Application no.	Drug	Applicant
86–652	Phenobarbital with Belladonna Alkaloids Elixir	Solvay Pharmaceuticals, 901 Sawyer Rd., Marietta, GA 30062.
86–662	Phenobarbital with Belladonna Alkaloids Elixir	Pharmaceutical Associates, P.O. Box 128, Conestee, SC 29636.
87–136	Hydrocortisone Cream, USP, 0.5%, 1%, and 2.5%	Westwood-Squibb Pharmaceuticals, 100 Forest Ave., Buffalo, NY 14213– 1091.
87–200	Aminophylline Injection USP, 25 mg/mL	Fujisawa USA, Inc., 3 Parkway North, 3d Floor, Deerfield, IL 60015–2548.
87–480	Prednisone Tablets, USP, 20 mg	Halsey Drug Co., Inc.
87–802	Dipyridamole Tablets, USP, 25 mg	Do.
87–803	Dipyridamole Tablets, USP, 75 mg	Do.
87–914	Diphenhydramine Hydrochloride Capsules, USP, 50 mg	Do.
88–048	Fluocinolone Acetonide Topical Solution, USP, 0.01%	Pharmaderm, Division of Altana, Inc., 60 Baylis Rd., Melville, NY 11747.
88–192	Triprolidine and Pseudoephedrine Hydrochloride Tablets, USP, 2.5 mg/60 mg.	Halsey Drug Co., Inc.
88–466	Dipyridamole Tablets, USP, 50 mg	Do.
88–662	Chlorpropamide Tablets, USP, 250 mg	Do.
89–218	Hydralazine Hydrochloride Tablets, USP, 10 mg	Do.
89–321	Chlorpropamide Tablets, USP, 100 mg	Do.
89–366	Hydroxyzine Hydrochloride Tablets, USP, 10 mg	Do.
89–396	Hydroxyzine Hydrochloride Tablets, USP, 50 mg	Do.
89–448	Butalbital, Aspirin, and Caffeine Tablets, USP, 50 mg/325 mg/40 mg.	Do.
89–465	Leucovorin Calcium for Injection, 50 mg/vial	Burroughs Wellcome Co.
89–476	Quinidine Gluconate Extended-Release Tablets, USP, 324 mg.	Halsey Drug Co., Inc.
89–738	Chlorthalidone Tablets, USP, 25 mg (Peach)	Mutual Pharmaceutical Co., Inc., 1100 Orthodox St., Philadelphia, PA 19124–3131.
89–739	Chlorthalidone Tablets, USP, 50 mg (Aqua)	Do.
89–833	Leucovorin Calcium for Injection, 25 mg/vial	Burroughs Wellcome Co.

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Drug Evaluation and Research (21 CFR 5.82), approval of the applications listed above, and all amendments and supplements thereto, is hereby withdrawn, effective March 14, 1996.

Dated: January 29, 1996.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 96–3077 Filed 2–12–96; 8:45 am]

BILLING CODE 4160–01–F

National Institutes of Health

National Heart, Lung, and Blood Institute; Opportunity for a Cooperative Research and Development Agreement (CRADA) for the Development of Lymphocyte ADP-Ribosyltransferase and its Corresponding Hydrolase as a Potential Target for Therapeutic Intervention in Diseases of the Immune System

AGENCY: Department of Health and Human Services, National Institutes of Health.

ACTION: Notice.

SUMMARY: The National Heart, Lung, and Blood Institute (NHLBI), of the National Institutes of Health is seeking capability statements from parties interested in entering into a Cooperative Research and Development Agreement (CRADA) on the further characterization of lymphocyte ADP-ribosyltransferase as a potential target for therapeutic intervention in diseases of the immune system. This project is with the National Heart, Lung, and Blood Institute, Division of Intramural Research, Pulmonary-Critical Care Medicine Branch, located in Bethesda, Maryland.

The goal is to use the respective strength of both partners in (1) identifying molecular targets of ADP-ribosylation in lymphocytes and muscle cells, and, (2) evaluating the potential use of this enzyme and its various substrates as targets of novel treatment modalities in certain diseases of the immune system and in hematological, pulmonary, and cardiac diseases.

ADP-ribosylation is a post-translational modification of proteins, in which the ADP-ribose moiety of NAD is transferred to a protein acceptor. In the case of certain bacterial toxins (e.g. pertussis toxin, cholera toxin), ADP-ribosylation modifies hormone action on their human target cells and is the mechanism responsible for toxin action and, in large part, the pathogensis of disease. Human cells have endogenous ADP-ribosylation pathways: the pathways are composed of enzymes that place ADP-ribose on proteins, ADP-ribosyltransferases, which catalyze a reaction similar to the bacterial toxins, and enzymes that remove ADP-ribose, ADP-ribosylarginine hydrolases. Hence, ADP-ribosylation may be reversible, with ADP-ribosyltransferases and ADP-ribosylarginine hydrolases serving as components of a regulatory cycle.

