STATEMENT OF CONSIDERATIONS

CLASS WAIVER OF THE GOVERNMENT'S DOMESTIC AND FOREIGN PATENT RIGHTS IN CERTAIN IDENTIFIED INVENTIONS TO LAWRENCE LIVERMORE NATIONAL SECURITY, LLC (LLNS), MADE AND TO BE MADE UNDER CONTRACT DE-AC52-07NA27344 WITH THE DEPARTMENT OF ENERGY'S NATIONAL NUCLEAR SECURITY ADMINISTRATION (NNSA) FOR THE MANAGEMENT AND OPERATION OF THE LAWRENCE LIVERMORE NATIONAL LABORATORY, INCLUDING A CLASS ADVANCE WAIVER OF TITLE TO INVENTIONS MADE IN THE PERFORMANCE OF COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENTS (CRADAS) ENTERED INTO BY LLNS PURSUANT TO CONTRACT DE-AC52-07NA27344.
W(C)-08-001

Background

The National Nuclear Security Administration awarded Prime Contract No. DE-AC52-07NA27344 to Lawrence Livermore National Security, LLC (LLNS) for management and operation of the Lawrence Livermore National Laboratory on May 8, 2007. LLNS is organized as a for-profit limited liability company whose members are Bechtel National, Inc.; The Regents of the University of California; BWX Technologies, Inc.; Washington Group International, Inc., and Battelle.

The Lawrence Livermore National Laboratory (LLNL) is a Government owned, Contractor-operated facility located in the San Francisco Bay Area of California. As a Federally Funded Research and Development Center (FFRDC), LLNL has a remarkable record of scientific and technical accomplishments since its inception in 1952. This success is due, in part, to the unique contractual relationship that exists between the Department of Energy (DOE) and its management and operating (M&O) contractors by way of the dedication of both technical and administrative skills of private organizations to a significant Federal mission in a close, long-term, cooperative relationship.

The National Competitiveness Technology Transfer Act of 1989 (Pub. L. 101-189 § 3133(d)), required DOE to include in appropriate contracts for the operation of a Government-owned laboratory operated under contract by a non-Federal entity, provisions that establish technology transfer as a mission of the laboratory. DOE's implementation of this requirement is found at DEAR 970.2770, which dates from 1995 and includes provisions that provide M&O contractors title to most new inventions made at the laboratory with federal funding. DOE's nonprofit M&O contractors have the right to retain title to inventions made in the performance of their prime contract with DOE pursuant to 35 U.S.C.§ 202 (Pub. L. 96-517 as amended by Pub. L. 98-620), other than those inventions excluded by Section 202(a)(ii-iv) and to the extent necessary to enable the Government to comply with Treaties and International Agreements.

In 1983, President Reagan's Memorandum on Government Patent Policy (Feb. 18, 1983) was issued. It directed that:

> To the extent permitted by law, agency policy with respect to the disposition of any invention made in the performance of a federally-funded research and development contract, grant or cooperative agreement award shall be the same or substantially the same as applied to small business firms and nonprofit organizations under Chapter 38, Title 35 of the United States Code.

Executive Order 12591 (Apr. 10, 1987) also provided that the head of each Executive department and agency promote the commercialization, in accordance with the Memorandum on Government Patent Policy, of patentable results of federally funded research by granting to all contractors, regardless of size, title to patents made in whole or in part with Federal funds, in exchange for royalty-free use by or on behalf of the government.

DOE has considered the impact of these statutes and directives on patent policy with respect to large for-profit business contractors, including its M&O contractors, and determined that section 152 of the Atomic Energy Act of 1954 (42 U.S.C. § 2182), as amended, and section 9 of the Federal Non-Nuclear Energy Research and Development Act of 1974 (42 U.S.C. § 5908), preclude the Department from automatically granting to its large for-profit contractors title to inventions made under their contracts.

In order to facilitate the commercialization of inventions resulting from the research and development performed under DOE's M&O contracts (including NNSA's contracts) in the most expeditious manner consistent with the statutes, policies and Executive Order cited above, the Department decided that it is in the best interest of the United States and its citizens to grant individual Class Waivers to each M&O contractor authorized to conduct technology transfer activities regarding certain inventions made under its Prime Contracts and a Class Advance Waiver of inventions made by a Participant under a CRADA to Participants. Class waivers of this nature exist for all appropriate M&O contractors.

If such class waivers were not granted, the Department's for-profit M&O contractors would have to file identified waiver petitions on inventions made in the performance of a Prime Contract in order to obtain title to such inventions in furtherance of their technology transfer mission. Such a process would impose a substantial administrative burden, both on the Government and on the contractor, in preparing and processing such individual waiver petitions.

