Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Newsletter survey (print)				
Individuals or households	204	1	0.050	10
Physicians	27	1	0.050	2
CAM/health practitioners	108	1	0.050	5
Newsletter survey (online)				
Individuals or households	300	1	0.050	15
Physicians	40	1	0.050	2
CAM/health practitioners	160	1	0.050	8
Annualized totals	2,049			133

The annualized cost to respondents is estimated at $1,770 for the telephone survey, $507 for the print newsletter survey, and $714 for the online newsletter survey. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Christy Thomsen, Director, Office of Communications and Public Liaison, NCCAM, 31 Center Drive, Room 2B–11, Bethesda, MD 20892–2182; or fax your request to 301–402–4741; or e-mail *thomsenc@mail.nih.gov*. Ms. Thomsen can be contacted by telephone at 301–451–8876.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: May 30, 2006.

Christy Thomsen,

Director, Office of Communications and Public Liaison, National Center for Complementary and Alternative Medicine, National Institutes of Health.

[FR Doc. E6–8679 Filed 6–2–06; 8:45 am]

BILLING CODE 4140–01–P

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.

Multiplex Microarray for Simultaneous Detection of Hepatitis C Virus, Hepatitis B Virus, and Human Immunodeficiency Virus Type-1

Description of Technology: Available for licensing and commercial development are patent rights that cover a specific and sensitive microarray (TTD–V–1) and multiplex assay for the simultaneous detection and discrimination of Hepatitis C Virus (HCV), Hepatitis B Virus (HBV) and Human Immunodeficiency Virus Type-1 (HIV–1), which include both RNA and DNA genomes. Four specific probes (30–45 bp oligonucleotides) for each of these three viruses as well as the two internal controls were designed. Totally, each microarray consists of 20 probes immobilized on silylated glass slides. The single-stranded Cy5-labeled samples for microarray hybridization were obtained from labeling the amplicons using primer extension thermocycling. The multiplex microarray assay was able to detect and discriminate as low as 3 copies of genotypes A, B, C, D, and 10 copies of genotype E of HBV, 10 copies of HCV (genotype 1b), and 20 copies of HIV–1 (group M, subtype B) in a single multiplex reaction. The microarray assay could also detect the coexistence of two or three of these viruses and discriminate them simultaneously. The results of this study demonstrated the feasibility and performance of microarray-based multiplex detection of the three viruses, HCV, HBV, and HIV–1 in comparison with conventional individual PCR and gel electrophoresis technique.

Inventors: Chu Chieh Xia, Gerardo Kaplan, Hira Nakhasi, Amy Yang, Raj Puri (FDA).

Patent Status: U.S. Provisional Application No. 60/759,214 filed January 17, 2006 (HHS Reference No. E–077–2006/0–US–01).

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

Licensing Contact: Michael A. Shmilovich, Esq.; 301/435–5019; *shmilovm@mail.nih.gov.*

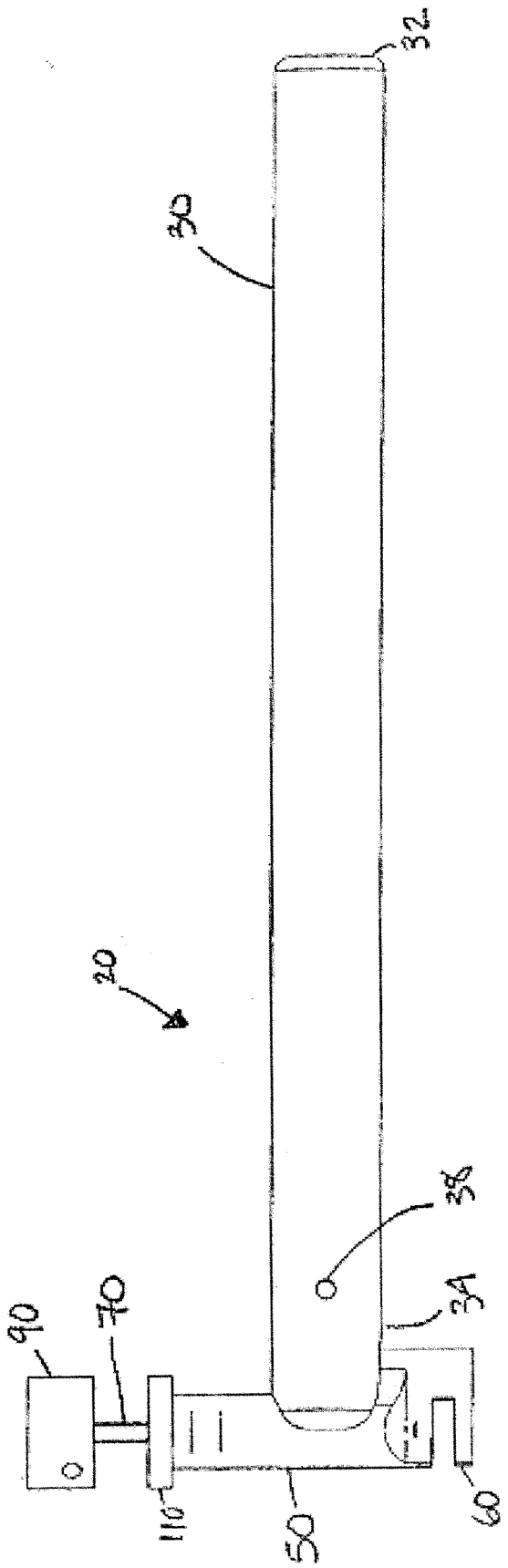
Collaborative Research Opportunity: The Food and Drug Administration's Center for Biologics Evaluation and Research (CBER) is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact Beatrice Droke, Technology Development Coordinator, FDA, (301) 827–7008 for more information.

