

cells in comparison to normal ovarian epithelial cells. A better knowledge of the mechanisms underlying ovarian tumorigenesis will likely result in the development of novel approaches for the diagnosis and therapy of this deadly disease.

*Applications:* Method to diagnose ovarian cancer; Methods to treat patients with compositions that inhibit ovarian biomarkers such as siRNA.

*Market:* Ovarian cancer is the fourth most common form of cancer in the U.S.; Ovarian cancer is three times more lethal than breast cancer; 22,430 new cases of ovarian cancer expected in 2007; 15,280 ovarian cancer deaths in the U.S. in 2007.

*Development Status:* The technology is currently in the pre-clinical stage of development.

*Inventors:* Patrice J. Morin *et al.* (NIA).

*Related Publications:*

1. KJ Hewitt, R Agarwal, PJ Morin. The claudin gene family: expression in normal and neoplastic tissues. *BMC Cancer*. 2006 Jul 12;6:186.

2. PJ Morin. Claudin proteins in human cancer: promising new targets for diagnosis and therapy. *Cancer Res*. 2005 Nov 1;65(21):9603–9606.

3. R Agarwal, T D'Souza, PJ Morin. Claudin-3 and claudin-4 expression in ovarian epithelial cells enhances invasion and is associated with increased matrix metalloproteinase-2 activity. *Cancer Res*. 2005 Aug 15;65(16):7378–7385.

4. CD Hough, CA Sherman-Baust, ES Pizer, PJ Morin. Use of SAGE to study gene expression in ovarian cancer. American Association for Cancer Research, 9th Annual Meeting, April 10–14, 1999, Philadelphia, Pennsylvania.

*Patent Status:* U.S. Provisional Application No. 60/194,336 filed 03 Apr 2000 (HHS Reference No. E-138-2000/0-US-01); PCT Patent Application No. PCT/US2001/10947 filed 03 Apr 2001, which published as WO 01/75177 on 11 Oct 2001 (HHS Reference No. E-138-2000/0-PCT-02); U.S. Patent Application No. 10/257,021 filed 03 Oct 2002 (HHS Reference No. E-138-2000/0-US-03)

*Licensing Status:* Available for exclusive or non-exclusive licensing.

*Licensing Contact:* Jennifer Wong; 301/435-4633; [wongje@mail.nih.gov](mailto:wongje@mail.nih.gov).

Dated: June 8, 2007.

**Steven M. Ferguson,**

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

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**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, HHS.

**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.

#### Construction of Recombinant Baculoviruses Carrying the Gene Encoding the Major Capsid Protein, VP1, From Calicivirus Strains (Including Norovirus Strains Toronto, Hawaii, Desert Shield, Snow Mountain, and MD145-12)

*Description of Technology:* The noroviruses (known as “Norwalk-like viruses”) are associated with an estimated 23,000,000 cases of acute gastroenteritis in the United States each year. Norovirus illness often occurs in outbreaks, affecting large numbers of individuals, illustrated recently by well-publicized reports of gastroenteritis outbreaks on several recreational cruise ships and in settings such as hospitals and schools. Norovirus disease is clearly important in terms of medical costs and missed workdays, and accumulating data support its emerging recognition as important agents of diarrhea-related morbidity.

Because the noroviruses cannot be propagated by any means in the laboratory, an important strategy in their study is the development of molecular biology-based tools. This invention reports the development of recombinant baculoviruses carrying the capsid gene from several caliciviruses associated

with human disease. Growth of these baculovirus recombinants in insect cells results in the expression of virus-like particles (VLPs) that are antigenically indistinguishable from the native calicivirus particle. These VLPs can be purified in large quantities for use as diagnostic reagents and potential vaccine candidates.

*Inventors:* Kim Y. Green, Judy F. Lew, Adriene D. King, Stanislav V. Sosnovtsev, Gael M. Belliot (NIAID).

*Publication:* An example of the application of these materials is further described in KY Green *et al.*, “A predominant role for Norwalk-like viruses as agents of epidemic gastroenteritis in Maryland nursing homes for the elderly,” *J. Infect. Dis.* 2002 Jan. 15;185(2):133–146.

*Patent Status:* HHS Reference No. E-198-2003/0—Research Material.

*Licensing Status:* The materials embodied in this invention are available nonexclusively through a biological materials license.

*Licensing Contact:* Peter A. Soukas, J.D.; 301/435-4646; [soukasp@mail.nih.gov](mailto:soukasp@mail.nih.gov)

*Collaborative Research Opportunity:* The Laboratory of Infectious Diseases, NIAID, NIH, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize norovirus VLP antigens. Please contact Kim Y. Green at [kgreen@niaid.nih.gov](mailto:kgreen@niaid.nih.gov) for more information.

#### Full-Length cDNA Clone Representing the Consensus Sequence of the RNA Genome of a Human Norovirus (strain MD145-12) That Encodes Biologically Active Proteins

*Description of Technology:* The invention provides for a full-length cloned cDNA copy of the RNA genome of a predominant norovirus strain (Genogroup II.4) designated MD145-12 that was associated with human gastrointestinal illness. The noroviruses, which were formerly known as “Norwalk-like” viruses are estimated to cause 23 million cases of acute gastroenteritis in the USA each year. The virus has been designated into category B of the CDC biodefense-related priority pathogens because it can be used as an agent of bioterrorism. The subject cDNA clone of the virus encodes proteins of the MD145-12 strain that, when expressed in vitro, exhibit properties that would be expected from those produced by the original infectious virus. This cDNA clone is presently the only source to obtain norovirus proteins to facilitate studies

aimed at developing control strategies such as vaccines and therapeutic drugs.

