[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, 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. 209 and 37 CFR Part 404 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.

FOR FURTHER INFORMATION: 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.

SUPPLEMENTARY INFORMATION: Technology descriptions follow.

Miniature Serial Microtome for Block-Face Imaging

Description of Technology: A microtome device is used in a variety of microcopy techniques to remove very thin (e.g., in the tens of nanometers range) portions from the top of a sample between successive images. This technology discloses a design for a microtome device that offers several unique features and advantages over commercially available microtomes. A prototype of the microtome has been built and demonstrated to work with a serial block-face scanning electron microscopy in order to serially collect ultrathin sections from plastic embedded biological tissues, specifically from brain tissues. This microtome design allows for a sample to be cut at a location removed from the electron beam axis, thus reducing interference from debris and allowing imaging at a greater range of working distances. This microtome device is lightweight and easy to install utilizing the built-in stage of existing microscopes such that a sample's position and orientation can be controlled along three-axes of rectilinear translation and two axes of rotation. This microtome design utilizes a diamond blade coupled to both the base plate and an actuator to control the movement of the blade in a direction perpendicular to the exposed surface of the pedestal, while producing an output signal that indicates the blade location with respect to the base plate. Advantageously, this allows for a stage coupled pedestal to be moved accurately from an imaging location on the beam axis to a cutting location off the beam axis.

Potential Commercial Applications:

Can be used in a variety of microscopy techniques:

• scanning electron microscopy

• light-based (optical, fluorescence) microscopy

• cathodoluminescence microscopy

Can be used to study any of various types of sample materials:

• tissue microscopy

• brain research

• tissue sectioning

• imaging

Competitive Advantages:

• is compatible with multiple microscopy systems

• incorporates a feedback sensor to monitor and optimize cutting thickness/forces

• can cut reproducible sections as thin as 25 nanometers

• performs cutting off-axis to prevent contamination

• mounts rapidly onto an existing SEM stage and does not require a custom vacuum chamber door

• uses the full range of an existing SEM stage for positioning samples

• incorporates a stage translation that is rectilinear

• utilizes a pivot flexure bearing for frictionless rotation during cutting

• cleans knife edge after each cut

Development Stage:

• In vitro data available

• Prototype

Inventor: Kevin Briggman (NINDS)

Intellectual Property: HHS Reference No. E-121-2014/0 - US Provisional Application No. 61/991,929 filed 12 May 2014

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

Collaborative Research Opportunity: The National Institute of Neurological Disorders and Stroke is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize the microtome device. For collaboration opportunities, please contact Melissa Maderia, Ph.D., M.B.A. at maderiam@mail.nih.gov or 240-276-5533.

Chimeric Receptors Targeting CD-19

Description of Technology: Available for licensing are compositions and methods for targeting and destroying CD19-expressing cancers, especially B-cell malignancies such as lymphomas and leukemias.

The antibody used in this technology is called anti-CD19. CD19 antibodies have been used to treat people with lymphoma and Leukemia. This technology has changed the anti-CD19 antibody so that instead of floating free in the blood, its CD19-binding domain is now joined to a T cell. When an antibody is joined to a T cell in this way it is called a chimeric receptor. Once localized at a CD19-expressing cancer cell, the T-cell portion of the chimeric receptor stimulates an immune response to destroy the cancer cell.

Potential Commercial Applications: Therapeutic agents to treat or prevent CD19-expressing cancers, including B-cell malignancies.

Competitive Advantages: Reduced toxicity and immunogenicity in humans of previous anti-CD19 chimeric receptors containing mouse sequences.

Development Stage:

• Early-stage

• In vitro data available

Inventor: James Kochenderfer (NCI)

Intellectual Property: HHS Reference No. E-042-2014/0 - US Provisional Application No. 62/006,313 filed 02 June 2014

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

Collaborative Research Opportunity: The National Cancer Institute is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize chimeric antigen receptors targeting CD19. For collaboration opportunities, please contact John D. Hewes, Ph.D. at hewesj@mail.nih.gov.

Use of Small Molecules to Treat PARP1-deficient Cancers

Description of Technology: Scientists at the National Human Genome Research Institute and the National Center for Advancing Translational Sciences have identified a class of small molecules synergistically working with known Poly (ADP-ribose) polymerase 1 (PARP-1)-inhibitors. These new small molecules can each effectively kill specific PARP-1 defective tumors cells and show synergy with known PARP1 inhibitors (PARP-1i) in killing tumor cells.

PARP1, a highly conserved DNA binding protein, is essential for repairing DNA damage and plays important roles in multiple DNA damage response pathways. Many cancer therapies utilize DNA-damaging agents to kill tumor cells, which often triggers DNA repair (e.g., by activating PARP1 pathways). Additionally, a variety of cancer types may also carry PARP1 mutation(s), such as glioma, breast cancer, and prostate cancer. Such mutations render the cancer cells resistant to these therapies. The key feature of these PARP-1i sensitizing molecules can be applied either as useful sensitizers in combinatorial treatment to increase the efficacy of DNA-damaging agents in cancer therapy, or selective targeting of cancer cells with specific DNA PARP-1 defects; thereby allowing for the development of new therapies.

Potential Commercial Applications: Therapies for cancers associated with PARP-1 defects.

Competitive Advantages:

• Utilizes proven small-molecule technology

• Specificity of mode of action may reduce potential side-effects

• Novel mode of action may limit market competition

• Combinatorial therapies of cancers with PARP-1 inhibitors

Development Stage: In vitro data available

Inventors: Kyungjae Myung (NHGRI), et al.

Publications:

1. Papeo G, et al. PARP inhibitors in cancer therapy: an update. Expert Opin Ther Pat. 2013 Apr;23(4):503-14. [PMID 23379721]

2. Chiarugi A. A snapshot of chemoresistance to PARP inhibitors. Trends Pharmacol Sci. 2012 Jan;33(1):42-8. [PMID 22055391]

3. Yu H, et al. Association between PARP-1 V762A polymorphism and cancer susceptibility: a meta-analysis. Genet Epidemiol. 2012 Jan;36(1):56-65. [PMID 22127734]

Intellectual Property:

• HHS Reference No. E-039-2014/0 - US Patent Application No. 61/930,291 filed 22 Jan 2014

• HHS Reference No. E-039-2014/1 - US Patent Application No. 61/988,502 filed 05 May 2014

Licensing Contact: Eggerton Campbell, Ph.D.; 301-435-5282; eggerton.campbell@nih.gov

Collaborative Research Opportunity: The National Human Genome Research Institute is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize small molecules to treat PARP1-deficient cancer. For collaboration opportunities, please contact Anna Solowiej, Ph.D., J.D. at solowieja@mail.nih.gov.

Dated: September 22, 2014

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

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