[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Intent to Grant Start-Up Exclusive Patent License: Real-Time PCR Point Mutation Assays for Detecting HIV-1 Resistance to Antiviral Drugs

AGENCY: Public Health Service, HHS

ACTION: Notice

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR 404, that the Public Health Service, Department of Health and Human Services, is contemplating the grant of an exclusive license to Research Think Tank Molecular Diagnostics, Inc. (RTTMDx) having a principal place of business in Georgia, U.S.A., to practice the inventions embodied in U.S. Provisional Patent Application No. 60/577,696, filed June 07, 2004, entitled "Real-Time PCR Point Mutation Assays for Detecting the 103N and 184V Mutations in the Reverse Transcriptase of HIV-1" (HHS Ref. No. E-198-2013/0-US-01); PCT Application No. PCT/US2005/019907, filed June 07, 2005, entitled "Real-Time PCR Point Mutation Assays for Detecting HIV-1 Resistance to Antiviral Drugs" (HHS Ref. No. E-198-2013/0-PCT-02); U.S. Patent Application No. 14/059,085, filed

October 21, 2013, entitled "Real-Time PCR Point Mutation Assays for Detecting HIV-1 Resistance to Antiviral Drugs" (HHS Ref. No. E-198-2013/0-US-11); U.S. Patent No. 8,043,809, filed December 07, 2006, entitled "Real-Time PCR Point Mutation Assays for Detecting HIV-1 Resistance to Antiviral Drugs" (HHS Ref. No. E-198-2013/0-US-07); U.S. Patent No. 8,318,428, filed January 24, 2012, entitled "Real-Time PCR Point Mutation Assays for Detecting HIV-1 Resistance for Antiviral Drugs" (HHS Ref. No. E-198-2013/0-US-08); US Patent No. 8,592,146, filed September 04, 2013, entitled "Real-Time PCR Point Mutation Assays for Detecting HIV-1 Resistance to Antiviral Drugs" (HHS Ref. No. E-198-2013/0-US-09); Australian Patent No. 20055252685, issued March 31, 2011, entitled "Real-Time PCR Point Mutation Assays for Detecting HIV-1 Resistance to Anti-Viral Drugs," (HHS Ref. No. E-198-2013/0-AU-03); Indian Patent No. 19/DELNP/2007, issued December 19, 2013, entitled "Real-Time PCR Point Mutation Assays for Detecting HIV-1 Resistance to Anti-Viral Drugs" (HHS Ref. No. E-198-2013/0-IN-06); Canadian Patent Application No. 2,891,079, filed May 19, 2015, entitled "Real-Time PCR Point Mutation Assays for Detecting HIV-1 Resistance to Anti-Viral Drugs" (HHS Ref. No. E-198-2013/0-CA-12); Canadian Patent Application No. 259747, filed December 07, 2006, entitled "Real-Time PCR Point Mutation Assays for Detecting HIV-1 Resistance to Anti-Viral Drugs" (HHS Ref. No. E-198-2013/0-CA-04); U.S. Provisional Patent Application No. 61/443,926, filed February 17, 2011, entitled "Real-Time PCR Point Mutation Assays for Detecting HIV-1 Resistance to Antiviral Drugs" (HHS Ref. No. E-214-2013/0-US-01); PCT Patent Application No. PCT/US2012/025638, filed February 17, 2012, entitled "Real-Time PCR Point Mutation Assays for Detecting HIV-1 Resistance to Anti-Viral Drugs" (HHS Ref. No. E-214-

2013/0-PCT-02); U.S. Application No. 13/985,499, filed February 17, 2012, entitled "Real-Time PCR Point Mutation Assays for Detecting HIV-1 Resistance to Anti-Viral Drugs" (HHS Ref. No. E-214-2013/0-US-06); Canadian Patent Application No. 2827324, filed February 17, 2012, entitled "Real-Time PCR Point Mutation Assays for Detecting HIV-1 Resistance to Anti-Viral Drugs" (HHS Ref. No. E-214-2013/0-CA-03); European Patent Application No. 12747199.3, filed February 17, 2012, entitled "Real-Time PCR Point Mutation Assays for Detecting HIV-1 Resistance to Anti-Viral Drugs" (HHS Ref. No. E-214-2013/0-EP-04); Indian Patent Application No. 7110/DELNP/2013, filed February 17, 2012, entitled "Real-Time PCR Point Mutation Assays for Detecting HIV-1 Resistance to Anti-Viral Drugs" (HHS Ref. No. E-214-2013/0-IN-05); U.S. Provisional Patent Application No. 61/829,473, filed May 31, 2013, entitled "Real-Time PCR Point Mutation Assays for Detecting HIV-1 Resistance to Anti-Viral Drugs (HHS Ref. No. E-511-2013/0-US-01); PCT Application No. PCT/US2014/040514, filed June 02, 2014, entitled, "Real-Time PCR Point Mutation Assays for Detecting HIV-1 Resistance to Anti-Viral Drugs" (HHS Ref. No. E-511-2013/0-PCT-02).

The patent rights in these inventions have been assigned to the Government of the United States of America. The territory of the prospective Start-Up Exclusive Patent License may be worldwide, and the field of use may be limited to "Development, manufacture, and sale of an FDA-approved or foreign equivalent-approved Class III real-time PCR diagnostic assay for HIV-1 genotyping utilizing whole HIV-1 *pol* viral sequencing, limited to use in humans."

DATE: Only written comments and/or applications for a license that 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.

ADDRESS: Requests for a copy of the patent application(s), inquiries, comments and other materials relating to the contemplated license should be directed to: Karen Surabian, J.D., M.B.A., Licensing and Patenting Manager, CDC Unit, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 594-3232; Facsimile: (301) 402-0220; E-mail: karen.surabian@nih.gov. A signed confidential disclosure agreement may be required to receive copies of the patent application assuming it has not already been published under the publication rules of either the United States Patent and Trademark Office or the World Intellectual Property Organization.

SUPPLEMENTARY INFORMATION:

The use of antiretroviral compounds to treat HIV infection has proliferated; consequently viruses have adapted and evolved mutations limiting the efficacy of these drugs and disrupting the success of treatment. The CDC has developed a novel assay featuring real-time PCR reagents and methods for detecting drug-resistance related mutations in HIV, for newly diagnosed patients and those individuals currently receiving antiretroviral therapies.

This RT-PCR assay can diagnose different point mutations in patient samples at an achievable sensitivity of 1-2 log greater than conventional point-mutation sequencing

methods. More specifically, this assay measures the differential amplifications of common and mutation-specific reactions that target specific codons of interest, which are the HIV-1 proteins of reverse transcriptase, protease, and integrase (HIV-1 *pol*).

Given its low cost, simplicity, high-throughput capability, and tremendous diagnostic sensitivity, this assay will be useful for detection and surveillance of drug resistance-associated mutations and will aid in the clinical management of HIV infection both domestically and in developing countries where the cost of surveillance has been prohibitive.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404. The prospective exclusive license may be granted unless, within fifteen (15) days from the date of this published notice, the NIH Office of Technology Transfer receives written evidence and argument that establishes that the grant of the contemplated license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.

Properly filed competing 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 contemplated 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: September 24, 2015

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Richard U. Rodriguez, M.B.A.

Acting Director
Office of Technology Transfer
National Institutes of Health

[FR Doc. 2015-24674 Filed: 9/28/2015 08:45 am; Publication Date: 9/29/2015]