

Dated: September 3, 2009.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. E9-21718 Filed 9-9-09; 8:45 am]

BILLING CODE 4184-01-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.

Use of a Modified Adaptor Molecule LAT to Improve Immunotherapy for Cancer and Other Diseases

Description of Technology: One problem with the development of immunotherapy for cancer or other diseases is the inability to stimulate a sufficient immune response in patients to tumor associated antigens. The Linker Adapted for T Cell Signaling molecule (LAT) has been shown to be an important molecule in T cell signaling. The inventions described and claimed in this patent application illustrate a new supportive role for LAT which may be harnessed to improve a patient's immune response to tumor-associated antigens.

A number of approaches to improving the immune response in cancer immunotherapy have been investigated. One such approach is to be able to influence the potency of T Cell Signaling. This invention exploits the role of LAT in T Cell signaling and

provides a means to create a more intense and effective T Cell response. This would have the end result of improving the overall response of a patient's immune system to the presence of tumor-associated antigens.

With T Cell signaling being important in the body's immune response to bacterial and viral antigens it may also be possible to harness the modified LAT molecules to improve the immune response in developing immunotherapy for infectious disease.

Applications

- As an adjuvant with immunotherapeutic agents to improve the overall response of a patient's immune system to tumor associated antigens.

- As an adjuvant with immunotherapeutic agents to improve the overall response of a patient's immune system to bacterial associated antigens.

- As an adjuvant with immunotherapeutic agents to improve the overall response of a patient's immune system to viral associated antigens.

Advantages: Enhanced T Cell Signaling should improve the overall effectiveness of immunotherapy producing a more robust patient response.

Development Status: Early stage, significant development efforts required to reach proof of principle.

Inventors: Lawrence E. Samelson *et al.* (NCI).

Publication: This work has not yet been published.

Patent Status

- U.S. Provisional Application No. 61/176,231 filed May 7, 2009 (HHS Reference No. E-159-2009/0-US-01).

- Interested parties wishing to review the U.S. Patent Application will need to sign a CDA.

Related Technologies: The NIH also has three patents related to the basic LAT molecule (HHS Reference No. E-010-1998)—US 7,118,889, AU 750543, and AU 776495—and several pending applications in the US published as 20060073562 A1 and 20070134749 A1 and corresponding applications in Canada (2316769) and Europe (1 141 281 A1).

Licensing Status: Available for licensing.

Licensing Contact: Susan S. Rucker; 301-435-4478; ruckersu@mail.nih.gov.

Immunogenic Tumor-Associated Antigen SPANX-B for Selective Cancer Immunotherapy

Description of Technology:

Researchers at the National Institutes of

Health (NIH) have characterized a novel tumor-associated antigen, SPANX-B, that is naturally immunogenic and is expressed in a variety of human malignancies, including melanoma and lung, colon, renal, ovarian and breast carcinomas. In melanoma specifically, SPANX-B expression is associated with advanced and metastatic disease. Moreover, the researchers have found several agonist epitope peptides from SPANX-B which can be used to activate the immune system to eradicate tumors utilizing T cells. SPANX-B peptides have significant clinical and immunotherapeutic potential for the development of cancer diagnostic assays and potent protective and/or therapeutic vaccines to combat a wide-range of cancers.

Applications

- *In vitro* diagnostic assays for highly-metastatic melanomas or other cancers.
- Therapeutic monoclonal antibodies.
- Cancer vaccine development.

Advantages

- *Immunogenic:* SPANX-B peptides are naturally able to elicit immune response.

- Expressed in a wide-range of cancers.

- Use of epitope peptides facilitates the activation of cells of the more therapeutically effective branch of the immune system.

- *Small epitope peptides:* Can be more easily manufactured in contrast to recombinant proteins.

Development Status: Pre-clinical.

Market: Cancer; Cancer, Therapy; Cancer, Diagnostics/Prognostics.

