the device(s) that would be addressed by a declaration of conformity.

VI. Electronic Access

You may obtain a copy of ''Guidance on the Recognition and Use of Consensus Standards'' by using the Internet. CDRH maintains a site on the Internet for easy access to information including text, graphics, and files that you may download to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes the guidance as well as the current list of recognized standards and other standards related documents. After publication in the **Federal Register**, this notice announcing ''Modification to the List of Recognized Standards, Recognition List Number: 019'' will be available on the CDRH home page. You may access the CDRH home page at *http://www.fda.gov/cdrh*.

You may access ''Guidance on the Recognition and Use of Consensus Standards,'' and the searchable database for ''FDA Recognized Consensus Standards'' through the hyperlink at *http://www.fda.gov/cdrh/stdsprog.html*.

This **Federal Register** document on modifications in FDA's recognition of consensus standards is available at *http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTopic/cdrhnew.cfm*.

VII. Submission of Comments and Effective Date

Interested persons may submit to the contact person (see **FOR FURTHER INFORMATION CONTACT**) written or electronic comments regarding this document. Two copies of any mailed comments are to be submitted, 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. FDA will consider any comments received in determining whether to amend the current listing of modifications to the list of recognized standards, Recognition List Number: 019. These modifications to the list or recognized standards are effective upon publication of this notice in the **Federal Register**.

Dated: December 13, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–24580 Filed 12–18–07; 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.

Aquaporin 2 Polyclonal Antibodies

Description of Technology: Aquaporins, also known as water channels, form pores in cell membranes and selectively transport water in and out of the cell. Aquaporins are involved in regulation of water balance and blood pressure, and thirteen different isoforms have been found in mammals. Aquaporin 2 (AQP2) is located in the collecting duct of the kidney, and is regulated by the peptide hormone vasopressin. AQP2 expression is increased in conditions where there is water retention, such as pregnancy and congestive heart failure, and mutations of AQP2 are associated with nephrogenic diabetes insipidus. Also, lithium treatment, often administered for bipolar disorder, can cause acquired diabetes insipidus by decreasing AQP2 expression.

The inventors have developed rabbit polyclonal antibodies directed against a peptide sequence in the C-terminal region of AQP2 (LKGLEPDTDWEEREVRRRQ). The sequence is upstream of phosphorylation sites in this region, and consequently the antibodies recognize both unphosphorylated and phosphorylated AQP2. The sequence is identical in human, rat, mouse, cow, and sheep.

Applications: Western blotting, immunohistochemistry, and immunoprecipitation.

Inventor: Mark A. Knepper (NHLBI).

Related Publication: SR DiGiovanni, S Nielsen, EI Christensen, MA Knepper. Regulation of collecting duct water channel expression by vasopressin in Brattleboro rat. Proc Natl Acad Sci U S A. 1994 Sep 13;91(19):8984–8988.

Patent Status: HHS Reference No. E–045–2008/0—Research Tool. Patent prosecution is not being pursued for this technology.

Licensing Status: This technology is available as a research tool under a Biological Materials License.

Licensing Contact: Tara L. Kirby, PhD; 301/435–4426; *tarak@mail.nih.gov*.

Treatment for Chronic Inflammatory Disease and Cancer by Inhibition of MMP–1

Description of Technology: The breakdown of connective tissue is a feature of many pathological diseases, including tumors as well as inflammatory diseases such as atherosclerosis, rheumatoid arthritis, and periodontitis. Proteases involved in connective tissue turnover, such as matrix metalloproteinases (MMPs) and the plasminogen activation system, have been shown to play a pivotal role in inflammatory disease and in tumor cell invasion, growth and metastasis. Matrix metalloproteinase-1 (MMP–1), a collagenase, is expressed in areas of rapid remodeling of the extracellular matrix in both normal and pathological conditions.

The inventors have determined that the serine protease plasmin stimulates MMP–1 production in monocytes through binding to the annexin A2 heterotetramer. The inventors have also determined that inactive plasmin is an inhibitor of plasmin induction of MMP–1. The invention discloses new methods of suppressing inflammation and tumors through inhibition of plasmin activity, for example by using agents, including inactive plasmin, to inhibit plasmin-stimulated MMP–1 production.

Applications: Therapeutics for inflammatory disease and tumor suppression.

Market: In the United States, approximately two percent of the population have atherosclerosis, more than five percent have an autoimmune inflammatory disease, and approximately fifty percent of all adults over thirty have periodontitis.

Development Status: Early stage.

Inventors: Yahong Zhang and Larry M. Wahl (NIDCR).

Related Publication: Y Zhang, ZH Zhou, TH Bugge, LM Wahl. Urokinase-type plasminogen activator stimulation of monocyte matrix metalloproteinase-1 production is mediated by plasmin-dependent signaling through annexin A2 and inhibited by inactive plasmin. J Immunol. 2007 Sep 1;179(5):3297–3304.

Patent Status: U.S. Provisional Application No. 60/980,009 filed 15 Oct 2007 (HHS Reference No. E–168–2007/0–US–01).

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

Licensing Contact: Tara Kirby, PhD; 301/435–4426; *tarak@mail.nih.gov*.

