

ligand Receptor Assembly and Function" [E-095-2000/0-AU-04]; Australian Patent Application No. 2006203490, filed on August 11, 2006, entitled "Identification of Novel Domain in the Tumor Necrosis Factor Receptor Family that Mediates Pre-ligand Receptor Assembly and Function" [E-095-2000/0-AU-07]; and Canadian Patent Application No. 2399388, filed February 9, 2001, entitled "Identification of Novel Domain in the Tumor Necrosis Factor Receptor Family that Mediates Pre-ligand Receptor Assembly and Function" [E-095-2000/0-CA-05] to Welson Pharmaceuticals, Inc.

The prospective exclusive license territory may be worldwide and the field of use may be limited to therapeutic applications for rheumatoid arthritis (RA) using Welson's proprietary platform.

**DATES:** Only written comments and/or license applications which are received by the National Institutes of Health on or before July 9, 2007 will be considered.

**ADDRESSES:** Requests for copies of the patent and/or patent applications, inquiries, comments and other materials relating to the contemplated exclusive license should be directed to: Mojdeh Bahar, J.D., M.A., Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804. Telephone: (301) 435-2950; Facsimile: (301) 402-0220; E-mail: [baharm@od.nih.gov](mailto:baharm@od.nih.gov).

**SUPPLEMENTARY INFORMATION:** The invention relates to methods and compositions that are useful for novel treatment of arthritis and other autoimmune diseases. This technology discloses the identification of a functional domain, Pre-ligand Assembly Domain (PLAD), an essential part in signaling involving receptors of the Tumor Necrosis Factor superfamily and its use in ameliorating rheumatoid arthritis (RA). PLAD is essential for signaling involving TNFR including TNFR-1 (p60), TNFR-2 (p80), Fas, TRAIL-R, LTR, CD40, CD30, CD27, HVEM, OX40 and DR4 and can be isolated as functional polypeptides which can be useful in inhibiting the first step in TNFR mediated signaling, ligand-independent assembly of members of the TNFR superfamily. The ability to inhibit TNFR signaling suggests that these PLAD polypeptides may be useful in development of new therapeutic molecules or as therapeutic molecules themselves used for modulation of immune responses, apoptosis, and inflammation. The

inventors have discovered compounds that interfere with PLAD and can block the effects of TNF-alpha.

The prospective exclusive license will be royalty-bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR part 404.7. The prospective exclusive license may be granted unless within sixty (60) days from the date of this published notice, the NIH receives written evidence and argument that establish that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.7.

Applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: April 30, 2007.

**Steven M. Ferguson,**  
Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.  
[FR Doc. E7-8889 Filed 5-8-07; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Prospective Grant of Exclusive License: Treatment of Inflammatory Bowel Disease (IBD) Using IL-13 Modulators and Inhibitors

**AGENCY:** National Institutes of Health, Public Health Service, HHS.

**ACTION:** Notice.

**SUMMARY:** This is notice, in accordance with 35 U.S.C. 209(c) (1) and 37 CFR 404.7(a)(1)(i), that the National Institutes of Health (NIH), Department of Health and Human Services (HHS), is contemplating the grant of an exclusive license to practice the invention embodied in:

PCT patent application PCT/US2002/018790 filed 14 June 2002, entitled: "Methods of Treating and Preventing Colitis involving IL-13 and NK-T Cells" [HHS Reference Number: E-131-2002/0-PCT-01], to

Wyeth Pharmaceuticals, based in Madison, New Jersey. The field of use may be limited to the use of IL-13 modulators or NK-T cell modulators (such as antibodies) for the treatment or prevention of Inflammatory Bowel Disease, including ulcerative colitis and

Crohn's disease. The United States of America is an assignee of the patent rights in these inventions.

**DATES:** Only written comments and/or application for a license, which are received by the NIH Office of Technology Transfer on or before July 9, 2007 will be considered.

**ADDRESSES:** Requests for a copy of the patent application, inquiries, comments and other materials relating to the contemplated license should be directed to: Susan Carson, D.Phil., Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; E-mail: [carsonsu@od.nih.gov](mailto:carsonsu@od.nih.gov); Telephone: (301) 435-5020; Facsimile: (301) 402-0220.

**SUPPLEMENTARY INFORMATION:** Ulcerative colitis (UC) is a chronic inflammatory disease of the colorectum and affects approximately 400,000 people in the United States. The cause of UC is not known, although an abnormal immunological response by the mucosal T cells responsive to bacterial antigens in the gut microflora, is thought to be involved. Present treatments for UC include anti-inflammatory therapy using aminosalicylates or corticosteroids, as well as immunomodulators and diet. However, 25–40% of ulcerative colitis patients must eventually have their colons removed due to massive bleeding, severe illness, rupture of the colon, risk of cancer or due to side effects of corticosteroids and novel treatments are still actively being sought. NIH scientists and their collaborators have used a mouse model of experimental colitis (oxazolone colitis, OC) to show that IL-13, a Th2 cytokine, is a significant pathologic factor in OC and that neutralizing IL-13 in these animals effectively prevents colitis (Immunity (2002) 17, 629–638).

