

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.

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 22, 2005.

Steven M. Ferguson,

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

[FR Doc. E5-8139 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: Software for Predicting Molecular Properties and Pathogen Detection

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-169-2000/0 "Drift Compensation Method for Fingerprint Spectra," U.S. Patent Application No. 09/975,530 filed October 10, 2001; E-297-2001/0 "Methods For Predicting Properties of Molecules," U.S. Patent Application No. 10/383,602 filed March 7, 2003; and E-017-2003/0 "Improved Pattern Recognition Of Whole Cell Mass Spectra Via Separation Of Specific Charge States," U.S. Patent Application No. 10/863,745 filed June 7, 2004; to Litmus, LLC an Arkansas corporation having its headquarters in Little Rock, Arkansas. 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 providing software solutions for pathogen detection and for predicting molecular properties.

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-297-2001 "Methods For Predicting Properties of Molecules" Quantitative Spectral data-activity relationships (QSDAR)

The invention relates to methods for predicting the biological, chemical, and physical properties of molecules from their chemical shift through bond and through spatial distance connectivity patterns. This invention is related to E-209-1999 (related to the SDAR patent that could use chemical shift through bond correlated data); however, here predicted NMR chemical shift data is used that has already been *structurally assigned*. The invention uses the carbon or other heteronuclear molecular skeleton atom to atom connectivity of the molecule instead of proton to proton or proton to carbon connectivity that can be obtained from NMR experimental spectra of unlabeled molecules. This allows a model to be built using a complete molecular connectivity pattern instead of a pattern developed from a set of individual 2 or 3 atom pieces of a molecule. A 2D through bond connectivity spectrum is produced with a cross peak bin "hit" occurring when there is an atom to atom bond connection. Only half of the spectrum is used because the spectrum is symmetrical. A 2D through space connectivity spectrum is simulated is produced with a cross peak bin "hit" occurring when there is a atom to atom distance r is within a certain specified range.

The through bond and through space spectra can be reduced to principal

components. The biological, chemical, and physical endpoints are added to the connectivity patterns and multiple linear regression (OVLS) or artificial neural networks (ANN) methods are applied to produce and validate the model. This provides a very rapid, reliable ability to model many different compounds. The model uses the structurally assigned chemical shifts from predicted NMR spectra. The through bond and through space connectivity patterns uses the structural assignment of the chemical shifts. The through bond connectivity pattern gives a local description of the atoms and the through space connectivity pattern gives a non-local description of the atoms. The combination of the through bond and through space molecular connectivity pattern provides a very precise pattern that can be used by pattern recognition software to produce a model. All parts of this model can be completely computerized. The ideas used in this model may be able to produce the highest cross-validated models of "endpoints" that are important to the public health service.

E-169-2000 "Microbial Identification Databases"

The invention is a method for, based on an assembled coherent database, containing an essentially unlimited number of pyrolysis mass spectra to enable rapid chemotaxonomy of unknown microbial samples. The invention corrects for short- and long-term drift of microbial pyrolysis mass spectra by using spectra of similar microbes as internal standards. The invention provides a way to assemble a coherent database containing an essentially unlimited number of pyrolysis mass spectra or other instrumental "fingerprints," where one or more is representative of each relevant strain, and representative of additional strains as they are added to the pool of microbial agents. Microorganisms can be identified using the invention from their fingerprint spectra regardless of the growth medium used to culture the bacteria. This is a result of the discovery that corrections made to the fingerprint spectrum of one type of bacterium to compensate for changes in growth medium may be applied successfully to metabolically similar bacteria. Fingerprint spectra to which the method of the invention may be applied include pyrolysis MALDI or other types of mass spectra, infrared spectra, chromatograms, NMR spectra and ion-mobility spectra. The present invention is especially useful for the rapid identification of microorganisms, including human pathogens.

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.

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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."

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