STATEMENT OF CONSIDERATIONS

ADVANCE WAIVER OF ALL OF THE GOVERNMENT'S U.S. AND FOREIGN PATENT RIGHTS FOR INVENTIONS AND IMPROVEMENTS RELATED TO PETITIONER'S PROPRIETARY TECHNOLOGY, INCLUDING THE RIGHTS NORMALLY RETAINED BY THE GOVERNMENT, UNDER WORK FOR OTHERS (WFO) AGREEMENT L-10990 BETWEEN THE REGENTS OF THE UNIVERSITY OF CALIFORNIA OPERATING THE LAWRENCE LIVERMORE NATIONAL LABORATORY (LLNL) AND C3L, LIMITED (C3L), DOE WAIVER NO. W(A) 06-017

Background: The Petitioner, C3L, is a wholly-owned subsidiary of Seldon Laboratories LLC (Seldon), a U.S. small business corporation having a research and manufacturing facility located in Windsor, Vermont. Seldon's primary focus is developing products based on nanoscale technology. The Petitioner, as a work for others sponsor, will qualify for waiver of the Government's U.S and Foreign Patent Rights under the Class Waiver of Government Rights in Inventions Arising From The Use of Department of Energy Facilities and Facility Contractors By or For Third Party Non-Federal Sponsors (Work for Others) (W(C) 95-009). 82-017 However, this class waiver provides that the waiver of the Government's rights is subject to (1) the Government's retention of a non-exclusive, non-transferable, irrevocable, paid-up license to practice or have practiced by or on behalf of the United States the waived invention throughout the world, (2) the Government's ability to exercise march-in rights as set out in 35 U.S.C. 203 or other comparable provisions for ensuring the desirable commercialization of the waived inventions as provided by the Assistant General Counsel for Technology Transfer and Intellectual Property, and (3) imposition of the preference for U.S. Industry Provisions of 35 U.S.C. 204. The Petitioner has requested an Advance Waiver of the Government's Intellectual Property Rights under the above-cited WFO Agreement, including deletion of the Government's retained rights listed above, for inventions and improvements related to the Petitioner proprietary technology.

The subject WFO Agreement has two phases: Phase I is a Radiological Assessment of an experiment being conducted at C3L's facility in Windsor, Vermont; Phase II is a Technological Assessment of the experiment and a subsequent replication of the experiment at LLNL. In Phase I, LLNL technical personnel will conduct on-site measurements of radioactivity in areas specified by C3L representatives. The measurements will be designed to identify whether there are any fluxes of energetic particles greater than normal background levels. LLNL will write a report explaining any safety characteristics and consequences of the measured radioactivity and devise a safety plan for personnel to work in the area of interest. In Phase II, C3L will disclose the technical details of the experiment to LLNL technical personnel and the LLNL personnel will determine what equipment, materials, and procedures should be used to neutralize the experiment at C3L's site, if that is necessary. LLNL will replicate the experiment at LLNL to determine if the results achieved at C3L are reproducible. LLNL will write a report setting out the results of the work on all of the tasks. Petitioner has agreed to pay the full cost of the WFO, estimated to be $75,616.

Any inventions resulting from the subject WFO Agreement are anticipated to fall within one of two categories: 1) methods for measuring of radioactivity or making a radiological assessment or 2) improvements to C3L's existing technology. The Petitioner has agreed that subject inventions in the first category do not fall under W(C) 95-009 and are not the subject of this waiver. On the other hand, subject inventions in the second category related to improvements to C3L's existing proprietary technology fall under W(C) 95-009 and this identified waiver. (A) 52-07

Although DOE and LLNL have a high interest in the general area of the Petitioner's technology, it is believed that the Petitioner's specific technology is a new approach which is not known to the Government and is not the subject of any past or currently funded research by DOE. The Petitioner has filed at least five provisional U.S. patent applications covering the experiment and the technology which will be assessed. All of the information related to the Petitioner's technology that has been received or will be developed under the WFO Agreement is proprietary to Petitioner.

