

**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 to practice the invention embodied in:

(1) U.S. Patent No. 6,194,390, issued Feb. 27, 2001, entitled "Procedure to block the replication of reverse transcriptase dependent viruses by the use of inhibitors of deoxynucleotides synthesis" (E-157-1993/7);

(2) U.S. Patent No. 6,046,175, issued April 4, 2000, entitled "Procedure to block the replication of reverse transcriptase dependent viruses by the use of inhibitors of deoxynucleotides synthesis" (E-157-1993/1);

(3) U.S. Patent No. 6,093,702, issued July 25, 2000, entitled "Mixtures of dideoxynucleosides and hydroxycarbamide for inhibiting retroviral spread" (E-157-1993/4);

(4) U.S. Patent No. 5,736,526, issued April 7, 1998, entitled "Mixtures of DDI and D4T with hydroxycarbamide for inhibiting retroviral replication" (E-157-1993/5);

(5) U.S. Patent No. 5,521,161, issued May 28, 1996, entitled "Method of treating HIV in humans by administration of ddI and hydroxycarbamide" (E-157-1993/2);

(6) U.S. Patent No. 5,736,527, issued April 08, 1998, entitled "Method of treating HIV in humans by administration of ddI and hydroxycarbamide" (E-157-1993/6);

(7) PCT/US94/05515 filed May 17, 1994, entitled "Procedure to block the replication of reverse transcriptase dependent viruses by the use of inhibitors of deoxynucleotides synthesis" (E-157-1993/1), National Stage filed May 17, 1994: in Canada application No. 2163456, in EPO application No. 94918016.0, in Japan application No. 518466/94, in Australia Patent No. 685128, issued April 30, 1998;

(8) PCT/US95/00153 filed Dec. 20, 1994, entitled "Method of treating HIV in humans by administration of ddI and hydroxycarbamide" (E-157-1993/2), National Stage filed Dec. 20, 1994: in Canada Patent No. 2179627, issued Feb. 22, 2000, in EPO Patent No. 0735890, issued April 17, 2002, in South Africa Patent No. 94/9219, issued Oct. 25, 1995, in Taiwan Patent No. NI-080011, issued Dec. 03, 1996, in Australia Patent No. 718325, issued July 27, 2000, OAIPO Patent Application No. 60849, in Brazil patent application No. PI1100041-4, in Mexico patent

application No. 9409706 to Research Institute for Genetic and Human Therapy (RIGHT), having a place of business in Washington, DC. The patent rights in these inventions have been assigned to the United States of America.

**DATES:** Only written comments and/or application for a license, which are received by the NIH Office of Technology Transfer on or before June 17, 2003 will be considered.

**ADDRESSES:** Requests for a copy of the patent application, inquiries, comments and other materials relating to the contemplated license should be directed to: Sally Hu, Ph.D., M.B.A., Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; E-mail: [hush@od.nih.gov](mailto:hush@od.nih.gov); Telephone: (301) 435-5606; Facsimile: (301) 402-0220.

**SUPPLEMENTARY INFORMATION:** 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, 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.

The subject inventions provide for formulations and methods for inhibiting replication of reverse transcription dependent viruses in animals cells comprising administering a compound that depletes the intracellular pool of deoxyribonucleoside phosphate (e.g. hydroxyurea), and further comprising administering a compound that serves to inhibit replication of the virus by terminating DNA chain elongation (e.g. DDI).

The field of use may be limited to development of drugs of hydroxyurea alone and in combination with dNTP competitors for blocking reverse transcriptase dependent viruses, including HIV.

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: April 10, 2003.

**Steven M. Ferguson,**

*Acting 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****Public Health Service****National Toxicology Program**

The National Toxicology Program (NTP) Center for the Evaluation of Risks to Human Reproduction (CERHR) Announces the Future Evaluations of Fluoxetine Hydrochloride (Prozac®; Sarafem™, CAS RN 54910-89-3) and Acrylamide (CAS RN 79-06-1), Requests Public Comments on These Chemicals, and Solicits the Nominations of Scientists Qualified to Serve on Expert Panels Evaluating Fluoxetine Hydrochloride and Acrylamide.

**Summary:** The CERHR plans to conduct an expert panel evaluation of fluoxetine hydrochloride and a separate expert panel evaluation of acrylamide. The exact dates for these expert panel meetings are not yet set, but the meetings are tentatively planned for 2003 and early 2004. Fluoxetine hydrochloride will be evaluated first. Additional details about the meetings, including the dates and locations, will be published in future **Federal Register** notices and posted on the NTP Web site (<http://ntp-server.niehs.nih.gov>).

The CERHR will convene expert panels to evaluate the reproductive and developmental toxicities of fluoxetine hydrochloride and acrylamide. For each of these meetings, the expert panel will consist of approximately 12 scientists, selected for their scientific expertise in various aspects of reproductive and developmental toxicology and other relevant areas of science. The expert panel meetings will be open to the public with time scheduled for oral public comment.

**Evaluation of Fluoxetine Hydrochloride**

Fluoxetine hydrochloride (Prozac®; Sarafem™; CAS RN 54910-89-3), an antidepressant, is a widely prescribed drug in the United States. The CERHR selected fluoxetine hydrochloride for evaluation because of (1) numerous reproductive and developmental studies in laboratory animals and humans, (2) human exposure information, and (3) changing prescription patterns. Fluoxetine hydrochloride, under the name Sarafem™, is now being