



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Apparatus for Microarray Binding Sensors Having Biological Probe Materials Using Carbon Nanotube Transistors

AGENCY: National Institutes of Health

ACTION: Notice.

SUMMARY: The National Cancer Institute, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Commercialization Patent License to practice the inventions embodied in the Patents and Patent Applications listed in the Supplementary Information section of this notice to Nanobernetics, LLC (“Nanobernetics”) located in Maryland.

DATES: Only written comments and/or applications for a license which are received by the National Cancer Institute’s Technology Transfer Center 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, and comments relating to the contemplated Exclusive Commercialization Patent License should be directed to: Jaime M. Greene, Senior Licensing and Patenting Manager, NCI Technology Transfer Center, 9609 Medical Center Drive, RM 1E530 MSC 9702, Bethesda, MD 20892-9702 (for business mail), Rockville, MD 20850-9702 Telephone: (240)-276-5530; Facsimile: (240)-276-5504 E-mail: greenejaime@mail.nih.gov

SUPPLEMENTARY INFORMATION:

Intellectual Property

EP Patent 1999277 (Application No. 07753436.0) filed 19 March 2007, titled “Apparatus for biosensor microarrays based on carbon nanotube transistors having biological probe materials,

method for its production and method of electronically detecting a biological target material”, validated in FR, DE, IE, and GB, HHS Reference No.: E-056-2007/0-EP-04;

Australia Patent 2007227415 (Application No. 2007227415) filed 10/16/08, titled “Apparatus for microarray binding sensors having biological probe materials using carbon nanotube transistors”, HHS Reference No.: E-056-2007/0-AU-05;

Canada Patent 2646465 (Application No. 2646465) filed 03/19/07, titled “Apparatus for microarray binding sensors having biological probe materials using carbon nanotube transistors”, HHS Reference No.: E-056-2007/0-CA-06;

Japan Patent 5048752 (Application No. 2009-501490) filed 03/19/07, titled “Apparatus for microarray binding sensors having biological probe materials using carbon nanotube transistors”, HHS Reference No.: E-056-2007/0-JP-07;

EP Patent 2570490 (Application No. 12160369.0) filed 03/19/07, titled “Apparatus for microarray binding sensors having biological probe materials using carbon nanotube transistors”, validated in FR, DE, and GB. HHS Reference No.: E-056-2007/0-EP-08;

U.S. Patent 8,017,938 (Application No. 11/723,369), filed 19 March 2007, titled “Apparatus for Microarray Binding Sensors Having Biological Probe Materials Using Carbon Nanotube Transistors”, HHS Ref. No.: E-056-2007/0-US-03; and

PCT Application No. PCT/US2007/06809, filed 19 March 2007, now abandoned, titled “Apparatus for Microarray Binding Sensors Having Biological Probe Materials Using Carbon Nanotube Transistors”, HHS Ref. No.: E-056-2007/0-PCT-02.

U.S. Provisional Patent Application No. 60/743,524, filed 17 March 2006, now abandoned, titled “Apparatus for Microarray DNA Binding Sensors Using Carbon Nanotube Transistors”, HHS Ref. No.: E-056-2007/0-US-01.

The patent rights in these inventions have been assigned and/or exclusively licensed to the government of the United States of America.

The prospective exclusive license territory may be worldwide and the field of use may be limited to: “The development of an FDA-approved or cleared *in vitro* diagnostic for the detection of hematological malignancies, wherein nucleic acids encoding one or more of the following genes are detected: 1) BCR-ABL, 2) FLT3, 3) Btk, 4) Alk, 5) Bcl-2, 6) Akt, and 7) PI3K.”

This technology discloses a microarray apparatus that uses carbon nanotubes transistors and electronic circuitry to quantitatively measure changes in gene expression levels. Typically, microarrays are microscope glass slides spotted with thousands of different genes. The array does not have built-in reader, and the detection is performed using a fluorescence scanner after

hybridization with fluorescent-tagged target DNA. For simple nucleic acid detection, current methods rely upon various combinations of enzymatic amplification of nucleic acids and fluorescent labeling of targets, which entail enzymatic manipulation of the nucleic acid being tested and chemical labeling, respectively. These methods are both time consuming and afford limited sensitivity. In cases where microarray technology is used as a tool for monitoring gene expression patterns and profiling of micro RNA (miRNA) in normal and cancerous tissue, quantification of changes has typically been optically-based. While this technique is highly sensitive, use of optical methods impedes progress in both system miniaturization and in direct interfacing with data collection electronics.

To overcome the limitation of current microarray technologies, the inventors have developed a highly sensitive microarray apparatus that uses carbon nanotube transistors for the electronic detection of biological probe-target binding. The present invention provides an apparatus for biological target material detection which uses an array of carbon nanotube transistors, with each being operated as a field effect transistor. A single carbon nanotube transistor is associated with a distinct biological probe material. The current versus voltage characteristics or transconductance between the source and drain electrodes is measured before and after a binding event between the biological probe and target materials. By using a mathematical relationship, the exact amount of target binding can be extracted. Importantly, the present apparatus offers a significant advantage in simplicity of protocol as the method used therewith does not require chemical or enzymatic manipulation of the target being detected.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR Part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the National Cancer Institute 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 filed in response to this notice will be treated as objections to the grant of the contemplated Exclusive Commercialization Patent License Agreement. 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: August 25, 2017

Richard U. Rodriguez,
Associate Director
Technology Transfer Center
National Cancer Institute

[FR Doc. 2017-18668 Filed: 9/1/2017 8:45 am; Publication Date: 9/5/2017]