

web http user interface. COEV interfaces with flat data file databases.

Under the present proposal, the goal of the CRADA will be:

- Improve portability to other operating system environments.
- Provide interactivity with a variety of database structures.
- Design and implement functions for data cleaning.
- Identify target concepts for machine learning.
- Expand and improve user interfaces.
- Design and execute all components of a commercial COEV product.
- Prepare and execute COEV marketing plan.

Party Contributions

The role of the LHNBCB in the collaboration will include:

(1) Provide Collaborator with the COEV prototype system design and code and with all available information necessary for further development of the COEV system.

(2) Provide COEV developer expertise and LHNBCB, NLM expertise in advanced machine learning systems engineering and in computer applications to chemical informatics, molecular biology and pharmaceutical chemistry.

(3) Provide ongoing input to and evaluation of collaborator project designs and work product.

The role of the Collaborator in the collaboration will include:

(1) Provide expertise, staff, work space, equipment and materials for COEV product development tasks to include project management, design, coding, technical and user testing and technical and user documentation development.

(2) Provide expertise, staff, work space, equipment and materials for COEV product marketing tasks to include marketing management, market analysis, product design advice, product packaging, promotion and sales, distribution and technical and user client support.

(3) Provide funding, if and as necessary, for COEV product development and COEV marketing tasks as described above.

Selection Criteria

Proposals submitted for consideration should address each of the following qualifications.

(1) Expertise

A. Demonstrated expertise in translating highly sophisticated statistical or machine learning technology prototypes into successful commercial products.

B. Demonstrated expertise in data mining, data warehousing and data visualization technology, preferably as related to the fields of biomedical science, medical care or public health.

C. Demonstrated intellectual abilities; able to understand and transform cutting-edge computer-based technology into commercial applications.

D. Demonstrated expertise in project design, project management and development of successful commercial software products.

E. Demonstrated ability to market sophisticated software products in national and international markets.

F. Demonstrated expertise and established resources for serving and supporting a substantial national and international client base.

(2) Reputation

The successful Collaborator must be recognized in the software industry for:

A. Producing, marketing and supporting software for data mining, data warehousing, data visualization or related applications;

B. High levels of satisfaction among end-users and client technical support staffs for both product performance and product support;

C. Success in the marketplace with an established range of successful software products and services.

(3) Physical Resources

A. Established headquarters with sufficient offices, space and equipment to support a level of effort as defined in the CRADA with LHNBCB.

B. Ability to communicate and collaborate by telephone, mail, e-mail, Internet, and other evolving technologies.

C. Sufficient financial and technical resources to support a level of effort as defined in the CRADA with LHNBCB.

Dated: December 23, 1997.

Kathleen Sybert,

Acting Director, Office of Technology Development, National Cancer Institute, National Institutes of Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: 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 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.

Hexadecasaccharide-Protein Conjugate Vaccine for *Shigella Dysenteria* Type 1

V Pozsgay, JB Robbins, R Schneerson (NICHHD)

Serial No. 60/052,869 filed 17 Jul 97

Licensing Contact: Robert Benson, 301/496-7056, ext. 267.

This invention is a conjugate vaccine to prevent infection by *Shigella dysenteria* type 1, a human pathogen which causes endemic and epidemic dysentery worldwide. The conjugate is the first one in which the polysaccharide antigen has been chemically synthesized and thus has a known structure. The polysaccharide has a structure resembling the O-specific polysaccharide portion of the lipopolysaccharide of *Shigella dysenteria* type 1. It is expected that the purity of the polysaccharide will lead to lessened side effects and greater immunogenicity. Mice immunized with the conjugate of the invention produced antibodies reactive with the O-specific polysaccharide isolated from *Shigella dysenteria* type 1. Synthesis of the hexadecasaccharide is described in the *Journal of the American Chemical Society*, June 28, 1995, pp. 6673-6681.

Cloning of a Gene Mutation for Parkinson's Disease

MH Polymeropoulos, C Lavedan (NHGRI)

Serial No. 60/050, 684 filed 25 June 97

Licensing Contact: Stephen Finley, 301/496-7056 ext. 215.

Parkinson's Disease (PD) affects between 500,000 to one million persons in the United States alone. The disease is most common in persons over the age

of 70. However, one form of PD appears to be hereditary and is probably responsible for early on-set PD, wherein the symptoms occur before the age of 60. The newly discovered gene mutation appears to be linked to the early on-set form of PD. The mutation, a threonine for alanine substitution, at amino acid position 53 of the human alpha-synuclein protein effects the secondary structure of the protein and causes an aggregation of Lewy bodies in the brain. This new mutation is considered to be a valuable tool in predicting a person's susceptibility to early on-set PD. Assays developed from this mutation can also be used for diagnostic purposes.

Non-Nucleoside Inhibitors of Reverse Transcriptase

C Michejda, M Morningstar, T Roth (NCI)

Serial No. 60/038,509 filed 25 Feb 97

Licensing Contact: J. Peter Kim, 301/496-7056 ext. 264.

