The device does not monitor the patient and may provide an audible or visible alarm when the respiratory rate, averaged over time, is outside operator settable alarm limits.

The ActiTrac and PAM–RL devices are classified within the generic type of device called the electroencephalograph (§ 882.1400). FDA identifies the electroencephalograph as a device used to measure and record the electrical activity of the patient’s brain obtained by placing two or more electrodes on the head.

V. FDA’s Decision

After reviewing both the reclassification petitions and the petitioner’s responses to our subsequent requests for information, FDA has found that the petitions do not contain any valid scientific evidence to support a conclusion that general controls would provide reasonable assurance of the devices’ safety and effectiveness for their intended uses or that special controls are not necessary to provide reasonable assurance of the safety and effectiveness of the devices. Therefore, FDA is denying the petitions for reclassification of these device types.

VI. References

The following references have been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. These references may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.


Dated: July 5, 2006.

Linda S. Kahan,
Deputy Director, Center for Devices and Radiological Health.

[FR Doc. E6–11115 Filed 7–13–06; 8:45 am]
BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health
Government-Owned Inventions; Availability for Licensing

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

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301–496–7057; fax: 301–402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Method for Expanding Allo-depleted Antigen Specific T Cells

Description of Technology: Available for licensing and commercial development are methods of producing a population of purified non-alloreactive antigen-specific T cells that recognize an antigen of interest. Thus, the population of donor T cells can be used to produce immune response against the antigen of interest (e.g., cytomegalovirus) in a recipient without producing an immune response to the recipient. Currently available methods for isolating and expanding antigen-specific T cells can be inefficient and produce populations of cells that include donor-reactive T cells. The present method enables rapid production of populations of T cells that recognize an antigen of interest but are depleted for alloreactive T cells: A population of donor T cells is contacted with a population of irradiated recipient antigen presenting cells (T–APCs) to produce a population of alloreactive T cells. The allreactive T cells are removed by purification with an antibody that specifically binds a cell surface marker (e.g., CD25, CD69, CD38 or CD71). The population of allo-depleted donor cells is then contacted with donor T antigen presenting cells (T–APCs) expressing an antigen of interest and produces a population of donor allo-depleted activated CD4 and CD8 T cells.

Applications: Immune response to opportunistic infectious in immunocompromised transplant or graft recipients.

Market: (1) Cytomegalovirus; (2) General post-transplant opportunistic infections.

Inventors: J. Joseph Melenhorst and A. John Barrett (NHBLI).

Publications:

leukemia are not defective in activation-
and replication-related apoptosis.” Leuk

2. H Fujiiwara, JI Melenhorst, F El
Ouriaghi, et al. “In vitro induction of
myeloid leukemia-specified CD4 and
CD8 T cells by CD40 ligand-activated B
cells gene modified to express primary
granule proteins.” Clin Cancer Res. 2005
Jun 15;11(12):4495–4503.

Patent Status: U.S. Provisional
Application No. 60/804,404 filed 09 Jun

Licensing Status: Available for non-
exclusive or exclusive licensing.

Licensing Contact: Michael A.
Shnilovich, Esq.; 301/435–5019;
shnilovm@mail.nih.gov.

Collaborative Research Opportunity:
The NHLBI Hematology Branch is
seeking statements of capability or interest from parties interested in
collaborative research to further
develop, evaluate, or commercialize a
Method for Expanding Allodepleted
Antigen-Specific T Cells. Please contact
Dr. A.J. Barrett at 301/402–4170 or
barrettjj@mail.nih.gov for more information.

A Newly Discovered Bacterium in the
Family Acetobacteraceae

Description of Technology: Available for licensing and commercial
development is a newly discovered
carcinogen in the Acetobacteraceae
family. This bacterium was isolated,
characterized and grown from lymph
nodes of a patient with chronic
granulomatous disease (CGD), a rare
genetic disorder that impairs the
immune system.

This Gram-negative bacterium is an
aerobic, facultative methylotroph that
produces yellow pigmented colonies.
The closest nucleic acid sequence match
was to Gluconacetobacter sacchari
(95.7% similarity) of the acetic acid
bacteria. The newly described bacterium
belongs to a new genus and species in
the Acetobacteraceae family and was
named Granulibacter bethesdenis. The
Acetobacteraceae are characterized by
their ability to convert alcohol (ethanol) to
acetic acid in the presence of air.

