been assigned to the United States of America.

The prospective exclusive license territory will be worldwide and the field of use may be limited to herpesvirus vectors encoding MART–1 and/or gp100 for use as immunotherapeutic vaccines against melanoma in humans, and specifically excluding the use of MART–1 and/or gp100 in any other manner or form.

DATES: Only written comments and/or license applications which are received by the National Institutes of Health on or before October 12, 2001 will be considered.

ADDRESSES: Requests for copies of the patent/patent applications, inquiries, comments and other materials relating to the contemplated exclusive license should be directed to: Elaine White, M.B.A., Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD. 20852–3804; Telephone: (301) 496–7056, x282; Facsimile (301) 402–0220; E-mail eg46t@nih.gov.

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 sixty (60) days from the date of this published notice, the NIH receives written evidence and argument that establish 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: August 3, 2001.

Jack Spiegel,

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

[FR Doc. 01–20194 Filed 8–10–01; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Antibodies and Other Ligands Directed Against KIR2DL4 Receptor For Production of Interferon Gamma

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

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: United States Patent Application 60/242,419 entitled ''Antibodies and Other Ligands Directed Against KIR2DL4 Receptor For Production of Interferon Gamma'' filed on October 23, 2000, to InterMune, Inc., having a place of business in Brisbane, California. The patent rights in this invention 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 October 12, 2001 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: Peter Soukas, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Email: ps193c@nih.gov; Telephone: (301) 496–7056, ext. 268; Facsimile: (301) 402–0220.

SUPPLEMENTARY INFORMATION: This invention concerns the natural production of interferon gamma by the stimulation of the KIR2DL4 receptor by an antibody or other ligand. Human natural killer (NK) cells express several killer cell immunoglobulin (Ig)-like receptors (KIRs) that inhibit their cytotoxicity upon recognition of human histocompatibility leukocyte antigen (HLA) class I molecules on target cells. Unlike other HLA class I-specific KIRs, which are clonally distributed on NK cells, KIR2DL4 is expressed at the surface of all NK cells. This invention may be used to treat infections and cancer.

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 field of use may be limited to therapy and prevention of human diseases.

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: August 2, 2001.

Jack Spiegel,

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

[FR Doc. 01–20192 Filed 8–10–01; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Melanoma Antigens and Their Use in Diagnostic and Therapeutic Methods, and Identification of TRP–2 as a New Human Tumor Antigen Recognized by Cytotoxic T Lymphocytes

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

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, Department of Health and Human Services, is contemplating the grant of an exclusive license to practice the inventions embodied in U.S. Patent Applications S/N 08/231,565, filed on April 22, 1994, and now U.S. Patent 5,874,560, which issued on February 23, 1999; S/N 08/417,174, filed on April 5, 1995, and now U.S. Patent 5,844,075; S/N 09/007,961, filed on January 16, 1998, and now U.S. Patent 5,994,523, issued November 30, 1999; S/N 09/073,138, filed on May 5, 1998; and S/N 09/267,439, filed on March 12, 1999, all entitled ''Melanoma Antigens and Their Use in Diagnostic and Therapeutic Methods' and U.S. Patent Applications S/N 08/725,736, filed on October 4, 1996, and now U.S. Patent 5,831,016 which issued on November 3, 1998; S/N 09/161,877 (DIV of 08/725,736), filed on September 28,

1998, and now U.S. Patent 6,132,980 which issued on October 17, 2000; S/N 09/162,368 (DIV of 08/725,736), filed on September 28, 1998, and now U.S. Patent 6,083,703 which issued on July 4, 2000; and S/N 09/651,210 (DIV of 08/725,736), filed on August 30, 2000, all entitled ''Identification of TRP–2 as a New Human Tumor Antigen Recognized by Cytotoxic T Lymphocytes' and PCT Patent Application PCT/US97/02186 (based upon U.S. Patent Applications S/N 08/599,602 and 08/725,736) filed on February 6, 1997, entitled ''Human Cancer Antigen of Tyrosinase-Related Protein 1 and 2 and Genes Encoding Same'', to Mojave Therapeutics, Inc. of Tarrytown, New York. The patent rights in these inventions have been assigned to the United States of America.

The prospective exclusive license territory will be worldwide and the field of use may be limited to gp100 and/or TRP–2 peptides, proteins, glycoproteins, and/or polynucleotides which are covalently or non-covalently bound to heat shock proteins for use as immunotherapeutic vaccines against melanoma in humans, and specifically excluding the use of gp100 and/or TRP–2 in any other manner or form.

