applicant seeks 827 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments and ask for a redetermination by July 14, 2014. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by November 12, 2014. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) electronic or written comments and written or electronic petitions. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. If you submit a written petition, two copies are required. A petition submitted electronically must be submitted to http://www.regulations.gov, Docket No. FDA–2013–S–0610. Comments and petitions that have not been made publicly available on http://www.regulations.gov may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 9, 2014.

Leslie Kux,
Assistant Commissioner for Policy.

FOR FURTHER INFORMATION CONTACT:
License 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.

Real Time Medical Image Processing Using Cloud Computing

Description of Technology: The invention pertains to a system for reconstructing images acquired from MR and CT scanners in a robust Gadgetron based cloud computing system. A hardware interface connects clinical imaging instruments (e.g., MR or CT scanners) with a cloud computing environment that includes image data reconstruction and processing software not limited by the computational constraints typical of static hardware with finite processor power. Raw imaging data acquired from an MR or CT instrument is evaluated and categorized based on a pre-prioritized dimensionality parameter (e.g., spatial dimension parameter; three- or two-dimensionality, a time parameter, a flow/velocity parameter, an experiment timing dimension parameter, a diffusion encoding parameter, a functional/physiological testing dimension parameter, or a physiologic gating index parameter) and transmitted to a corresponding cloud computing environment for processing and reconstruction. The final processed image is retransmitted to a user interface that can be read by a radiologist or technician.

Potential Commercial Applications:
• MRI imaging
• CT imaging
• Image processing
• Diagnostic radiology

Competitive Advantages: Eliminates the need for purchasing expensive data processing equipment that becomes obsolete.
Less equipment leads to lower costs and space efficiency.
Exponentially more robust computer power, data acquisition and image reconstruction.

Development Stage:
• Early-stage
• In vitro data available
• In vivo data available (animal)
• In situ data available (on-site)
• Prototype
Inventors: Michael Hansen, Peter Kellman, Hui Xue (all of NHLBI)

Intellectual Property:
• HHS Reference No. E–074–2014/0—U.S. Provisional Application No. 61/934,987 filed 03 Feb 2014
• HHS Reference No. E–074–2014/1—U.S. Provisional Application No. 61/953,017 filed 14 Mar 2014

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

Collaborative Research Opportunity: The National Heart Lung & Blood Institute is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize Gadgetron mediated clinical image processing. For collaboration opportunities, please contact Denise Crooks, Ph.D. at 301–435–0103 or crooksd@nhlbi.nih.gov.

Personal Respirator Safety: Flushed Seal for an Improved, More Protective, Negative-Pressure Respirator

Description of Technology: This CDC-developed technology relates to improved, full-face flushed-seal personal respirators for lowering costs, improving user mobility, and ensuring occupational health and safety. Currently, the most common type of respirator in use, the negative pressure respirator, seals to a user’s face so that inhaled air is pulled through a purifying filter by inhalation-generated negative pressure; the weakest link in this type of respirator is typically the seal at the face-to-mask interface. When there is face-seal leakage, toxic air will be drawn into the facepiece of the respirator and inhaled by the wearer, though designers and engineers of respirators attempt to minimize this face-seal leakage. Over the last several decades, facepiece design has been optimized by this design approach so that the ambient leakage of half-facepiece respirators and full-facepiece respirators are 10% and 2%, respectively. This technology incorporates an additional element to reduce face-seal leakage and therefore increases user protection. In the respirator described by this technology, a primary sealing element is situated adjacent to the user’s breathing space and a secondary sealing element. Exhaled air (i.e., clean air obtained by filter passage) is passed from the breathing space into a flushing channel formed between the primary and secondary seals. If there is leakage in the primary seal, air from this...
moiety containing at least two HIV Env-binding motifs, linked to a transmembrane domain and a cytoplasmic signaling domain. The invention further discloses nucleic acids encoding the novel chimeric antigen receptors to enable their expression in host T cells for treatment of HIV infection and disease. Importantly, CAR-transduced CD8 T cells recognize HIV-infected target cells in MHC independent fashion by binding the highly conserved regions of the HIV Env glycoprotein, thus minimizing the selection of viral escape mutants. Furthermore, the present invention also relates to methods of generating a recombinant CD8 T cells expressing a CAR with a CD4-based targeting moiety that does not confer susceptibility to HIV infection.

**Potential Commercial Applications:**
- Therapy for HIV infection
- Research on antiretroviral infection
- Generate HIV-unsusceptible T cells

**Competitive Advantages:**
- Inexpensive to implement
- Inexpensive alternatives for air-line systems or powered air-purifying respirators (PAPRs) that are currently in use
- Unlike PAPR devices, no heavy, mobility-limiting battery packs are required for this technology; no battery recharge time or noisy blowers with this respirator technology
- Compared to “air-line” respirators, this technology is significantly less expensive to purchase and maintain and does not limit the range of a user’s mobility

**Development Stage:**
- In situ data available (onsite)
- Prototype

**Inventors:** Donald L. Campbell, Christopher C. Coffey, William A. Hoffman, Judith B. Hudnall (all of CDC)


**Description of Technology:**
This CDC developed technology entails a novel method of near real-time elemental analysis of aerosols by corona assisted microwave induced plasma spectroscopy (CAMPS).