Ear Hole Cutter for Animal Identification and Tissue Sampling

Description of Technology: This invention provides a better way of identification and tissue sampling for lab animals. Current systems rely on a technology that was never meant for biological use, namely the technology of paper punches. Such punches punch a hole through a mouse's ear with predictable consequences: ''hanging chads'' of tissue that must be excised with scissors, wasting time and further traumatizing the mouse's delicate physiology. Equally inefficient, the technician must pick up the tissue with a forceps to put it in a tube, if DNA typing is needed.

In contrast, a new device designed by a veterinarian and his collaborators allows rapid and painless punching/sampling. It cuts, rather than punches, holes of various diameters through animal ears. This thumb-powered cutter utilizes stainless steel hypo-tubing (like a hypodermic needle, but without the sharp point) to make holes. Instead of pressing with all of one's might to punch a hole, just a light press on the spring-loaded shaft is sufficient to quickly and nearly-painlessly cut a perfectly round hole through an ear. A tube can be loaded underneath the hypo-tubing to catch the tissue plug for genotyping of each animal.

A prototype of the apparatus is currently available (see figure below). Although designed for mice, the device can be scaled for use with other rodents, pigs, cows, rabbits, sheep or other animals.


32
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34
90
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110
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60

Inventors: Brandon P. Reines (NIAID), Andriy Morgun (NIAID), Natalia Shulzhenko (NIAID), Franklin Sharpnack (ORS), Howard E. Metger (ORS), Jimmie Powell (ORS).

Patent Status: U.S. Provisional Application No. 60/783,209 filed March 16, 2006 (HHS Reference No. E–012–2006/0–US–01).

Licensing Contact: Michael A. Shmilovich. Esq.; 301/435–5019; *shmilovm@mail.nih.gov*.

System and Methods for Detecting and Characterizing Macromolecular Interactions in Solution

Description of Technology: The present invention relates to systems and methods for sensitive detection and characterization of macromolecular interactions in homogenous or heterogeneous solutions of biological and/or synthetic macromolecules. The disclosed method of detection does not require labeling or chemical modification of any test substance, and it is as rapid or more rapid than presently available methods. The system includes a dispenser to dispense a solution containing one or more macromolecular solute components whose concentrations vary with time in a controlled fashion, and two detectors to measure, respectively, the time-dependent static light scattering and composition of the dispensed solution. The composition of solution may be determined from measurements of either UV-visible absorbance or differential refractive index. The light scattering and composition detectors are installed in parallel, so that at any given time point, both detectors collect data from elements of solution of identical composition. High resolution information about the stoichiometry and strength of macromolecular interactions is subsequently obtained by quantitative analysis of the composition dependence of static light scattering. This invention could provide a valuable tool for high-throughput proteomics research.

Inventors: Allen P. Minton *et al.* (NIDDK).

