

care providers, librarians, students, as well as individuals of the general public. *Estimated Number of Respondents:* 104,000. *Number of*

*Respondents Per Respondent:* 1. *Average Burden Hours Per Response:* 0.084. *Burden Hours Requested:* 8684. Total annualized cost to respondents is

estimated at \$130,260. There are also no capital costs, operating costs and/or maintenance costs to report.

**SURVEY TITLE: WEB CUSTOMER SATISFACTION SURVEY, ANNUAL REPORTING BURDEN\***

[Web-based; Required for Federal Register requests under PRA, Paperwork Reduction Act.]

Survey area	Number of respondents	Frequency of response	Avg. burden per response (hours)	Burden hours
NIH Organization-wide (1 entity) .....	4,000	.....	.....	334
Overall customer satisfaction .....	2,000	1	0.1002	200
Specific indicator: Top-level/Entry pages .....	1,000	1	0.0668	67
Specific indicator: Tools and initiatives .....	1,000	1	0.0668	67
Individual Institute/Office .....	100,000	.....	.....	8,350
Overall customer satisfaction .....	50,000	1	0.1002	5,010
Specific indicator: Top-level/Entry pages .....	25,000	1	0.0668	1,670
Specific indicator: Tools and initiatives .....	25,000	1	0.0668	1,670
<b>Total</b> .....	<b>104,000</b>	.....	<b>0.084</b>	<b>8,684</b>

*Request for Comments:* Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

**FOR FURTHER INFORMATION CONTACT:** To request additional information on the proposed collection of information contact:

Dennis Rodrigues, NIH Office of Communications and Public Liaison, 9000 Rockville Pike, Bldg. 31, Rm. 2B03, Bethesda, Maryland 20892-2094, or call non toll-free at (301) 435-2932. You may also e-mail your request to [dr3p@nih.gov](mailto:dr3p@nih.gov).

*Comments Due Date:* Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: January 5, 2004.

**John Burklow,**

*Associate Director for Communications, Office of the Director, National Institutes of Health.*

[FR Doc. 04-3713 Filed 2-19-04; 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.

**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.

**Strand-Specific Amplification**

Vinay K. Pathak, David C. Thomas (NCI) DHHS Reference No. E-018-2004/0-US-01 filed 04 Dec 2003

*Licensing Contact:* Michael Ambrose; 301/594-6565; [ambrosemail.nih.gov](mailto:ambrosemail.nih.gov).

Replication of genetic material for all organisms involves synthesis of different strands of nucleic acid. In addition, replication of these strands requires the coordinated effort of several proteins and as such, are potential targets for drug therapy. In HIV infection, the potential for drug therapy targeted to specific steps in viral replication is advantageous as it might enable the therapeutic intervention to be more efficient and specific to the viral replication.

This technology enables the researcher to evaluate the effects novel therapies and therapeutic protocols have on viral replication by assessing the impact of therapy on specific steps in viral replication. The technology involves using padlock probes that attached at the 5' and 3' ends and ligate together forming a circle. The circle is then amplified using the rolling amplification technique. The amplified circles can be detected and quantitated using real-time PCR for assessment.

The technology can be used in the development of test kits for prognostics and therapeutic evaluation as well as assessing the effects and efficacy of new and novel therapeutics for HIV infection.

### A Novel Approach to Genome-Wide Identification of Gene Regulatory Sequences

Gregory E. Crawford (NHGRI).  
U.S. Provisional Application 60/511,905  
filed 15 Oct 2003 (DHHS Reference  
No. E-286-2003/0-US-01)

*Licensing Contact:* Fatima Sayyid; (301)  
435-4521; [sayyidf@mail.nih.gov](mailto:sayyidf@mail.nih.gov)

Sequence analysis of the human genome has identified approximately 30,000 protein-coding genes, but little is known about how most of these genes are regulated. A major goal of current genome research is to identify the location of all cis-acting gene regulatory elements for all genes. This will be necessary if we are to understand global gene regulation in different tissues as well as identify regulatory variants that make individuals more susceptible to common diseases.