Members of this family are used
industrially in the production of
vinegar, and are encountered during
fermentation of wine.

G. bethesdenis can breakdown
methanol, formaldehyde, ethanol and
their intermediate breakdown products
into non-toxic end-products. Examples of
non-toxic end-products include
carbon dioxide, water, and acetic acid.

This provides the complete genome
sequence from the bacterium. Also
included are permission to purify
and utilize unique enzymes that the
bacterium uses to degrade organic
materials, for example methanol
dehydrogenase, formaldehyde-activating
enzyme, and methylenetetrahydrofolate
dehydrogenase (NAPD+).

Applications: (1) Biodegradation of
organic waste; (2) Microbial fuel cell; (3)
Production of purified polypeptide
enzymes for industrial use.

Inventors: Steven M. Holland (NIAID),
Patrick Murray (CC), Adrian M. Zelazny
(CC), David E. Greenberg (NIAID).
Publication: DE Greenberg, L Ding,
AM Zelazny, F Stock, A Wong, et al. “A
new bacterium associated with
lymphadenitis in a patient with chronic
granulomatous disease.” PLoS Pathog
2006 Apr;2(4):e28. Epub 2006 Apr 14,
doi: 10.1371/journal.ppat.0020028.

Patent Status: U.S. Provisional
Application No. 60/788,521 filed 31 Mar

Licensing Status: Available for non-
exclusive or exclusive licensing.

Licensing Contact: Dr. A.J. Barrett
at 301/402–4170 or
barrettjj@mail.nih.gov for more
information.

Fluorescent Imaging and Photodynamic
Treatment of Tumors

Description of Technology: Available for
licensing and commercial
development are methods and
compositions for optically detecting
tumors, in particular disseminated
intraepithelial cancers. Unlike existing
detection methods using avidin and/or
galactosyl serum albumin (GSA), the
current invention allows tumors to be
visualized in situ, with high sensitivity
and without hazardous radioactive
probes. The invention also provides
methods of treating tumors.

The invention describes the labeling
of avidin and GSA with fluorophores.
The fluorescently labeled agents
selectively bind to cells expressing
asialoglycoprotein receptors on the
surface of the neoplastic cells in tumors
of the ovary, stomach, colon or
pancreas. Metastatic tumor cells can
then be detected endoscopically,
laparoscopically, or during surgery with
an appropriate imaging system.

The fluorescently labeled avidin and
GSA can be used diagnostically, but also
have an application for treating cancer.
Using photosactivatable fluorophores
linked to avidin or GSA, free radicals
can be produced which results in
localized death of tumor cells upon
exposure to excitation with the
appropriate wavelength.

Applications: (1) Optical detection of
tumor cells and metastatic nodules; (2)
Photodynamic treatment of tumors.
Inventors: Hisataka Kobayashi and
Peter Choyke (NCI).

Patent Status: U.S. Provisional
Application No. 60/751,429 filed 16 Dec

Licensing Status: Available for non-
exclusive or exclusive licensing.

Licensing Contact: Chekesha
Clingman, Ph.D.; 301/435–5018;
clingmac@mail.nih.gov.

Collaborative Research Opportunity:
The National Cancer Institute Molecular
Imaging Program is seeking statements of
capability or interest from parties interested in
collaborative research to further
develop, evaluate, or
commercialize tumor specific imaging
agents. Please contact Laurie Zipper,
Ph.D., at 301–594–4650 or
zipperl@mail.nih.gov for more
information.

Coacervate Microparticles Useful for
the Sustained Release Administration
of Therapeutics Agents

Description of Technology: The
described technology is a biodegradable
microbead or microparticle, useful for
the sustained localized delivery of
biologically active proteins or other
molecules of pharmaceutical interest.

The microbeads are produced from
several USP grade materials, a cationic
polymer, an anionic polymer and a
binding component (e.g., gelatin,
chondroitin sulfate and avidin), in
predetermined ratios. Biologically active
proteins are incorporated into
preformed microbeads via an
introduced binding moiety under
nondenaturing conditions.

