[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Development of *in vitro* diagnostics for the detection of diseases or pathogenic agents.

AGENCY: National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health, Public Health Service, HHS

ACTION: Notice

SUMMARY: This notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR Part 404.7(a)(1)(i), that the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), at the National Institutes of Health, Department of Health and Human Services, is contemplating the grant to Omega Diagnostics Group PLC ("Omega"), a company incorporated under the laws of the United Kingdom, having an office in Alva, Scotland, an exclusive patent license to practice the following inventions embodied in the following patent applications: US Provisional Patent Application No.60/846,354, entitled, "(S,S)-trans-1,2-cyclopentane Diamine-modified and Gamma-lysine-modified Peptide Nucleic Acids as Probes for Nucleic Acid Detection: Synthesis and Applications," filed 22 Sep 2006 [HHS Ref No. E-308-2006/0-US-01]; US Provisional Patent Application No. 60/896,667, entitled, "Synthesis of Trans-tert-butyl-2-aminocyclopentylcarbamate,"

filed 23 Mar 2007 [HHS Ref No. E-308-2006/1-US-01]; International Application PCT/US2007/020466, entitled, "Synthesis of Trans-tert-butyl-2-aminocyclopentylcarbamate," filed 21 Sep 2007 [HHS Ref No. E-308-2006/2-PCT-01]; US Patent Application No. 12/441,925, filed 21 Sep 2007, [HHS Ref No. E-308-2006/2-US-02]; US Patent Application No. 12/409,159, entitled, "Cross-Coupled Peptide Nucleic Acids for Detection of Nucleic Acids of Pathogens," filed 23 Mar 2009 [HHS Ref No. E-308-2006/3-US-01]; US Patent No. 9,156,778, entitled, "Cross-Coupled Peptide Nucleic Acids for Detection of Nucleic Acids of Pathogens," issued 13 Oct 2015 [HHS Ref No. E-308-2006/3-US-02]; US Provisional Patent Application No. 61/684,354, entitled, Cyclopentane-peptide Nucleic Acids for Qualitative and Quantitative Detection of Nucleic Acids," filed 17 Aug 2012 [HHS Ref No. E-260-2012/0-US-01]; International Application PCT/US2013/055252, filed 16 Aug 2013 [HHS Ref No. E-260-2012/0-PCT-02]; European Patent Application No. 13753962.3, filed 11 Feb 2015, [HHS Ref No E-260-2012/0-EP-03]; Korea Patent Application No. 10-2015-7006286, filed 11 Mar 2015, [HHS Ref No E-260-2012/0-KR-04]; and US Patent Application No. 14/421,732, filed 13 Feb 2015, [HHS Ref No E-260-2012/0-US-05].

The patent rights in these inventions have been assigned to the United States of America. Omega is seeking a worldwide territory for this license. The field of use may be limited to use of the Patent Rights for the development and sale of trans-cyclopentane-modified peptide nucleic acids (PNA) in a diagnostic system incorporating an enzyme-linked immunosorbent assay or Omega's proprietary VISITECT® technology for the detection of diseases or pathogenic agents including viruses and microorganisms.

DATES: Only written comments or applications for a license (or both) which are received by the Technology Advancement Office, NIDDK, on or before [INSERT DATE 15DAYS FROM DATE OF PUBLICATION OF NOTICE IN THE FEDERAL REGISTER] will be considered.

ADDRESSES: Requests for copies of the patent application, patents, inquiries, comments, and other materials relating to the contemplated exclusive license should be directed to: the Patrick McCue, Ph.D., Senior Licensing and Patenting Manager, Technology Advancement Office, The National Institutes of Diabetes and Digestive and Kidney Diseases, 12A South Drive, Bethesda, MD 20892, Telephone: (301) 451-5560; E-mail: patrick.mccue@nih.gov. A signed confidentiality non-disclosure agreement will be required to receive copies of any patent applications that have not been published by the United States Patent and Trademark Office or the World Intellectual Property Organization.

SUPPLEMENTARY INFORMATION:

These technologies, and the corresponding patent applications, are directed to cyclopentane-peptide nucleic acids (PNA) and their use in qualitative and quantitative detection of nucleic acids. The technologies overcome a stability problem and sensitivity to outside contamination that is inherent to PCR-based detection systems, wherein the

PNA probes bind to DNA with greater stability and selectivity compared to a complementary DNA sequence.

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 Part 404. The prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the Technology Advancement Office, NIDDK, 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.

Properly filed competing applications for a license 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: November 17, 2015.

Anna Z. Amar,
Acting Deputy Director,
Technology Advancement Office, NIDDK.

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