Excluded from the scope of this Class Waiver are inventions which:

> 1) Fall within NNSA's weapons programs, which inventions principally relate to weapons or inherently disclose or suggest a weapons application where such disclosure or suggestion would be detrimental to national security;

2) Relate to the Naval Nuclear Propulsion Program;

3) Relate to the Uranium Enrichment (including Isotope Separation) Program;

4) Are classified or sensitive under section 148 of the Atomic Energy Act of 1954, as amended;

5) Are included in international agreements or treaties to the extent necessary to implement the treaty or international agreement;

(6) Are covered by existing or future Class Waivers granted to third parties by DOE such as waivers relating to "Work for Others" or "User Facilities"; and

(7) Fall within any further exceptions that may, in the national interest, be unilaterally designated by the Secretary or his designee.

For inventions relating to Federal storage and disposal of civilian high-level nuclear waste and spent nuclear fuels, LLNS's right to elect title is subject to the reservation in DOE of the right to require nonexclusive, nontransferable royalty-free licensing to any organization, such as a utility, that is contributing to the costs of activities relating to such storage and disposal.

This Class Waiver does not include inventions of subcontractors under the Prime Contract. It does apply to inventions of laboratory employees made under an agreement, such as a work for others agreement where a third party sponsor having the right to elect title to a laboratory employee's invention, elects not to retain title to the invention. It also applies to laboratory employee inventions as to which DOE determines that a class waiver that would normally grant a work for others sponsor or user the right to elect title to the invention does not apply and no other exception to the M&O contractor obtaining title applies.

Identified Invention Waiver to LLNS

Under certain circumstances, the scope of the Class Waiver is directed to and includes domestic and foreign patent rights to identified subject inventions made in the performance of the Prime Contract for LLNL. Many of the inventions made under the Prime Contract require additional development before they can be made available in the commercial marketplace. Additionally, many of these inventions are conceptual in nature and are on a laboratory or proof-of-principle scale. Scale-up to a commercially sized demonstration of the inventive concept is often a prerequisite to negotiating royalty-bearing licenses. Finally, many of the inventions arising out of NNSA's weapons research and production require substantial capital in order to translate the inventions into commercial reality; such costs, for example, include engineering, design, start-up and marketing.

A Class Waiver of the Government's rights in identified inventions as set forth herein will create sufficient exclusive rights in those inventions to bring forth private venture capital to expeditiously promote and move the technology into the commercial marketplace and thereby make the benefits of NNSA's program widely available to the public in the shortest practicable time.

Additionally, under the M&O Contract, LLNS is authorized to carry out technical liaison with universities, the private sector and other federal facilities in connection with Cooperative Agreements of the Department and CRADAs for the purpose of promoting technology transfer between the federal laboratories and the private sector in the United States. By having a waiver of the Government's rights in subject inventions falling within the scope of this Class Waiver, LLNS will be able, where appropriate, to enhance the movement of the waived inventions to the commercial marketplace.

Furthermore, the grant of a Class Waiver of identified inventions as set forth herein will enable NNSA to take advantage of the technology transfer capabilities of LLNS. Permitting LLNS to retain title to a broad range of important inventions, except those imbued with the national interest, should further enhance the technology transfer initiatives of NNSA in the M&O Contract.

LLNS has agreed to attempt to commercialize waived inventions within five years from the time the waiver is effective. This commitment to early commercialization by LLNS will promote the commercial utilization of such inventions and make the benefits of the research effort conducted under the M&O Contract widely available to the public in the shortest practicable time.

Class Waiver for the Benefit of LLNS After Lapse of Two-Year Election Time Limit and for Inventor Employees

In a particular situation, the scope of this Class Waiver is directed to and includes U.S. and foreign patent rights to identified subject inventions made in the performance of the M&O Contract for the Lawrence Livermore National Laboratory that were electable under the conditions set forth above, but for which a request for waiver of government rights is submitted after the expiration of the two-year period for making such an election.

The scope of this waiver also includes those electable subject inventions that LLNS has previously indicated, in writing or otherwise, that they do not desire to take title and for which an inventor employee of LLNS, with permission of LLNS, seeks title. A waiver of such inventions to inventor employees shall be at the discretion of the NNSA Patent Counsel responsible for administration of the LLNS prime contract based on the inventor employee having sufficient plans and intents to commercialize the invention.

Because this waiver includes inventions in which the two-year period of election has expired, the invention may not be available for waiver due to licensing and related activities carried out by the Office of the Assistant General Counsel for Technology

Transfer and Intellectual Property at DOE Headquarters. In order to assess any prior commitments or on-going negotiations for licenses and related activities in government-owned patents, the NNSA Patent Counsel or designee will confer with said Office to determine the availability of any invention for application of this waiver.

Furthermore, if the Department of Energy has expended Federal funds to patent or pay any fees in relation to an invention that LLNS is seeking title under this waiver, the NNSA Patent Counsel, in his or her discretion, may require LLNS to reimburse the Department, in some fashion, for these expenditures before approving LLNS' waiver request.

