



DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Start-Up Exclusive Evaluation Option License Agreement: Development of Diagnostic Tests and Kits for Detection of Pathological Angiogenesis in Cancer

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR part 404, that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of a Start-Up Exclusive Evaluation Option License Agreement to Angio360 Diagnostics, LLC, a company having a place of business in Wauwatosa, Wisconsin, to practice the inventions embodied in US Provisional Patent Application No. 60/858,068, entitled “Differential Gene Expression in Physiological and Pathological Angiogenesis,” filed November 9, 2006 (HHS Ref. No.: E-285-2006/0-US-01); US Provisional Patent Application No. 60/879,457, entitled “Organ And Tumor Associated Endothelial Markers,” filed January 8, 2007 (HHS Ref. No. E-285-2006/1-US-01); PCT Application No. PCT/US2007/072395, entitled “Differential Gene Expression in Physiological and Pathological Angiogenesis,” filed June 8, 2007 (HHS Ref. No. E-285-2006/2-PCT-01); US Patent Application No. 12/514,297, entitled “Differential Gene

Expression in Physiological and Pathological Angiogenesis,” filed May 8, 2009 (HHS Ref No. E-285-2006/2-US-02); Australian Patent No. 2007-317753, entitled “Differential Gene Expression in Physiological and Pathological Angiogenesis,” filed June 28, 2007 (HHS Ref No. E-285-2006/2-AU-03); Canadian Patent Application No. 2,669,260, entitled “Differential Gene Expression in Physiological and Pathological Angiogenesis,” filed June 28, 2007 (HHS Ref. No. E-285-2006/2-CA-04); U.S. Patent No.: 8,440,411, entitled “Differential Gene Expression in Physiological and Pathological Angiogenesis,” filed March 21, 2011 (HHS Ref. No. E-285-2006/2-US-05); U.S. Patent Application No. 13/052,878, entitled “Differential Gene Expression in Physiological and Pathological Angiogenesis,” filed April 16, 2013 (HHS Ref. No.: E-285-2006/2-US-06); and Australian Application Patent No.: 2014-200453, entitled “Differential Gene Expression in Physiological and Pathological Angiogenesis,” filed January 28, 2014 (HHS Ref No. E-285-2006/2-AU-07). 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 Evaluation Option License Agreement may be worldwide, and the field of use may be limited to “Development of diagnostic tests and kits to determine or monitor pathological angiogenesis related to cancer in animals or humans.”

Upon the expiration or termination of the Start-up Exclusive Evaluation Option License Agreement, Angio360 Diagnostics, LLC will have the exclusive right to execute a Start-Up Exclusive Patent License Agreement which will supersede and replace the Start-up Exclusive Evaluation Option License Agreement, with no greater field of use and territory than granted in the Start-up Exclusive Evaluation Option License Agreement.

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 AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]** will be considered.

ADDRESSES: Requests for copies of the patent application(s), inquiries, comments, and other materials relating to the contemplated Start-Up Exclusive Evaluation Option License Agreement should be directed to: Rose M. Freel, Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301)402-9521; Facsimile: (301) 402-0220; E-mail: rose.freel@nih.gov. A signed confidentiality nondisclosure agreement will be required to receive copies of any patent applications that have not been published or issued by the United States Patent and Trademark Office or the World Intellectual Property Organization.

SUPPLEMENTARY INFORMATION: This technology describes a method of detecting pathological angiogenesis (formation of new blood vessels) using the expression levels of certain proteins for the diagnosis of cancer or monitoring response to cancer treatment.

The prospective Start-Up Exclusive Evaluation Option License Agreement is being considered under the small business initiative launched on October 1, 2011 and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR part 404. The prospective Start-Up Exclusive Evaluation Option License Agreement and a subsequent Start-Up Exclusive Patent License Agreement may be granted unless the NIH receives written evidence and argument, within fifteen (15) days from the date of this published

notice, that establishes that the grant of the contemplated Start-Up Exclusive Evaluation Option License Agreement 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 Start-Up Exclusive Evaluation Option 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: September 21, 2015.

Richard U. Rodriguez,
Acting Director,
Office of Technology Transfer,
National Institutes of Health.

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