TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

Citation	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Total					186

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA's estimate of the number of respondents in table 1 is based on the number of regulatory submissions submitted to TTB for beers that do not meet the definition of a ''malt beverage'' under the FAA Act. Based on its records of submissions received from manufacturers of such products, TTB estimates the number of respondents to be 12 and the number of submissions annually to be 25. Thus, FDA adopts TTB's estimate of 12 respondents, and an annual frequency per response of 2, in table 1 of this document.

FDA's estimate of the hours per response for each regulation is based on FDA's experience with food labeling under the agency's jurisdiction. The estimated hours per response for §§ 101.3, 101.4, 101.5, 101.9, 101.22, and 101.105 in table 1 of this document are equal to, and based upon, the estimated hours per response approved by OMB in OMB Control No. 0910–0381. FDA further estimates that the labeling burden of section 403(w)(1) of the FD&C Act, which specifies requirements for the declaration of food allergens, will be 1 hour based upon the similarity of the requirements to that of § 101.4. Finally, FDA estimates that a respondent will spend 1 hour reading the guidance document, once finalized.

Thus, FDA estimates that 12 respondents will each label two products annually, for a total of 24 labels. FDA estimates that the manufacturers will spend 7.25 hours (0.5 hours + 1 hour + 0.25 hour + 4 hours + 0.5 hour + 1 hour = 7.25 hours) on each label to comply with FDA's labeling regulations and the requirements of section 403(w)(1), for a total of 174 hours (24 labels x 7.25 hours = 174 hours). In addition, 12 respondents will each spend 1 hour reading the guidance document, for a total of 12 hours. Thus, FDA estimates the total hour burden of the proposed collection of information to be 186 hours (174 hours + 12 hours = 186 hours).

Before the proposed information collection provisions contained in this draft guidance become effective, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

This draft guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in §§ 101.3, 101.4, 101.5, 101.9, 101.22, and 101.105 have been approved under OMB Control No. 0910–0381.

III. Comments

Interested persons may submit written or electronic comments regarding this draft guidance document, including comments regarding the proposed collection of information. Written comments should be submitted to the Division of Dockets Management (see **ADDRESSES**). Electronic comments should be submitted to *http://www.regulations.gov*. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at *http://www.fda.gov/FoodGuidances*.

V. References

We have placed the following references on display in the Division of Dockets Management (see **ADDRESSES**). The references may be seen between 9 a.m. and 4 p.m., Monday through Friday. FDA has verified the Web site addresses, but it is not responsible for any subsequent changes to the Web site addresses after this document publishes in the **Federal Register**.

1. FDA Compliance Policy Guide (CPG) 7101.04 (Dealcoholized Wine and Malt Beverages- Labeling), available at *http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074430.htm* and CPG 7101.05 (Labeling —Diluted Wines and Cider with Less Than 7% Alcohol), available at *http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074431.htm*.

2. Memorandum of Understanding 225–88–2000 between FDA and Bureau of Alcohol, Tobacco and Firearms, available at *http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm116370.htm*.

3. TTB Ruling 2008–3 dated July 7, 2008, available at *http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm116370.htm*.

Dated: August 11, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–19640 Filed 8–14–09; 8:45 am]

BILLING CODE 4160–01–S

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.

Development of a New Carbohydrate Antibody to GalNac1–3Gal

Description of Technology: The present invention provides a monoclonal antibody that binds

specifically to the antigen GalNAc1–3Gal present in human cancers, including squamous cell cancer, human cervical cancer, human esophageal cancer, human laryngeal cancer, and human skin cancer. The antibody can be used to monitor expression of this carbohydrate for a variety of purposes. In immunohistochemical staining of tissues, the antibody stains a variety of carcinomas, with good staining of cervical, larynx, and skin squamous cell carcinomas. Positive antibody staining of cervical cancer tissue correlates with a good prognosis (increased 5 year survival rate) and as such may be useful as a prognostic marker. NCI also has the parent cell line for production of the antibody and several other variant antibodies with similar reactivity.

Applications

- Cervical cancer diagnostics and prognosis.
- A research tool.

Market

- Cancer is the second leading cause of death in the U.S.A. There is an acute need for cancer biomarkers that can be detected from clinically relevant samples and used for early diagnosis, therapeutic follow-up and prognosis of malignant diseases.
- Estimated new cases and deaths from cervical (uterine cervix) cancer in the United States in 2009: 11,270 new cases; 4,070 deaths according to the National Cancer Institute.

