



BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

**Prospective Grant of Exclusive Patent Commercialization License: Direct Reading
Detection Kits for Surface Contamination by Antineoplastic Drugs**

AGENCY: Centers for Disease Control and Prevention, National Institutes of Health.

ACTION: Notice.

SUMMARY: The National Institute of Allergy and Infectious Diseases, an institute of the National Institutes of Health, Department of Health and Human Services, on behalf of the Centers for Disease Control and Prevention, Department of Health and Human Services, is contemplating the grant of an exclusive patent commercialization license to Becton, Dickinson and Company, located in Franklin Lakes, New Jersey, to practice the inventions embodied in the patent applications listed in the Supplementary Information section of this notice.

DATES: Only written comments and/or applications for a license which are received by the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases on or before **[INSERT DATE 15 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]** will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, and comments relating to the contemplated exclusive patent commercialization license should be directed to: Karen Surabian, Licensing and Patenting Manager, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601

Fishers Lane, Suite 2G, MSC9804, Rockville, MD 20852-9804, phone number 301-594-9719, or karen.surabian@nih.gov.

SUPPLEMENTARY INFORMATION: The following represents the intellectual property to be licensed under the prospective agreement: HHS Reference No. E-162-2013/0-US-01, United States Provisional Patent Application Serial Number 61/672,059, filed 07/16/2012; HHS Reference No. E-162-2013/0-PCT-02, PCT Patent Application Serial Number PCT/US2013/050688, filed 07/16/2013; HHS Reference No. E-162-2013/0-US-03, United States Patent Application Serial Number 13/943,430, filed 07/16/2013; HHS Reference No. E-162-2013/0-EP-04, European Patent Application Serial Number 13819718.1, filed 02/05/2015; and HHS Reference No. E-162-2013/0-JP-05, Japanese Patent Application Serial Number 2015-523183, filed 01/08/2015. All rights in these inventions have been assigned to the Government of the United States of America.

The prospective exclusive patent commercialization license territory may be worldwide and the field of use may be limited to: “Use of the licensed patent rights for the development, manufacture, and sale of a lateral flow device for detection of antineoplastic drugs from surfaces”.

Many types of cancers are treated with antineoplastic drugs, also known as anti-cancer drugs or chemotherapy. Exposure of healthcare workers to these hazardous drugs from contaminated surfaces may cause acute and long-term effects. Approximately eight (8) million United States healthcare workers are potentially exposed to these hazardous drugs. Although there are potential therapeutic benefits of hazardous drugs that outweigh the risks of side effects for ill patients, healthcare workers are exposed to the risk with the

same side effects with no therapeutic benefit. Occupational exposures to hazardous drugs can lead to skin rashes and major reproductive effects, which include increased fetal loss, congenital malformations, low birth weight, congenital abnormalities, and infertility. The risk of cancer is also increased after exposure to these drugs.

This invention, developed within the National Institute for Occupational Safety and Health at the Centers for Disease Control and Prevention, describes a lateral flow assay-based antineoplastic drug detection method that utilizes antibodies specific for individual drugs. It uses detectors for the assessment of drug residues on surfaces, which can be incorporated into small, portable drug detection devices that allow healthcare workers to sample surfaces in near real time, avoiding the need to take samples back to the laboratory to be tested.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR Part 404. The prospective exclusive patent commercialization license will be royalty bearing and may be granted unless within fifteen (15) days from the date of this published notice, the National Institute of Allergy and Infectious Diseases receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR Part 404.

Complete applications for a license in the prospective field of use that are timely filed in response to this notice will be treated as objections to the grant of the contemplated exclusive patent commercialization license. Comments and objections submitted in response to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the *Freedom of Information Act*, 5 U.S.C. 552.

Dated: November 9, 2017.

Suzanne Frisbie,

Deputy Director,

Technology Transfer and Intellectual Property Office,

National Institute of Allergy and Infectious Diseases.

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