

The annual reporting burden is as follows:

Estimated Number of Respondents: 156.

Estimated Number of Responses per Respondent: 1.

Average Burden Hours Per Response: .5.

Estimated Total Annual Burden Hours Requested: 78.

The annualized cost to respondents is estimated at: \$780. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

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 more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Dr. Mark Parascandola, Cancer Prevention Fellow, OPO, DCP, NCI, NIH, 6130 Executive Boulevard, Suite 3109, Bethesda, MD 20892, or call non-toll-free number (301) 594-1576 or E-mail your request, including your address to: paramark@mail.nih.gov.

Comments Due Date

Comments regarding this information collection are best assured of having their full effect if received on or before May 13, 2002.

Dated: February 19, 2002.

Reesa L. Nichols,

NCI Project Clearance Liaison.

[FR Doc. 02-5930 Filed 3-12-02; 8:45 am]

BILLING CODE 4140-01-M

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 agencies 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.

Artificial Chromosomes That Can Shuttle Between Bacteria, Yeast, and Mammalian Cells

Larionov et al. (NCI)

DHHS Reference No. E-253-00/0 filed April 6, 2001

Licensing Contact: Pradeep Ghosh; 301/496-7736 ext. 211; e-mail ghoshp@od.nih.gov.

Development of a novel cloning system in mammalian cells based on Mammalian Artificial Chromosome (MAC) may have profound effects on human gene therapy. The technology described in invention pertains to methods and compositions that allow for the selective isolation of centromeric regions from mammalian chromosomes, including those of humans. Also included in the invention are cloned and characterized centromeric regions of humans and other mammalian chromosomes. The isolation of these centromeric regions provides a material for engineering of MACs that are capable of being shuttled between bacterial, yeast and mammalian cells, such as human cells. These MACs may serve as effective tools for the characterization of cis-active loci controlling transmission of mammalian

chromosomes. The present invention has broad utilities in studies related to genetic diseases. It can be used for studying of expression of entire copies of human genes. Gene therapy may have therapeutic and preventative applications and a range of gene therapy approaches are currently being evaluated for treatment of cancer and a large number of autoimmune and genetic disorders. Gene therapy necessitates an efficient system for gene delivery. The MACs constructed in this invention provide useful vehicles for the delivery and expression of transgenes within cells. Thus, the present invention provides a novel method allowing a direct isolation of mammalian centromeres and efficient system for gene delivery associated with gene therapy.

Treatment of Pain Based on Parathyroid Hormone-2 (PTH2) Receptors

Ted B. Usdin (NIMH)

DHHS Reference No. E-079-01/0 filed Jun 13 2001

Licensing Contact: Norbert Pontzer; 301/496-7736 ext. 284; e-mail: np59n@nih.gov.

Current medications for pain, especially chronic pain, are only partially effective and can involve unacceptable side effects. A unique receptor (PTH2) and an endogenous ligand (TIP39) which binds to the receptor were previously discovered by this inventor. The PTH2 receptor and the endogenous ligand were found to have an anatomical distribution suggesting a role in nociception. The PTH2 receptor is present at relatively high levels in nerve terminals within the outer layers of the dorsal horn of the spinal cord where it is primarily coupled to generation of cAMP (Usdin, T.B., et al., 1999, *Nature Neurosci.* 2: 941-943; Wang, T., et al., 2000, *Neuroscience* 100: 629-49; Usdin, T.B., et al., 2000, *Front Neuroendocrinol* 21: 349-83) The DRG neurons that project to this area are largely nociceptors and this region contains the central nervous system neurons they activate. Most receptors present in the central terminals of DRG neurons are also found in their peripheral terminals. Thus, activation of the PTH2 receptor could modulate peripheral excitation of nociceptors, neurotransmitter release from their central terminals in the spinal cord, and some of their postsynaptic effects.

This inventor has now shown the PTH2 receptor system to have very potent actions in animal tests of nociception. Both peripheral and

intrathecal administration of TIP39 cause nociceptive responses. Intrathecal delivery of an antibody that sequesters TIP39 decreases sensitivity in several acute nociceptive assays, and administration of TIP39 potentiates responses in these same tests. Neurochemical changes that occur in neurons in outer layers of the dorsal horn in response to intense pain or injury may lead to manifestations of chronic pain, including hyperalgesia and allodynia. As TIP39 potentiates pain perception and increases cAMP, the PTH2 receptor system may be involved in the transition from acute to chronic pain. Novel drugs which block this system could thus be useful in treating acute or chronic pain. The invention described and claimed in the pending patent application provides novel methods of treating pain and methods of screening to find new and useful drugs acting on this newly discovered pain modulation system.