Inventors: Jeffrey C. Gildersleeve *et al.* (NCI).

Patent Status: U.S. Provisional Application No. 61/165, 675 filed 01 Apr 2009 (HHS Reference No. E–058–2009/0–US–01).

Licensing Status: Available for licensing.

Licensing Contact: Betty B. Tong, Ph.D.; 301–594–6565; *tongb@mail.nih.gov*.

Deletion of the Beta 20–21 Loop in HIV GP120 Exposes the CD4 Binding Site for Improved Antibody Binding and Antibody

Description of Technology: With the number of individuals infected with HIV approaching nearly one percent (1%) of the world's population, an effective vaccine is urgently needed. As an enveloped virus, HIV hides most of its proteins and genes from humoral recognition behind a protective lipid bilayer. An available exposed viral target for neutralizing antibodies is the envelope spike. Genetic, immunologic and structural studies of the HIV envelope glycoproteins have revealed extraordinary diversity as well as multiple overlapping mechanisms of humoral evasion, including self-masquerading glycan, immunodominant variable loops, and conformational masking. These evolutionarily-honed barriers of antigenic diversity and immune evasion have confounded traditional means of vaccine development. It is believed that immunization with effectively immunogenic HIV gp120 envelope glycoprotein can elicit a neutralizing response directed against gp120, and thus HIV. The need exists for immunogens that are capable of eliciting a protective immune response.

This application claims isolated immunogens, including variant gp120 polypeptides and the use of these polypeptides to induce an immune response to HIV. This application also claims virus-like particles including the variant gp120 polypeptides. More specifically, this application claims virus-like particles including variant gp120–HBsAg hybrid constructs, which may also include at least one TLR ligand.

Application: Development of Human Immunodeficiency Virus (HIV) vaccines, therapeutics and diagnostics.

Advantages: VLP gp120 vaccine, use of HBsAg vector for delivery.

Development Status: Vaccine candidates have been synthesized and preclinical studies have been performed.

Inventor: Ira Berkower (FDA).

Publication: I Berkower *et al.* Targeted deletion in the beta20-beta21 loop of HIV envelope glycoprotein gp120 exposes the CD4 binding site for antibody binding. Virology. 2008 Aug 1;377(2):330–338.

Patent Status: U.S. Provisional Application 61/155,782 filed 26 Feb 2009 (HHS Reference No. E–299–2008/0–US–01).

Licensing Status: Available for licensing.

Licensing Contact: Peter A. Soukas, J.D.; 301–435–4646; *soukasp@mail.nih.gov*.

Multilayered RF Coil System for Improving Transmit B1 Field Homogeneity in High-Field MRI

Description of Technology: Available for licensing and commercial development is a multilayered radio-frequency (RF) coil system for improving the transmit B1 field homogeneity for magnetic resonance imaging (MRI) at high field strengths. The current invention aims at manipulating the inhomogeneous profile of the transmit B1 field, which causes MR images to become less uniform as the magnetic field strength is increased, by utilizing an inner array of RF elements (*e.g.* surface coils) within and coupled to an outer transmit unit (*e.g.* a birdcage coil or other volume coil). Improvement in B1 field homogeneity is achieved by tuning the surface coils of the inner layer to an appropriate resonant frequency and then passively coupling them to the outer-layer volume coil. Furthermore, the amount of coupling is determined by the intrinsic properties of the transmit unit and can be adjusted accordingly. The current design provides an effective approach for reducing B1 field homogeneity at high fields and can be implemented without the need for independent RF channels, thereby reducing MRI system complexity. Furthermore it can be readily implemented on existing MRI coil systems by detuning surface coils rather than decoupling them during the transmit phase.

Applications

- High-Field MRI.
- Improvement of MR Image Uniformity.

Market: Manufacturers of MRI hardware and accessories.

Development Status: The technology is ready to be used and requires only testing in humans for development.

Inventors: Alan Koretsky, Jeff Duyn, Shumin Wang, Hellmut Merkle (NINDS).

Publications

1. S Wang and JH Duyn, ''Three-Dimensional Automatic Mesh Generation for Hybrid Electromagnetic Simulations'', IEEE Antennas and Propagation Magazine, Vol. 51, pp. 71–85, April 2009.

