Determination

Based on the foregoing, I hereby determine that it is the Government's best interests to approve the use of Alternate 1 to the Clause at FAR 52.232–23 which authorizes incorporation of a no-setoff provision.

Dated: February 22, 2007.

Daniel J. Frasier,

Head of the Contracting Activity, Director, OAMP, OA, OM, National Institutes of Health.

[FR Doc. 07–960 Filed 3–1–07; 8:45 am]

BILLING CODE 4140–01–M

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.

Model for Study of Glomerular Disorders: Conditionally-Immortalized Mouse Podocyte Cell Line With Tet-on-Regulated Gene Expression

Description of Technology: Podocytes, cells of the visceral epithelium in the kidneys, are a key component of the glomerular filtration barrier. As such, they play a vital role in glomerular disorders, which are a major cause of chronic kidney disease. Examples of these disorders include focal segmental glomerulosclerosis, membranous glomerulonephritis, minimal change disease, and diabetic nephropathy.

The inventors have developed a conditionally-immortalized mouse podocyte cell line with tightly controlled conditional gene expression. The cell line has been conditionally immortalized through the introduction of the H-2Kb-tsA58 transgene, which is a temperature-sensitive mutant of the SV40T antigen. Inducible gene expression is tightly controlled through two introduced transgenes, podocin-rtTA and CMV-tTS, that produce a ''Tet-on'' system wherein gene expression is induced by tetracycline or doxycycline. The combination of the two transgenes for Tet-on gene expression has resulted in much tighter regulation and lower background expression compared to cells carrying the podocin-rtTA transgene alone.

Applications: Model system for study of glomerular disorders; Model system for podocyte cell biology.

Market: Glomerular disorders are a major cause of chronic kidney disease. Approximately 20 to 35 percent of patients requiring renal replacement therapy have a glomerular disorder.

Inventors: Jeffrey B. Kopp (NIDDK) *et al.*

Relevant Publication: T Shigehara, C Zaragoza, C Kitiyakara, H Takahashi, H Lu, M Moeller, LB Holzman, and JB Kopp. Inducible podocyte-specific gene expression in transgenic mice. J Am Soc Nephrol. 2003 Aug;14(8):1998–2003.

Patent Status: HHS Reference No. E–049–2007/0—Research Tool.

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

Licensing Contact: Tara L. Kirby, PhD.; 301/435–4426; *tarak@mail.nih.gov.*

Collaborative Research Opportunity: The *NIDDK Kidney Disease Section* is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize a model system for the study of glomerular disorders. Please contact Jeffrey B. Kopp, MD, by phone (301/594–3403), fax (301/402–0014) or e-mail (*jbkopp@nih.gov*) for more information.

Latrophilin 3, a Gene Involved in Attention Deficit Hyperactivity Disorder

Description of Technology: Attention Deficit Hyperactivity Disorder (ADHD) is the most common behavioral disorder in childhood, and is estimated to affect three to five percent of people in the United States, both children and adults. Treatment typically involves a combination of behavior modification, educational interventions, and medication. There are a variety of medications available for treatment of ADHD; the most frequently prescribed drugs are stimulants or antidepressants. However, currently there is no way to tell in advance which medication will be most helpful for a particular individual.

The inventors have identified haplotypes of latrophilin 3 (LPHN3) that increase susceptibility for development of ADHD. LPHN3 is a G-protein coupled receptor that is specifically expressed in the brain's mesolimbic system, which is associated with ADHD. The invention describes methods of identifying LPHN3 haplotypes in an individual for determining susceptibility for development of ADHD. Identification of LPHN3 haplotypes in an ADHD-affected individual may also make possible individualized drug treatment plans.

Applications: Identify individuals with enhanced susceptibility for ADHD; Use LPHN3 haplotype information to design individualized treatments.

Inventors: Maximillian Muenke (NHGRI), Mauricio Arcos-Burgos (NHGRI), and F. Xavier Castellanos (NIMH).

Patent Status: U.S. Provisional Application No. 60/850,972 filed 11 Oct 2006 (HHS Reference No. E–312–2006/0-US–01).

Licensing Status: Available for exclusive or nonexclusive licensing.

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

A Fertility Test To Detect Ovarian Autoimmune Disease Using Human Recombinant MATER Protein

Description of Technology: The inventors have identified MATER, a gene that plays an important role in fertility, and have shown that antibodies against MATER protein are detected at higher frequencies in women experiencing infertility and irregular menstrual periods than in healthy women. The discovery of MATER as an important factor in autoimmune-mediated ovarian dysfunction will facilitate diagnosis and treatment of these disorders. In addition to its critical role in ovarian autoimmunity, the inventors have also discovered that the MATER gene plays an essential role in embryonic development.

The invention discloses the MATER gene, MATER protein and MATER-specific antibodies. Also disclosed are methods and kits for evaluating female infertility through detection of an abnormal autoimmune response, an abnormal MATER gene, or abnormal MATER protein expression.

Applications: Diagnostic test for women suffering from infertility or irregular menstrual periods; Tool for the study of early embryonic development;

Tool for the development of MATER-based contraceptives.

Market: Approximately 10% of women of reproductive age experience infertility, and approximately 5% per year experience menstrual irregularity.

Development Status: Established research test, ready for additional clinical research and commercial development.

