



**[Billing Code 4140-01-P]**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Prospective Grant of Exclusive Patent License: DNA-based Vaccine for Prevention of Zika Virus Infection**

**AGENCY:** National Institutes of Health.

**ACTION:** Notice.

**SUMMARY:** The National Institute of Allergy and Infectious Diseases (NIAID), 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 PaxVax, Inc., located in Redwood City, California, to practice the inventions embodied in the patent applications listed in the Supplementary Information section of this notice.

**DATES:** Only written comments and/or applications for a license which are received by the National Institute of Allergy and Infectious Diseases' Technology Transfer and Intellectual Property Office on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER] will be considered.

**ADDRESSES:** Requests for copies of the patent applications, inquiries, and comments

relating to the contemplated Exclusive Commercialization Patent License should be directed to: Dr. Amy Petrik, Technology Transfer and Patent Specialist, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Suite 2G, MSC9804, Rockville, MD 20852-9804, phone number 301-496-2644, or petrika@mail.nih.gov.

**SUPPLEMENTARY INFORMATION:**

The following represents the intellectual property is to be licensed under the prospective agreement: HHS Ref. No. E-181-2016/0, including provisional patent applications 62/396,613 filed September 19, 2016 entitled “Zika Virus Vaccines”, and all continuing U.S. and foreign patents/patent applications for the technology family, to PaxVax Inc.

All rights in these inventions have been assigned to the Government of the United States of America.

The prospective Exclusive Patent License territory may be worldwide and the field of use may be limited to: “Development and use of DNA-based vaccines expressing virus-like particle antigens comprising Zika virus membrane and/or envelope proteins for prevention of Zika virus infection in humans.”

Since 2015, Zika virus (ZIKV) outbreaks have had a significant effect on global public health. The mosquito-borne disease, which causes several congenital abnormalities in the developing fetus, as well as other neurological disorders in infected individuals has no approved vaccine to treat or prevent infection. To address this critical need, several approaches are being explored for a vaccine against ZIKV infection in priority

populations including women of child-bearing age and their partners.

Many entities, governmental, academic, and commercial, are actively pursuing development of ZIKV vaccines each using a different approach to address this public health need. The U.S. Government is coordinating its vaccine development response to ZIKV and has published this plan at <https://www.phe.gov/Preparedness/planning/Pages/zika-white-paper.aspx>.

Vaccine development approaches for ZIKV include but are not limited to inactivated virus (dead virus), live attenuated virus (weakened virus), recombinant viral vectors (weakened virus with target genes added), and subunit (portion of a virus) as well as mRNA- and DNA-based (gene-targeted). These various strategies provide multiple redundancies, expanded choice, and ensure short and long term maximal benefits to the public.

The subject invention relates to the use of nucleic acid molecules encoding Zika virus (ZIKV) proteins that when introduced in a cell produces noninfectious virus-like particles (VLPs) capable of eliciting a protective immune response against viral infection. More specifically, the subject vaccine is a DNA-based candidate encoding a polypeptide of a ZIKV membrane and envelope proteins that when expressed results in production of noninfectious VLPs that generate protective neutralizing antibodies against ZIKA infection. The vaccine, which is based on a similar vaccine developed for the related West Nile virus, is currently undergoing clinical trial evaluation. The subject invention has been advertised in the *Federal Register* and published on 12 December 2016.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR Part 404. The prospective Exclusive Patent License will be royalty bearing and may be granted unless

within thirty (30) days from the date of this published notice, the NIAID 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 timely filed in response to this notice will be treated as objections to the grant of the contemplated Exclusive Patent 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: October 5, 2017.

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Suzanne Frisbie,  
Deputy Director,  
Technology Transfer and Intellectual Property Office,  
National Institute of Allergy and Infectious Diseases.

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