2. H Merkle, J Murphy-Boesch, S Wang, P van Gelderen, AP Koretsky, and JH Duyn, ''Graded Transmit B1 Field Correction at 7T Using Tunable Inner Elements'', ISMRM High-field Workshop, Rome, Italy, October 2008.

3. H Merkle, S Wang, P van Gelderen, TQ Li, J Murphy-Boesch, AP Koretsky, and JH Duyn, ''B1 Transmit Field Correction at 7T Using Coupled Inner Elements'', ISMRM 2008, Toronto, Canada, May, 2008.

4. S Wang, H Merkle, AP Koretsky, and JH Duyn, ''Improving High-Field Transmit B1 Field Homogeneity Using Coupled Inner Elements'', 15th Scientific Meeting and Exhibition, International Society for Magnetic Resonance in Medicine, Berlin, Germany, May 2007.

Patent Status

- U.S. Provisional Application No. 60/900,972 filed 13 Feb 2007 (HHS Reference No. E–020–2007/0–US–01).
- PCT Application No. PCT/US2008/001911 filed 13 Feb 2008 (HHS Reference No. E–020–2007/0–PCT–02).

Licensing Status: Available for licensing.

Licensing Contact: John Stansberry, Ph.D.; 301/435–5236; *stansbej@mail.nih.gov*.

Collaborative Research Opportunity: The Laboratory of Functional and Molecular Imaging (LFMI) at the National Institute of Neurological Disorders and Stroke (NINDS) is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize MRI applications that aim to provide novel functional and molecular imaging techniques to study brain structure and function. Please contact Melissa Maderia, Ph.D. at *maderiam@mail.nih.gov* or 301–451–3943 for more information.

Quantifying Gene Relatedness via Nonlinear Prediction of Gene Expression Levels

Description of Technology: This invention relates to a new way to analyze the function of a newly identified gene. Working together, the genes within a genomic system constitute a control system for modulating gene expression activity and protein production. Regulation within this control system depends on multivariate relations among genes. Therefore, a key window into understanding genomic activity is to quantify the manner in which the expression profile among a set of genes can be used to predict the expression levels of other genes. This invention provides the experimental, statistical, and computational basis for nonlinear and linear multivariate prediction and co-determination among gene expression levels, and it is applied in the context of cDNA microarrays. Using these measures of multi-gene interactivity, it is possible to infer genomic regulatory mechanisms and thereby identify the manner in which genetic malfunction contributes to cancer and developmental anomalies.

Inventors: Michael Bittner (NHGRI), Yidong Chen (NHGRI), *et al.*

Patent Status: U.S. Patent No. 7,003,403 issued 21 Feb 2006 (HHS Reference No. E–059–2000/0–US–01).

Licensing Status: Available for licensing.

Licensing Contact: Jeffrey A. James, Ph.D.; 301–435–5474; *jeffreyja@mail.nih.gov*.

Isolated Helicobacter hepaticus

Description of Technology: An isolated bacterium of the genus *Helicobacter,* characterized by the 16S ribosomal RNA encoding nucleotide sequence defined in the Sequence Listing as SEQ ID NO:1 is provided. An isolated nucleic acid having the nucleotide sequence defined in the Sequence Listing as SEQ ID NO:1 is provided. Such a nucleic acid can be used for diagnosis of infection with *H. hepaticus.* A nucleic acid of the present invention in a vector suitable for expression of the nucleic acid is also provided. The vector can be in a host suitable for expressing the nucleic acid. A purified antigen specific for *H. hepaticus* is provided. A method of making an animal model for chronic *Helicobacter* infection is also provided.

Inventors: Jerrold M. Ward *et al.* (NCI).

Patent Status: U.S. Patent 5,610,060 issued 11 Mar 1997 (HHS Reference No. E–010–1994/0–US–01).

Licensing Status: Available for licensing.

Licensing Contact: Jeffrey A. James, Ph.D.; 301–435–5474; *jeffreyja@mail.nih.gov*.

Recombinant Vaccines Based on Poxvirus Vectors

Description of Technology: The technology offered for licensing is foundational in the area of recombinant DNA vaccines. In the last several years, facilitated through a licensing program of the NIH, the technology has been broadly applied in the development and commercialization of several novel human and veterinary vaccines in the areas of infectious disease as well as cancer therapeutics. The NIH wishes to expand its licensing program of the subject technology in a variety of applications that will benefit public health.