OC is a colitis induced by intrarectal administration of a relatively low dose of the haptenating agent oxazolone subsequent to skin sensitization with oxazolone. A highly reproducible and chronic colonic inflammation is obtained that is histologically similar to human ulcerative colitis. Studies show that NKT cells rather than conventional CD4+T cells mediate oxazolone colitis and that NKT cells are the source of IL-13, and are activated by CD1 expressing intestinal epithelial cells. Tissue removed from UC patients was also shown to contain increased numbers of nonclassical NKT cells that produce markedly increased amounts of IL-13 and that in keeping with epithelial damage being a key factor in UC, these NKT cells are cytotoxic for epithelial cells (J Clin. Investigation (2004) 113,

1490–1497). Methods of use claims are directed to treatments preventing the inflammatory response of colitis by modulating IL-13 and NKT cell activity and to methods for screening for therapeutic compounds effective for colitis.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless, within 60 days from the date of this published Notice, NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

Properly filed competing applications for a license filed in response to this notice will be treated as objections to the contemplated license. Comments and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: April 30, 2007.

**Steven M. Ferguson,**

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

[FR Doc. E7-8892 Filed 5-8-07; 8:45 am]

BILLING CODE 4140-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Office of Biotechnology Activities; Recombinant DNA Research: Proposed Actions Under the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)

**ACTION:** Notice of consideration of proposed actions under the NIH Guidelines.

**SUMMARY:** Proposals to conduct research involving the deliberate transfer of a tetracycline resistance trait to *Chlamydia Trachomatis* have been submitted to the NIH Office of Biotechnology Activities (OBA). The acquisition of this antibiotic resistance trait could possibly compromise the use of a class of antibiotics for the treatment of Chlamydia infections in humans. Under the NIH Guidelines, these experiments can proceed only after they are reviewed by the NIH Recombinant DNA Advisory Committee (RAC) and specifically approved by the NIH Director as Major Actions. These

proposals will be discussed at the June 19–21, 2007 meeting of NIH Recombinant DNA Advisory Committee.

**DATES:** The public is encouraged to submit written comments on these proposed actions. Comments may be submitted to the OBA in paper or electronic form at the OBA mailing, fax, and e-mail addresses shown below under the heading **FOR FURTHER INFORMATION**.

**INFORMATION.** The NIH will consider all comments submitted by June 15, 2007. Written comments submitted by May 24, 2007 will be reproduced and distributed to the RAC for consideration at its June 19–21 meeting. In addition, an opportunity for public comment will be provided at that meeting. All written comments received in response to this notice will be available for public inspection at the NIH OBA office, 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892 (telephone, 301-496-9838), weekdays between the hours of 8:30 a.m. and 5 p.m.

**FOR FURTHER INFORMATION CONTACT:** Contact OBA by e-mail at [oba@od.nih.gov](mailto:oba@od.nih.gov), or telephone at 301-496-9838, if you have questions, or require additional information about these proposed actions. Comments may be submitted to the same e-mail address or by fax at 301-496-9839 or sent by U.S. mail to the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, Maryland 20892-7985. For additional information about the RAC meeting at which these proposed actions will be deliberated, please visit the NIH OBA Web site at: <http://www4.od.nih.gov/oba/>.

**SUPPLEMENTARY INFORMATION:** OBA has received information from two Institutional Biosafety Committees regarding proposed experiments, which, to proceed, would require Major Actions under Section III-A-1-a of the NIH Guidelines. Under this section, if the deliberate transfer of a drug resistance trait to microorganisms could compromise the use of the drug to control disease in humans, veterinary medicine, or agriculture the experiment must be reviewed by the RAC. Dr. Dan Rockey and Dr. Walter Stamm (at Oregon State University and the University of Washington, respectively), are proposing to develop a genetic transformation system to study the pathogenesis of *Chlamydia trachomatis*, a human pathogen that is a leading cause of sexually transmitted disease worldwide and, mostly in the developing world, a preventable cause of blindness. Per the investigators, the lack of genetic tools to study the mechanisms of pathogenesis in these

obligate intracellular bacterial parasites hinders research. The recent discovery of naturally occurring tetracycline resistant strains of *C. suis* (a swine pathogen) may provide the necessary genetic elements to develop such a transformation system. To accomplish this goal, experiments are planned to transfer tetracycline resistance from *C. suis* into *C. trachomatis* (a human pathogen). It is asserted that success in these proposed studies will lead to opportunities for “rapid developments in our understanding of chlamydial biology.” The investigators are proposing to perform these experiments under Biosafety Level 2 containment.

Background information may be obtained by contacting NIH OBA via e-mail at [oba@od.nih.gov](mailto:oba@od.nih.gov). Alternatively, information is available on the OBA Web site at <http://www4.od.nih.gov/oba/rac/latestnewsrac.htm>.

Dated: May 3, 2007.

**Amy P. Patterson,**

Director, Office of Biotechnology Activities, National Institutes of Health.

[FR Doc. E7-8900 Filed 5-8-07; 8:45 am]

BILLING CODE 4140-01-P

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

[USCG-2007-28034]

#### Chemical Transportation Advisory Committee; Vacancies

**AGENCY:** Coast Guard, DHS.

**ACTION:** Request for applications.

**SUMMARY:** The Coast Guard is seeking applications for appointment to membership on the Chemical Transportation Advisory Committee (CTAC). CTAC advises, consults with, and makes recommendations to the Coast Guard on matters relating to the safe and secure transportation and handling of hazardous materials in bulk on U.S.-flag vessels in U.S. ports and waterways.

**DATES:** Application forms should reach the Coast Guard on or before August 31, 2007.

**ADDRESSES:** You may request an application form by writing to Commandant (CG-3PSO-3), U.S. Coast Guard, 2100 Second Street SW., Washington, DC 20593-0001; by calling (202) 372-1425/1422; or by faxing (202) 372-1926. Submit application forms to the same address. This notice and the application form are available on the Internet at <http://dms.dot.gov>. The application form is also available at