E–017–2003 ''Pattern Recognition of Whole Cell Mass Spectra''

This invention analyzes mass spectra (MALDI, SELDI) from a plurality of microorganism sources and biological agents. The invention is useful for diagnosing disease, anticipating epidemic outbreaks, monitoring food supplies for contamination, regulating bio-processing operations, and is especially useful for detecting agents of war. The invention dramatically improves spectral analysis through deconvolution of complex spectra by collapsing multiple peaks showing different molecular mass originating from the same molecular fragment into a single peak. The differences in molecular mass are apparent differences caused by different charge states of the fragment and/or different metal ion adducts of one or more of the charge states. The deconvoluted spectrum is compared to a library of mass spectra acquired from samples of known identity to unambiguously determine the identity of one or more components of the sample undergoing analysis.

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

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: December 14, 2005.

Steven M. Ferguson,

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

[FR Doc. E5–8133 Filed 12–29–05; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Implants for Sustained Ocular Therapeutic Agent Delivery

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 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 worldwide license to practice the invention embodied in E–241–1999/0, ''Ocular Therapeutic Agent Delivery Devices And Methods For Making And Using Such Devices;'' U.S. Patent 6,713,081 issued March 30, 2004 and expires March 15, 2021; U.S. Patent Application 10/471,468 filed September 12, 2004; and European Patent Application 02723446.7 filed March 14, 2002; to Lux Biosciences, a Delaware corporation having a principle place of business in Jersey City, New Jersey. The United States of America is the assignee of the patent rights of the above inventions.

The contemplated exclusive license may be granted in the field of ocular cyclosporine A delivery for the treatment of graft-versus-host-disease-associated dry eye and Sjögren's Syndrome.

DATES: Only written comments and/or applications for a license received by the NIH Office of Technology Transfer on or before February 28, 2006 will be considered.

ADDRESSES: Requests for a copy of the patent applications, inquiries, comments and other materials relating to the contemplated license should be directed to: Michael A. Shmilovich, Esq., Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone: (301) 435–5019; Facsimile: (301) 402–0220; E-mail: *shmilovm@mail.nih.gov*. A signed confidentiality nondisclosure agreement may be required to receive copies of the patent applications.

SUPPLEMENTARY INFORMATION: The patent applications intended for licensure disclose and/or cover the following: E–241–1999/0, ''Ocular Therapeutic Agent Delivery Devices And Methods For Making And Using Such Devices.'' The invention is a method and apparatus for delivering a precisely controlled amount of drug to the eye on a sustained basis using an implantable polymer cylinder containing a drug pellet. In this method, the thickness of the polymer around the drug pellet is precisely controlled to provide a predictable release rate of the drug to the eye. Drug pellets made using a modified press are placed in a teflon tube having a silicone base, the top of the tube is filled with wet silicone and the pellet is spun down and centered in the teflon tubing. The teflon tubing is removed and the top and bottom ends of the silicone cylinder surrounding the pellet are trimmed. Thus, an annulus of uniform thickness surrounds the drug pellet, resulting in a uniform and predictable release rate. The invention also comprises a method, apparatus and implant design developed for surgical subconjunctival implantation to deliver an initial bolus of drug to the eye compartments followed by slow release of drug from the polymer matrix of the implant. A pellet of drug (e.g., cyclosporine) is imbedded between two saucer or disk shaped polyvinyl alcohol (PVA) components, forming a ''wafer'' shaped implant. The drug is also mixed into the matrix of the PVA itself at a nominal 10% concentration. Soon after implantation, a high level of drug is delivered to the eye for the first month and, thereafter, the embedded pellet sustains a continuous release of the drug.

The invention has also been described along with preclinical data in a recent publication by Kim *et al.* (2005) IOVS 46(2):655–662, ''Preclinical Evaluation of a Novel Episcleral Cyclosporine Implant for Ocular Graft-Versus-Host Disease.''

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

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: December 21, 2005.