Inventors: Arya Biragyn (NIA) and Vladimir Larionov (NCI).

Publication: G Almanzar *et al.* Sperm-derived SPANX-B is a clinically relevant tumor antigen that is expressed in human tumors and readily recognized by human CD4+ and CD8+ T cells. Clin Cancer Res. 2009 Mar 15;15(6):1954-1963.

Patent Status: U.S. Provisional Application No. 61/156,435 filed February 27, 2009 (HHS Reference No. E-089-2009/0-US-01).

Licensing Status: Available for licensing.

Licensing Contact: Patrick P. McCue, Ph.D.; 301-435-5560; mccuepat@mail.nih.gov.

Collaborative Research Opportunity: The National Institute on Aging, Laboratory of Immunology, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize the use of SPANX-B-based therapeutic approaches to combat

cancers. Please contact John D. Hewes, PhD at 301-435-3121 or hewesj@mail.nih.gov for more information.

Biomarkers for Sjögren's Syndrome

Description of Technology: This technology provides differentially-expressed microRNAs that may be utilized for the development of diagnostics and therapeutics for Sjögren's syndrome.

Sjögren's syndrome is an autoimmune disorder in which immune cells attack and destroy the glands that produce tears and saliva. The hallmark symptoms of this disorder are dry mouth and dry eyes, but it can also cause serious complications throughout the body. Sjögren's syndrome affects as many as four million people in the United States, making it the second most common autoimmune rheumatic disease. Unfortunately, there is currently no cure for Sjögren's syndrome, nor is there a specific treatment to restore gland secretion. Treatment is generally symptomatic and supportive, including moisture replacement therapies and the use of non-steroidal anti-inflammatory drugs to treat musculoskeletal symptoms. For individuals with severe complications, corticosteroids or immunosuppressive drugs are often prescribed, but these drugs can have serious side effects.

The inventors have identified microRNAs that are differentially expressed in patients with Sjögren's syndrome compared to the normal population; these biomarkers can be used to diagnose Sjögren's syndrome, and are potential targets for treatment of this disease. The inventors have also identified microRNAs associated with high or low salivary flow in this patient population; these markers may serve as targets for therapeutics that restore salivary flow.

Applications: Development of diagnostics and therapeutics for Sjögren's syndrome.

Development Status: Discovery stage.

Market: Sjögren's syndrome affects four million people in the United States.

Inventors: Ilias Alevizos and Gabor G. Illei (NIDCR).

Related Publication: A Michael *et al.* Exosomes from human saliva as a source of microRNA biomarkers. Oral Dis. 2009 Jul 15. Epub ahead of print, doi: 10.1111/j.1601-0825.2009.01604.x.

Patent Status: U.S. Provisional Application No. 61/165,142 filed March 31, 2009 (HHS Reference No. E-018-2009/0-US-01).

Licensing Status: Available for licensing.

Licensing Contact: Tara Kirby, PhD; 301-435-4426; tarak@mail.nih.gov.

Collaborative Research Opportunity: The NIDCR is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize differentially-expressed microRNAs. Please contact David Bradley at bradleyda@nidcr.nih.gov.

Treatment of Airway Diseases, Including Asthma and COPD, by Targeting Airway Hyperresponsiveness

Description of Technology: This technology provides methods of treatment for airway diseases, including asthma and chronic obstructive pulmonary disease (COPD), utilizing molecules that target the airway hyperresponsiveness (AHR) pathway.

Airway diseases are a major health burden in the developed world. A major component of airway disease is airway hyperresponsiveness (AHR), defined as the exaggerated airway constrictive response to external triggers. The inventors have shown that inter-alpha-trypsin inhibitor (IaI), a mammalian protein involved in tissue inflammation and repair, is necessary for the development of AHR, and that inhibitors of IaI prevent the development of AHR. Specifically, the inventors tested their hypothesis that IaI inhibition or absence modifies airway smooth muscle cell binding to hyaluronan, a molecule known to contribute to the response to non-infectious lung injury, which also mediates induced AHR.