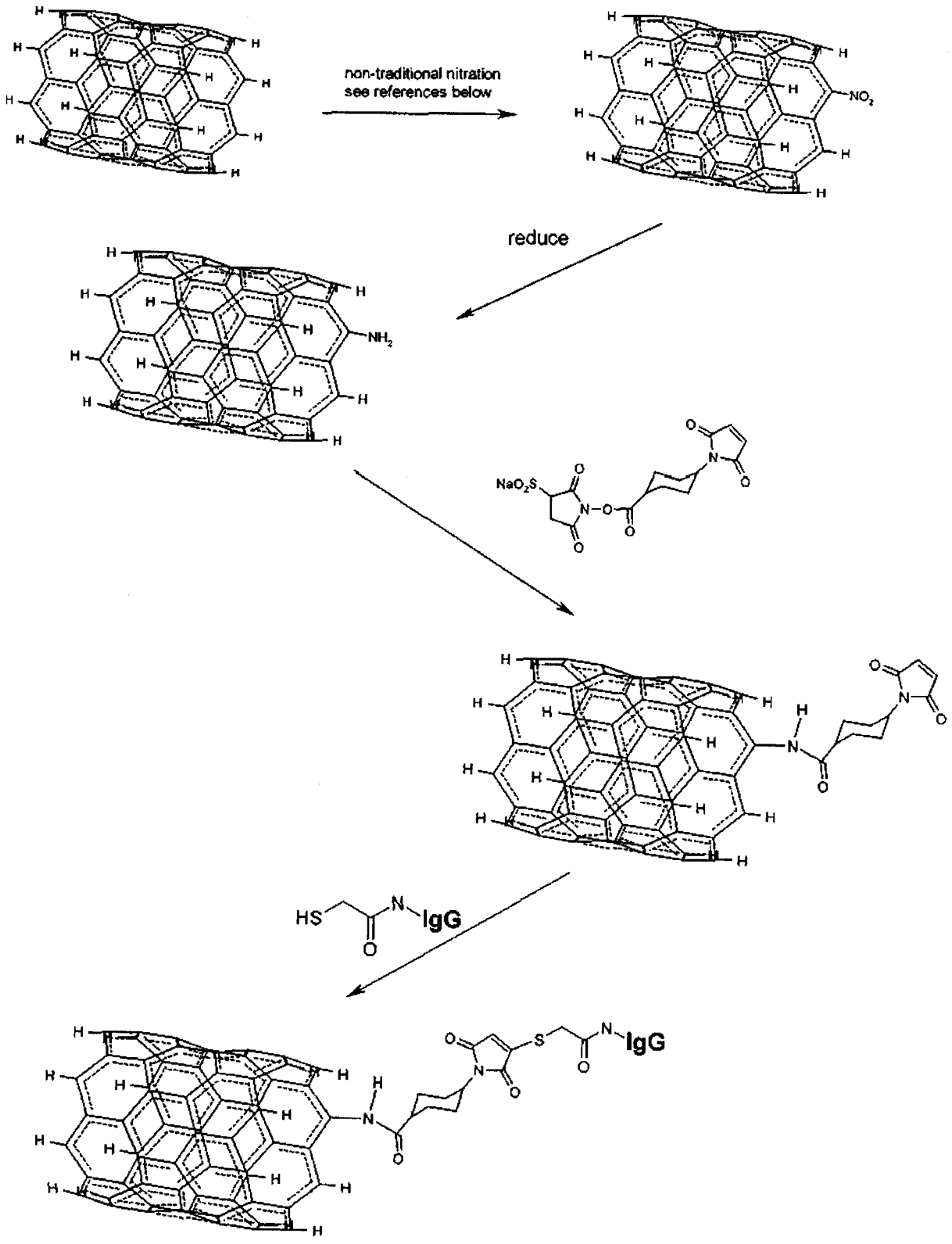
Patent Status: U.S. Provisional Application No. 60/703,814 filed July 28, 2005 (HHS Reference No. E–167–2005/0–US–01).

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

Ultrasonic Waves With Nanovessels or Tethered Nanotube/Monoclonal Antibody Composites for Cancer Therapy

Description of Technology: Available for licensing and commercial development are compositions and their methods of use for delivering therapeutic agents transported on or inside nanostructures to target sites for cancer therapy. Ultrasonic waves are aimed at the therapeutic site and tuned to open nanostructures delivered to the site. Alternately, nanostructures violently exploding by ultrasound may not need to contain additional specific therapeutic agents in order to destroy cells in close proximity to the blast. Therapeutic site-specific cloned antibodies (immunoglobulin (IgG)) or other immunity-based biomolecules are used to carry nanotubes (single wall nanovessels). These are covalently bound to the IgGs, to the sites of interest.

