STATEMENT OF CONSIDERATIONS

REQUEST BY INVENTOR FOR THE WAIVER OF DOMESTIC AND FOREIGN RIGHTS TO AN IDENTIFIED INVENTION ENTITLED "METHOD FOR ANALYZING MITOCHONDRIAL MYOPATHIES USING NANOLASER SPECTROSCOPY" DEVELOPED UNDER DOE CONTRACT NO. DE-AC04-94AL8500; DOE INVENTION DISCLOSURE NO. S-111,180; DOE WAIVER NO. W(I) 2008-005.

The Petitioner, Paul L. Gourley (co-Inventor), has requested a waiver of the Government's domestic and foreign patent rights in a subject invention entitled "Method for Analyzing Mitochondrial Myopathies using Nanolaser Spectroscopy." The invention was conceived by the co-Inventor while an employee of the Sandia Corporation (Sandia). Sandia is the M&O contractor for the Sandia National Laboratories (SNL), a government-owned, contractor-operated (GOCO) facility, subject to DOE contract number DE-AC04-94AL8500 at the time the invention was made. The other co-Inventor will not be seeking any rights.

The subject invention relates to detection of diseases in cells by measurement of biological particles such a mitochondrial myopathies using nanolaser spectroscopy. The invention utilizes a biocavity laser and the natural optics of cells to gain insight into the cell itself. SNL, in writing, supports the Inventor's request for title of this invention.

This invention was developed under a Laboratory-directed research and development (LDRD) award. Federal expenditures in this subject invention were approximately $50,000. In order to preserve possible patent rights, a patent application will be filed by the Petitioner, at his own personal cost. No further program funding for or related to this technology has been approved nor is anticipated. On the other hand, Petitioner shall spend his own funds to commercialize and further develop this invention should he be granted title. Petitioner will also expend such sums as may be required to obtain and maintain the necessary patent protection as well as provide incentive for commercial development of the invention.

This technology is not export controlled. Furthermore, the technology does not apply to the Naval Nuclear Propulsion Program or to the nuclear weapons programs or other nuclear or atomic energy defense activities of DOE.

Petitioner has agreed to abide by 35 U.S.C. §§ 202, 203 and 204. Petitioner (co-Inventor), as part of this petition, has agreed to the provisions of the U.S. Competitiveness Clause, which reads as follows: "The Petitioner agrees that any product embodying any waived invention or produced through the use of any waived invention will be manufactured substantially in the United States, unless Petitioner can show to the satisfaction of DOE that it is not commercially feasible to do so. In the event DOE agrees to foreign manufacture, there will be a requirement that the Government's support of the technology be recognized in some appropriate manner, e.g., recoupment of

Government investment, etc." Furthermore, Petitioner has agreed to make this condition binding on any assignee or licensee. Petitioner will also abide by the Export Control laws and will require its licensees, if any, to do the same.

Granting the waiver is the only way to promote prompt commercial utilization and development of this invention. Petitioner Paul L. Gourley is a Distinguished Member of the Technical Staff in Biomolecular Materials and Interfaces Department at Sandia National Laboratories, and has considerable experience in this technology field, including multiple patents and scientific papers. Gourley is a nationally and internationally recognized scientist and the recipient of many awards from DOE, scientific and technological societies, and industrial organizations. Petitioner Paul L. Gourley has experience with other technical ventures, including spinning off semiconductor laser technology he invented to MODE (later EMCORE). He intends to develop and market this and other health care-related technologies. The other co-Inventor, Robert K. Naviaux, was an independent collaborator and will not be seeking any rights. He is also an Associate Professor of Medicine and Pediatrics at the University of California, San Diego. He is founder and co-director of the Mitochondrial and Metabolic Disease Center (MMDC) at UCSD. The Petitioners' interest in obtaining title and actively seeking commercialization sufficiently satisfies DOE/NNSA's technology transfer mission without the need to expend additional funds.

New biotechnologies are being introduced to the market place at a very fast pace. Advances in this technological field can become obsolete within months. Based on this, it is not foreseen that the grant of this specific waiver would in any way cause a decrease in competition, cause an undesirable market concentration, nor place Petitioner in a dominant market position.

As such, upon evaluation of the Waiver Petition and in view of the objectives and considerations set forth in 10 CFR 784, all of which have been considered, it is recommended that the requested waiver be granted.

[redacted]

Arthur N Trausch
Patent Attorney, NNSA

Based on the foregoing Statement of Considerations and the representations of the attached Waiver Petition, it is determined that the interests of the United States and the general public will best be served by a waiver of patent rights of the scope described above and, therefore, the waiver is granted.

CONCURRENCE: [redacted]

Dan Sanchez
LDRD Program Manager
Sandia Site Office
National Nuclear Security Administration

Date: 6/19/08

APPROVAL: [redacted]

Paul A. Gottlieb
Assistant General Counsel
For Technology Transfer and
Intellectual Property (GC-62)

Date: 7-28-08