Development of a Plant Derived Recombinant Subunit Vaccine Candidate Against Hepatitis C

Lev G. Nemchinov and Jerry M. Keith (NIDCR)

DHHS Reference No. E-249-01/0

Licensing Contact: Carol Salata; 301/496-7735 ext. 232; salatac@od.nih.gov.

Hepatitis C virus (HCV) is a major cause of acute and chronic hepatitis with over 180 million cases worldwide. Development of a vaccine to combat HCV has been difficult. Presently, the virus cannot be grown in tissue culture and there is no vaccine or effective therapy against this virus. This technology relates to the development of an experimental plant-derived subunit vaccine against HCV. A tobamoviral vector was engineered to encode a consensus sequence of hypervariable region 1 (HVR1), a potential neutralizing epitope of HCV, which was genetically fused to the C-terminus of the B subunit of cholera toxin (CTB). This epitope was selected from the amino acid sequences of HVR1 "mimotopes" previously derived by phage display technology. The nucleotide sequence encoding this epitope was designed utilizing plant codons. This mimotope is capable of inducing cross-neutralizing antibodies against different variants of the virus. Plants infected with recombinant tobacco mosaic virus (TMV) engineered to express the HVR1/CTB chimeric protein, contained intact TMV particles and produced the HVR1 consensus peptide fused to the functionally active, pentameric B subunit of cholera toxin.

Plant-derived HVR1/CTB reacted with HVR1-specific monoclonal antibodies and immune sera from individuals infected with virus from four of the major genotypes of HCV. Intranasal immunization of mice with a crude plant extract containing the recombinant HVR1/CTB protein elicited both anti-CTB serum antibody and anti-HVR1 serum antibody which specifically bound to HCV virus-like particles. Using plant-virus transient expression to produce this unique chimeric antigen will facilitate the development and production of an experimental HCV vaccine. A plant-derived recombinant HCV vaccine can potentially reduce expenses normally associated with production and delivery of conventional vaccines.

Endotracheal Tube Using Leak Hole to Lower Dead Space

Theodor Kolobow (NHLBI)

Serial No. 09/967,903 filed Sep 28, 2001

Licensing Contact: Dale Berkley; 301/496-7735 ext. 223; e-mail: berkleyd@od.nih.gov.

The invention is a tracheal tube ventilation apparatus which, through the use of one or more tube leak holes or connecting tubes positioned in the wall of the endotracheal tube above the larynx, is able to efficiently rid the patient of expired gases and promote healthier breathing. A first stage of the apparatus has a smaller diameter such that it fits within the confined area of the lower trachea and the second stage has a larger diameter, which fits properly within the larger diameter of the patient's pharynx. The endotracheal tube is preferably wire reinforced and ultra-thin walled so as to reduce airway resistance. The invention substantially reduces endotracheal dead space and is expected to benefit those patients with both early and late stage acute respiratory failure, and reduce or obviate the need for mechanical pulmonary ventilation in many patients.

Dated: March 5, 2002.

Jack Spiegel,

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

[FR Doc. 02-5931 Filed 3-12-02; 8:45 am]

BILLING CODE 4140-01-P

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National Institutes of Health

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Method and Apparatus to Improve an MRI Image

Peter Kellman and Elliot McVeigh (NHLBI)

DHHS Reference No. E-361-01/0 filed Oct 19, 2001

Licensing Contact: Dale Berkley; 301/496-7735 ext. 223; e-mail: berkleyd@od.nih.gov

The invention is a method for improving image quality in MR imaging methods using the SENSE (SENSitivity Encoding) method, which is known to have degraded image quality due to numerical ill-conditioning (so called g-factor loss). The invention improves the numerical conditioning by means of an adaptive regularization (matrix conditioning), thereby improving image quality for a given scan time. This is accomplished by adaptively adjusting the regularization parameter for each pixel position to achieve a target ghost artifact suppression. In this manner, a higher degree of matrix conditioning is used in regions which have less artifact, thus improving the SNR in these regions.

Use of CpG Oligodeoxynucleotides to Encourage Angiogenesis

Dennis M. Klinman (FDA), Mei Zheng (EM), Barry T. Rouse (EM)