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.

Monoclonal Antibodies Against Bordetella pertussis Filamentous Hemagglutinin (FHA) Protein

Description of Technology: Filamentous hemagglutinin (FHA) is one of the major adhesion molecules of *Bordetella pertussis*, a bacterial infection that causes whopping cough. Once thought to be primarily a childhood disease, *B. pertussis* infection shows an increasing incidence among adults as well as infants. Recent CDC reports show an almost 19-fold increase in the number of cases among 10–19 year olds and an almost 16-fold increase among those 20 and older. These data underscore the need for a new generation of vaccines and detailed studies focused on the pathways of *B. pertussis* infectivity.

Available for licensing are three hybridoma cell lines capable of expressing monoclonal antibodies against FHA. ELISA and Western blot analyses have shown that these antibodies, map to specific epitopes, can successfully bind to FHA as well as prevent binding of the purified FHA to various cells. The additional studies showed that one antibody was able to prevent the adhesion of *B. pertussis* to epithelial cell monolayers. These findings show that monoclonal antibodies expressed in featured hybridoma cell lines can be successfully used for studies of infectivity mechanisms as well as development of new diagnostics and acellular vaccines against *B. pertussis*.

Applications:

- New generation of diagnostics.
- Acellular vaccine development.

Inventor: Michael Brennan (CBER/FDA).

Relevant Publications:

1. Leininger E, Probst PG, Brennan MJ, Kenimer JG. Inhibition of Bordetella pertussis filamentous hemagglutinin-mediated cell adherence with monoclonal antibodies. FEMS Microbiol Lett. 1993 Jan 1;106(1):31–38.

2. Leininger E, Bowen S, Renauld-Mongénie G, Rouse JH, Menozzi FD, Locht C, Heron I, Brennan MJ. Immunodominant domains present on the Bordetella pertussis vaccine component filamentous hemagglutinin. J Infect Dis. 1997 Jun;175(6):1423–1431.

Patent Status: HHS Reference No. E–044–2008/0—Research Tool. Patent protection is not being sought for this technology.

Licensing Status: Available for non-exclusive licensing.

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

Automated Method for Rapid Detection of Sickle Cell Disease Inhibitors

Description of Technology: Available for licensing is a rapid and automated method for discovering potential drugs for the treatment of sickle cell anemia by determining the sickling times for a large population of red blood cells. The method uses a combination of laser photolysis and statistical processing of digital images. Sickle cell disease is an inherited disorder that affects over 70,000 Americans. The disease is characterized by presence of mutant hemoglobin S in red blood cells, which polymerizes to form fibers when deoxygenated. Such fibers lead to distortion of red blood cells into the shape of a sickle and alter the mechanical properties of these cells. Studies demonstrate that the time to polymerization involves a delay time and rapid growth phase and is particularly sensitive to hemoglobin concentration. As a result, identification of drugs that inhibit sickle cell disease is accomplished using an assay for delay times for populations of red blood cells. The invention creates a uniform time at which polymerization is initiated for all red blood cells in the sample region and accurately determines the time at which cellular distortion begins for each cell. Potential drugs are those compounds that significantly increase the delay time of sickling time, *i.e.* the time at which the cell changes shape due to intracellular polymerization.

Applications:

- Rapid automated detection of compounds that inhibit sickling and are therefore potential drugs for sickle cell disease.
- Objective assay for monitoring disease severity.

Development Status: The technology is capable of determining the distribution of cellular delay times in a large number of samples in series in a 48 well plate format

Inventors: Jeffrey F. Smith, H. James Hofrichter, and William A. Eaton (NIDDK).

Patent Status:

- U.S. Patent Application No. 11/652,843, filed 11 Jan 2007 (HHS Reference No. E–021–2007/0–US–01).
- PCT Application No. PCT/US2008/000427 filed 11 Jan 2008 (HHS Reference No. E–021–2007/0–PCT–02).

Licensing Status: Available for licensing.

Licensing Contact: Cristina Thalhammer-Reyero, PhD, M.B.A.; 301–435–4507; *thalhamc@mail.nih.gov*.

Collaborative Research Opportunity: The NIDDK Laboratory of Chemical Physics is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact Rochelle S. Blaustein, J.D. at 301–451–3636 or *rochelle.blaustein@nih.gov* for more information.

Dated: September 9, 2008.

Richard U. Rodriguez,

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

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