Analysis of elemental composition of aerosol particles holds significant implications for environmental and workplace pollution monitoring. Various plasma based analytical techniques, including laser-induced breakdown spectroscopy (LIBS) and spark-induced breakdown spectroscopy (SIBS), have been successfully used for multi-elemental analyses in solids, liquids, and gases, including aerosols. However, the characterization of fine and ultrafine aerosols using these techniques is particularly challenging due to small plasma volume, miniscule sample mass, and inferior sampling statistics, often leading to poor detection limits and precision.

This technology utilizes a microwave plasma-based detection system for aerosol analysis that features increased microplasma lifetime, repeatability, and stability over currently-available pulsed microplasma-based methods. This system produces microplasma lifetimes in the range of 5 to 50 milliseconds, a duration that is orders of magnitude larger than lifetimes for laser-induced or spark plasmas, as well as larger plasma volumes, which together are expected to provide improved detection limits over currently-available techniques.

**Potential Commercial Applications:**
- Elemental quantification of aerosols in near real-time
- Air pollution studies, Particulate Matter monitoring
- Hazardous materials exposure determinations and identification
- Biodefense, chemical-defense, homeland-security applications
- Environmental and occupational epidemiology
- Evaluation of engineering controls

**Competitive Advantages:**
- Makes it possible to conduct accurate, near-real-time measurement of the elemental composition of aerosols in industrial and ambient atmospheres
- Corona field stabilizes the microwave plasma and results in repeatable plasma formation
- Larger size of CAMPS plasma provides sufficient plasma volume which can lead to complete ablation of deposited aerosol in the tip of the electrode
- Longer duration of CAMPS plasma (∼10–50 ms) allows longer integration
time which results in signal enhancement

**Development Stage:**
- In situ data available (on-site)
- Prototype

**Inventors:**
- Pramod Kulkarni (CDC), et al.

**Intellectual Property:**
- HHS Reference No. E–205–2013/0 –

**Related Technology:**
- HHS Reference No. E–205–2013/0
- Licensing Contact: Whitney Blair, J.D., M.P.H.; 301–435–4937; whitney.blair@nih.gov

**Local Positioning System for Increasing Occupational Safety**

**Description of Technology:** This CDC-developed technology describes an automated system for monitoring worker hazard exposures by recording data about where and when hazards occur in a workplace or other environment. This allows the hazards to be identified and hazardous exposures and risks reduced. This field-tested technology consists of an integrated, hand-held electronics instrument and software system that will precisely correlate multiple exposure levels with position coordinates of the user and features real-time data acquisition.

**Development Stage:**
- In situ data available (on-site)
- Prototype

**Inventors:**
- Larry A. Lee, Sidney C. Soderholm, Michael Flemmer, Jennifer L. Hornsby-Myers, Ramesh Gali (all of CDC)

**Publication:**
- Licensing Contact: Whitney Blair, J.D., M.P.H.; 301–435–4937; whitney.blair@nih.gov

**Novel Dopamine D2 Receptor Antagonists and Methods of Their Use**

**Description of Technology:**

Investigators at the NIH have identified a series of novel, small molecule antagonists of the dopamine D2 receptor. Among the dopamine receptor (DAR) subtypes, D2 DAR is arguably one of the most validated drug targets in neurology and psychiatry. For instance, all receptor-based anti-Parkinsonian drugs work via stimulating the D2 DAR, whereas all FDA approved antipsychotic agents are antagonists of this receptor. Unfortunately, most agents that act as antagonists of D2 DAR are problematic, either they are less efficacious than desired or cause multiple adverse effects. Thus, it is desirable to develop a class of novel therapeutic agents with high selectivity for the D2 DAR. This invention describes dibhydrobenzo[h,f][1,4]thiazepine-8-carboxamide compounds, methods of making these compounds, methods of characterizing their in vitro activity, demonstration of in vivo activity in animals, as well as methods of using these compounds to treat central nervous system (CNS) related disorders.

**Potential Commercial Applications:**
- Antipsychotic agent
- Treatment for schizophrenia, Tourette’s syndrome, depression
- Alternative therapy for disorders currently treated with non-selective D2 antagonists

**Development Stage:**
- In vitro data available
- In vivo data available (animal)

**Inventors:**
- David Sibley (NINDS), R. Benjamin Free (NINDS), Juan J. Marugan (NCATS), Jingbo Xiao (NCATS), Marc Ferrer-Alegre (NCATS), Noel T. Southall (NCATS)

**Publication:**
- Licensing Contact: Charlene S. Maddox, Ph.D.; 301–435–4689; maddoxcs@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 Novel Dopamine D2 Receptor Antagonists and Methods of Their Use. For collaboration opportunities, please contact Laurie Arrants at ArrantsL@ninds.nih.gov.