Claims in the provisional patent application are directed to methods of treating an airway disease or disorder by administering an inhibitor of IaI, such as an antibody, a polypeptide, a carbohydrate, a small molecule, or an antisense compound.

Applications: Development of therapeutics for airway diseases, including asthma and COPD.

Development Status: Discovery stage.

Market: Asthma affects over six percent of the U.S. population, and COPD affects approximately five percent. The combined asthma/COPD market is expected to reach over \$25 billion in 2017.

Inventors: Stavros Garantziotis (NIEHS) *et al.*

Related Publication: S Garantziotis *et al.* Hyaluronan mediates ozone-induced airway hyperresponsiveness in mice. J Biol Chem. 2009 Apr 24;284(17):11309-11317.

Patent Status: PCT Application Serial No. PCT/US09/039157 filed April 1, 2009 (HHS Reference No. E-009-2009/0-PCT-02).

Licensing Status: Available for licensing.

Licensing Contact: Tara Kirby, PhD; 301-435-4426; tarak@mail.nih.gov.

Collaborative Research Opportunity: The NIEHS Division of Intramural Research is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact Dr. Elizabeth M. Denholm, Director of the Office of Technology Transfer, at denholme@niehs.nih.gov for more information.

MRI Coil Holder for Both Dynamic and Static Imaging of Joints

Description of Technology: Two new designs of the MRI coil, each of which can be used for both dynamic and static imaging of joints, particularly knee and ankle joints, have been developed. The first design is based on the current cylindrical coil designs: While maintaining the overall shape, the top portion of the coil can slide, providing room for joint movement during a dynamic exam. To improve the signal-to-noise ratio, the adjustable section would be able to transmit and receive the MRI signal. The second design describes a coil in the form of a rectangular prism. The sides would be adjustable so that the size and proportion of the coil can be changed. The top of the coil can slide, providing room for a bent knee. All four sides of the coil would be able to transmit and receive the MRI signal.

Applications: MRI (human and veterinary).

Advantages: Allows for higher quality dynamic imaging while maintaining current quality of static imaging, particularly useful for imaging knee and ankle joints while they move. Housing is adjustable to allow for bent joints while maintaining a favorable signal-to-noise ratio.

Development Status: Detailed design drawings have been completed.

Inventors: Frances T. (Sheehan) Gavelli and Nicole A. Wilson (NIHCC).

Patent Status: U.S. Provisional Application No. 61/151,300 filed February 10, 2009 (HHS Reference No. E-298-2008/0-US-01).

Licensing Status: Available for licensing.

Licensing Contact: Bruce Goldstein, J.D., M.S.; 301-435-5470; goldsteb@mail.nih.gov.

Dated: September 1, 2009.

Richard U. Rodriguez,

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

[FR Doc. E9-21786 Filed 9-9-09; 8:45 am]

BILLING CODE 4140-01-P

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Rapid Diagnostic Applications of Phage

Description of Technology: The NIH has available for licensing two techniques for rapid detection of a particular bacteria strain. Similar detection using currently available technologies take 1-2 days; this technology reduces the time to less than one hour. These technologies utilize phage, which has no pathogenic effect on higher plants and animals and are part of approved food-preparation formulations, indicating their known safety profile and an existing regulatory pathway. The first technique involves a phage that incorporates a reporter gene (e.g., luciferase) that will be expressed only when the phage successfully infects a bacterium. This technique is particularly useful where only bacteria-killing ("lytic") phages are known because the method also deactivates the lytic genes, enabling infection and subsequent detection. The second

technique involves an engineered phage that will bind with quantum dots upon infection of bacteria; if a sample is treated first with this phage and then with quantum dots, the sample will only respond if the bacteria are present. Both techniques can be used to diagnose a clinical sample (tissue, blood, etc.) or an environmental isolate.

