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.

Transforming Growth Factor Beta-1 (TGF-β1) Transgenic Mouse Model

Description of Technology: Transforming Growth Factor-β1 (TGF-β1) is a multifunctional cytokine that is involved in many physiological processes such as immune regulation, cell proliferation, angiogenesis, apoptosis, and extracellular matrix deposition. Overexpression of activated TGF-β1 signaling pathway is known to play a role in many disease processes, such as inflammation, fibrosis and tumor metastasis.

NIH inventors have developed a transgenic mouse model, designated $\beta 1^{glo}$, which permits conditional, gene-specific overexpression of TGF-β1. The model features a TGF-β1 transgene for which expression is blocked by a floxed enhanced green fluorescent protein (EGFP) gene downstream of the promoter. Excision of the EGFP gene by Cre recombinase allows expression of TGF-β1. Thus, these mice may be cross-bred with a variety of Cre transgenic mouse lines in order to study the role of TGF-β1 in targeted organ systems and tissues.

Inventors: Ashok B. Kulkarni and Bradford E. Hall (NIDCR).

Publication: BE Hall, C Zheng, WD Swaim, A Cho, CN Nagineni, MA Eckhaus, KC Flanders, IS Ambudkar, BJ Baum, AB Kulkarni. Conditional overexpression of TGF-beta1 disrupts mouse salivary gland development and function. Lab Invest. 2010 Apr;90(4):543–555. [PubMed: 20142803].

Patent Status: HHS Reference No. E–016–2010/0—Research Tool. Patent protection is not being pursued for this technology.

Licensing Status: Available for licensing under a Biological Materials License.

Licensing Contact: Tara Kirby, PhD; 301–435–4426; *tk200h@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.

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

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

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. [PubMed: 10433232].

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. [PubMed: 14670992].

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. [PubMed: 11925379].

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. [PubMed: 11062459].

Patent Status

- U.S. Patent 7,217,811 issued 15 May 2007 (HHS Reference No. E–239–2000/0–US–03).
- U.S. Patent 7,531,635 issued 12 May 2009 (HHS Reference No. E–239–2000/0–US–08).
- U.S. Patent 7,432,067 issued 07 Oct 2008 (HHS Reference No. E–239–2000/0–US–09).
- U.S. Patent 7,189,812 issued 13 Mar 2007 (HHS Reference No. E–239–2000/1–US–02).
- Foreign counterparts issued/pending in Australia, Canada, Europe, and Japan.

Licensing Status: Available for licensing.

Licensing Contact: Tara Kirby, PhD; 301–435–4427; *tk200h@nih.gov.*

Dated: August 17, 2010.

Richard U. Rodriguez,

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

[FR Doc. 2010–20863 Filed 8–20–10; 8:45 am]

BILLING CODE 4140–01–P

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