*Inventors:* Gael M. Belliot, Kim Y. Green, Stanislav V. Sosnovtsev (NIAID)

*Patent Status:* HHS Reference No. E-212-2003/0—Research Material

*Licensing Status:* The cDNA clone for norovirus strain MD145-12 is available for licensing via a biological material license (BML).

*Licensing Contact:* Peter A. Soukas, J.D.; 301/435-4646; [soukasp@mail.nih.gov](mailto:soukasp@mail.nih.gov).

*Collaborative Research Opportunity:* The Laboratory of Infectious Diseases, NIAID, NIH, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize reagents derived from a cDNA clone of the genome of a predominant human norovirus strain, Genogroup II.4. Please contact Kim Y. Green at [kgreen@niaid.nih.gov](mailto:kgreen@niaid.nih.gov) for more information.

#### **Construction of an Infectious Full-Length cDNA Clone of the Porcine Enteric Calicivirus RNA Genome**

*Description of Technology:* Porcine enteric calicivirus (PEC) is a member of the genus Sapovirus in the family Caliciviridae. This virus causes diarrheal illness in pigs. In addition, PEC serves as an important model for the study of enteric caliciviruses that cause diarrhea and that cannot be grown in cell culture (including the noroviruses represented by Norwalk virus and the sapoviruses represented by Sapporo virus). The development of an infectious cDNA clone is important because it enables the use of “reverse genetics” to engineer mutations of interest into the genome of PEC and to study their effects. In addition, it allows the introduction of foreign coding sequences into the genome of PEC that could be useful for vaccine development in swine and possibly humans. This discovery has both basic research applications such as mapping mutations involved in tissue culture adaptation, tissue tropism, and virulence as well as practical applications such as providing a genetic backbone for the development of chimeric vaccine viruses.

*Inventors:* Kyeong-Ok Chang (NIAID), Stanislav V. Sosnovtsev (NIAID), Gael M. Belliot (NIAID), Kim Y. Green (NIAID), *et al.*

*Publication:* The materials are further described in KO Chang *et al.*, “Cell-culture propagation of porcine enteric calicivirus mediated by intestinal contents is dependent on the cyclic AMP signaling pathway,” *Virology*. 2002 Dec 20;304(2):302-310.

*Patent Status:* HHS Reference No. E-214-2003/0—Research Material.

*Licensing Status:* The materials embodied in this invention are available nonexclusively through a biological materials license.

*Licensing Contact:* Peter A. Soukas, J.D.; 301/435-4646; [soukasp@mail.nih.gov](mailto:soukasp@mail.nih.gov)

*Collaborative Research Opportunity:* The Laboratory of Infectious Diseases, NIAID, NIH, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize reagents derived from an infectious cDNA copy of the genome of porcine enteric calicivirus. Please contact Kim Y. Green at [kgreen@niaid.nih.gov](mailto:kgreen@niaid.nih.gov) for more information.

#### **Enzymatically-Active RNA-Dependent RNA Polymerase From a Human Norovirus (Calicivirus)**

*Description of Technology:* The noroviruses (formerly known as “Norwalk-like viruses”) are associated with gastroenteritis outbreaks, affecting large numbers of individuals each year. Emerging data are supporting their increasing recognition as important agents of diarrhea-related morbidity and mortality. The frequency with which noroviruses are associated with gastroenteritis as “food and water-borne pathogens” has led to the inclusion of caliciviruses as Category B Bioterrorism Agents/Diseases. Because the noroviruses cannot be propagated by any means in the laboratory, an important strategy in their study is the development of molecular biology-based tools and replication systems. This invention reports the isolation of the first recombinant, enzymatically-active proteinase and RNA dependent RNA polymerase (RdRp) complex for a human norovirus. This enzyme should facilitate studies aimed at developing therapeutic drugs for norovirus disease.

*Inventors:* Gael M. Belliot, Stanislav V. Sosnovtsev, Kyeong-Ok Chang, Kim Y. Green (NIAID).

*Publication:* The materials are further described in L Wei *et al.*, “Proteinase-polymerase precursor as the active form of feline calicivirus RNA-dependent RNA polymerase,” *J. Virol.* 2001 Feb;75(3):1211-1219.

*Patent Status:* HHS Reference No. E-283-2003/0—Research Material.

*Licensing Status:* The materials embodied in this invention are available nonexclusively through a biological materials license.

*Licensing Contact:* Peter A. Soukas, J.D.; 301/435-4646; [soukasp@mail.nih.gov](mailto:soukasp@mail.nih.gov).

*Collaborative Research Opportunity:* The Laboratory of Infectious Diseases, NIAID, NIH, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize an active human norovirus proteinase-polymerase enzyme. Please contact Kim Y. Green at [kgreen@niaid.nih.gov](mailto:kgreen@niaid.nih.gov) for more information.

Dated: June 8, 2007.

**Steven M. Ferguson,**

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

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#### **Methods for Prevention and Treatment of Polyomavirus Infection or Reactivation**

*Description of Technology:* Available for licensing and commercial development are methods of using two MAP kinase kinase (MEK) inhibitors, PD98059 and U0126, in the prevention and treatment of polyomavirus infection. Decrease in viral protein expression upon treatment with the MEK inhibitors has been demonstrated