

Thereon and Methods of Use Thereof"; USP SN: 4,892,827, entitled, "Recombinant *Pseudomonas* Exotoxin: Construction of an Active Immunotoxin with Low Side Effects"—excluding any foreign equivalents corresponding to 4,892,827 (= USSN 06/911,227); USP SN: 5,747,654, entitled, "Recombinant Disulfide-Stabilized Polypeptide Fragments Having Binding Specificity"; USPA SN: 09/002,753, entitled: "Recombinant Disulfide-Stabilized Polypeptide Fragments Having Binding Specificity"; USP SN: 6,051,435, entitled: "Recombinant Antibody-Toxin Fusion Protein"; USPN 5,863,745, entitled: Recombinant Antibody-Toxin Fusion Protein; USPN 5,696,237, entitled: "Recombinant Antibody-Toxin Fusion Protein" and corresponding foreign patent applications to IVAX Corporation having an address in Miami, Florida. The United States of America is an assignee of the patent rights in these inventions and the contemplated exclusive license may be limited to the use of TGF-Alpha-PE38 and MR-1-1(dsFv)-PE38KDEL [= Anti-EGFRvIII (dsFv)-PE38KDEL] based immunotoxins as an *In vitro* diagnostic and therapeutic modality for the treatment of human brain tumors.

**DATES:** Only written comments and/or applications for a license which are received by NIH on or before November 6, 2000 will be considered.

**ADDRESSES:** Requests for copies of the patent applications, inquiries, comments and other materials relating to this contemplated exclusive licenses should be directed to: J. R. Dixon, Ph.D., Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804. Telephone: (301) 496-7735 ext. 206; Facsimile: (301) 402-0220, E-Mail: DixonJ@OD.NIH.GOV. A signed Confidentiality Agreement will be required to receive copies of any patent applications.

**SUPPLEMENTARY INFORMATION:** The technology is directed to the use of TGF-Alpha-PE38 and MR-1-1(dsFv)-PE38KDEL [= Anti-EGFRvIII(dsFv)-PE38KDEL] based immunotoxins as an *in vitro* diagnostic and therapeutic modality for the treatment of human brain 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 sixty (60) days from the date of this published notice, NIH receives written evidence and argument that establishes that the grant

of the exclusive license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

Applications for a license [*i.e.*, completed "Application for License to Public Health Service Inventions"] in the field of use of TGF-Alpha-PE38 and MR-1-1(dsFv)-PE38KDEL [= Anti-EGFRvIII(dsFv)-PE38KDEL] based immunotoxins as an *in vitro* diagnostic and therapeutic modality for the treatment of human brain tumors filed in response to this notice will be treated as objections to the grant of the contemplated exclusive license. Comments and objections will not be made available for public inspection and, to the extent permitted by law, will not be subject to disclosure under the Freedom of Information Act, 5 U.S.C. 552.

Dated: August 30, 2000.

**Jack Spiegel,**

*Director, Division of Technology Development and Transfer, Office of Technology Transfer.*

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**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Principles for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Request for Comments

**AGENCY:** National Institutes of Health (NIH), Public Health Service, DHHS.

**ACTION:** Notice.

*Introduction:* On December 23, 1999, the National Institutes of Health (NIH) published in the **Federal Register** its final notice of a policy entitled Sharing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts [64 FR 72090]. The policy is designed to provide recipients of NIH funding with guidance concerning appropriate terms for disseminating and acquiring unique research resources developed with federal funds and assist recipients in complying with their obligations under the Bayh-Dole Act and NIH funding policy. This Notice is to obtain public comment on experience realized in implementing the Principles and Guidelines.

*Purpose:* The subject policy document set forth fundamental principles and guidelines for implementation by patenting and licensing professionals and sponsored research administrators. The intent of the document is to assist

Recipients in ensuring that the conditions they impose and accept on the transfer of research tools will facilitate further biomedical research, consistent with the requirements of the Bayh-Dole Act and NIH funding agreements.

*Request for Comments:* NIH is seeking comments from NIH recipients, academic, not-for-profit, government, and private sector participants (both individuals and institutions or organizations) in biomedical research and development on their experience in implementing and utilizing the Principles and Guidelines included in the subject document. It is the intent of the NIH to use the comments and anecdotal information received from Recipients throughout this first year of implementation to provide the basis for a report to the Advisory Council to the Director, NIH.

Respondents should provide their views on the value of the NIH document and their experience in implementing the document within their institution and with other entities when providing or receiving research tools. We would appreciate receiving information as to the issues or situations encountered, the effect on operations or research, any specific terms or actions in the Guidelines and/or in institution/company documents that were found to be of assistance or problematic, and the name or type of organizations involved (educational institution, for-profit, etc.). Comments offered in confidence should be marked as such.

Comments should be addressed to: Research Tools Guidelines Project, Theodore J. Roumel, NIH Office of Technology Transfer, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804. Comments may also be sent by facsimile transmission to Research Tools Guidelines Project, Attention: Theodore J. Roumel, at 301-402-3257, or by e-mail to [nihott@od.nih.gov](mailto:nihott@od.nih.gov).

**DATES:** Comments must be received by NIH on or before October 12, 2000.

Dated: August 29, 2000.

**Maria C. Freire,**

*Director, Office of Technology Transfer, National Institutes of Health.*

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