

Suite 2C212, Bethesda, MD 20892,
(Telephone Conference Call)

Contact Person: Bitu Nakhai, PhD,
Scientific Review Officer, Scientific Review
Branch, National Institute on Aging, Gateway
Bldg., 2C212, 7201 Wisconsin Avenue,
Bethesda, MD 20814, 301-402-7701,
nakhaib@nia.nih.gov.

Name of Committee: National Institute on
Aging Special Emphasis Panel; Adiposity,
Aging, and Stem Cells.

Date: June 23, 2010.

Time: 1 p.m. to 5 p.m.

Agenda: To review and evaluate grant
applications.

Place: National Institute on Aging,
Gateway Building, 7201 Wisconsin Avenue,
Suite 2C212, Bethesda, MD 20892,
(Telephone Conference Call)

Contact Person: Rebecca J. Ferrell, PhD,
Scientific Review Officer, National Institute
on Aging, Gateway Building Rm. 2C212, 7201
Wisconsin Avenue, Bethesda, MD 20892,
301-402-7703, ferrellrj@mail.nih.gov.

(Catalogue of Federal Domestic Assistance
Program Nos. 93.866, Aging Research,
National Institutes of Health, HHS)

Dated: March 29, 2010.

Jennifer Spaeth,

*Director, Office of Federal Advisory
Committee Policy.*

[FR Doc. 2010-7344 Filed 3-31-10; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Development of PANVAC and Tumor Associated Antigens as Cancer Vaccines

AGENCY: National Institutes of Health,
Public Health Service, HHS.

ACTION: Notice.

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:

1. U.S. Patent No. 6,756,038 issued
June 29, 2004 as well as issued and
pending foreign counterparts [HHS Ref.
No. E-099-1996/0-US-07];

2. U.S. Patent Application No. 10/
725,373 (recently allowed) filed
December 3, 2003 as well as
continuation and divisional
applications, and issued and pending
foreign counterparts [HHS Ref. No. E-
099-1996/0-US-08];

3. U.S. Patent No. 6,001,349 issued 14
Dec. 1999 as well as issued and pending
foreign counterparts [HHS Ref. No. E-
200-1990/3-US-01];

4. U.S. Patent Application No. 10/
579,025 filed May 11, 2006 as well as
all continuation and divisional
applications, and issued and pending
foreign counterparts [E-087-2005/0-
US-03];

5. U.S. Patent Application No. 10/
579,007 filed May 11, 2006 as well as
all continuation and divisional
applications, and issued and pending
foreign counterparts [E-088-2005/0-
US-03];

6. U.S. Patent No. 7,118,738 issued
October 10, 2006 as well as all
continuations and divisional
applications, and issued and pending
foreign counterparts [HHS Ref. No. E-
154-1998/0-US-07];

7. U.S. Patent Application Nos. 08/
686,280 filed July 25, 1996 as well as all
issued and pending foreign counterparts
[HHS Ref. No. E-259-1994/3-US-01];

8. U.S. Patent No. 7,410,644 issued
August 12, 2008 as well as all
continuation and divisional
applications, and issued and pending
foreign counterparts [HHS Ref. No. E-
259-1994/3-US-08];

9. U.S. Patent Nos. 6,893,869,
6,548,068 and 6,045,802 issued May 17,
2005, April 15, 2003 and April 4, 2000
respectively, as well as issued and
pending foreign counterparts [HHS Ref.
Nos. E-260-1994/1-US-03, US-02, US-
01]; U.S. Patent No. 7,368,116 issued
May 6, 2008 and U.S. Patent
Application No. 12/112,819, as well as
all continuation and divisional
applications [HHS Ref. Nos. E-260-
1994/1-US-04 and US-05];

