

DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health
Prospective Grant of Exclusive License: Treating and Preventing Inflammatory Bowel Disease (IBD) Involving Interleukin-13 (IL-13) and Natural Killer T (NKT) Cells

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 Part 404.7(a)(1)(i), that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to practice the inventions embodied in PCT Patent Application No. PCT/US02/18790, filed June 14, 2002, which published as WO 2004/001655 on December 31, 2003, now expired, entitled "Method of Treating and Preventing Colitis Involving IL-13 and NK-T Cells" [HHS Ref. No. E-131-2002/0-PCT-01]; U.S. Patent Application No. 10/517,898, filed December 13, 2004, which was published as US-2006-0024306 A1 on February 2, 2006, entitled "A Method of Treating Inflammatory Bowel Disease (IBD)" [HHS Ref. No. E-131-2002/0-US-02]; European Patent Application No. 02742057.9, filed June 14, 2002, which published as 1552462 on July 13, 2005, entitled "Method of Treating and Preventing Colitis Involving IL-13 and NK-T Cells" [HHS Ref. No. E-131-2002/0-EP-08]; Australian Patent Application No. 2002315115, filed June 14, 2002, entitled "Method of Treating and Preventing Colitis Involving IL-13 and NK-T Cells" [HHS Ref. No. E-131-2002/0-AU-05]; Japanese Patent Application No. 2004515561, filed June 14, 2002, entitled "Method of Treating and Preventing Colitis Involving IL-13 and NK-T Cells" [HHS Ref. No. E-131-2002/0-JP-04]; New Zealand Patent Application No. 537726, filed June 14, 2002, entitled "Method of Treating and Preventing Colitis Involving IL-13 and NK-T Cells" [HHS Ref. No. E-131-2002/0-NZ-06]; Hong Kong Patent Application No. 05112119.6, filed June 14, 2002, entitled "Method of Treating and Preventing Colitis Involving IL-13 and NK-T Cells" [HHS Ref. No. E-131-2002/0-HK-09]; South African Patent Application No. 2005/00375, filed June 14, 2002, entitled "Method of Treating and Preventing Colitis Involving IL-13 and NK-T Cells" [HHS Ref. No. E-131-2002/0-ZA-07]; Canadian Patent Application No. 2489540, filed June 14,

2002, entitled "Method of Treating and Preventing Colitis Involving IL-13 and NK-T Cells" [HHS Ref. No. E-131-2002/0-CA-03]; U.S. Provisional Patent Application No. 60/671,624, filed April 15, 2005, now abandoned, entitled "Treatment and prevention of IBD using Mutant and Chimeric IL-13 Molecules" [HHS Ref. No. E-003-2005/0-US-01]; PCT Patent Application No. PCT/US06/014393, filed April 14, 2006, now expired, entitled "Methods of Treating and Preventing Inflammatory Bowel Disease Involving IL-13 and NKT Cells," which published as WO 2006/113614 on October 20, 2006 [HHS Ref. No. E-003-2005/0-PCT-02]; European Patent Application No. 06750435.7, filed November 12, 2007, entitled "Methods of Treating and Preventing Inflammatory Bowel Disease Involving IL-13 and NKT Cells," which published as 1877074 on January 16, 2008, [HHS Ref. No. E-003-2005/0-EP-04]; and U.S. Patent Application No. 11/918,711, filed April 14, 2006, entitled "Treatment and Prevention of Inflammatory Bowel Disease (IBD) Using Mutant and Chimeric IL-13 Molecules" [HHS Ref. No. E-003-2005/0-US-03] to Innate Immune, Inc. which has an office in Stanford, California, U.S.A. The patent rights in these inventions have been assigned to the United States of America and Brigham and Women's Hospital.

The prospective exclusive license territory may be "worldwide", and the field of use may be limited to "the use of agents that modulate Natural Killer T cell (NKT cell) activity and/or NKT cell number a) by interaction with antigen-presenting cells expressing CD1d family of proteins, and/or b) by interaction with NKT cell receptors that bind to antigen-presenting cells expressing CD1d family of proteins, as therapeutics for the treatment or prevention of inflammatory bowel disease (IBD), including ulcerative colitis and Crohn's disease."

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before June 29, 2009 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive license should be directed to: Suryanarayana (Sury) Vepa, Ph.D., J.D., Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-5020; Facsimile: (301) 402-0220; E-mail: vepas@mail.nih.gov.

SUPPLEMENTARY INFORMATION: The subject technology is directed to methods of treating inflammatory bowel disease (IBD), more specifically Ulcerative Colitis (UC). The inventors of this technology have used a mouse model of experimental colitis (OC) to show that Interleukin (IL)-13, a Th2 cytokine, is a significant pathologic factor in OC and that neutralizing IL-13 in these animals effectively prevents colitis (Immunity (2002) 17, 629-638). The subject technology provides for methods of treating UC by reducing NKT cell activity. This reduction in NKT cell activity can be accomplished by inhibition of the cytokine IL-13 or its receptor, IL-13R, or through modulation of another NKT cell surface receptor, such as the T-cell receptor. The T-cell receptor is activated by the glycoprotein, CD1d, which is expressed on the surface of antigen-presenting cells.

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, 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.

Applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive license. Comments and objections submitted 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 23, 2009.

Richard U. Rodriguez,
Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Substance Abuse and Mental Health Services Administration
Request for Comment on Minimum Requirements for Criteria in Grant Applications Under the National All Schedules Prescription Electronic Reporting Act of 2005 (NASPER)

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.