The present invention relates to methods of studying gene regulatory elements on a genome-wide scale. Particularly, it relates to methods of generating libraries of DNase hypersensitive genomic sequences, which are believed to correlate well with the locations of gene regulatory elements. These methods involve obtaining nuclei from the cell sample, subjecting the nuclei to DNase I digestion, and embedding the DNAsed sample in low melt agarose to substantially prevent non-specific shearing of the genomic DNA. The DNAsed fragments are then blunted and further processed, to permit isolation and analysis of the putative regulatory elements.

### Retrovirus-Like Particles and Retroviral Vaccines

David E. Ott (NCI)  
PCT Application filed 27 Oct 2003  
(DHHS Reference No. E-236-2003/0-  
PCT-01)

*Licensing Contact:* Susan Ano; (301)  
435-5515; [anos@mail.nih.gov](mailto:anos@mail.nih.gov)

This technology describes retrovirus-like particles and their production from retroviral constructs in which the gene encoding all but seven amino acids of the nucleocapsid (NC) protein was deleted. This deletion functionally eliminates packaging of the genomic RNA, thus resulting in non-infectious retrovirus-like particles. These particles can be used in vaccines or immunogenic compositions. Specific examples using HIV-1 constructs are given. Furthermore, efficient formation of these particles requires inhibition of the protease enzymatic activity, either by mutation of the protease gene in the construct or by protease inhibitor thereby ensuring the production of non-

infectious retrovirus-like particles. This technology is further described in Ott *et al.*, *Journal of Virology*, 2003, 77(5), 5547.

### Aerosolized Capreomycin for Inhibition of Pulmonary Tuberculosis

Carl N. Kraus, Clifton E. Barry III,  
Bernard Doan (NIAID)

U.S. Provisional Application No. 60/  
500,001 filed 11 Sep 2002 (DHHS  
Reference No. E-286-2002/0-US-01).

*Licensing Contact:* Michael Ambrose;  
(301) 594-6565;  
[ambrosem@mail.nih.gov](mailto:ambrosem@mail.nih.gov).

This technology involves the methods of reformulation of Capreomycin for the aerosol treatment of pulmonary tuberculosis.

Tuberculosis is a devastating lung disease that is highly infectious and easily transmitted, especially in areas of overcrowding such as prisons. Furthermore, underdeveloped countries with large populations living in close quarters maintain an endemic disease reservoir limiting the health and economic viability of the population. The WHO estimates that as many as 1/3 of the population may be infected. Current treatment requires the patient to take medication over an extended period of time, up to 12 months or more in some cases. This leads to clinical failure and the potential development of multi-drug resistant strains. Resistant strains of tuberculosis further tax the health care delivery as second line anti-tubercular therapies are more likely to have side effects yet still require long-term adherence to therapy regimens.

The disclosed technology provides for the delivery of Capreomycin in an aerosol formulation. This provides for ease of delivery in both first and second line tuberculosis regimens. Furthermore, the aerosol formulation does not require extensive training of health-care workers to administer the therapy, minimizing the need for added personnel in underdeveloped countries. This, along with the increased product stability will enhance patient adherence to therapy and the potential reduction of disease burden, both for the patient and the population.

Dated: February 13, 2004.

#### Steven M. Ferguson,

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

[FR Doc. 04-3710 Filed 2-19-04; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Prospective Grant of Exclusive License: Combined Growth Factor-Deleted and Thymidine Kinase-Deleted Vaccinia Virus Vector

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

**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 PCT Patent Application No. PCT/US00/14679, filed May 26, 2000 [DHHS ref. E-181-1999/0-PCT-02], entitled "Combined Growth Factor-Deleted and Thymidine Kinase-Deleted Vaccinia Virus Vector," and all related foreign patents/patent applications, to PNP Therapeutics, Inc., which is located in Birmingham, Alabama. The patent rights in these inventions have been assigned to the United States of America.

The prospective exclusive license territory will be worldwide and the field of use may be limited to human therapeutics for the treatment of cancer via use of vaccinia virus vector in combination with the company's proprietary technology. This notice should be considered a modification of an earlier **Federal Register** notice (68 FR 6930-6931; February 11, 2003).

**DATES:** Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before April 20, 2004, 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: George G. Pipia, Ph.D., Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-5560; Facsimile: (301) 402-0220; E-mail: [pipiag@mail.nih.gov](mailto:pipiag@mail.nih.gov).

**SUPPLEMENTARY INFORMATION:** 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