The present invention is related to non-nucleoside inhibitors of reverse transcriptase comprising a novel class of substituted benzimidazole compounds which are potentially effective in the inhibition of HIV RT and potentially against other infections. The present invention provides for methods for treating HIV infection utilizing a compound having anti-reverse transcriptase activity, wherein said compound comprises at least one substituted benzimidazole. This technology may present a potent, non-toxic compound which is effective against wild type RTs and RTs which have undergone mutations and become resistant to currently used anti-HIV therapies.

Enhanced Suppression of HIV-1 by the Combination of Cytidine Dideoxynucleoside Analogues and CTP Synthase Inhibitors

W-Y Gao, DG Johns, H. Mitsuya, V Marquez (NCI)

Serial No. 60/033,918 filed 21 Jan 97

Licensing Contract: J. Peter Kim, 301/496-7056 ext. 264.

The present invention provides for compositions and methods to increase the activity of cytidine-based anti-HIV drugs and to overcome resistance of human immunodeficiency virus (HIV) to cytidine-based anti-HIV drugs. More specifically, the invention provides for composition, methods of preventing or inhibiting the spread of a virus, methods of treatment, and methods of improving the antiviral activity of a cytidine dideoxynucleoside analogue drug in patients with viral infection. Typical

drugs suitable for potentiation by this method include ddC, 3TC, D4C (2', 3'-dideoxycytidine-2', 3'-ene), 5-fluoroddC, and 3'- α -fluoroddC. The virus may be HIV-2, HTLV-1, HTLV-2, SIV, HBV, but most preferably HIV-1.

Interferon-Inducible Protein 10 is a Potent Inhibitor of Angiogenesis

G Tosato, AL Angiolillo, C Sgardari (FDA)

Serial No. 08/455,079 filed 31 May 95

Licensing Contact: Jaconda Wagner, 301/496-7735 ext. 284.

Human Interferon inducible protein 10 (IP-10) is a member of the chemokine family of molecules. It is a secreted protein with a molecular weight of approximately 8.6 kD. Previous work has demonstrated that IP-10 exhibits various activities, including the inhibition of colony formation by bone marrow hematopoietic cell, exertion of an antitumor effect, and function as a chemoattractant. In addition, this work shows that IP-10 is a potent inhibitor of angiogenesis. Unbalanced angiogenesis is thought to contribute to the pathogenesis of several diseases including arthritis, psoriasis, hemangiomas, diabetic retinopathy, and retrolental fibroplasia. Therefore, IP-10 may be very useful alone or in combination with other treatments to prevent unbalanced angiogenesis.

This research has been published in Proc. Natl. Acad. Sci. USA 1996 Nov 26;93(24):13791-6 and J. Exp. Med. 1995 Jul 1;182(1):155-62.

A related case is also available for licensing: Serial No. 08/850,914 filed 02 May 97 entitled "Method of Promoting Tumor Necrosis Using Mig"; inventors are G Tosato (FDA), J Farber (NIAID), and C Sgardari (FDA).

Dominant Negative Deletion Mutants of C-Jun and Their Use in the Prevention and Treatment of Cancer

NH Colburn, Z Dong, PH Brown, MJ Birrer (NCI)

Serial No. 08/213,433 filed 10 Mar 94

Licensing Contact: Ken Hemby, 301/496-7735 ext. 265.

A number of mutants of the c-jun oncogene have been developed, which may be particularly useful in the prevention and treatment of cancer. Numerous studies have shown that tumor promotion is a long-term process that is partially reversible and that requires chronic exposure to a tumor promoter, and that subsequent progression of tumors through invasive and metastatic stages is also a long term process. In recent years, numerous

cellular oncogenes have been implicated in the transactivation of genes associated with cellular growth and differentiation. One such cellular oncogene, c-jun, encodes a phosphoprotein that is a component of the dimeric transcriptional activator AP-1 along with c-Fos or other Jun or Fos Family proto-oncoproteins. Several genes that may be involved in tumor promotion or progression have been shown to be dependent on AP-1 transactivation, including collagenase and stromelysin (transin). AP-1 inhibiting dominant negative detection mutants of the c-jun gene have been developed that, when given to a mammal, may prevent or reverse carcinogenesis during early or late stages. For the treatment of cancer, a deletion mutant of the c-jun gene or the protein product may inhibit the elevated AP-1 transactivation that frequently characterizes tumor progression and may consequently prevent or reverse the development or further progression of tumors. This invention also includes a method for determining whether a tumor promoter induces transformation via a pathway that depends on induction or elevation of AP-1 transcriptional activity and AP-1 target gene expression.

Dated: December 23, 1997.

Barbara M. McGarey,
Deputy Director, Office of Technology Transfer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Institute of Environmental Health Sciences National Toxicology Program; Announcement of Nominated Chemicals Under Consideration for Toxicological Studies by the National Toxicology Program (NTP)—Recommendations by the Interagency Committee for Chemical Evaluation and Coordination (ICCEC)—Request for Comments

Background

As part of an effort to earlier inform and obtain public input into the selection of chemicals for evaluation, the National Toxicology Program (NTP) routinely seeks public input on (1) chemicals nominated to the Program for toxicological studies, and (2) the testing recommendations made by the Interagency Committee for Chemical Evaluation and Coordination (ICCEC).