

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Use of the Licensed Patent Rights To Develop Fully Human and/or Humanized Monoclonal Antibodies Against IGF-I and/or IGF-II for the Treatment of Human Cancers

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 part 404.7(a)(1)(i), that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to practice the inventions embodied in the following U.S. Patent Applications to Systems Medicine, Inc., which is located in Tucson, Arizona.

1. PCT Patent Application No. PCT/US2006/031814 entitled "Human Monoclonal Antibodies that Specifically Bind IGF-II" [HHS Ref. Nos. E-217-2005/0, 1, and 2]; and

2. PCT Application Serial No. PCT/US2007/66180 entitled "Human IGF-I-Specific and IGF-I and IGF-II Cross-Reactive Human Monoclonal Antibodies" [HHS Ref. No. E-336-2005/0].

The patent rights in these inventions have been assigned to the United States of America.

The prospective exclusive license territory may be worldwide and the field of use may be limited to the use of the antibodies and their method of use in the Licensed Patent Rights for the treatment of human cancers

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before August 11, 2008 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive license should be directed to: Whitney Hastings, PhD, Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 451-7337; Facsimile: (301) 402-0220; E-mail: hastingsw@mail.nih.gov.

SUPPLEMENTARY INFORMATION: The type 1 insulin-like growth factor (IGF) receptor (IGF1R) is over-expressed by many tumors and mediates proliferation, motility, and protection from apoptosis. Agents that inhibit IGF1R expression or

function can potentially block tumor growth and metastasis. Its major ligand, IGF-II, is over-expressed by multiple tumor types. Previous studies indicate that inhibition of IGF-II binding to its cognizant receptor negatively modulates signal transduction through the IGF pathway and concomitant cell growth. Therefore, use of humanized or fully human antibodies against IGFs represents a valid approach to inhibit tumor growth.

The above identified patent applications relate to the identification of multiple, novel fully human monoclonal antibodies that are specific for IGF-II and do not cross-react with IGF-1 or insulin and identification and characterization of three (3) novel fully human monoclonal antibodies designated m705, m706, and m708, which are specific for insulin-like growth factor (IGF)-I. Two (2) of the three (3) antibodies, m705 and m706 are specific for IGF-I and do not cross react with IGF-II and insulin while, m708 cross reacts with IGF-II.

These antibodies can be used to prevent binding of IGF-I to its concomitant receptor IGFIR, consequently, modulating diseases such as cancer. Additional embodiments describe methods for treating various human diseases associated with aberrant cell growth and motility including breast, prostate, and leukemia carcinomas. Thus, these novel antibodies may provide a therapeutic intervention for multiple carcinomas without the negative side effects associated with insulin inhibition.

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 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.

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: May 30, 2008.

Steven M. Ferguson,

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

[FR Doc. E8-12925 Filed 6-9-08; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, Office of Biotechnology Activities; Recombinant DNA Research: Action Under the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)

AGENCY: National Institutes of Health (NIH), DHHS.

ACTION: Notice of a final action under the NIH Guidelines and notice of additions to Appendix D of the NIH Guidelines.

SUMMARY: Proposal to conduct research involving the deliberate transfer of a drug resistance trait to a microorganism that causes disease in humans has been reviewed by the Recombinant DNA Advisory Committee (RAC) and approved by the NIH Director.

DATES: The final action is effective April 7, 2008.

FOR FURTHER INFORMATION CONTACT: Background documentation and additional information can be obtained from the Office of Biotechnology Activities (OBA), National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, Maryland 20892-7985; e-mail at oba@od.nih.gov, or telephone at 301-496-9838. The NIH/OBA Web site is located at: <http://www4.od.nih.gov/oba/>.

SUPPLEMENTARY INFORMATION: This final action allows Dr. David Walker, University of Texas Medical Branch at Galveston to deliberately introduce a gene encoding chloramphenicol resistance into *Rickettsia conorii*. This approval is specific to Dr. Walker. His research with these resistant organisms may only occur under the conditions outlined below. It should be noted that any work involving the introduction of chloramphenicol resistance into *R. conorii* by other investigators would need to be reviewed by the RAC and specifically approved by the NIH Director.

Background Information and Response to Comments: On July 24, 2007, background on the proposed action and information on how to submit public comment, was published

in the **Federal Register** (72 FR 40320). On September 17, 2007, and December 5, 2007, the RAC discussed this proposed action and a proposed action to allow the transfer of chloramphenicol resistance into *R. typhi*. The RAC reviewed the three public comments received regarding the transfer of chloramphenicol resistance to *R. conorii* and to *R. typhi*. The RAC unanimously recommended that the transfer of chloramphenicol resistance to *R. conorii* be approved at this time and the majority of the members present did not recommend the transfer of chloramphenicol resistance to *R. typhi*. On April 7, 2008, the NIH Director approved the transfer of chloramphenicol resistance to *R. conorii* with the following containment provisions/stipulations:

(1) Perform all research involving the introduction of chloramphenicol resistance into *Rickettsia conorii* at minimum biosafety level 3 (BL-3) containment. Access will therefore be restricted to well-trained personnel whose presence is required for the conduct of this work. In addition, there must be a standard training procedure to make sure that personnel are trained and training is ongoing.

