraftment by Enhancement of CXCR4 Activity

Description of Technology: The success of allogeneic Hematopoietic Stem Cell (HSC) transplant is dependent upon factors affecting engraftment of donor HSC. Engraftment is affected by type and intensity of bone marrow conditioning and immunosuppression achieved by chemotherapy or radiation treatments as well as the number of stem cells present in the graft. Factors influencing HSC trafficking, such as HSC chemotaxis and adhesion, modulate the ability of HSCs to engraft in the transplant recipient. Chemokine receptor CXCR4 (present on HSC) and its ligand, SDF–1, play an important role in attracting HSC to and retaining HSC in the bone marrow after transplantation. Studies indicate that with increased amounts of CXCR4 in human HSC there is a several fold increase in the engraftment of HSCs in a xenograft mouse transplant model.

This technology is directed to compositions comprising HSCs and methods for promoting CXCR4 expression in a HSC by inhibiting GRK3 or GRK6 (G-protein coupled receptor kinase (GRK) regulators of CXCR4) with an antisense compound.

Application: Treatment of donor HSC for enhancement of engrafting in the recipient.

Market: More than 45,000 HSC transplants are performed every year worldwide. Despite significant progress over the past half century, the overall five-year survival rate is below 55%. This technology, directed to enhancing HSC engrafting can help increase the survival rate after HSC transplant.

Development Status: Preclinical.

Inventor: Harry L. Malech (NIAID).

Patent Status: U.S. Provisional Application No. 61/085,689 filed 01 Aug 2008 (HHS Reference No. E–007–2008/0–US–01).

Licensing Status: Available for licensing.

Licensing Contact: Fatima Sayyid, M.H.P.M.; 301–435–4521; *Fatima.Sayyid@hhs.nih.gov*.

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases, Laboratory of Host Defenses, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize a method to improve hematopoietic stem cell transplantation through the enhancement of CXCR4 activity. Please contact Rosemary C. Walsh, PhD. at 301–451–3528 or *rcwalsh@niaid.nih.gov* for more information.

AFMAnalyze: Software Automation and Analysis of Atomic Force Microscopy (AFM) Data

Description of Technology: AFMAnalyze is a software package that is designed to significantly enhance the analysis and application of Atomic Force Microscopy (AFM) data. This software automates AFM data collection and analysis, and is equipped with a Graphical User Interface (GUI)-intensive

computational tool that is capable of replacing the manual or algorithmic methods for reconstructing, analyzing and interpreting large AFM data sets. AFMAnalyze provides a more robust, objective, and automated method for collecting and interpreting AFM results. A user, for example, can compute the Young's modulus of a sample at the press of a button located on the software interface.

The software also enables ''reverse fitting'' of the data in order to calibrate AFM cantilevers using materials (such as reference gels) with known properties. This ability can significantly enhance the sensitivity, interpretation, and use of AFM measurements which depend on accurate determinations of cantilever properties. In a demonstration of the capabilities of AFMAnalyze, the software was successfully used to map the elasticity of the tectoral membrane (TM) by incorporating the analysis of over 500 force-distance curves. Generating such a map without automation would be prohibitively expensive and time consuming.

AFMAnalyze is also flexibly designed for expansion, and incorporates modular programs for additional data analysis. Further modifications to the software could enable the analysis of force-volume data. This type of data has been, so far, difficult to analyze, but has significant use as a tool for distinguishing the different mechanical properties of materials including metals, polymers, semiconductors, ceramics, and biological specimens on the sub-nanometer scale.

Applications:

• Automated, objective, and efficient AFM measurements of the nano-scale properties of materials.

• Efficient AFM cantilever calibration.

• Potential for AFM force-volume measurements.

Development Status: Late stage.

Inventor: Brett D. Shoelson (NIDCD).

Publication: B Shoelson, EK Dimitriadis, H Cai, B Kachar, RS Chadwick. Evidence and implications of inhomogeneity in tectorial membrane elasticity. Biophys J. 2004 Oct;87(4):2768–2777.

