[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Evaluation Option Exclusive License: Development of a Diagnostic and Prognostic for Breast and Prostate Cancer Using Spatial Genome Organization

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR 404, that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive evaluation option license to practice the inventions embodied in U.S. Provisional Application 61/094,318 filed September 4, 2008 entitled "Method for detection of cancer based on spatial genome organization" (HHS Ref No. E-283-2008/0-US-01); International Application PCT/US2009/055857 filed September 3, 2009 entitled "Method for detection of cancer based on spatial genome organization" (HHS Ref No. E-283-2008/0-PCT-02); U.S. Patent Application 13/062,247 filed March 4, 2011 entitled "Method for detection of cancer based on spatial genome organization" (HHS Ref No. E-283-2008/0-US-0; and foreign equivalents thereof to

Radial Genomics, Ltd. ("RG"), a company located in Cambridge, U.K. The patent rights in these inventions have been assigned to the United States of America.

The prospective exclusive evaluation option license territory may be worldwide and the field of use may be limited to the use of the Licensed Patent Rights for the diagnosis, prognosis, and prediction of cancer.

Upon the expiration or termination of the exclusive evaluation option license, RG will have the exclusive right to execute an exclusive commercialization license which will supersede and replace the exclusive evaluation option license with no greater field of use and territory than granted in the exclusive evaluation option license.

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before [INSERT DATE 15 DAYS FROM DATE OF PUBLICATION OF NOTICE IN THE FEDERAL REGISTER] will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive license should be directed to: Whitney A. Hastings, Ph.D., Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 451-7337; Facsimile: (301) 402-0220; E-mail: hastingw@mail.nih.gov.

SUPPLEMENTARY INFORMATION: The successful treatment of cancer is correlated with the early detection of the cancerous cells. Conventional cancer diagnosis is largely based on qualitative morphological criteria, but more accurate quantitative tests could greatly increase early detection of malignant cells. It has been observed that the spatial arrangement of DNA in the nucleus is altered in cancer cells in comparison to normal cells. Therefore, it is possible to distinguish malignant cells by mapping the position of labeled marker genes in the nucleus. This NIH invention provides methods of detecting abnormal cells in a sample using the spatial position of one or more genes within the nucleus of a cell, as well as a kit for detecting abnormal cells using such methods. It also provides methods of identifying gene markers for abnormal cells using the spatial position of one or more genes within the nucleus of a cell. Therefore, this invention could be used as a very effective cancer diagnostic from tumor biopsies after non-invasive techniques such as a mammogram or PSA assay have suggested cancer.

The primary product arising from this technology would be a diagnostic for cancer using tumor biopsies after non-invasive techniques such as a mammogram or PSA assay have suggested the presence of cancer. This novel in vitro diagnostic test for cancer has use in oncology laboratories of hospitals and commercial clinical laboratories. It has several advantages over other diagnostics including sensitive cancer detection, small sample size (100-200 cells), probes to all genomic regions are available, and it does not require mitotic chromosomes. Additionally, it is applicable to both solid tumors and blood cancers, allows analysis of subpopulations from biopsy, measures metastatic potential of cancer cells, determines tumor type, and can be alternative to or complementary to conventional diagnostics.

The prospective exclusive evaluation option license, and a subsequent exclusive commercialization license, may be granted unless the NIH 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 within fifteen (15) days from the date of this published notice.

Complete applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive evaluation option license. Comments and objections submitted 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: July 9, 2014.

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

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