(2) Maintain at least one back-up power source to insure computer based security remains in place at all times.

(3) Include a signature nucleic acid sequence ("bar-code") to allow identification of laboratory-created (chloramphenicol resistant) strains.

(4) Incorporate the following elements into a health surveillance program for individuals working with chloramphenicol resistant *R. conorii*:

(a) Exclude those with a known allergy or sensitivity to tetracycline, and in particular doxycycline, from working with chloramphenicol resistant *R. conorii*;

(b) Obtain and store a baseline blood sample from laboratory workers;

(c) Do not permit pregnant individuals to work in any laboratory in which chloramphenicol resistant rickettsia is being handled;

(d) Provide workers education on the possible clinical manifestations of a rickettsial laboratory acquired infection;

(e) Develop a medical card that would be carried by all laboratory workers that includes at a minimum the following:

(i) Identification of the organism to which the labworker has been exposed;

(ii) Identification of key personnel responsible for providing diagnosis and treatment;

(iii) A CDC telephone number for reporting the infection and obtaining treatment recommendations; and

(iv) A twenty-four hour contact number for the principal investigators.

(5) Have a detailed standard operating procedures outlining the specific steps to be taken in the case of a laboratory exposure or infection containing at a minimum:

(a) Identification of key personnel who would provide diagnostic testing and treatment; and

(b) Instructions on managing exposures or infections discovered during off hours (after close of business, holidays, weekends, etc.).

Additions to Appendix D of the NIH Guidelines: In accordance with Section III-A of the NIH Guidelines, Appendix D of the NIH Guidelines will be modified as follows to reflect the recent approvals for the transfer of drug resistance traits to microorganisms.

Specifically, Appendix D will be modified to include approval of experiments to be conducted by Dr. Daniel Rockey, Oregon State University and Dr. Walter Stamm, University of Washington in which tetracycline resistance will be transferred into *Chlamydia trachomatis* (72 FR 61661) and approval of the Dr. Walker's experiment to transfer chloramphenicol resistance to *Rickettsia conorii*.

Appendix D-116. Dr. Daniel Rockey at Oregon State University and Dr. Walter Stamm at the University of Washington may conduct experiments to deliberately transfer a gene encoding tetracycline resistance from *Chlamydia suis* (a swine pathogen) into *C. trachomatis* (a human pathogen). This approval is specific to Drs. Rockey and Stamm and research with these resistant organisms may only occur under the conditions specified by the NIH Director. It should be noted that any work involving the introduction of tetracycline resistance into *C. trachomatis* by other investigators would need to be reviewed by the RAC and specifically approved by the NIH Director. This approval was effective as of September 24, 2007 (72 FR 61661).

Appendix D-117. Dr. David Walker at the University of Texas Medical Branch at Galveston may conduct experiments to deliberately introduce a gene encoding chloramphenicol resistance into *Rickettsia conorii*. This approval is specific to Dr. Walker and research with these resistant organisms may only occur under the conditions specified by the NIH Director. It should be noted that any work involving the introduction of chloramphenicol resistance into *R. conorii* by other investigators would need to be reviewed by the RAC and specifically approved by the NIH Director. This approval was effective as of April 7, 2008.

Dated: June 3, 2008.

Amy P. Patterson,

Director, Office of Biotechnology Activities.

[FR Doc. E8-12924 Filed 6-9-08; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

[DHS-2008-0052]

Privacy Act of 1974; Department of Homeland Security, U.S. Customs and Border Protection—Electronic System for Travel Authorization (ESTA), Systems of Records

AGENCY: Privacy Office; Office of the Secretary; DHS.

ACTION: Notice of Privacy Act system of records.

SUMMARY: To provide notice and transparency to the public, the Department of Homeland Security, U.S. Customs and Border Protection announces a new Privacy Act system of records, the Electronic System for Travel Authorization, to collect and maintain a record of nonimmigrant aliens who want to travel to the United States under the Visa Waiver Program (VWP). This new system will determine whether the applicant is eligible to travel to the United States under the VWP by checking their information against various security and law enforcement databases. CBP is publishing a new system of records notice to permit the traveling public greater access to individual information and to provide a more complete understanding of how and where information pertaining to them is collected and maintained.

DATES: In accordance with 5 U.S.C. 552a(e)(4) and (11), the public is given a 30-day period in which to comment on this notice; and the Office of Management and Budget (OMB), which has oversight responsibility under the Act, requires a 40-day period in which to conclude its review of the system. Therefore, the public, OMB, and Congress are invited to submit comments by July 21, 2008.

ADDRESSES: You may submit comments, identified by DHS-2008-0052 by one of the following methods:

- *Federal e-Rulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *Fax:* 1-866-466-5370.

- *Mail:* Hugo Teufel III, Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528.