Respondents	Number of respondents	Responses per respondent	Total responses	Minutes per response	Total burden (hours)
Participants	1000	1	1000	30	500

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 11A–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of notice.

Dated: February 17, 2005.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. 05–3712 Filed 2–25–05; 8:45 am]

BILLING CODE 4165–15–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, DHHS.

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.

Compositions and Methods for the Treatment of Immune-Related Disease

F. Xavier Valencia and Peter E. Lipsky (NIAMS), U.S. Provisional Application filed 07 Jan 2005 (DHHS Reference No. E–355–2004/0–US–01).

Licensing Contact: Fatima Sayyid; 301/435–4521; *sayyidf@mail.nih.gov.*

The ability of the immune system to discriminate between self and non-self is controlled by central and peripheral tolerance mechanisms. One of the most important ways the immune system controls the outcome of such a response is through naturally occurring CD4+CD25+ regulatory T cells.

The present invention relates to compositions and methods for treating immune related disease, a method for determining the presence of or predisposition to an immune related disease, and a pharmaceutical composition for treating an immune related disease in a mammal.

In addition to licensing, the technology is available for further development through collaborative research opportunities with the inventors.

Expression Tags for High Yield Soluble Expression of Recombinant Proteins

Deb K. Chatterjee and Dominic Esposito (NCI), U.S. Provisional Application No. 60/564,982 filed 26 Apr 2004 (DHHS Reference No. E–103–2004/0–US–01).

Licensing Contact: Susan Carson, 301–435–5020; *carsonsu@mail.nih.gov.*

Production of large quantities of soluble and correctly folded proteins is essential for a variety of applications ranging from functional analysis and structure determination to clinical trials. *E. coli* is a widely used expression system that offers the advantages of ease of handling, cost-effectiveness and the ability to produce proteins in high yield. However, the enhanced production obtainable with *E. coli* expression systems is frequently accompanied by problems of protein insolubility, production host non-viability and aberrant protein folding. Many strategies have been proposed to address these problems, in particular the use of fusion vectors that mediate the expression of a target gene linked to a peptide signal sequence or to a ''chaperone'' or ''carrier'' protein that is capable of ''escorting'' the fusion protein out of the cytoplasm and into the periplasmic space. However, there remains a need for methods that provide soluble proteins that are correctly folded and in functional form without unacceptably diminishing the yield of recovered protein or requiring complex host strains.

NIH researchers have developed a fusion polynucleotide in which a polynucleotide encoding a desired target protein is linked to one or more chaperone protein domains (Skp and DsbC) with or without the signal sequence. This permits the expressed proteins to be transported to the periplasm or to be retained in the cytoplasm respectively and these vectors were used to successfully express significant amounts of such difficult to express proteins as Hif1a, Folliculin (fol), a Folliculin domain (FD), Wnt5a, Endostatin, YopD, IL13 and IFN-Hybrid3. These fusion vectors are available for licensing and are useful tools for the expression of commercially viable amounts of functional proteins of therapeutic and scientific interest.

In addition to licensing, the technology is available for further development through collaborative research with the inventors via a Cooperative Research and Development Agreement (CRADA).

Novel Potent Monoamine Oxidase Inhibitors

Kenneth L. Kirk *et al.* (NIDDK), U.S. Provisional Application No. 60/484,710 filed 03 Jul 2003 (DHHS Reference No. E–226–2003/0–US–01); PCT Application No. PCT/US04/21505 filed 01 Jul 2004 (DHHS Reference No. E–226–2003/0–PCT–02).

Licensing Contact: Norbert Pontzer; 301/435–5502; *pontzern@mail.nih.gov.*

Copper- (EC, 1.4.3.6) and flavin-containing amine oxidases (EC, 1.4.3.4) make up two general classes of the widely distributed monoamine oxidases. Reversible and irreversible inhibitors of the flavin monoamine oxidases have been developed and investigated for treatment of diseases of the CNS such as depression, Parkinson's disease and Alzheimer's disease. These researchers have developed several new arylethyl and benzyl amine derivatives that incorporate both the key cyclopropane ring and fluorine substitution at strategic positions. The combined effects of this substitution pattern have led to new inhibitors of greatly increased potency and selectivity for all classes of monoamine oxidases. Their potent copper amine oxidase inhibitors are the best reversible inhibitors known and could provide vascular protection in advanced diabetics. Further information on these compounds can be found in Yoshida *et al.*, J. Med. Chem. (25 Mar 2004) 47 (7): 1796–1806, 2004, and Yoshida *et al.*,

Bioorg. Med. Chem. (15 May 2004) 12 (10): 2645–2652.

Dated: February 17, 2005.

Steven M. Ferguson,

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

[FR Doc. 05–3830 Filed 2–25–05; 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, DHHS.

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.

