docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: May 15, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–12928 Filed 5–29–12; 8:45 am]

BILLING CODE 4160–01–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.

FOR FURTHER INFORMATION CONTACT: 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.

Rabbit Polyclonal Antibody To Detect a Pro-Peptide Fragment of NSAID-Activated Gene (NAG–1)/GDF15, a Protein Associated With Cancer

Description of Technology: Chronic inflammation is clearly associated with an increase in the risk of cancer. Non-steroidal anti-inflammatory drugs (NSAIDs) are well documented as agents that inhibit tumor growth and with long-term use can prevent tumor development. NSAID-activated gene (NAG–1), a unique member of the TGF-beta superfamily, is highly induced by NSAIDs and numerous drugs and chemicals with anti-tumorigenic activities.

The protein product of NAG–1 is first formed into an immature peptide dimer that must be cut at a specific site before it can be secreted as a mature protein. Currently available antibodies can only detect either the immature form of NAG–1 or the secreted mature protein, but do not recognize the peptide fragment that remains when the immature dimer is cut to form the mature protein. Now available for the first time, the present new antibody recognizes this NAG–1 pro-peptide fragment.

Potential Commercial Applications: As a research tool to detect expression of the NAG–1/GDF15 cleavage fragment in cells and media from cultured cells.

Competitive Advantages: No other antibody is currently available to detect the NAG–1/GDF15 pro-peptide fragment.

Development Stage: In vitro data available

Inventor: Thomas Eling (NIEHS)

Intellectual Property: HHS Reference No. E–177–2012/0—Research Tool. Patent protection is not being pursued for this technology.

Related Technology: HHS Reference No. E–093–2011/0—Transgenic mice expressing human GDF15/Nag-1/Mic-1

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

Collaborative Research Opportunity: The NIEHS is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize this antibody. For collaboration opportunities, please contact Elizabeth M. Denholm, Ph.D. at *denholme@niehs.nih.gov.*

Software for Automated Determination of Macromolecular Structure Using Cryo-Electron Microscopy

Description of Technology: Available for licensing is software for automated generation of density maps of macromolecular structures from series of 2D digital micrographs of frozen hydrated specimens collected using an electron microscope equipped with an ultra-cooled computerized stage. Series of images of biological specimens collected at different tilt angles relative to the electron beam are aligned to compensate for mechanical errors of the stage and combined to obtain 3D images (tomograms). Sub volumes containing a single macromolecular complex can be extracted from the 3D image of a protein solution, or suspension of viruses or cells. These individual sub-volumes of identical structures are aligned and averaged together to generate a density map of the macromolecular complex of interest.

Potential Commercial Applications:

- Macromolecular imaging
- Molecular interaction
- Molecular structure and reactivity

Competitive Advantages:

- Noise processing
- Algorithmic averaging

Development Stage: Prototype

Inventors: Mario Juan Borgnia, Alberto Bartesaghi, Sriram Subramaniam (all of NCI)

Publications:

1. Amat F, et al. Markov random field based automatic image alignment for electron tomography. J Struct Biol. 2008 Mar;161(3):260–75. [PMID 17855124]

2. Kremer JR, et al. Computer visualization of three-dimensional image data using IMOD. J Struct Biol. 1996 Jan–Feb;116(1):71–76. [PMID 8742726]

3. Mastronarde DN. Dual-axis tomography: an approach with alignment methods that preserve resolution. J Struct Biol. 1997 Dec;120(3):343–52. [PMID 9441937]

4. Bartesaghi A, et al. An energy-based three-dimensional segmentation approach for the quantitative interpretation of electron tomograms. IEEE Trans Image Process. 2005 Sep;14(9):1314–23. [PMID 16190467]

Intellectual Property: HHS Reference No. E–162–2012/0—Research Tool. Patent protection is not being pursued for this technology.

Licensing Contact: Michael Shmilovich; 301–435–5019; *mish@codon.nih.gov.*

Collaborative Research Opportunity: The NCI Laboratory of Cell Biology 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, Ph.D. at *hewesj@mail.nih.gov.*

Chimeric Antigen Receptors That Recognize Mesothelin for Cancer Immunotherapy

Description of Technology: Scientists at the National Institutes of Health (NIH) have developed chimeric antigen receptors (CARs) with high affinity for mesothelin to use as a promising immunotherapy to treat cancers, such as pancreatic cancer, ovarian cancer, and mesothelioma. Mesothelin is a protein cancer antigen with limited expression on normal cells that is overexpressed by

cancer cells. CARs are hybrid proteins consisting of an antibody portion that recognizes a cancer antigen, such as a mesothelin-specific antibody, fused to receptor signaling domains that serve to activate the CAR-expressing cell to kill tumor cells. Cells that express CARs, most notably T cells, are highly reactive against their specific tumor antigen in an MHC-unrestricted manner to generate an immune response that promotes robust tumor cell elimination when infused into cancer patients. The instant technology includes CAR constructs with one of three different mesothelin-specific antibody portions, including either the mouse-derived SS or SS1 antibody fragments or the human HN1 antibody fragment. Infusion of cells expressing these mesothelin-specific CARs into patients could prove to be a powerful new immunotherapeutic tool for treating various cancers that express mesothelin.