10. Europe Patent Application No.
00102998.2 filed October 2, 1995,
Europe Patent No. 0784483 issued
November 29, 2001, Europe Patent
Application No. 09013495.8 filed
October 26, 2009, as well as all
continuation, and divisional
applications [HHS Ref. Nos. E-260-
1994/2-EP-15, EP-16 and EP-27]; Japan
Patent Application No. 512100/96 filed
October 2, 1995; Japan Patent No.
4078319 issued February 8, 2008 [HHS
Ref. No. E-260-1994/2-JP-25]; and
Japan Patent No. 4160612 issued July
25, 2008, as well as all continuation and
divisional applications; [HHS Ref. No.
E-260-1994/2-JP-21, JP-25 and JP-26];
Australia Patent No. 688606 issued July
2, 1998 [E-260-1994/2-AU-11]; Canada
Patent No. 2201587 issued June 25, 2002
[E-260-1994/2-CA-12];

11. Canada Patent Application No.
2,412,050 filed June 15, 2001 [HHS Ref.
No. E-187-2000/0-CA-05]; Australia
Patent No. 2001268452 issued

November 30, 2006 [HHS Ref. No. E-
187-2000/0-AU-06]; Japan Patent
Application No. 2002-510097 filed June
15, 2001 [HHS Ref. No. E-187-2000/0-
JP-07]; Hong Kong Patent Application
No. 03105975.5 filed June 15, 2001
[HHS Ref. No. E-187-2000/0-HK-08];
as well as all continuation and
divisional applications;

12. U.S. Patent Application No. 12/
280,534 filed February 21, 2007, [HHS
Ref. No. E-104-2006/0-US-06];
Australia Patent Application No.
2007221255 filed February 21, 2007
[HHS Ref. No. E-104-2006/0-AU-03];
Europe Patent Application No.
07751371.1 filed February 21, 2007,
[HHS Ref. No. E-104-2006/0-US-06];
filed February 21, 2007, [HHS Ref. No.
E-104-2006/0-EP-05]; Canada Patent
Application No. 2642994 filed February
21, 2007 [HHS Ref. No. E-104-2006/0-
CA-04]; as well as all continuation and
divisional and applications;

13. U.S. Patent Application No. 12/
528,796 filed August 26, 2009 [HHS Ref.
No. E-074-2007/0-US-07]; Australia
Patent Application No. 2008221383
filed February 27, 2008 [HHS Ref. No.
E-074-2007/0-AU-03]; Europe Patent
Application No. 08743578.0 filed
February 27, 2008 [HHS Ref. No. E-074-
2007/0-EP-05]; Canada Patent
Application No. 2,678,404 filed
February 27, 2008 [HHS Ref. No. E-074-
2007/0-CA-04]; Japan Patent
Application No. not yet assigned filed
February 27, 2008 [HHS Ref. No. E-074-
2007/0-JP-06] as well as all
continuation, divisional and pending
foreign counterpart applications;

Group II—Nonexclusive Licensed Patent Rights:

1. U.S. Patent No. 6,969,609 issued
November 29, 2005; U.S. Patent No.
7,211,432 issued May 1, 2007; U.S.
Patent Application No. 11/723,666 filed
March 21, 2007; as well as all
continuation and divisional
applications, and issued and pending
foreign counterparts [HHS Ref. No. E-
256-1998/0, 1];

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];

3. U.S. Patent No. 6,699,475 issued
March 2, 2004, as well as all
continuation and divisional
applications, and issued and pending
foreign counterparts [HHS Ref. No. E-
134-2007/0];

4. U.S. Patent No. 5,093,258 issued
March 3, 1992, as well as all
continuation and divisional
applications, and issued and pending

foreign counterparts [HHS Ref. No. E-135-2007/0];

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 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 results 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 tumors of the lung, intestine, stomach, kidney, bladder, uterus, ovary, and testis, and in chronic lymphocytic leukemia. When used in combination with costimulatory molecules, it can effectively activate T-cells to kill tumors cells that originated from above

mentioned 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.

[FR Doc. 2010-7341 Filed 3-31-10; 8:45 am]

BILLING CODE 4140-01-P

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