SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR part 404.7(a)(1)(i), that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to practice the inventions embodied in the following U.S. Patents and Patent Applications to Bavarian Nordic Immunotherapeutics ("BNIT") located in Mountain View, CA, USA.

Intellectual Property:
2. U.S. Patent Application Nos. 60/448,591 and 10/543,944 filed February 20, 2003 and February 20, 2004 respectively, as well as all continuation and divisional applications, and issued and pending foreign counterparts [HHS Ref. No. E–028–2007/0];
foreign counterparts [HHS Ref. No. E–135–2007];
5. U.S. Patent Application No. 07/205,189 filed June 10, 1988, as well as all continuation and divisional applications, and issued and pending foreign counterparts [HHS Ref No. E–136–2007];
6. U.S. Patent Application No. 60/625,321 filed November 5, 2004, as well as all continuation and divisional applications, and issued and pending foreign counterparts [HHS Ref No. E–138–2007]; and
7. U.S. Patent Application No. 07/340,052 filed April 18, 1989, as well as all continuation and divisional applications, and issued and pending foreign counterparts [HHS Ref No. E–147–2007].

The patent rights in these inventions have been assigned to the United States of America.

The prospective exclusive license territory may be worldwide and the field of use may be use of Licensed Patent Rights for development of therapeutics for human cancers. The field of use will specifically exclude prostate cancer, melanoma and colorectal cancer. For the avoidance of doubt, delivery formulations shall specifically exclude canary poxvirus vectors, NYVAC, non-viral eukaryotic expression vectors and recombinant yeast vectors in all geographic territories.

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before May 3, 2010 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive license that should be directed to: Sabarni K. Chatterjee, Ph.D. Licensing and Patenting Associate, Cancer Branch, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone: (301) 435–5587; Facsimile: (301) 435–4013; E-mail: chatterjeesa@od.nih.gov.

SUPPLEMENTARY INFORMATION: Cancer immunotherapy is a recent approach where tumor associated antigens (TAAs), which are primarily expressed in human tumor cells, and not expressed or minimally expressed in normal tissues, are employed to generate a tumor-specific immune response. Specifically, these antigens serve as targets for the host immune system and elicit responses that result in tumor destruction. The initiation of an effective T-cell immune response to antigens requires two signals. The first one is antigen-specific via the peptide/major histocompatibility complex and the second or “costimulatory” signal is required for cytokine production, proliferation, and other aspects of T-cell activation.

The patents and patent applications describe a vaccine technology, TRICOM, in conjunction with tumor associated antigens (TAAs). The TRICOM technology employs avirulent poxviruses to present a combination of costimulatory signaling molecules with tumor-associated antigens (TAAs) to activate T-cells and break the immune systems tolerance towards cancer cells. This is achieved using recombinant poxvirus DNA vectors that encode both T-cell costimulatory molecules and TAAs. The combination of the three (3) costimulatory molecules B7.1, ICAM–1 and LFA–3, hence the name TRICOM, has been shown to have more than the additive effect of each costimulatory molecule when used individually to optimally activate both CD4+ and CD8+ T cells. When a TRICOM based vaccine expressing TAAs is administered it greatly enhances the immune response against the malignant cells expressing those TAAs. By changing the TAAs used for immunization with TRICOM vaccines, immune responses can be generated to diverse types of cancers. The versatility of the vector-based TRICOM based vaccine is that it allows, including several TAAs, to help maximize the effectiveness. Transgenes reflecting alterations of TAAs can also be inserted into TRICOM based vaccines to further enhance immunogenicity. The addition of the two well-known TAAs, carcinoembryonic antigen (CEA) and MUC–1 to the TRICOM vector results in the PANVAC vaccine, which is used in a prime and boost vaccine strategy. It is well established that the overexpression of these two (2) TAAs are associated with the presence of a variety of carcinomas; therefore PANVAC can potentially be effective against a range of tumor types.

Additionally, new TAAs are being continually identified. One such example is the antigen Brachyury. Although Brachyury has been well known for its role in developmental cell biology, it has recently been implicated in tumor cell invasion and metastasis. Pre-clinical data indicates that Brachyury is aberrantly expressed on several tumors. Therefore, as one example, Brachyury combined with TRICOM also has potential as a cancer immunotherapy for the treatment of several tumors.

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 thirty (30) days from the date of this published notice, the 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.

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: March 26, 2010.
Richard U. Rodriguez,
Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

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DEPARTMENT OF HOMELAND SECURITY

[DOcket No. DHS–2010–0026]

Science and Technology Directorate; Submission for Review; Information Collection Request for the Department of Homeland Security Science and Technology Directorate First Responders Community of Practice

AGENCY: Science and Technology Directorate, DHS.

ACTION: 30-day Notice and request for comment.

SUMMARY: The Department of Homeland Security (DHS) invites the general public to comment on a new data collection form for the Science and Technology Directorate (S&T) First Responders Community of Practice (FRCoP): User Registration Page (DHS Form 10059 (9/09)). The FRCoP web-based tool will be collecting profile information from first responders and select authorized non-first responder users to facilitate networking and formation of online communities. All users will be required to authenticate prior to entering the site. In addition, the tool will provide members the