Potential Commercial Applications:

- Immunotherapeutics to treat and/or prevent the reoccurrence of cancers that overexpress mesothelin, including pancreatic cancer, ovarian cancer, and mesothelioma and other cancers with few effective treatment options.
- A personalized cancer treatment strategy for patients whose tumor cells express mesothelin whereby the patient's own T cells are isolated, engineered to express a mesothelin-specific CAR, and re-infused into the body to attack the tumor(s).
- Tools to diagnose the presence of mesothelin-expressing tumors in patients.

Competitive Advantages:

- Minimal side effects: Mesothelin is overexpressed on tumor cells. CARs specific for the mesothelin antigen they are expected to primarily target tumor cells, and thus, generate fewer side effects than other cancer treatment approaches.
- Successful track record: Immunotoxins containing the antibody portions of some of these CARs have shown promising results in clinical studies for cancer treatment.
- Cutting edge: With the advent of Provenge(R) and Yervoy(R), immunotherapy is now more widely accepted as a viable cancer treatment option.

Development Stage:

- Pre-clinical.
- Clinical.
- In vitro data available.

Inventors: Steven A. Feldman, Steven A. Rosenberg, Ira Pastan (all of NCI).

Intellectual Property: HHS Reference No. E–078–2012/0—U.S. Patent Application No. 61/614,612 filed 23 Mar 2012.

Related Technologies:

- HHS Reference No. E–002–1996/1.
- HHS Reference No. E–021–1998/0.
- HHS Reference No. E–139–1999/0.
- HHS Reference No. E–091–2009/0.
- HHS Reference Nos. E–093–1995/1,/2.

Licensing Contact: Samuel E. Bish, Ph.D.; 301–435–5282; *bishse@mail.nih.gov.*

Low-dose Cardiac Computed Tomography Method for Whole Heart Extracellular Volume

Description of Technology: Myocardial infarction and cardiomyopathies result in myocardial scar and diffuse fibrosis. Together these result in poor cardiac function. Myocardial scar is a specific target for therapy, but is difficult to identify. Cardiac Computed Tomography (CCT) struggles to identify large scars, and could not previously identify fibrosis. MRI is often used, but MRI is expensive and not widely available. We have developed a method to quantify both diffuse and focal myocardial scar by CCT using low radiation dose methods. Extracellular volume fraction (ECV) is the distribution of iodine in the scar relative to blood pool. ECV is abnormally elevated in scar. The new CCT technique involves (a) CCT data about the myocardium and blood pool is extracted (via a shape constrained graph cut technique), (b) an algorithm (Demons deformable registration) is applied to pre-contrast and low dose post-contrast image information, (c) the ECV value is computed. Along with coronary artery depiction on CCT, the ECV can be used to quantitatively measure myocardial scar and diffuse myocardial fibrosis for a complete depiction of the patient's myocardial status/health.

Potential Commercial Applications: Medical imaging

Competitive Advantages: Cardiac Computed Tomography is faster, more widely available and comparatively inexpensive versus Cardiac Magnetic Resonance Imaging.

Development Stage:

- Prototype
- Pre-clinical
- Clinical

Inventors: David Bluemke, Songtao Liu, Marcelo N. Nacif, Jianhua Yao, Christopher T. Sibley, Xinjian Chen, Ronald M. Summers (all of NIHCC)

Intellectual Property: HHS Reference No. E–267–2011/0

Licensing Contact: Tedd Fenn; 301–435–5031; *Tedd.Fenn@nih.gov*

Collaborative Research Opportunity: The NIH Clinical Center is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize Cardiac CT, Cardiac CTA, myocardial scar, myocardial fibrosis, coronary artery disease imaging. For collaboration opportunities, please contact Ken Rose, Ph.D. at *rosek@mail.nih.gov*.

Quantitative in Vivo Methods To Estimate the Conduction Time of Nerve Impulses in the Brain

Description of Technology: The axon diameter distribution (ADD) is an important anatomical feature of nerve fascicles both in normal and abnormal development. Axon diameter directly affects nerve function. It is well known that in myelinated axons, the conduction velocity is directly proportional to axon diameter. Moreover, it is hypothesized that in amyotrophic lateral sclerosis (ALS) large diameter axons are damaged selectively, while in autism, small-diameter axons are over-expressed. Despite its importance, the ADD within nerve fascicles has not been measurable in-vivo, and currently can only be assessed by invasive histological means. Previously, the NICHD inventors developed magnetic resonance imaging (MRI) methods to measure the ADD within nerve fascicles (e.g., by AxCaliber MRI). This invention extends from the inventor's prior work to AxCaliber MRI along with the non-invasive measurement of the arc-length of a nerve pathway (e.g., using DTI tractography), to estimate the mean conduction time of nerve impulses along that pathway, as well as other statistical moments of the conduction time distribution. This method could be used to diagnose abnormalities in nerve conduction in brain regions and providing a neuroanatomical basis for many cognitive and behavior disorders.