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Mouse Lactoferrin Antibody

Christina T. Teng (NIEHS), DHHS Reference No. E–158–2004/0—Research Tool. *Licensing Contact:* Marlene Shinn-Astor; 301/435–4426; *shinnm@mail.nih.gov.*

Lactoferrin, an iron-binding glycoprotein, kills bacteria and modulates inflammatory and immune responses. It is expressed in mucosa membrane and is present in saliva, tears, vaginal secretion and neutrophils. It modulates immune and inflammatory response by down-regulating several cytokines. Therefore, lactoferrin is an important protein in first line of defense and protecting health. Changes in lactoferrin expression could also be used as a marker of gene activation, especially estrogen-induced gene activity in the uterus.

The inventors have uniquely purified a novel 70 kDa estrogen-stimulated glycoprotein, lactoferrin, from mouse uterine luminal fluid. CM-Affi-Gel Blue column chromatography provided a simple one step separation of lactoferrin from the other luminal and serum proteins. Furthermore, a polyclonal antibody was created in rabbit, which has been utilized for immunostaining, Western blot, and elisa assays on human, mouse, rat, and hamster tissues. The cDNA to both human and mouse were cloned. Probes designed to detect the methylation status or polymorphisms of the human lactoferrin gene are available and can be used as diagnostic tool in cancer study.

The inventor has available polyclonal antibodies for both human and mouse, as well as purified mouse lactoferrin protein.

References: (1) Teng, CT *et al.* 1986. Purification and properties of an oestrogen-stimulated mouse uterine glycoprotein (approx. 70 kDa). Biochemical Journal. 240:413–422. (2) Teng, *et al.* 2002. Differential expression and estrogen response of lactoferrin gene in the female reproductive tract of mouse, rat, and hamster. Biology of Reproduction. 67:1439–1449.

In addition to licensing, the technology is available for further development through collaborative research opportunities with the inventors.

Antibody to Estrogen Related Receptor Alpha

Christina T. Teng (NIEHS), DHHS Reference No. E–157–2004/0—Research Tool.

Licensing Contact: Marlene Shinn-Astor; 301/435–4426; *shinnm@mail.nih.gov.*

Estrogen related receptor alpha (ERRalpha) is a family member of the steroid/thyroid nuclear receptor superfamily. Estrogen related receptors are thought to regulate similar target genes in the absence of known ligands. For example, the inventors previously cloned the human estrogen receptor-related orphan receptor alpha1 cDNA and demonstrated that it enhances estrogen responsiveness of the lactoferrin gene promoter in transfected human endometrial carcinoma cells.

The inventors have produced a peptide and fusion protein rabbit polyclonal antibody against ERRalpha1-C terminal (anti-ERRalpha-CT), which has been utilized for immunostaining, Chromatin immunoprecipitation (ChIP), immunoprecipitation/immunoblottin (IP/IB) and Western blot. This antibody targets the C-terminus of the protein which is a conserved region in human and mouse. The antibody will be a valuable tool to study the expression and function of the protein in rodent models, whereas the human antibody is already commercially available. The inventors also have available mouse cDNA for ERRalpha1 which can be used to detect mRNA.

Reference: Shigeta, H, *et al.* 1997. The mouse estrogen receptor-related orphan receptor alpha1: molecular cloning and estrogen responsiveness. Journal of Molecular Endocrinology. 19:299–309.

In addition to licensing, the technology is available for further development through collaborative research opportunities with the inventors.

A Novel, Preservative-Free Steroid Formulation for Use as an Anti-Inflammatory

Michael R. Robinson (NEI), George Grimes (CC), Luisa Gravlin (CC), Gopal Potti (CC), Peng Yuan (CC) and Karl Csaky (NEI), U.S. Provisional Patent Application No. 60/628,741 filed 17 Nov 2004 (DHHS Reference No. E–094–2003/0–US–01).

Licensing Contact: Susan Carson; 301/435–5020; *carsonsu@mail.nih.gov.*

Corticosteroids, such as dexamethasone, methylprednisolone and triamcinolone acetonide (TAC), have been used for many years in the treatment of inflammation and in relieving pain caused by inflammation (for example chronic back and joint pain). Intraocular inflammation is also treated with steroids; however, there are no commercial corticosteroid preparations approved by the FDA for use in the eye and off-label use of current commercial formulations can be accompanied by toxic side effects, which can lead to vision loss. Inflammation is present in eye diseases including uveitis, diabetic retinopathy, venous occlusive disease and age-related macular degeneration, which are estimated to affect more than 200,000 patients in the U.S. alone. This number is likely to increase as the population ages, and there remains a need for a cost-effective, safe, efficient steroid formulation for treating these conditions.

NIH researchers at the National Eye Institute and the Clinical Center have devised a novel preservative-free formulation of the generic steroid TAC with an improved safety profile that permits intravitreal injection. The invention is a pharmaceutical composition free of preservatives and dispersion agents (TAC–PF) that are thought to be responsible for certain toxic side effects. Pre-clinical ocular toxicology and pharmacokinetic studies