

the diagnostic classification of cancers based on gene expression profiling data derived from cDNA microarrays. The ANNs were first trained to be used as models, and then correctly classified all samples tested and identified the genes most relevant to the classification. Their study demonstrated the potential applications of these methods for tumor diagnosis and for the identification of candidate targets for therapy. The uniqueness of this method is taking gene expression data generated by microarrays, minimizing the genes from the original 1000s to less than 100, identifying which genes are the most relevant to a classification, which gives an immediate clue to the actual biological processes involved, not just surrogate markers which have no bearing on the biology.

The field of use may be limited to "FDA Cleared Pediatric Cancer Diagnostics and Prognostics".

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 20, 2007.

**Steven M. Ferguson,**

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

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**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Prospective Grant of Exclusive License: Method for Determining the Redox Status of a Tissue

**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 license to practice the inventions embodied in: PCT Application No. PCT/US2006/031208 (E-258-2005/0-PCT-02) filed August 10, 2006 claiming priority to U.S. Provisional Application No. 60/707,518 (E-258-2005/0-US-01), titled "Method for Determining the

Redox Status of a Tissue" (Inventors: Dr James Mitchell *et al.*) to Mitos Pharmaceutical, Inc. (hereafter Mitos), having a place of business in Newport Beach, California. 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 October 29, 2007 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: Chekesha Clingman, PhD, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; e-mail: [clingmac@mail.nih.gov](mailto:clingmac@mail.nih.gov); Telephone: (301) 435-5018; Facsimile: (301) 402-0220.

**SUPPLEMENTARY INFORMATION:** The present invention relates to a method of determining the redox status of tissues by administering a cell-permeable nitroxide, such as 4-hydroxy-2,2,6,6-tetramethylpiperidine-1-oxyl (or Tempol), as a contrast agent and employing magnetic resonance imaging (MRI). Also provided by the invention are a method for diagnosing a tumor and other pathologies associated with oxidative stress and a method for determining a cancer treatment protocol. Tumor tissues exhibit viable but hypoxic regions that allow them to reduce nitroxide compounds more efficiently than normal tissue. The paramagnetic relaxivity of nitroxide compounds makes it possible to use standard MRI scanners to determine the redox status of tissue in vivo. By determining the redox status of a tumor it is possible to not only diagnose a tumor due to its enhanced reduction of intracellular nitroxide contrast agent, but also to determine appropriate radiation treatment fields spatially to deliver therapeutic doses of radiation, and to determine appropriate timing sequences after the administration of a nitroxide contrast agent such that the maximum difference between normal and tumor tissue with respect to the radioprotective form of the nitroxide is present in the normal tissue, thereby limiting collateral damage to the normal tissue.

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 methods for determining the redox status of tissues by utilizing nitroxide contrast agents in combination with MRI for diagnosis of cancer and other pathologies.

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 20, 2007.

**Steven M. Ferguson,**

*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

### National Institutes of Health

#### Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies (GWAS)

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

#### Background

The NIH is interested in advancing genome-wide association studies (GWAS) to identify common genetic factors that influence health and disease. For the purposes of this policy, a genome-wide association study is defined as any study of genetic variation across the entire human genome that is designed to identify genetic associations with observable traits (such as blood pressure or weight), or the presence or absence of a disease or condition.<sup>1</sup> Whole genome information, when combined with clinical and other phenotype data, offers the potential for increased understanding of basic biological processes affecting human health, improvement in the prediction of disease and patient care, and

<sup>1</sup> To meet the definition of a GWAS, the density of genetic markers and the extent of linkage disequilibrium should be sufficient to capture (by the  $r^2$  parameter) a large proportion of the common variation in the genome of the population under study, and the number of samples (in a case-control or trio design) should provide sufficient power to detect variants of modest effect.