Patent Status: U.S. Patent No. 6,993,959 issued 07 Feb 2006 (HHS Reference No. E–003–2004/0–US–01); No foreign rights available.

Licensing Status: Available for exclusive or non-exclusive licensing.

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

Methods and Compositions for Selectively Enriching Microbes

Description of Technology: The described technology provides markedly improved enrichment of *E. coli* O157:H7, Shiga toxin-producing *E. coli* (STEC) and *Shigella*. This improved enrichment can be complimentary to, and enhance performance of, existing nucleic acid or antibody based detection methods. In addition, the improved enrichment method facilitates isolation of pathogens following positive results by any nucleic acid or antibody based test. Such isolation by cultural methods is essential for epidemiology, antibiotic sensitivity testing and other biochemical characterization.

Current enrichment protocols are often inadequate as they allow large numbers of interfering bacteria to grow. This makes it necessary for microbiologists to screen hundreds of presumptive colonies to achieve successful isolation (A Khan et al., Emerg Infect Dis. 2002 Jan; 8:54–62). The new technology is a simple two step process. The sample is first placed in a low pH solution for a brief period and then transferred to a medium permitting maximal growth of target bacteria. With this new technology there is no risk of false negative results due to inadvertent inhibition of target bacteria by novobiocin, tellurite, cefixime, or other additives commonly used in existing enrichment procedures.

This new technology has been shown to be effective with food, water, environmental and clinical samples. Its components are inexpensive and microbiologists are not required to impede their workflow by adding separate selective agents at specified intervals such as four or six hours.

Applications: Improved detection of *E. coli* O157:H7, STEC and *Shigella* in:

• Clinical samples
• Food
• Beverages
• Dairy
• Water
• Wastewater
• Environmental
• Veterinary Samples

Advantages:

• Simple
• Inexpensive
• Requires no addition of antibiotic or other inhibitor solutions
• Reduces interfering bacterial competitors and makes detection of target pathogens easier

Market: Manufacturers of Microbiological Media and Tests for use in:

• Hospitals
• Clinics
• Food and Beverage Manufacturers
• Testing Laboratories
• Dairies
• Veterinary Clinics
• Water Testing Laboratories
• Water and Wastewater Facilities

Inventor: Michael A. Grant (FDA).

Publications:

1. MA Grant. Comparison of *Escherichia coli* O157:H7 enrichment in spiked produce samples. J Food Prot. 2008 Jan;71(1):139–145.

2. MA Grant. Comparison of a new enrichment procedure for Shiga toxin-producing *Escherichia coli* with five standard methods. J Food Prot. 2005 Aug;68(8):1593–1599.

3. MA Grant. Improved laboratory enrichment for enterohemorrhagic *Escherichia coli* by exposure to extremely acidic conditions. Appl Environ Microbiol. 2004 Feb;70(2):1226–1230.

4. Submitted for publication—two papers demonstrating effectiveness of new enrichment procedure with clinical and environmental samples.

Patent Status:

• U.S. Provisional Application No. 60/435,639 filed 20 Dec 2002 (HHS Reference No. E–228–2002/0–US–01).

• International Application No. PCT/US03/40806 filed 19 Dec 2003, which published as WO 2004/111180 on 23 Dec 2004 (HHS Reference No. E–228–2002/0–PCT–02).

• U.S. Patent Application No. 10/539,765 filed 20 Jun 2005 (HHS Reference No. E–228–2002/0–US–04).

Licensing Status: Available for exclusive or non-exclusive licensing.

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

Collaborative Research Opportunity: The FDA is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize methods for detecting pathogenic bacteria, especially *E. coli* O157:H7, Shiga toxin-producing *E. coli* (STEC) and *Shigella*. Please contact Alice Welch at *Alice.Welch@fda.hhs.gov* for more information.

Dated: December 18, 2008.

Richard U. Rodriguez,

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

[FR Doc. E8–30849 Filed 12–29–08; 8:45 am]

BILLING CODE 4140–01–P