DATES: Only written comments and/or license applications which are received by the National Institutes of Health on or before October 12, 2001 will be considered.

ADDRESSES: Requests for copies of the patent/patent applications, inquiries, comments and other materials relating to the contemplated exclusive license should be directed to: Elaine White, M.B.A., Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD. 20852–3804; Telephone: (301) 496–7056, x282; Facsimile (301) 402–0220; E-mail eg46t@nih.gov.

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 sixty (60) days from the date of this published notice, the NIH receives written evidence and argument that establish 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: August 2, 2001.

Jack Spiegel,

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

[FR Doc. 01–20195 Filed 8–10–01; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of Biotechnology Activities Recombinant DNA Research: Proposed Actions Under the NIH Guidelines

AGENCY: National Institutes of Health (NIH), PHS, DHHS.

ACTION: Notice of proposed actions under the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines).

SUMMARY: The NIH is proposing to amend Appendix B–I of the NIH Guidelines to establish criteria for designating strains of *E. coli* as risk group 1 agents.

DATES: The public is encouraged to submit written comments on the proposed change. Comments may be submitted to the NIH Office of Biotechnology Activities (OBA) in paper or electronic form. Comments received on or before September 12, 2001 will be considered by NIH. All comments received in response to this notice will be available for public inspection in the NIH OBA office, 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892–7985, 301–496–9838, weekdays between the hours of 8:30 a.m. and 5 p.m.

FOR FURTHER INFORMATION CONTACT: If you have questions, or want additional information about these proposed changes, please contact OBA by e-mail at *oba@od.nih.gov,* or telephone at 301–496–9838. Comments can be submitted to the same e-mail address, by fax to 301–496–9839, or mail to the Office of Biotechnology Activities address set forth above.

SUPPLEMENTARY INFORMATION: The University of Florida has asked OBA to set the risk group level for strain B of the common bacterium *E. coli,* which is non-virulent. Strain B is widely used in industry for large-scale work (greater than 10 liters of culture) due to increased stability of cloned sequences in this strain versus *E. coli* K–12. Currently, the only non-virulent strain of *E. coli* designated as a risk group 1 agent (agents not associated with disease in healthy adult humans) in the NIH Guidelines is strain K–12. Potentially pathogenic strains of E. coli are designated as risk group 2 agents in the NIH Guidelines.

At the March 2001 RAC meeting, a recommendation was made to define the criteria for designating strains of *E. coli* as risk group 1 agents. The establishment of general criteria is preferable to narrowly addressing a single strain. The suggested criteria were: ''(1) they [the *E. coli* strain] carry deletions in metabolic genes to engender the requirement for specialized laboratory media; and (2) they do not pose a threat of disease: they do not carry any active virulence markers nor do they make any toxins (nor do they carry the genes for these toxins).''

Following the March 2001 meeting, the University of Florida Institutional Biosafety Committee responded that the investigator, Dr. Luli (Adjunct Professor in Microbiology and Cell Science at the University of Florida and also Research Director for BC International Corp.), who made the initial request had reservations regarding the requirement for deletions in metabolic genes. Dr. Luli stated that the use of specialized laboratory media would pose a problem for large-scale, industrial work. Dr. Luli suggested that instead of an absolute requirement for specialized laboratory media, that the ''* * * scope of the [first] requirement be broadened to simply demonstrate ''crippled'' or adversely affected metabolism.'' The rationale for this modification is that the strains of *E. coli* B that Dr. Luli proposes to use have reduced growth rates compared to wild type *E. coli* even in complete, rich laboratory media.

The proposed criteria for designating an *E. coli* strain as a risk group 1 agent were revisited at the June 2001 RAC meeting. *Ad hoc* consultant, Dr. James Kaper, University of Maryland School of Medicine, also participated in the RAC review and discussion. During the June meeting discussion, it was pointed out that a growth requirement is not a current criteria in the NIH Guidelines for designation of *E. coli* K–12 as a risk group 1 agent. Accordingly, the criteria for designating strains of *E. coli* as risk group 1 agents were revised as follows: ''(1) they [the *E. coli* strain] do not possess a complete lipopolysaccharide (i.e., they lack the O antigen and have a ''rough'' colony morphology); and (2) they do not carry any active virulence factors—such as—toxin, or colonization factors nor do they carry genes for these factors.'' A ''rough'' colony morphology is indicative of the absence of a