Steven M. Ferguson,

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

[FR Doc. E5–8120 Filed 12–29–05; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Fusion Proteins Comprising Circularly Permuted Ligands

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 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 United States Patent No. 4,892,827, issued on January 9, 1990, entitled ''Recombinant Pseudomonas Exotoxin: Construction Of An Active Immunotoxin With Low Side Effects'' [E–385–1986/0–US–01]; U.S. Patent No. 5,635,599, issued on June 3, 1997, entitled ''Fusion Proteins Comprising Circularly Permuted Ligands'' [E–047–1994/0–US–01]; PCT Patent Application No. PCT/US95/04468, filed April 6, 1995, entitled ''Fusion Proteins Comprising Circularly Permuted Ligands'' [E–047–1994/0–PCT–02]; Switzerland Patent No. 0754192, issued on January 29, 2003, entitled ''Fusion Proteins Comprising Circularly Permuted Ligands'' [E–047–1994/0–CH–03]; Spain Patent No. 0754192, issued on January 29, 2003, entitled ''Fusion Proteins Comprising Circularly Permuted Ligands'' [E–047–1994/0–ES–04]; United Kingdom Patent No. 0754192, issued on January 29, 2003, entitled ''Fusion Proteins Comprising Circularly Permuted Ligands'' [E–047–1994/0–GB–05]; Italy Patent No. 0754192, issued on January 29, 2003, entitled ''Fusion Proteins Comprising Circularly Permuted Ligands'' [E–047–1994/0–IT–06]; Luxembourg Patent No. 0754192, issued on January 29, 2003, entitled ''Fusion Proteins Comprising Circularly Permuted Ligands'' [E–047–1994/0–LU–07]; Netherlands Patent No. 0754192, issued on January 29, 2003, entitled ''Fusion Proteins Comprising Circularly Permuted Ligands'' [E–047–1994/0–NL–09]; German Patent No. 0754192, issued on January 29, 2003, entitled ''Fusion Proteins Comprising Circularly Permuted Ligands'' [E–047–1994/0–DE–10]; Austria Patent No. 0754192, issued on January 29, 2003, entitled ''Fusion Proteins Comprising Circularly Permuted Ligands'' [E–047–1994/0–AT–11]; Australia Patent No. 694211, issued on November 5, 1998, entitled ''Fusion Proteins Comprising Circularly Permuted Ligands'' [E–047–1994/0–AU–12]; Belgium Patent No. 0754192, issued on January 29, 2003, entitled ''Fusion Proteins Comprising Circularly Permuted Ligands'' [E–047–1994/0–BE–13]; Canada Patent No. 2187283, filed on April 6, 1995, entitled ''Fusion Proteins Comprising Circularly Permuted Ligands'' [E–047–1994/0–CA–14]; European Patent No. 0754192, issued on January 29, 2003, entitled ''Fusion Proteins Comprising Circularly Permuted Ligands'' [E–047–1994/0–EP–15]; France Patent No. 0754192, issued on January 29, 2003, entitled ''Fusion Proteins Comprising Circularly Permuted Ligands'' [E–047–1994/0–FR–16]; Ireland Patent No. 0754192, issued on January 29, 2003, entitled ''Fusion Proteins Comprising Circularly Permuted Ligands'' [E–047–1994/0–IE–17]; Liechtenstein Patent No. 0754192, issued on January 29, 2003, entitled ''Fusion Proteins Comprising Circularly Permuted Ligands'' [E–047–1994/0–LI–18]; and U.S. Patent No. 6,011,002, issued on January 4, 2000, entitled ''Circularly Permutated Ligands And Circularly Permuted Chimeric Molecules'' [E–047–1994/1–US–01] to Protox Therapeutics, Inc., which has offices in Vancouver, British Columbia, Canada. The patent rights in these inventions have been assigned to the United States of America.

The prospective exclusive license territory may be worldwide, and the field of use may be limited to the use of Interleukin-4/cytotoxin fusion proteins for the treatment of cancer.

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before February 28, 2006 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: Jesse S. Kindra, J.D., M.S., Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone: (301) 435–5559; Facsimile: (301) 402–0220; E-mail: *kindraj@mail.nih.gov.*

SUPPLEMENTARY INFORMATION: The technology relates to circularly permuted ligands having the ability to change the conformation of certain proteins so that they can be more effectively used as therapeutics. Specifically, growth factors such as IL–4 can be used in fusion proteins to target cell surface receptors. Accordingly, these growth factors can be used, when linked with cytotoxic moieties (i.e., Pseudomonas Exotoxin), to target and then kill desired cells. These circularly permuted molecules are advantageous over prior molecules in that they allow greater binding specificity of an immunotoxin to the targeted cell. This change in conformation is a result of the production of new carboxyl and amino termini. The new termini are located away from the active binding site and hence cause less steric hindrance between the active site and the fused protein. Hence, the targeting moiety is closer to its native conformation. Without such a conformational change, binding specificity for the immunotoxin is greatly reduced. Therefore, these circularly permuted molecules allow for greater binding specificity without retarding the cytotoxicity of the toxin to which they are bound.

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: December 14, 2005.

Steven M. Ferguson,

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

[FR Doc. E5–8131 Filed 12–29–05; 8:45 am]

BILLING CODE 4140–01–P