Applications

- Bacterial detection and diagnostics, including clinical or environment samples.
- Food safety and biodefense.

Advantages

- Detection methods are novel, rapid, and potentially applicable in many contexts (e.g., clinic, food preparation, bioterror response).
- Phage is easy and inexpensive to cultivate.
- Phage is on sale in the US for food-preparation formulations and thus has a known regulatory pathway.

Development Status: A range of phages have been synthesized, many of which have been tested proof-of-principle using major standardized testing systems.

Inventors: Dr. Carl Merrill (NIMH), Dr. Sankar Adhya (NCI), *et al.*

Publications

1. R Edgar *et al.* High-sensitivity bacterial detection using biotin-tagged phage and quantum-dot nanocomplexes. *Proc Natl Acad Sci. USA* 2006 Mar 28;103(13):4841-4845.
2. C Merrill *et al.* The prospect for bacteriophage therapy in Western medicine. *Nat Rev Drug Discov.* 2003 Jun;2(6):489-497.

Patent Status

HHS Reference No. E-169-2004—U.S. Patent Application No. 11/547,587 filed 05 Oct 2006.

HHS Reference No. E-281-2005—U.S. Patent Application No. 11/884,604 filed 17 Aug 2007.

HHS Reference No. E-318-2000—Research Materials (patent protection is not being pursued for this technology): "Method for Determining Sensitivity to a Bacteriophage."

Licensing Status: Technologies are available for licensing, either individually or as a package.

Licensing Contact: Bruce Goldstein, J.D., M.S.; 301-435-5470; goldsteb@mail.nih.gov.

Collaborative Research Opportunity: The NCI Laboratory of Molecular Biology is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or

commercialize this technology. Please contact John D. Hewes, PhD at 301-435-3121 or hewesj@mail.nih.gov for more information.

Therapeutic Antibacterial Applications of Phage

Description of Technology: The NIH, in collaboration with others, has developed three groups of inventions related to the use of bacteriophages in therapeutic situations. The first group is a method of adapting phages to survive in the body substantially longer than wild-type phages, using serial passaging and/or genetic engineering. The second group involves phages designed to bind the toxins and cytokines that killed bacteria release into the bloodstream, reducing the pathogenic properties of the bacteria. The third group is a method of engineering a phage to have multiple binding sites, such that a single phage can target multiple types of bacteria.

Application: Therapeutic applications of phage to treat bacterial infection.

Advantages

- Improved efficacy through longer circulation.
- Additional antibacterial functions.
- Can be used independently or as an adjuvant to another antibacterial therapy.

Development Status: A range of phages have been synthesized and tested *in vivo*. A Phase 1 study of a phage targeting vancomycin-resistant *Enterococcus faecium* was completed by Exponential Biotherapies, Inc., with no adverse effects reported.

Inventors: Dr. Carl Merrill (NIMH), Dr. Sankar Adhya (NCI), *et al.*

Publications

1. C Merrill *et al.* The prospect for bacteriophage therapy in Western medicine. *Nat Rev Drug Discov.* 2003 Jun;2(6):489-497.
2. B Biswas *et al.* Bacteriophage therapy rescues mice bacteremic from a clinical isolate of vancomycin-resistant *Enterococcus faecium*. *Infect Immun.* 2002 Jan;70(1):204-210.
3. C Merrill *et al.* Long-circulating bacteriophage as antibacterial agents. *Proc Natl Acad Sci. USA* 1996 Apr 16;93(8):3188-3192.

Patent Status

HHS Reference No. E-110-1993—U.S. Patent No. 5,688,601 issued 19 Jun 1997; U.S. Patent No. 7,332,307 issued 19 Feb 2008.

HHS Reference No. E-257-2000—U.S. Patent No. 7,163,818 issued 16 Jan 2007.

HHS Reference No. E-178-1996—Research Materials (patent protection is