Inventors: Lawrence M. Nelson and Zhi-Bin Tong (NICHD).

Publications:

1. Zhi-Bin Tong *et al.* A mouse gene encoding an oocyte antigen associated with autoimmune premature ovarian failure. Endocrinology. 1999 Aug;140(8):3720–3726.

2. Zhi-Bin Tong *et al.* Developmental expression and subcellular localization of mouse MATER, an oocyte-specific protein essential for early development. Endocrinology. 2004 Mar;145(3):1427–1434.

3. Zhi-Bin Tong *et al.* A human homologue of mouse Mater, a maternal effect gene essential for early embryonic development. Hum Reprod. 2002 Apr; 17(4):903–911.

4. Zhi-Bin Tong *et al.* Mater, a maternal effect gene required for early embryonic development in mice. Nat Genet. 2000 Nov;26(3):267–268.

Patent Status:

1. PCT Application No. PCT/US01/10981 filed 04 Apr 2001, which published as WO02/032955 on 25 Apr 2002 (HHS Reference No. E–239–2000/0-PCT–02).

2. U.S. Application No. 10/399,443 filed 16 Apr 2003 (allowed) (HHS Reference No. E–239–2000/0-US–03).

3. U.S. Application No. 11/586,160 filed 24 Oct 2006 (HHS Reference No. E–239–2000/0-US–08).

4. U.S. Application No. 11/586,075 filed 24 Oct 2006 (HHS Reference No. E–239–2000/0-US–09).

5. U.S. Application No. 10/677,943 filed 01 Oct 2003 (allowed) (HHS Reference No. E–239–2000/1-US–02).

6. Foreign counterparts pending in Australia, Canada, Europe, and Japan.

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

Licensing Contact: Tara L. Kirby, Ph.D.; 301/435–4426; *tarak@mail.nih.gov*.

Dated: February 26, 2007.

Steven M. Ferguson,

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

[FR Doc. E7–3694 Filed 3–1–07; 8:45 am]

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.

Identification and Isolation of the Receptor for Pigment Epithelium-Derived Factor (PEDF)

Description of Technology: This application describes and claims compositions and methods related to PEDF-R, a receptor for pigment epithelium-derived factor (PEDF). PEDF (aka serpin f1 gene product) is a protein, belonging to the serpin superfamily with neurotrophic, gliastatic, neuronotrophic, antiangiogenic, and antitumorigenic properties. However, PEDF lacks the characteristic ability of serpins to inhibit serine protease activity. In particular, the compositions and methods described and claimed in this application are related to the isolation, cloning, expression and characterization of a receptor for PEDF, PEDF-R. The PEDF-R gene (also known as TTS-2.2, iPLA-zeta, ATGL, desnutrin, or PNPLA2) is located on chromosome 11. The sequence of the PEDF-R polypeptide is composed of 504 amino acids, and shares homology with other genes such as for adiponutrin and GS2, contains a patatin-like phospholipase A2 domain and up to four transmembrane regions. PEDF-R exhibits a potent phospholipase A2 activity, binds to PEDF ligands with high affinity, and it localizes to plasma membranes. An extracellular loop region is available for the interactions with extracellular PEDF ligand, which stimulate the phospholipase activity of PEDF-R. The identification of this novel PEDF-R gene in the retina for a phospholipase-linked membrane protein with high affinity for PEDF, suggests a molecular pathway by which ligand/receptor interaction on the cell surface could generate a cellular signal.

Applications:

1. Basic research to further elucidate the role of PEDF and its receptor in signal transduction pathways.

2. Development of drug screening assays to identify agonists and antagonists of PEDF activity.

3. Development of new biological molecules to regulate PEDF signaling such as monoclonal antibodies and chimeric IgG-receptor constructs.

Development Stage: Information on research being conducted in Dr. Becerra's laboratory can be found on the Internet at *http://www.nei.nih.gov/intramural/protein_struct_func.asp.* The ability of the receptor or receptor-targeted molecules and biologics to be used as therapeutics remains the subject of early research and development efforts.

Inventors: S. Patricia Becerra (NEI), Luigi Notari (NEI), Jorge Laborda (CDER/FDA), *et al.*

Publications:

1. The patent application has been published as WO 2005/014645 A2 on 17 Feb 2005.

2. L Notari *et al.* Identification of a lipase-linked cell membrane receptor for pigment epithelium-derived factor. J Biol Chem. 2006 Dec 8; 281(49):38022–38037.

Patent Status:

1. U.S. Patent Application No. 10/566,540 filed 16 Oct 2006, entitled ''PEDF-R Receptor and Uses,'' is pending (HHS Reference No. E–314–2003/2–US–02). The U.S. Application has not been published. Only U.S. Patent protection has been sought for this technology. There are no foreign counterpart patent applications.

2. PCT/US2004/025560 filed 05 Aug 2004 and published as WO 2005/014645 A2 on 17 Feb 2005, now expired (HHS Reference No. E–314–2003/2–PCT–01).

3. U.S. Provisional Application No. 60/579,177 filed 12 Jun 2004, now abandoned (HHS Reference No. E–314–2003/1–US–01).

4. U.S. Provisional Application No. 60/493,713 filed 07 Aug 2003, now abandoned (HHS Reference No. E–314–2003/0–US–01).