

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Prospective Grant of Exclusive License: "Compositions and Methods for In Vitro Fertilization"

**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, is contemplating the grant of an exclusive license worldwide to practice the invention embodied in: U.S. Patent Application Serial No. 60/091,771, filed July 6, 1998, now converted into PCT application number PCT/US99/14841 filed June 30, 1999 along with foreign filed patent applications in Europe, Canada, Japan, and Australia, entitled, "Compositions and Methods for In Vitro Fertilization" to Amrad Corporation Limited, having a place of business in the country of Australia. The field of use may be limited to the clinical treatment of infertility in humans. The United States of America is the assignee of the patent rights in this invention.

**DATES:** Only written comments and/or application for a license, which are received by the NIH Office of Technology Transfer on or before November 12, 2002, will be considered.

**ADDRESSES:** Requests for a copy of the patent applications, inquiries, comments and other materials relating to the contemplated license should be directed to: Marlene Shinn, Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 496-7056, ext. 285; Facsimile: (301) 402-0220; e-mail: [MS482M@NIH.GOV](mailto:MS482M@NIH.GOV).

**SUPPLEMENTARY INFORMATION:** This technology relates to methods for utilizing Leukemia Inhibitory Factor (LIF) (a member of the IL-6 family of cytokines that functions through the gp130 receptor pathway) to enhance embryo implantation and LIF antagonists to block implantation in mammals. Previous studies have concentrated on the dependence on estrogen for embryo implantation. However, the identification of LIF as an absolute factor necessary for embryo implantation offers new routes to treatment. This invention portrays that a single dose injection of recombinant LIF in LIF deficient mice restores their

ability to successfully implant an embryo. During In Vitro Fertilization (IVF) treatments, the majority of embryos are lost after transfer prior to implantation. Apparently the decreased receptivity of the uterus to implantation may be due to exposures of high concentrations of estradiol after recovery of the eggs prior to IVF. The current invention portrays that LIF may be substituted for estrogen in embryo transfer (during IVF) which can increase implantation frequencies and alleviate side effects associated with increased levels of estrogen in the uterine environment. Furthermore, the viability of subsequent embryonic development is not compromised with LIF.

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: September 9, 2002.

**Jack Spiegel,**

*Director, Division of Technology Development and Transfer, Office of Technology Transfer.*

[FR Doc. 02-23336 Filed 9-12-02; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Prospective Grant of Exclusive License: "Laser Capture Microdissection (LCM) for Cellular Protein Analysis"

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

**ACTION:** Notice.

**SUMMARY:** This is a public 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, is contemplating the grant of an exclusive license worldwide to practice the inventions embodied in:

U.S. Patent Application No. 09/913,667, filed August 16, 2001, and PCT Application No. PCT/US00/04023, filed February 16, 2000, "Methods and Devices for Isolation and Analysis of Cellular Protein Content" by Liotta, Petricoin, Simone, and Emmert-Buck (NIH Reference Numbers E-261-98/0, 1, 2)

to EntPharma, Inc., having a place of business in Rockville, Maryland.

The United States of America is the assignee to the patent rights of these inventions.

The contemplated limited term exclusive license may be restricted to the field of providing in-house commercial services for drug design using reverse phase protein microarrays, for non-cancer indications only. The field may further include a co-exclusive commercial license limited to the licensee and a fixed number of co-exclusive licensees, for diagnostic products and services using reverse phase protein microarrays, for non-cancer indications.

**DATES:** Only written comments and/or applications for a license that are received by the NIH Office of Technology Transfer on or before November 12, 2002, 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: Dale D. Berkley, Ph.D., J.D. Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 496-7735, ext. 223; Facsimile: (301) 402-0220; e-mail: [berkleyd@od.nih.gov](mailto:berkleyd@od.nih.gov). A signed Confidential Disclosure Agreement will be required to receive copies of the patent application.

**SUPPLEMENTARY INFORMATION:** The invention is a method and device for the analysis of cell samples where the samples are pure populations or subpopulations of desired types. Laser Capture Microdissection (LCM) is used in this invention to retrieve cells of interest from a tissue sample, which permits proteomic analysis on cells of different populations. The proteins in the micro-dissected cells are subjected to various analytic processes, such as immunoassays, 1D and 2D electrophoresis characterization, Western blotting, Matrix Assisted Desorption/Ionization/Time of Flight (MALDI/TOF), Liquid Chromatography Quadrupole Ion Trap Electrospray (LCQ-MS), and Surface Enhanced Laser Desorption Ionization Spectroscopy (SELDI). These methods allow for convenient and direct comparison of qualitative and quantitative protein

content of diseased cells and normal cells from the same tissue sample.