Proteins or other biologically active
molecules are easily denatured, and
once introduced into the body, rapidly
cleared. These problems are
circumvented by first incorporating the
protein into the microbead. Microbeads
with protein payloads are then
introduced into the tissue of interest,
where the microbeads remain while
delivering the protein/drug payload for adjustable periods of

CD8 T cells by CD40 ligand-activated B
lymphocytes.

References:

H Fujiwara, JJ Melenhorst, F El
Ouriaghi, et al. “In vitro induction of
myeloid leukemia-specified CD4 and
CD8 T cells by CD40 ligand-activated B
cells gene modified to express primary
granule proteins.” Clin Cancer Res. 2005
Jun 15;11(12):4495–4503.

Patent Status: U.S. Provisional
Application No. 60/804,404 filed 09 Jun

Licensing Status: Available for non-
exclusive or exclusive licensing.

Licensing Contact: Dr. A.J. Barrett
at 301/402–4170 or
barrettjj@mail.nih.gov for more
information.
time ranging from hours to weeks. This technology is an improvement of the microbead technology described in U.S. Patent No. 5,759,582.

**Applications:** This technology has two commercial applications. The first is a pharmaceutical drug delivery application. The bead allows the incorporated protein or drug to be delivered locally at high concentration, ensuring that therapeutic levels are reached at the target site while reducing side effects by keeping systemic concentration low. This microbead accomplishes this while protecting the biologically active protein from harsh conditions traditionally encountered during microbead formation/drug formulation.

The microbeads are inert, biodegradable, and allow a sustained release or multiple-release profile of treatment with various active agents without major side effects. In addition, the bead maintains functionality under physiological conditions.

Second, the microbead and microparticles can be used in various research assays, such as isolation and separation assays, to bind target proteins from biological samples. A disadvantage of the conventional methods is that the proteins become denatured. The denaturation results in incorrect binding studies or inappropriate binding complexes being formed. The instant technology corrects this disadvantage by using a bead created in a more neutral pH environment. It is the same environment that is used for the finding of the protein of interest as well.

**Inventor:** Phillip F. Heller (NIA).


**Licensing Status:** Available for non-exclusive or exclusive licensing.

**Licensing Contact:** Susan O. Ano, Ph.D.; 301-435-5515; anos@mail.nih.gov.

**Methods and Compositions Related to GHS–R Antagonist**

**Description of Technology:** This invention describes that additional functional role for D–Lys3 GHRP–6 (a known GHS–R antagonist, peptide) as a blocker of two well-known chemokine receptors, namely CCR5 and CXCR4. These receptors are major HIV co-receptors and are critical for HIV binding, fusion and entry into human T cells, monocytes, dendritic cells, and various other cells within the body.

Moreover, these receptors and their ligands play a major role in inflammation and a variety of acute and chronic disease states. Overall, these two mammalian chemokine receptors are currently major drug targets for treatment of AIDS, cancer and many immunoregulatory disorders. Many identified antagonists block one or the other receptor. Since D–Lys3 GHRP–6 actually binds and blocks both these chemokines receptors at the same time hindering their activity and HIV infectivity, D–Lys3 GHRP–6 may be a good therapeutic candidate for treatment of AIDS and inflammatory diseases.

**Inventors:** Vishwa D. Dixit and Dennis D. Taub (NIA).


**Licensing Status:** Available for non-exclusive or exclusive licensing.

**Licensing Contact:** Sally Hu, Ph.D., M.B.A.; 301–435–5605; hsa@od.nih.gov.

**Collaborative Research Opportunity:** The National Institute on Aging’s Laboratory of Immunology is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact Nicole D. Guyton at 301–435–3101 or darackn@mail.nih.gov for more information.

Dated: July 3, 2006

David R. Sadowski, Acting Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 06–6211 Filed 7–13–06; 8:45 am]

**BILLING CODE 4140–01–M**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Cancer Institute; Notice of Closed Meeting**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which could constitute a clearly unwarranted invasion of personal privacy.