ADP-ribosyltransferases have been found in peripheral blood mononuclear cells and in skeletal and cardiac muscle. These enzymes have been cloned and are identical. The transferases, are linked to the cell surface through glycosylphosphatidylinositol (GPI)-anchors. In the muscle, they ADP-ribosylate the extracellular domain of an integrin and hence may participate in the regulation of cell-matrix interactions. Other data suggest that ADP-ribosylation may be involved in the regulation of cytotoxic lymphocyte activity. The cell surface location of the transferases may facilitate their specific targeting by chemotherapeutic agents. In particular, they may be targeted in diseases where lymphocytes are readily

accessible (e.g., lymphocytic alveolitis amenable to inhalation therapy).

It is anticipated that the commercial collaborator will participate in ongoing studies to determine whether modifying ADP-ribosyltransferase activity and cell surface ADP-ribosylation can affect the immune system (e.g., mononuclear cell function) and cardiac skeletal and muscle function, and hence the progression of some hematological, pulmonary, cardiac, and musculoskeletal diseases. It is expected that the collaborator will assist in the development of specific inhibitors. These would be focussed on the structure of known NAD-binding sites that participate in ADP-ribosylation reactions, taking into account the facts that a cell surface enzyme is being targeted and the enzyme is preferentially located on lymphocytes, and cardiac and skeletal muscle. In diseases of the pulmonary system characterized by lymphocytic infiltration, one route for selective targeting of the transferase may involve the use of inhalation therapies that minimize systemic toxicity. Collaborator may also be expected to contribute funding for supplies and personnel to support this project. The NHLBI has applied for patents, both domestic and foreign, claiming this core technology. Non-exclusive and/or exclusive licenses for these patents covering core aspects of this project are available to interested parties.

Capability statements should be submitted to: Ms. Lili M. Portilla, Technology Transfer Specialist, National Institutes of Health, National Heart, Lung, and Blood Institute, Technology Transfer and Commercialization Team, 31 Center Drive MSC 2490, Room 31/5A48 Bethesda, MD 20892–2490. Capability statements must be received by NHLBI 30 days after date of publication in the Federal Register.

Dated: February 1, 1996

Claude Lenfant,

Director, NHLBI.

[FR Doc. 96–3179 Filed 2–12–96; 8:45 am]

BILLING CODE 4140–01–M

Government-Owned Inventions; Notice of Availability for Licensing

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

ACTION: Notice.

SUMMARY: The invention listed below is owned by the Department of Health and Human Services and is 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.

U.S. Patent 4,405,712, issued on September 20, 1983 and entitled ''LTR Vectors''—This patent broadly claims processes of obtaining the expression of any gene via the use of retroviral expression vectors containing long terminal repeat (LTR) sequences. The processes claimed in this patent are of fundamental significance for the retroviral mediated expression of genes *in vitro* for research and biopharmaceutical production and *in vivo* for research, biopharmaceutical production, and therapeutic applications such as somatic cell gene therapy. The invention claimed in this patent is available for licensing on a nonexclusive basis.

Favorable licensing terms will be offered to companies filing a license application within three months of the publication of this notice. After that deadline May 13, 1996, licensing fees will be increased.

ADDRESSES: Licensing information may be obtained by writing to: George H. Keller, Ph.D., Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804 (telephone 301/496–7057; fax: 301/402–0220).

Dated: February 5, 1996.

Barbara M. McGarey,

Deputy Director, Office of Technology Transfer.

[FR Doc. 96–3182 Filed 2–12–96; 8:45 am]

BILLING CODE 4140–01–M

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

The inventions listed below are owned by agencies 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 U.S. 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 specialist 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.

Antipsychotic Composition and Method for Treatment

Pickar, D., Litman, R.E., Potter, W.Z. (NIMH)
Filed 7 Jun 95
Serial No. 08/479,039 (CIP of 07/987,728)
Licensing Contact: Stephen Finley, 301/496–7735 ext 215

This invention comprises a novel treatment method for patients suffering from serious psychotic mental illness that offers to significantly improve the treatment of such illnesses. Conventional antipsychotic drugs are effective in improving symptoms of schizophrenia, but a significant number of patients have proven resistant to such treatments. Recently, the drug clozapine has been found effective in treating such drug-resistant patients; however, clozapine has severe toxic side effects. This newly developed treatment method, which combines the use of an α_2-adrenergic receptor antagonist with a standard antipsychotic drug, is effective in treating psychosis without serious side effects. It is especially effective in patients who previously had been resistant to treatment with standard antipsychotic drugs alone. (portfolio: Central Nervous System—Therapeutics, psychotherapeutics, antipsychotics)

Amino Acid Sequencing Peptides and Methods for Their Use

Parmelee, D.C., Sechi, S. (NCI)
Filed 6 Feb 95
Serial No. 08/384,212 (DIV of 07/920,130)
Licensing Contact: J. Peter Kim, 301/496–7056 ext 264

The present invention provides a novel internal standard for amino acid sequencing which consist of a peptide containing at least two different unnatural amino acid residues, such as ornithine, norvaline, norleucine and α-aminobutyric acid. The PTH-derivatives of these have retention times distinct from those of natural amino acids. This peptide can be sequenced simultaneously with an unknown peptide or protein without interfering with the analysis. Simultaneous sequencing of this standard provides information which allows for the determination of repetitive yields, lags, N-terminal blockage and discrimination between blank cycles caused by missed injection and blank cycles caused by faulty delivery of chemicals during the sequencing reactions. (portfolio: Gene-