**Therapeutic Compounds Targeting Thioesterase Deficiency Disorders**

**Description of Technology:**

Compositions comprising N-t-butyl hydroxylamine (NtBuHA), a small molecule that partially or fully mimics thioesterase activity are provided to treat or prevent thioesterase deficiency disorders. Lysoosomal storage disorders (LSDs) represent a group of >50 genetically distinct, inherited diseases. Included amongst these are a group of neurodegenerative LSDs called neuronal ceroid lipofuscinoses (NCLs), also commonly known as Batten disease. The infantile type of NCL (or INCL) is one of the most devastating diseases. It is caused by mutations in the CLN1 gene encoding palmitoyl-protein thioesterase-1 (PPT1). Hydroxylamine (HA) is a potent nucleophilic small molecule and it functionally mimics thioesterase
activity including that of PPT1. Unfortunately, the inherent toxicity of HA precludes its clinical use for any disorder. The inventors evaluated several non-toxic derivatives of HA for anti-oxidant properties, the ability to cleave thioester linkage in S-acylated proteins, the ability to mediate ceroid depletion, to suppress apoptosis in cultured cells from INCL patients and in Ppt1-knockout (Ppt1−/−) mice. Specifically, the inventors have discovered that NtBuHA is non-toxic, manifests potent antioxidant property, cleaves thioester linkages in S-acylated proteins, depletes intracellular ceroid in Ppt1−/− mice and extends lifespan. These results demonstrated that NtBuHA may be broadly useful as therapeutic agents for thioesterase deficiency disorders including INCL.

Potential Commercial Applications: Compositions and methods to treat or prevent thioesterase deficiency disorders

Competitive Advantages:
- Currently there are no effective treatments for INCL and N-t-BuHA will be the first specific treatment targeting INCL
- N-t-BuHA can be developed as a broad spectrum therapeutic against thioesterase deficiency disorders.

Development Stage: In vivo data available (animal)

Inventors: Anil Baran Mukherjee, Chinmoy Sarkar, Zhonglian Zhang (all of NICHD)


Licensing Contact: Suryanarayana Vepa, Ph.D., J.D.; 301–435–5200; vepas@mail.nih.gov

Collaborative Research Opportunity: The Eunice Kennedy Shriver National Institute of Child Health and Human Development is seeking volunteers for appropriate thioesterase deficiency diseases including infantile neuronal ceroid lipofuscinosis (INCL). For collaboration opportunities, please contact Joseph M. Conrad, Ph.D., J.D. at jmconrad@mail.nih.gov or 240–276–5495.

Non-Invasive In Vivo MR Method to Image Salient Features of Nerves

Description of Technology: The invention consists of a novel diffusion MRI experiment and modeling framework that describes white matter in the central nervous system (CNS) and nerves in the peripheral nervous system (PNS) as composite media having intra- and extra axonal spaces with different water diffusion characteristics. Specifically, fascicles in the nervous system are modeled as having a hindered extracellular region and a restricted intracellular or intra-axonal region. Diffusion of water in these two distinct compartments contributes to the total measured diffusion MRI signal. This method provides a voxel-by-voxel measurement of the intra- and extra-axonal volume fractions, and an estimate of the mean axon diameter. This technology is also incorporated in NIH’s AxCaliber MRI technology, which extends it, treating fascicles as a bundle of impermeable cylinders having a distribution of internal diameters. The significance of this invention is that it provides measurements of new and useful microanatomical features of white matter (and gray matter) that are closely related to the function of the nervous system—particularly the speed that information travels along axons—critically important in medicine and the neurosciences. Previously, the data provided by this non-invasive MRI imaging method were only available using invasive and laborious histological means requiring tissue biopsy.

Potential Commercial Applications:
- clinical MRI
- small animal or pre-clinical MRI

Competitive Advantages:
- non-invasive, painless, in vivo measurement of microanatomical features of nerves and muscles.
- no contrast agents required
- modest data requirements allow for scans to be performed in a clinically feasible time-frame

Development Stage:
- Early-stage
- In vitro data available
- In vivo data available (animal)
- In vivo data available (human)
- In situ data available (on-site)
- Prototype

Inventors: Peter J. Bassar (NICHD), Yanniv Assaf (Tel Aviv University)

Publications:


Related Technologies:

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

Collaborative Research Opportunity: The Eunice Kennedy Shriver National Institute of Child Health and Human Development is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize novel MRI methods to probe tissue structure and organization, particularly for neuroimaging applications. For collaboration opportunities, please contact Alan E. Hubbs at hubbsa@mail.nih.gov or 240–276–5530.

Dated: May 12, 2014.

Richard U. Rodriguez,
Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.
[FR Doc. 2014–11146 Filed 5–14–14; 8:45 am]
BILING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center For Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Clinical and Integrative Diabetes and Obesity Study...