

## STATEMENT OF CONSIDERATIONS

REQUEST BY INVENTOR FOR THE WAIVER OF DOMESTIC AND FOREIGN RIGHTS TO AN IDENTIFIED INVENTION ENTITLED "LASER APPARATUS AND METHOD FOR MICROSCOPIC AND SPECTROSCOPIC ANALYSIS AND PROCESSING OF BIOLOGICAL CELLS" USP 5,608,519, DEVELOPED UNDER DOE CONTRACT NO. DE-AC04-94AL85000; DOE INVENTION DISCLOSURE NO. S-81,512 (SD-5444); DOE WAIVER NO. W(I) 2011-004; rv3

The Petitioner, Paul L. Gourley (co-Inventor), has requested a waiver of the Government's undivided one-half interest in domestic and foreign patent rights in a subject invention entitled "Laser Apparatus and Method for Microscopic and Spectroscopic Analysis and Processing of Biological Cells." The invention was conceived by the Petitioner 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-AC04-94AL85000 at the time the invention was made. The other co-Inventor, Dr Mark F Gourley, brother of Paul Gourley, was, to DOE's knowledge, not under obligation to DOE in the other undivided one-half interest. This waiver, accordingly, relates only to a waiver of DOE's rights to the undivided interest of co-inventor Paul L. Gourley.

The subject invention relates to detection of diseases in cells by measurement of biological particles such as mitochondrial myopathies using nanolaser spectroscopy. The invention utilizes a biocavity laser and the natural optics of cells to gain insight into the cell itself. Sandia rescinded its election and disclaimed right, title and interest in this invention under I-90(d)(1) of its contract with DOE. Furthermore, Sandia in an Authorization to DOE dated April 28, 2010, supports the Inventor's request for title of this invention.

This invention was initially conceived by both Paul Gourley and Mark Gourley without any government funding. It was developed by Paul Gourley under a SNL Laboratory-Directed Research and Development (LDRD) award. Federal expenditures in this subject invention were approximately \$300,000. A Notice of Election to retain title was filed by SNL and approved by DOE on June 2, 1995. In order to preserve patent rights, a patent application was filed by Sandia Corp on March 20, 1995, and issued on March 4, 1997 as US Patent 5,608,519. There is no USPTO recorded assignment of invention from either inventor to SNL, and thus there is no assignment on the face of the patent. No further program funding, other than approximately \$5750 paid in US Patent Maintenance Fees by SNL, for or related to this technology has been approved nor is anticipated. On the other hand, Petitioner, since leaving SNL in 2009, has and shall spend his own funds (approximately \$30,000 to date) to commercialize and further develop this invention should he be granted title. Petitioner will also expend such sums as may be required to

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, 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 was a Distinguished Member of the Technical Staff in Biomolecular Materials and Interfaces Department at Sandia National Laboratories until he left to start a company in 2009 to commercialize this technology. He has considerable experience in this technology field, including multiple patents and scientific papers. Paul Gourley is a nationally and internationally recognized scientist and the recipient of many awards from DOE, scientific and technological societies, and industrial organizations. Petitioner Gourley has experience with other technical ventures, including spinning off semiconductor laser technology he invented to MODI (later EMCORE). He intends to develop and market this and other health care-related technologies. The other co-Inventor, Mark F. Gourley, MD is the brother of Paul Gourley and was an independent collaborator. He is a Director in the Institute of Arthritis and Musculoskeletal and Skin Disease (NIAMS) at the National Institutes of Health. The Petitioner's interest in obtaining title and actively seeking commercialization sufficiently satisfies DOE/NNSA's technology transfer mission without the need to expend additional government 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 of DOE's rights to its undivided interest be granted.

  
Artie 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:


  
Aaron Perea  
LDRD Program Manager  
Sandia Site Office  
National Nuclear Security Administration

Date: 4/24/2012

APPROVAL:

  
John T. Lucas  
Assistant General Counsel  
For Technology Transfer and  
Intellectual Property (GC-62)

Date: \_\_\_\_\_

  
Arthur N Trausch  
Patent Attorney, NNSA

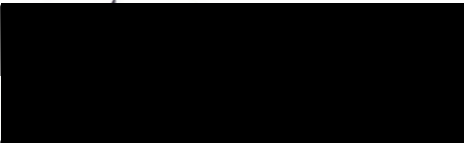
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Aaron Perea  
LDRD Program Manager  
Sandia Site Office  
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APPROVAL:

  
John T. Lucas  
Assistant General Counsel  
For Technology Transfer and  
Intellectual Property (GC-62)

Date: 4/23/2012