Briefly, the technology describes and claims methods of constructing recombinant vaccines utilizing any recombinant poxvirus, and in particular vaccinia virus (*i.e.* Modified Vaccinia Ankara or other strains) as a backbone that carries a foreign DNA. The foreign DNA can be related to a viral pathogen for example, or to a tumor-associated antigen. Upon administration of the recombinant virus to a human or animal subject, the foreign gene is expressed *in vivo* to elicit an immune response against the respective pathogen or the respective tumor.

The technology takes advantage of the unique properties of poxviruses as a delivering vehicle and of the ease of preparation of such constructs.

The applications of this technology have been extensively covered by many publications, including more than 100 publications from the inventor (*see* sampling below). The publications cover a wide variety of vaccines such as HIV, papilloma virus, influenza and others.

Note: Samples of plasmids and vaccinia virus used in the invention are deposited in the American Type Culture Collection and in the NIH and may be available for licensees upon request.

Applications

- Prophylactic and/or therapeutic vaccines.
- Infectious disease and cancer Human and animal vaccines.
- Immunotherapy.
- Protein expression system.

Advantages: Recombinant Poxviruses vectors in DNA vaccines have exhibited some advantages as compared to other viral vectors such as adenovirus, retrovirus or papillomavirus:

- High safety profile.
- Wide host range.
- Ability to accommodate large amounts of foreign DNA including multiple genes.
- No loss of infectivity upon insertion of foreign DNA.
- Unique transcriptional regulatory signals of the virus facilitates flexibility in genome strategy.

In addition, the following properties have been demonstrated:

- Immunization with vaccinia-vectored vaccines provides long-lasting protection.
- Vaccinia virus is very stable and no cold-chain is required in distribution network.
- Induce mucosal immune response.
- Induce humeral and cellular immunity.

Development Status: Fully developed. The technology has been already successfully implemented in commercial veterinary vaccines (*i.e.* rabies) and is in advance clinical trials in several companies in the area of cancer immunotherapy.

Market

- The market for vaccines against infectious diseases is in the multibillion dollars and keeps growing at an annual rate of approximately 40%. This is compared to approximately 8% growth for the overall pharmaceutical companies. Live recombinant vaccines as offered in the subject technology offer an attractive alternative to existing vaccines as well as for future vaccines and therefore may be commercially attractive for vaccine and pharmaceutical companies.
- The market for therapeutic cancer vaccines, which is the subject of this technology, is expected to mirror the growth seen in the monoclonal antibody market and reach sales in excess of $5

billion by 2012 according to some reports.

Overall, the potential commercial opportunity based on the subject technology is immense.

Inventors: Bernard Moss *et al.* (NIAID).

Publications: The inventor, Dr. Bernard Moss, is an author of more than 100 publications in the area covered by the subject patents. The following is just a sampling of his publications in the area:

1. B Moss and PL Earl. Overview of the vaccinia virus expression system. Curr Protoc Mol Biol. 2002 Nov; Chapter 16: Unit16.15.
2. HL Robinson, S Sharma, J Zhao, S Kannanganat, L Lai, L Chennareddi, T Yu, DC Montefiori, RR Amara, LS Wyatt, B Moss. Immunogenicity in macaques of the clinical product for a clade B DNA/MVA HIV vaccine: elicitation of IFN-gamma, IL–2, and TNF-alpha coproducing CD4 and CD8 T cells. AIDS Res Hum Retroviruses. 2007 Dec;23(12):1555–1562.
3. LS Wyatt, PL Earl, J Vogt, LA Eller, D Chandran, J Liu, HL Robinson, B Moss. Correlation of immunogenicities and in vitro expression levels of recombinant modified vaccinia virus Ankara HIV vaccines. Vaccine 2008 Jan 24;26(4):486–493.
4. M Hebben, J Brants, C Birck, JP Samama, B Wasylyk, D Spehner, K Pradeau, A Domi, B Moss, P Schultz, R Drillien. High level protein expression in mammalian cells using a safe viral vector: modified vaccinia virus Ankara. Protein Expr Purif. 2007 Dec;56(2):269–278.

