

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****National Institutes of Health****Prospective Grant of Exclusive License: Recombinant Virus Expressing Human Carcinoembryonic Antigen and Methods of Use Thereof**

**AGENCY:** National Institutes of Health, Public Health Service, DHHS.

**ACTION:** Notice.

**SUMMARY:** This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i), that the National Institutes of Health and Human Services is contemplating the grant of an exclusive license to practice the inventions embodied in U.S. Patent Applications S/N 07/695,024 filed on May 6, 1991, S/N 07/879,649 filed on May 6, 1992, S/N 08/198,691 filed on February 18, 1994, and S/N 08/270,106 filed on July 1, 1994 (U.S. Patent 5,698,530 issued on December 16, 1997), entitled "Recombinant Virus Expressing Human Carcinoembryonic Antigen and Methods of Use Thereof," to Therion Biologics Corporation of Cambridge, Massachusetts. The patent rights in these inventions have been assigned to the United States of America.

The prospective exclusive license territory will be worldwide and the field of use may be limited to the use of recombinant poxviruses, excluding vaccinia and swinepox viruses, expressing the carcinoembryonic antigen (CEA) gene or portions thereof with the aim of eliciting an immunogenic response. The immune response *in vivo*, elicited after exposure to the recombinant virus, would be directed against malignant cells expressing CEA. The purpose of the prospective license is to develop poxvirus based vaccines directed against cancers expressing CEA.

**DATES:** Only written comments and/or license applications which are received by the National Institutes of Health on or before July 31, 2000 will be considered.

**ADDRESSES:** Requests for copies of these patents/patent applications, inquiries, comments and other materials relating to the contemplated exclusive license should be directed to: Elaine F. Gese, M.B.A., Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD. 20852-3804. Telephone: (301) 496-7056, x282; Facsimile (301) 402-0220; E-mail eg46t@nih.gov.

**SUPPLEMENTARY INFORMATION:** 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 404.7. The prospective exclusive license may be granted unless within sixty (60) days from the date of this published notice, the NIH receives written evidence and argument that establish that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

Applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive 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: May 23, 2000.

**Jack Spiegel,**

*Director, Division of Technology Development and Transfer, Office of Technology Transfer.*  
[FR Doc. 00-13731 Filed 5-31-00; 8:45 am]

**BILLING CODE 4140-01-M**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****National Institutes of Health****Prospective Grant of Exclusive License: "Anti-Notch Antibodies and Pharmaceutical Compositions for the Therapeutic Treatment of Tumors Which Over Express Notch Protein"**

**AGENCY:** National Institutes of Health, Public Health Service, DHHS.

**ACTION:** Notice.

**SUMMARY:** This notice in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i) that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive world-wide license to U.S. Patent Applications 60/124,119, entitled: "Anti-Notch-1 Monoclonal Antibodies for Inducing Cellular Differentiation and Apoptosis" and 60/102,816, entitled: "Apoptosis Inducing Agents and Methods" plus, if available, corresponding foreign patent applications to Viragen, Inc. having a place of business in Plantation, Florida. The patent rights in these inventions have been assigned to the United States of America.

**DATES:** Only written comments and/or applications for a license which are received by NIH on or before July 31, 2000 will be considered.

**ADDRESSES:** Requests for copies of the patent applications, inquiries, comments and other materials relating to the contemplated licenses should be directed to: J.R. Dixon, Ph.D., Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804. Telephone: (301) 496-7735 ext. 206; Facsimile: (301) 402-0220. A signed Confidentiality Agreement will be required to receive copies of the patent applications.

**SUPPLEMENTARY INFORMATION:** The technology disclosed in USPA SN: 60/124,119 and 60/102,816 relates to a method, pharmaceutical composition, and antibodies to treat tumors by causing apoptosis in tumor cells that over express Notch protein.

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 404.7. The prospective exclusive license may be granted unless within sixty (60) days from the date of this published notice, NIH 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 404.7.

The field of use may be limited to the use of anti-Notch antibodies and pharmaceutical composition for the diagnosis and therapeutic treatment of tumors which over express Notch protein.

Applications for a license [*i.e.*, completed "Application for License to Public Health Service Inventions"] in the field of use of anti-Notch antibodies and pharmaceutical composition for the therapeutic treatment of tumors which over express Notch protein filed in response to this notice will be treated as objections to the grant of the contemplated license. Comments and objections will not be made available for public inspection and, to the extent permitted by law, will not be subject to disclosure under the Freedom of Information Act, 5 U.S.C. 552.

Dated: May 22, 2000.

**Jack Spiegel,**

*Director, Division of Technology Development and Transfer, Office of Technology Transfer.*  
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