

Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3028D, MSC 7770, Bethesda, MD 20892, 301-435-1251, melnicks@csr.nih.gov.

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Dated: February 8, 2007.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: The Use of Adenovirus Vectors for the Development of Vaccines Against Human Immunodeficiency Virus and Other Infectious Agents

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 (NIH), Department of Health and Human Services (HHS), is contemplating the grant of an exclusive patent license to practice the inventions embodied in Patent Cooperation Treaty Application No. PCT/US02/27592 filed August 29, 2002 and United States National Stage Application Serial No. 10/487,974 filed February 27, 2004, entitled "New Adenovirus Type 7 Vectors" [HHS Reference No. E-236-2001/0], and United States Patent Application Serial No. 11/282,319 filed November 17, 2005, entitled "Improved Replication-Competent Adenovirus Vectors" [HHS Reference No. E-203-2004/0], to PaxVax, Inc., which has offices in Menlo Park, CA. The patent rights in these inventions have been assigned and/or exclusively licensed to the Government of the United States of America.

The prospective exclusive license territory may be the United States of America, and the field of use may be limited to the development of vaccines against human immunodeficiency virus, human papillomavirus, influenza, malaria, and tuberculosis.

DATES: Only written comments and/or applications for a license which are received by the NIH Office of

Technology Transfer on or before April 23, 2007 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: Susan Ano, Ph.D., Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-5515; Facsimile: (301) 402-0220; E-mail: anos@mail.nih.gov.

SUPPLEMENTARY INFORMATION: The subject application addresses two (2) technologies related to specific techniques for producing adenoviral vectors and application of such vectors for gene transfer, vaccine development and therapeutics. Use of the present technologies in the prevention and/or treatment of disease, especially human immunodeficiency virus (HIV), is the primary focus of the current subject inventions.

The first technology (HHS Reference No. E-236-2001/0) describes a cosmid adenoviral serotype 7 (Ad7) vector for use in the prevention and/or treatment of HIV-1. This invention includes methods for producing and administering both replication-competent and incompetent Ad7. The cosmid Ad7 vector includes an Ad7 genome that can be modified to express specific nucleic acid sequences for production of a desired protein or epitope such as an HIV-1 gene product. This system may be used to generate proteins or epitopes of infectious agents for stimulation of desired immunogenic responses.

The second invention (HHS Reference No. E-203-2004/0) discloses improvements upon replication-competent Ad vectors, which serve to produce high level expression of any gene of interest, *i.e.*, a transgene. This system incorporates a novel hybrid gene regulatory unit comprising a CMV promoter and an adenovirus tripartite leader sequence for regulation of transgene expression. Additionally, the present disclosure provides methods of producing and administering the described adenoviral expression vectors, containing the nucleic acid sequence of significant HIV-1 proteins as transgenes for stimulation of an immune response to HIV-1.

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 within ninety (90) days from the date of this published notice, unless 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 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: February 12, 2007.

Steven M. Ferguson,

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

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Conference of the Parties to the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES); Fourteenth Regular Meeting; Provisional Agenda; Announcement of Public Meeting

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice.

SUMMARY: We, the United States, as a Party to the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), will attend the fourteenth regular meeting of the Conference of the Parties to CITES (CoP14) in The Hague, The Netherlands, June 3-15, 2007. Currently, the United States is developing its negotiating positions on proposed resolutions, decisions, and amendments to the CITES Appendices (species proposals), as well as other agenda items that have been submitted by other Party countries and the CITES Secretariat for consideration at CoP14. With this notice we announce the provisional agenda for CoP14, solicit your comments on the items on the provisional agenda, and announce a public meeting to discuss the items on the provisional agenda.

DATES: The public meeting will be held on April 9, 2007, at 1:30 p.m. In developing the U.S. negotiating positions on proposed resolutions, decisions, and species proposals, and other agenda items submitted by other Party countries and the CITES Secretariat for consideration at CoP14, we will consider written information