



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive Patent License: Magnetic Resonance Imaging system and method for the measurement of geometric features of axons (including without limitation diameter, radius, perimeter, volume, surface and angle) for the characterization and diagnosis of Central Nervous System diseases and disorders

AGENCY: National Institutes of Health, HHS.

ACTION: Notice

SUMMARY: The *Eunice Kennedy Shriver* National Institute for Child Health and Human Development (NICHD), an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to Brainvivo Ltd. (Brainvivo), located in Tel Aviv, Israel, to practice the inventions embodied in the patent applications listed in the Supplementary Information section of this notice.

DATES: Only written comments and/or complete applications for a license which are received by the NCI Technology Transfer Center on or before [INSERT DATE 15 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER] will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, and comments relating to the contemplated Exclusive Patent License should be directed to: Surekha Vathyam, Ph.D., Senior Technology Transfer Manager, NCI Technology Transfer Center, 9609 Medical Center Drive, RM 1E530 MSC 9702, Bethesda, MD 20892-9702 (for business mail), Rockville, MD 20850-9702 Telephone: (240)-276-5530; E-mail: vathyams@mail.nih.gov.

SUPPLEMENTARY INFORMATION:

The following represents the intellectual property to be licensed under the prospective agreement:

- United States Provisional Patent Application No. 60/485,658, filed July 8, 2003, titled "Diffusion Tensor and Q-Space MRI Specimen Characterization" [HHS Reference No. E-079-2003/0-US-01], status: expired;

- United States Provisional Patent Application No. 60/571,064, filed May 14, 2004, titled “Diffusion Tensor and Q-Space MRI Specimen Characterization” [HHS Reference No. E-079-2003/0-US-04], status: expired;
- United States Patent Application No. 10/888,917, filed July 8, 2004, titled “Diffusion Tensor and Q-Space MRI Specimen Characterization” [HHS Reference No. E-079-2003/0-US-02], status: issued as Patent No. 7,643,863;
- International Patent Application No. PCT/US2004/22027, July 8, 2004, titled “Diffusion Tensor and Q-Space MRI Specimen Characterization” [HHS Reference No. E-079-2003/0-PCT-03], status: expired; and
- United States Patent Application No. 12/114,713, filed May 2, 2008, titled “Non-Invasive *in vivo* MRI Axon Diameter Measurement Methods” [HHS Reference No. E-079-2003/1-US-01], status: issued as Patent No. 8,380,280.

With respect to persons who have an obligation to assign their right, title and interest to the Government of the United States of America, the patent rights in these inventions have been assigned to the Government of the United States of America.

The prospective Exclusive Patent License territory may be worldwide for the following field of use:

“Magnetic Resonance Imaging system and method for the measurement of geometric features of axons (including without limitation diameter, radius, perimeter, volume, surface and angle) for the characterization and diagnosis of Central Nervous System diseases and disorders.”

A non-invasive, painless means for measuring axon diameter distribution (ADD) is disclosed in the intellectual property to be licensed, which has significance for imaging of the central nervous system, and for *in vivo* measurement of microanatomical (histological) features of nerves that are critically important in medicine, particularly, in neuroscience. ADD is altered in abnormal development (possibly even in autism), in degenerative process (e.g., aging, alcoholism, Alzheimer’s disease) and diseases such as ALS (Lou Gehrig’s disease). The invention provides a painless way to measure microanatomical features previously measurable using invasive histological means requiring biopsy.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective Exclusive

Patent License will be royalty bearing and may be granted unless within fifteen (15) days from the date of this published notice, the National Cancer Institute 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 part 404.

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a completed license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this Notice must be complete and in acceptable form by the expiration date of this Notice to be considered for a license. License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information in these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 USC 552.

Dated: March 7, 2018.

Richard U. Rodriguez,
Associate Director
Technology Transfer Center
National Cancer Institute

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