Ultrasound waves with a frequency absorbed by the nanotubes (about 20–40 KHz), are used to explode the carbon nanotubes in proximity to the tumor. The concept of using ultrasound waves to explode carbon nanotubes is analogous to the ultrasonic method that is used to destroy kidney stones. Ultrasound is capable of penetrating deep through tissue without tissue damage because the frequency of the waves can be adjusted to be absorbed only by the target, here carbon, boron-nitride, or other nanostructures. The technique can also be used to deliver substances that are cytotoxic to tumor cells, encapsulated inside the nanostructures. Once the IgG delivers drug-filled nanostructures to the tumor, ultrasonic waves are used to break open the nanostructures and release the tumor toxic substances. In each case, antibodies (immunoglobulins (IgGs)) are used to carry nanotubes specifically to a tumor and ultrasonic waves are used to either explode or break open the nanotubes, destroying the tumor. The covalent attachment of the carbon nanotubes to the antibody will rely on the terminal carbon atoms of each tube. Hydrogen atoms covalently liked to the carbon can be nitrogenated to facilitate later attachment to IgG through a linker:


non-traditional nitration
see references below
reduce
IgG
IgG

Inventors: Jon G. Wilkes (FDA), Dan A. Buzatu (FDA), Dwight W. Miller (FDA), Jerry A. Darsey (Univ Arkansas), Thomas M. Heinze (FDA), Alexandru S. Biris (Univ Arkansas), Mark Diggs (Diggs & Assocs).

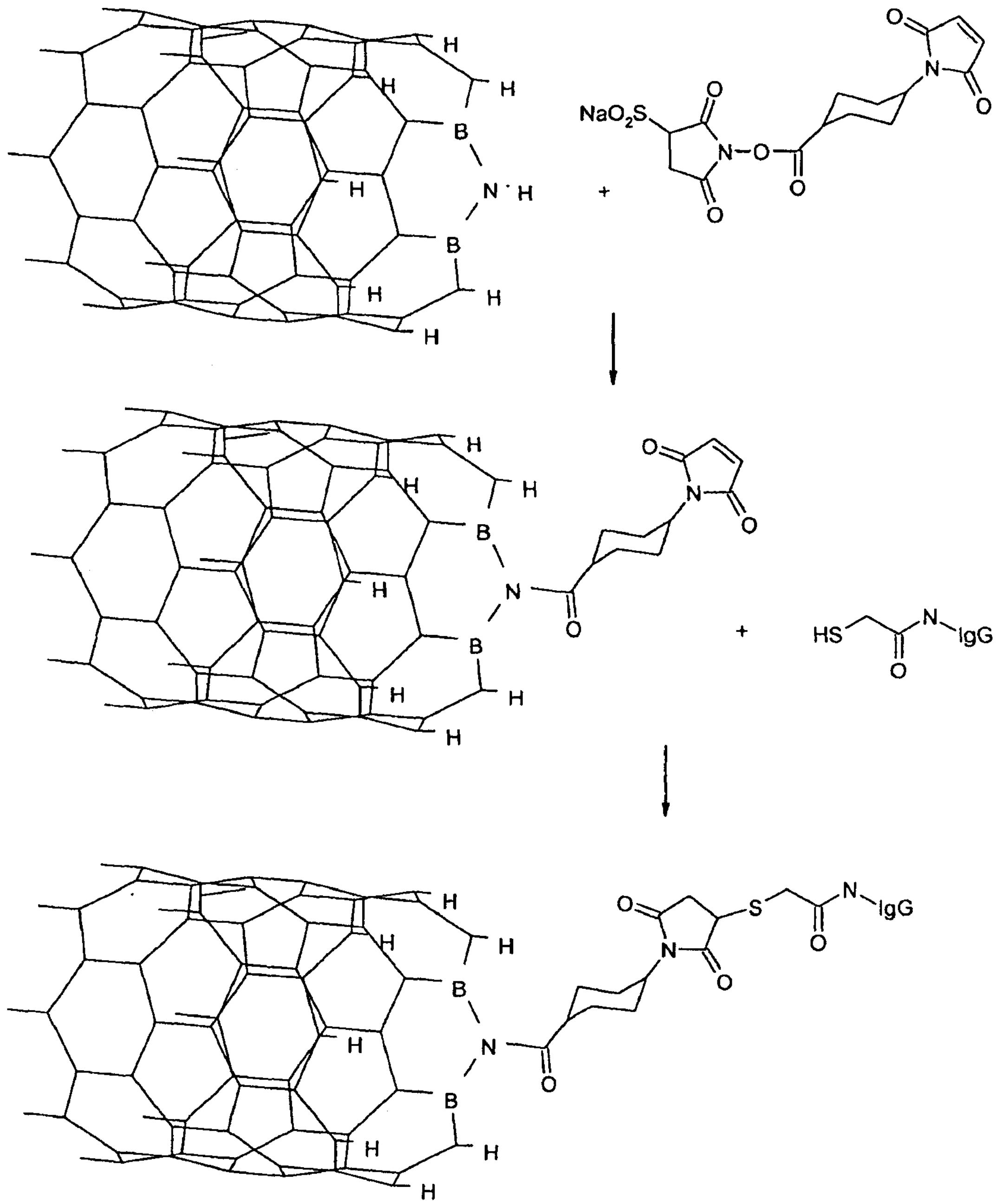
Patent Status: U.S. Patent Application No. 11/005,380 filed December 6, 2004 (HHS Reference No. E–091–2004/0–US–01).