Patent Status: The technology is described and claimed in the following four (4) patents that were issued in the U.S. in 2006 (HHS Reference E–552–1982/2):

1. USPN 6,998,252 issued February 14, 2006, ''Recombinant Poxviruses Having Foreign DNA Expressed under the Control of Poxvirus Regulatory Sequences''.

2. USPN 7,015,024 issued March 21, 2006, ''Compositions Containing Recombinant Poxviruses Having Foreign DNA Expressed Under the Control of Poxvirus Regulatory Sequences''.

3. USPN 7,045,313 issued May 16, 2006, ''Recombinant Vaccinia Virus Containing Chimeric Gene Having Foreign DNA Flanked by Vaccinia Regulatory DNA''.

4. USPN 7,045,136 issued May 16, 2006, ''Methods of Immunization Using Recombinant Poxviruses Having Foreign DNA Expressed Under the Control of Poxvirus Regulatory Sequences''.

Licensing Status: Available for licensing.

Licensing Contacts: Uri Reichman, Ph.D., MBA; 301–435–4616; *ur7a@nih.gov*; RC Tang, JD, LLM; 301–435–5031; *tangrc@mail.nih.gov*.

Dated: August 10, 2009.

Richard U. Rodriguez,

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

[FR Doc. E9–19693 Filed 8–14–09; 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, 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.

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Superior Method of Preparing Dendrimers for Use as Magnetic Resonance Imaging (MRI) Contrast Agents

Description of Technology: There is a need to develop more efficient gadolinium-containing (Gd) contrast agents for magnetic resonance imaging (MRI) as the small molecules presently used clinically have the disadvantage of being rapidly cleared from circulation and excreted by the kidneys.

Dendrimer-based macromolecular MRI contrast agents in which numerous chelated Gd ions are covalently attached to a multivalent dendritic architecture are a promising class of diagnostic agents for medical imaging applications. Clinical development of the dendrimer-based agents has been limited as the current methods for synthesizing them result in a complex mixture that produces inconsistent imaging results.

The present technology describes the development of a new method of pre-forming the metal-ligand chelate in alcohol prior to conjugation to the dendrimer. Specifically, for example, a 1B4M–DTPA–Gd chelate is preformed in methanol and purified prior to conjugation to a PAMAM dendrimer molecule. This results in a dendrimer-based MRI contrast agent with greatly improved homogeneity and stability, and possessing an unexpectedly greater molar relaxivity that allows the use of much less of the agent than previously required to obtain comparable images. The use of a DOTA–Gd chelate is equally possible.

Application: An improved method for synthesis of dendrimer-based MRI contrast agents that is greatly suited for clinical development.

Advantages

- Efficient preparation of stable dendrimer-based contrast agents suitable for medical imaging.
- Higher molar relaxivity translates into a lower dosage needed for imaging.
- Ability to control dendrimer size conducive for development of compartment-specific imaging agents.

Market: Dendrimers show particular promise for the development of cancer imaging agents. The ability to exquisitely control dendrimer size enables delivering them to specific compartments such as small tumors allowing for early cancer detection. Gadolinium (Gd) chelates are extensively used as MRI contrast agents and have proven to be safe. The combination of gadolinium chelates with dendrimer chemistry could greatly enhance the versatility of MRI imaging.

Inventors: Kido Nwe and Martin W. Brechbiel (NCI).

Publications

1. K Nwe, H Xu, CA Regino, M Bernardo, L Ileva, L Riffle, KJ Wong, MW Brechbiel. A new approach in the preparation of dendrimer-based bifunctional diethylenetriaminepentaacetic acid MR contrast agent derivatives. Bioconjugate Chem. 2009 Jul;20(7):1412–1418.
2. OA Gansow, MW Brechbiel, MA Magerstadt. Complexes of functionalized tetraazacyclododecane chelates with bismuth, lead, yttrium, actinium, or lanthanide metal ions. U.S. Patent 5,428,154 issued 27 Jun 1995.

Patent Status: U.S. Provisional Application No. 61/180,327 filed 21 May 2009 (HHS Reference No. E–207–2009/0–US–01).

Related Technology: OA Gansow, MW Brechbiel, MA Magerstadt, ''Complexes of Functionalized Tetraazacyclododecane Chelates with Bismuth, Lead, Yttrium, Actinium, or