(A) 52-07

Analysis: Under Class Waiver W(~~C) 91-005~~, DOE has previously granted waivers to "proprietary users" , i.e. users of particular facilities who fully fund their own experiments and provide full cost recovery including depreciation and added factor These proprietary user waivers have allowed the deletion of the Government's retained rights in view of the full cost recovery and the fact that the research that is being performed is not that of the Department. These two conditions are also present in this WFO Agreement since the Petitioner is providing full cost recovery and the Department is not conducting research in this technological area and was not even aware of this technology until it was disclosed by the Petitioner under a Nondisclosure Agreement for protecting the Petitioner's proprietary information.

Furthermore, the work being done by LLNL in this WFO Agreement is analogous to the use of the DOE user facilities by the proprietary users in an additional aspect as follows: LLNL has the necessary equipment to measure radioactivity and has vast expertise in making radiological assessments such that these tasks under this WFO Agreement are routine. The task of replicating an experiment under the guidance of the originator of the experiment is also routine. Therefore, the services being provided by the LLNL personnel are analogous to the use of a machine or a research tool that is part of an existing DOE facility by a proprietary user.

As is the case with the proprietary user agreements, this WFO Agreement does not take the form of a research contract, cooperative agreement or grant as these terms are used in the Federal Grant and Cooperative Agreement Act of 1977 (U.S.C. §§6303-05) and implementing guidance by OMB and OFPP. Also, the requirements of DOE's regulations covering contracts, cooperative agreements and grants are not followed. As a result, this WFO does not

fall within the definition of "funding agreement" of 35 U.S.C. § 200 *et seq.* (commonly referred to as the Bayh-Dole legislation), and the patent policy set forth therein as applicable to small businesses and non profit organizations does not apply. Accordingly, there is no statutory or regulatory requirement that the Government must retain a Government license, march-in rights, or U.S. preference provisions for subject inventions in this WFO Agreement.

The experiment being conducted by the Petitioner is in an area of technology which would be of great interest DOE if the assessment shows promise. The technology of the Petitioner has potential for providing substantial public benefit if it is successful. However, it is believed that DOE is currently not pursuing the technological approach of Petitioner's experiment – which the Petitioner believes is novel and provides unexpected results. DOE would not even be aware of the technology without the proprietary information provided by the Petitioner under the Nondisclosure Agreement and may not pursue investigation into this technology unless developed independently from the information provided by the Petitioner. Any inventions related to the Petitioner's technology made under the WFO Agreement will presumably be dominated by Petitioner's rights in the technology due to its already-filed patent applications.

Petitioner has indicated that it is interested in developing this technology in cooperation with LLNL and DOE beyond this initial WFO Agreement.. LLNL is also interested in pursing development of this technology. However, Petitioner has stated that it will not pursue the WFO Agreement without this waiver. The scope of work for this WFO Agreement is limited and may be a first step in opening a promising new area of research to DOE and bringing the benefits of this technology to the public. This waiver will not, however, serve as precedent for any additional interactions with C3L, each of which will be considered on its own merits.

Conclusion: The Petitioner already has the right to elect title to any invention made in the course of the WFO Agreement subject to the Government's retained interests under W(~~C~~)~~95-009~~. In view of the foregoing circumstances and analysis, and in view of the statutory objectives to be obtained and the factors to be considered under DOE's statutory waiver policy, the objectives of Public Law 101-189, and Executive Order 12591, all of which have been considered, it is submitted the waiver of the Government's retained rights as set forth above will best serve the interest of the United States and the general public.

This waiver is limited to ~~for~~ this proposed WFO Agreement for the radiological assessment, the technological assessment of the Petitioner's existing technology at the Petition's facility, and the replication of Petitioner's experiment at LLNL. Any change in the scope of work beyond that currently contemplated is not covered by this waiver.

[redacted]

Date: 5/18/2006

William Daubenspeck
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NNSA Service Center

Based on the foregoing Statement of Considerations, it is determined that the interests of the United States and the general public will best be served by waiver of the United States' domestic and foreign patent rights including waiver of the Governments retained rights.

CONCURRENCE:

[redacted]

Date: 5/23/2006

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APPROVED:

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