Potential Commercial Applications:

- Used to diagnose abnormalities in nerve conduction in brain regions
- Provides a neuroanatomical basis for many cognitive and behavior disorders
- A basic tool in neuroscience research to explore the dynamic functioning of the brain

Competitive Advantages:

- Diagnose a number of cognitive and behavioral abnormalities, disease and disorders [currently only assessed using psychological or psychiatric testing].
- A new quantitative imaging biomarker
- Used to understand and follow brain changes during normal aging and in Alzheimer's disease.
- Used to explain motor deficits in ALS disease.

• Provides way of classifying and understanding various neurological and neuropsychiatric conditions according to conduction delays.

Development Stage:

• Prototype
• Clinical
• In vivo data available (animal)
• In vivo data available (human)

Inventor: Peter J. Basser (NICHD)

Publications:

1. Assaf Y, et al. Ax-Caliber: a method for measuring axon diameter distribution from diffusion MRI. Magn Reson Med. 2008 Jun;59(6):1347–54. [PMID 18506799]

2. Barazany D, et al. In vivo measurement of axon diameter distribution in the corpus callosum of rat brain. Brain 2009 May;132(Pt 5):1210–20. [PMID 19403788]

Intellectual Property: HHS Reference No. E–226–2010/0—U.S. Provisional Application No. 61/535,851 filed 16 Sep 2011

Related Technology: HHS Reference No. E–079–2003/1—U.S. Patent Application No. 12/114,713 filed 02 May 2008

Licensing Contact: John Stansberry, Ph.D.; 301–435–5236; *stansbej@mail.nih.gov.*

Collaborative Research Opportunity: The NICHD is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize methods to estimate conduction time of nerve impulses in brain. For collaboration opportunities, please contact Charlotte McGuinness at *mcguinnc@mail.nih.gov.*

Simple, Quantitative Sensitive High-Throughput Antibody Detection for Lyme Disease

Description of Technology: This technology is for compositions and methods for diagnosis of Lyme disease. Currently, Lyme disease is diagnosed by clinical exam and a history of exposure to endemic regions. Although, laboratory tests may aid diagnosis, the best tests currently available are slow and labor intensive and require understanding of the test, and infection stage. A two-step antibody based test process is currently the recommended laboratory test. The first step is either an enzyme immunoassay (EIA), or an indirect immunofluorescence assay (IFA). If the first step is positive, a ''Western blot'' test is then performed. Because early intervention is critical to prevent neurological, rheumatological and cardiac damage from advanced infection, more sensitive, specific, simpler, high-throughput format laboratory diagnostics are needed. This technology uses a novel synthetic gene (VOVO) in a highly sensitive, specific and high-throughput Luciferase Immunoprecipitation Systems (LIPS) format. LIPS screening using VOVO offers an efficient and qualitative approach for serological screening of antibodies in Lyme disease in human and veterinary applications.

Potential Commercial Applications: Diagnostic for Lyme disease in human and veterinary applications.

Competitive Advantages: Higher efficiencies, High-throughput Format Qualitative

Development Stage:

• Early-stage
• Pre-clinical

Inventors: Peter D. Burbelo (NIDCR), Michael J. Iadarola (NIDCR), Adriana Marques (NIAID)

Publication: Burbelo PD, et al. Simple, quantitative, and highly sensitive antibody detection for Lyme disease. Clin Vaccine Immunol. 2010 Jun;17(6):904–9. [PMID: 20392886]

Intellectual Property: HHS Reference No. E–036–2010/1—PCT application PCT/US2011/027888 filed 10 Mar 2011

Licensing Contact: Tedd Fenn; 301–435–5031; Tedd.Fenn@nih.gov

Collaborative Research Opportunity: The NIDCR, Laboratory of Sensory Biology, Neurobiology and Pain Therapeutics Section, 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 David Bradley, Ph.D. at *bradleyda@nidcr.nih.gov*.

Dated: May 23, 2012.

Richard U. Rodriguez,

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

[FR Doc. 2012–13007 Filed 5–29–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Neurodevelopment and Metabolism.

Date: June 14, 2012.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Laurent Taupenot, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4811, MSC 7850, Bethesda, MD 20892, 301–435–1203, *taupenol@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business Grant Applications: Immunology

Date: June 18, 2012.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The River Inn, 924 25th Street NW., Washington, DC 20037.

Contact Person: Stephen M. Nigida, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4212, MSC 7812, Bethesda, MD 20892, 301–435–1222, *nigidas@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR 10–018: Accelerating the Pace of Drug Abuse Research Using Existing Epidemiology, Prevention, and Treatment Research Data.

Date: June 19, 2012.

Time: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: George Vogler, Ph.D., Scientific Review Officer, PSE IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3140, Bethesda, MD 20892, 301–435–0694, *voglergp@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Teen Relationship Violence.

Date: June 20, 2012.

Time: 2:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Monica Basco, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3220, MSC 7808, Bethesda, MD 20892, 301–496–7010, *bascoma@mail.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Clinical and