Licensing Status: All licensing inquiries should be directed to Michael McAllister, University of Arkansas at Little Rock, Office of Technology Transfer, 2801 South University Avenue, Little Rock, AR 72204–1099; Phone: 501/569–8658; E-mail: *Jmmccalliste@uaur.edu.*

NIH Contact: Michael A. Shmilovich, Esq.; 301/435–5019; *shmilovm@mail.nih.gov.*

Radio-Activated Boron-Nitride Nanotube-Antibody Conjugates for Cancer Therapy and Diagnostics

Description of Technology: Available for licensing and commercial development is a cancer therapy and diagnostic that utilizes a variation of ''Boron Neutron Capture Therapy'' (BNCT) using radio-activate boron-nitride (BN) nanotubes, covalently bound to tumor-cloned antibodies (immunoglobulins (IgGs)) to deliver intense, short-lived, therapeutic doses of radiation specifically to active tumor sites. The therapy involves activation of the BN nanotubes with a neutron beam (as in BNCT) once the antibody (immunoglobulin (IgG)) carrier molecules reach their target tissue. This invention addresses two important limitations in of present BNCT: (1) The ability to target accurately the tumor tissue, and (2) the amount of radiation, *e.g.*, how many boron atoms can be delivered to the tumor site. Most molecules that are currently used by BNCT can only deliver one or two boron atoms per molecule and do so without cancer cell target specificity. Thus BNCT is only as specific as the columniation of the neutron-activating beam allows. The instant BN nanotubes can deliver significant numbers of boron atoms (100s to 1000s) *specifically* to the tumor site while avoiding exposures to surrounding tissue. BNCT is a technique that relies on (non-radioactive) ^{10}B delivery specifically to a tumor site and then activating it using an accurate beam of epithermal neutrons (low energy neutrons with velocities adjusted to penetrate tissue to the specific tumor depth where the ^{10}B has lodged). BN nanotube structure is similar to the ''rolled-up-graphite'' structure of a carbon nanotube, six member rings but with boron atoms bound to three surrounding nitrogen atoms, and the nitrogen atoms bound to surrounding boron atoms (no conjugation). Thus, each BN nanotube is composed of a substantial number of boron atoms: *e.g.*,—50%, meaning hundreds to thousands for each nanotube. Boron has a relatively large radioactive cross section and can be easily made radioactive in a neutron flux. Radioactive boron is an alpha and gamma emitter with isotopes of 12B and 13B, having gamma energies of 4.439MeV and 3.68MeV, respectively. The covalent attachment of the BN nanotubes to the antibody (Immunoglobulin (IgG)) will rely on the terminal nitrogen atoms of each tube and can be accomplished using the following linker reaction:


H
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N H
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NaO2S
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N-O
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IgG
O
H
H
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IgG
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Inventors: Dan A. Buzatu (FDA), Jon G. Wilkes (FDA), Dwight W. Miller (FDA), Jerry A. Darsey (Univ Arkansas), Thomas M. Heinze (FDA), Alexandru S. Biris (Univ Arkansas), Richard Beger (FDA).

Patent Status: U.S. Patent Application No. 11/005,412 filed December 6, 2004 (HHS Reference No. E–090–2004/0-US–01).