Establishment of Two Cell Lines That Stably Express Luciferase for In Vivo Tracking

Description of Technology: Available for licensing are two renal carcinoma cell lines, 786-O(luc) and 786-O/VHL/(luc) which both stably express luciferase. 786-O(luc) lacks von Hippel-Landau (VHL) protein expression and it has constitutively high expression of hypoxia-inducible transcription factor-2alpha (HIF–2alpha). The second stably expresses VHL, a tumor suppressor, and has minimal HIF–2alpha expression. These cell lines can be tracked in vivo and can be used to study VHL-dependent and HIF–2alpha-dependent events such as tumorigenesis. VHL mutations lead to the clinical manifestations of von Hippel-Lindau disease, a rare autosomal dominant syndrome characterized by abnormal growth of blood vessels in multiple organs, including the brain and kidneys.

Applications: Model to study VHL pathology.

Advantages: Cell lines that stably express luciferase for in vivo tracking.

Benefits: Easy, ready to use positive and negative VHL and HIF–2alpha cells that stably express luciferase for in vivo tests.

Market: Incidence of VHL syndrome is 1 in 38,951; HCC is the third leading cause of cancer death worldwide; HCC is the fifth most common cancer in the world; Post-operative five year survival rate of HCC patients is 30–40%.

Inventor: Leonard M. Neckers, Marston Linehan (NCI).

Patent Status: HHS Reference No. E–005–2007/0—Research Tool. Patent protection is not being pursued for this technology.

Licensing Status: Available for non-exclusive licensing.

Licensing Contact: Jennifer Wong; 301/435–4633; *wongje@mail.nih.gov*.

Collaborative Research Opportunity: The National Cancer Institute (Urologic Oncology Branch) is seeking statements of capability or interest from parties interested in collaborative research to develop further uses for these two cell lines that stably express luciferase for in vivo tracking. Please contact John D. Hewes, PhD at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

HIV gp41-Membrane Proximal Region Arrayed on Hepatitis B Surface Antigen Particles for HIV Diagnostic and Vaccine Applications

Description of Invention: This technology describes vectors encoding the membrane proximal region (MPR) and select variants from HIV–1 gp41 linked to the hepatitis B surface antigen (HBsAg) and the resulting expressed particles for use in HIV diagnostic and vaccine applications. HIV–1 gp41 membrane proximal region contains two epitopes recognized by broadly neutralizing human monoclonal antibodies 2F5 and 4E10. However, immunization with gp41 MPR or the 2F5 or 4E10 epitopes have failed to raise neutralizing antibodies. In the subject technology, the particles were shown to bind antibodies from broadly neutralizing human sera and to the two known broadly neutralizing antibodies 2F5 and 4E10 with high relative affinities, demonstrating that the relevant epitopes are accessible for antibody binding and the potential utility of the particles in diagnostic applications. Additionally, these particles could be used to screen phage-display libraries for novel broadly cross-reactive neutralizing antibodies, of which only five are currently known. These particles could also be used for selection of MPR specific B cells. Lastly, these particles have been shown to be immunogenic and raise antibodies that recognize HIV–1 Env gp160 expressed on the cell surface. These immunogens can elicit neutralizing antibodies specific for HIV gp41 MPR, the MPR of gp41 is highly conserved across various HIV clades and therefore is likely to generate broadly neutralizing antibodies when administered in a proper presentation in a lipid context as is the case in HBsAg particles. Multiple copies of the MPR of HIV–1 gp41 arrayed on the particles could significantly increase the immunogenic potential compared to monomeric molecules. An increase of this nature has been observed with HBsAg and HPV virus-like particles in hepatitis B and cervical cancer vaccines, respectively, suggesting that particulate array may improve the presentation of selected epitopes to the immune system.

Applications: HIV vaccines; HIV diagnostics.

Advantages: These immunogens can elicit neutralizing antibodies specific for HIV gp41 MPR, which is highly conserved across various HIV clades and therefore is likely to generate broadly neutralizing antibodies when administered in a proper presentation in a lipid context as is the case in HBsAg particles. Multiple copies of the MPR of HIV–1 gp41 arrayed on the particles could significantly increase the immunogenic potential compared to monomeric molecules.

Inventors: Richard T. Wyatt (NIAID), Sanjay K. Phogat (NIAID), Ira Berkower (FDA).

Patent Status: U.S. Provisional Application No. 60/653,930 filed 18 Feb 2005 (HHS Reference No. E–123–2005/0–US–01); PCT Application No. PCT/US2006/005613 filed 17 Feb 2006, which published as WO 2006/112929 on 30 Nov 2006 (HHS Reference No. E–123–2005/1–PCT–01); U.S. Patent Application No. 11/816,069 filed 10 Aug 2007 (HHS Reference No. E–123–2005/1–US–02).

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

Licensing Contact: Susan Ano, Ph.D.; 301/435–5515; *anos@mail.nih.gov*.

Collaborative Research Opportunity: The NIAID Vaccine Research Center Structural Virology Section is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize HIV–1 MPR regions coupled with the hepatitis B surface antigen particles. Please contact Richard Wyatt, Ph.D. at *richardwyatt@nih.gov* for more information.

Dated: December 11, 2007.

Steven M. Ferguson,

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

[FR Doc. E7–24529 Filed 12–18–07; 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