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: September 6, 2002.

**Jack Spiegel,**

*Director, Division of Technology Development and Transfer, Office of Technology Transfer.*

[FR Doc. 02-23335 Filed 9-12-02; 8:45 am]

**BILLING CODE 4140-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Substance Abuse and Mental Health Services Administration**

**Fiscal Year (FY) 2003 Funding Opportunities**

**AGENCY:** Substance Abuse and Mental Health Services Administration, HHS.

**ACTION:** Notice of Funding Availability for American Indian/Alaska Native National Resource Center for Substance Abuse Services.

**SUMMARY:** The Substance Abuse and Mental Health Services Administration (SAMHSA) Center for Substance Abuse Prevention (CSAP) and Center for Substance Abuse Treatment (CSAT) announce the availability of FY 2003 funds for a cooperative agreement for the following activity. This notice is not a complete description of the activity; potential applicants must obtain a copy of the Guidance for Applicants (GFA), including Part I, American Indian/Alaska Native National Resource Center for Substance Abuse Services (SP 03-001), and Part II, General Policies and Procedures Applicable to all SAMHSA Applications for Discretionary Grants and Cooperative Agreements, before preparing and submitting an application.

Activity	Application deadline	Est. funds FY 2003	Est. number of awards	Project period
American Indian/Alaska Native National Resource Center for Substance Abuse.	Nov. 18, 2002 .....	\$1,000,000	1	3 years.

The actual amount available for the award may vary depending on unanticipated program requirements and actual SAMHSA appropriations. This program is being announced prior to the annual appropriation for FY 2003 for SAMHSA's programs. Applications are invited based on the assumption that sufficient funds will be appropriated for FY 2003 to permit funding of an American Indian/Alaska Native National Resource Center cooperative agreement. This program is being announced in order to allow applicants sufficient time to plan and prepare applications. Solicitation of applications in advance of a final appropriation will also enable the award of appropriated grant funds in an expeditious manner and thus allow prompt implementation and evaluation of promising practices. All applicants are reminded, however, that we cannot guarantee sufficient funds will be appropriated to permit SAMHSA to fund the cooperative agreement. This program is authorized under section 516(5) and section 509 of the Public Health Service Act. SAMHSA's policies and procedures for peer review and Advisory Council review of grant and cooperative agreement applications were published in the **Federal Register** (Vol. 58, No. 126) on July 2, 1993.

**General Instructions**

Applicants must use application form PHS 5161-1 (Rev. 7/00). The

application kit contains the two-part application materials (complete programmatic guidance and instructions for preparing and submitting applications), the PHS 5161-1 which includes Standard Form 424 (Face Page), and other documentation and forms. Application kits may be obtained from: National Clearinghouse for Alcohol and Drug Information (NCADI), P.O. Box 2345, Rockville, MD 20847-2345, Telephone: 1-800-729-6686.

The PHS 5161-1 application form and the full text of the grant announcement are also available electronically via SAMHSA's World Wide Web Home Page: <http://www.samhsa.gov> (Click on "Grant Opportunities").

When requesting an application kit, the applicant must specify the particular announcement number for which detailed information is desired. All information necessary to apply, including where to submit applications and application deadline instructions, are included in the application kit.

**Purpose:** The Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Prevention (CSAP) and Center for Substance Abuse Treatment (CSAT) are accepting applications for a fiscal year (FY) 2003 cooperative agreement for implementing the American Indian/Alaska Native National Resource Center for Substance Abuse Services (AI/AN-NRC).

**Eligibility:** Eligible applicants are domestic public and private non-profit entities such as Tribes, AI/AN national organizations, tribal or non-tribal community based and faith based organizations, universities and colleges, or a consortium of any of the above with a lead agency/entity designated for legal and accounting purposes.

**Availability of Funds:** It is expected that one cooperative agreement, in the amount of approximately \$1.0 million, will be available per year in total costs (direct and indirect). Annual continuation awards are dependent on the availability of funds and progress achieved.

**Period of Support:** Awards may be requested for up to 3 years.

**Criteria for Review and Funding:**  
**General Review Criteria:** Competing applications requesting funding under this activity will be reviewed for technical merit in accordance with established PHS/SAMHSA peer review procedures. Review criteria that will be used by the peer review groups are specified in the application guidance material.

**Award Criteria for Scored Applications:** Applications will be considered for funding on the basis of their overall technical merit as determined through the peer review group and the appropriate National Advisory Council review process. Availability of funds will also be an award criterion. Additional award