Licensing Status: All licensing inquiries should be directed to Michael McAllister, University of Arkansas at Little Rock, Office of Technology Transfer, 2801 South University Avenue, Little Rock, AR 72204–1099; Phone: 501/569–8658; E-mail: *Jmmccalliste@uaur.edu.*

NIH Contact: Michael A. Shmilovich, Esq.; 301/435–5019; *shmilovm@mail.nih.gov.*

Dated: May 24, 2006.

David R. Sadowski,

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

[FR Doc. 06–5105 Filed 6–2–06; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: GLP-1 Exendin-4 Peptide Analogs and Uses Thereof

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 404.7(a)(1)(i), that the National Institutes of Health (NIH), Department of Health and Human Services, is contemplating the grant of an exclusive license worldwide to practice the invention embodied in U.S. Patent Application Number 10/485,140 filed January 27, 2004, entitled ''GLP-1 Exendrin-4 Peptide Analogs and Uses Thereof,'' to Amylin Pharmaceuticals, Inc., having a place of business in San Diego, CA 92121. The contemplated exclusive license may be limited to use to human therapeutics for diabetes, obesity and cardiovascular disease, as well as neurological and neurodegenerative diseases, disorders and injuries. The United States of America is the assignee of the patent rights in this invention.

DATES: Only written comments and/or application for a license which is received by the NIH Office of Technology Transfer on or before August 4, 2006 will be considered.

ADDRESSES: Request for a copy of the patent, inquires, comments, and other materials relating to the contemplated license should be directed to: Marlene Astor, Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone: 301–435–4426; Facsimile: 301–402–0220; e-mail: *ms482m@nih.gov*.

SUPPLEMENTARY INFORMATION: Type-2 diabetes and neurodegeneration (*e.g.*, Alzheimer's disease, Parkinson's disease, peripheral neuropathy, stroke) are leading causes of death in the United States and worldwide. The present invention pertains to the disclosure of novel peptide analogues of Glucagons-like peptide-1 (GLP-1) and Exendin-4 and their uses in the treatment of (i) diabetes and (ii) neurodegenerative disorders.

Type-2 diabetes is caused by dysfunction of the pancreatic beta cells that may result in concomitant decrease in insulin production. Insulin replacement has been an effective therapy for the treatment of Type-2 diabetes. However, insulin therapy, although life saving, does not restore normal levels of glucose and postprandial levels of glucose continues to be excessively high in individuals on insulin therapy. Further, the therapy may result in adverse effects including hyperglycemia, hypoglycemia, metabolic acidosis and ketosis. Therefore, a better therapeutic formula may be needed that may increase the efficacy of the treatment and minimize the side effects. The present invention discloses a method of treating a subject with diabetes with novel GLP-1/Exendin-4 peptides. These are GLP-1 agonists and elicit insulinotropic actions.

The GLP-1 receptor is additionally found in the brain as well as associated to pancreatic islets cells. Its stimulation in brain has been found to be neurotrophic and neuroprotective in both tissue culture and in vivo against a variety of toxic insults. Peptides of the said invention possess activity in a variety of predictive models of neurodegeneration, and may have potential in a variety of diseases both associated (peripheral neuropathy) and unassociated (Alzheimer's disease, Parkinson's disease, stroke and peripheral neuropathy) with diabetes J. Alz. Dis. 4: 487–96, 2002; J. Pharmacol. Exp. Ther. 300:958–66, 2002 & 302:881–888, 2002.

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 60 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.

Properly filed competing applications for a license filed in response to this notice will be treated as objections to the contemplated license. Comments and objections submitted in response 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 26, 2006.

David R. Sadowski,

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

[FR Doc. E6–8678 Filed 6–2–06; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Co-Exclusive License: Human Monoclonal Antibody, Their Fragments and Derivatives as Biotherapeutics for the Treatment of HIV Infections

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 404.7(a)(1)(i), that the National Institutes of Health (NIH), Department of Health and Human Services, is contemplating the grant of a co-exclusive license to practice the inventions embodied in:

1. U.S. Provisional Patent Application Serial No. S/N 60/378,406, PCT/US03/14905, NIH (DHHS) Ref. No. E–144–2002/1–PCT–02 converted into 03733940.5 (E–144–2002/1–EP–04) filed in Europe on November 25, 2004, and 2003239356 (E–144–2002/1–AU–05) filed in Australia October 29, 2004, 10/512,966 (E–144–2002/1–US–03) filed in USA October 28, 2004, as well as 2485120 (E–144–2002/1–CA–06) filed in Canada May 6, 2003, entitled: ''Identification of Novel Broadly Cross-Reactive Neutralizing Human