Implementation of This Waiver When LLNS Is Obtaining Title

Implementation of this Class Waiver is to be by a simple procedure that requires:

(1) LLNS reporting of the invention pursuant to the M&O Contract and identifying the cognizant Department of Energy program official in the invention disclosure;
(2) LLNS electing in writing to retain title to the invention at the time of disclosure or within two years of disclosure;
(3) LLNS representing after reasonable internal inquiry that the invention falls within this Class Waiver;
(4) LLNS representing that, to the best of its knowledge and belief after reasonable internal inquiry, the invention does not fall within international agreements or treaties ; and
(5) LLNS representing that it will attempt to commercialize the invention through its licensees within five years from the time the waiver is effective.

After review of the invention disclosure and relevant facts, the NNSA Patent Counsel, or other member of the Office of NNSA Patent Counsel designated by the NNSA Patent Counsel, will certify whether the waiver is applicable to the invention. Except as hereinafter provided with respect to inventions funded by or through NNSA's Office of Defense Programs, herein "DP-funded inventions", the election for inventions shall become effective sixty (60) days after receipt by NNSA Patent Counsel, unless the NNSA Patent Counsel rejects the election, as set forth in this Class Waiver, or NNSA Patent Counsel elects for a one-time extension of thirty (30) days.

It is recognized that significant research and development under the M&O Contract is funded by the Department of Energy that result in valuable patentable technology. It is further noted that the ownership of such patentable technology by LLNS, in all instances, would not compromise national security or the Department's program or patent position by application of appropriate safeguards.

The fact that certain inventions arising under the M&O Contract may fall within the scope of this Class Waiver requires that particular attention be given to each invention to ensure that the transfer of technology would not directly or indirectly compromise

national security or other aspects of this sensitive program, as specifically prescribed in 48 C.F.R. § 927.370.

With regard to any invention that LLNS reports with an election to retain title, LLNS shall, to its best knowledge or belief, provide to NNSA Patent Counsel a supporting statement addressing:

> (1) Whether national security would be compromised by development, commercialization or licensing activities involving the invention;
> (2) Whether sensitive technical information (classified or unclassified) under the Naval Nuclear Propulsion Program, the Nuclear Weapons Programs or other defense activities of the NNSA, for which dissemination is controlled under Federal Statutes and regulations, would be released to unauthorized persons;
> (3) Whether failure to assert such a claim (i.e., failure by the Department of Energy to retain title to a subject invention) would adversely affect the operation of the Naval Nuclear Propulsion Program, the Nuclear Weapons Program or other defense activities of the Department; and
> (4) Whether there is any export controlled information or material present and, if so, how such information or material would be protected.

Additionally, LLNS shall provide a statement of any safeguards it proposes to protect national security while commercializing the subject matter of the invention.

All elections of DP-funded inventions shall be subject to the independent concurrence of a designated NNSA Program Official, in addition to the approval of the NNSA Patent Counsel. The NNSA Patent Counsel shall base the approval determination on the written election and any notifications provided in paragraph (J), of the Technology Transfer Mission Clause of the M&O Contract as of the date of approval of this waiver. The concurrence of the designated NNSA Program Official shall be based on a review of the national security impact of the election including the issues set forth above, and the approval of such election by NNSA Patent Counsel shall not be effective until such concurrence has been provided to NNSA Patent Counsel. NNSA shall use best efforts to provide approval and concurrence within 10 business days of the date that a complete election is received.

Furthermore, if the Department of Energy has expended federal funds to patent or pay any fees in relation to an invention that LLNS is seeking title under this waiver, the NNSA Patent Counsel, in his or her discretion, may require LLNS to reimburse the Department, in some fashion, for these expenditures before approving LLNS' waiver request.

This waiver of the Government's rights in LLNL inventions as set forth herein is subject to the Government's retention of: (1) a nonexclusive, nontransferable, irrevocable, paid-up license to practice or to have practiced for or on behalf of the United States the waived inventions throughout the world, and (2) march-in rights in accordance with the attachment hereto entitled "March-In Rights."

All of the above implementation procedures are to be included in the Patent clause included in the M&O contract for operation of LLNL which is attached hereto.

Class Advance Waiver to CRADA Participants' Inventions

In another set of circumstances, the scope of this Class Waiver is directed to an advance waiver to the Participant of inventions made by employees of, or persons acting on behalf of Participants under the class of CRADAs entered into by Participants with LLNS under the M&O Contract, pursuant to the technology transfer mission of the Department of Energy. Since CRADAs do not fall within the definition of "funding agreements" of Public Law 96-517, the patent policy set forth therein as applicable to small businesses and non-profit organizations does not apply. Hence, inventions made by any small business, non-profit organization or for-profit large business Participants to the CRADAs are intended to be covered by this Class Waiver.

With respect to the advance Class Waiver to the class of CRADAs described above, it is expected that LLNS will negotiate agreements that provide for a substantial cost sharing of the joint research effort by the Participants, thereby achieving a leveraging of the Government-funded portion of the joint work. In so doing, this advance Class Waiver is seen to be an extension of the Department's patent waiver policy which recognizes that substantial cost sharing by Participants is an indication of commitment by the Participants to advance the technology and effect commercial utilization. Additionally, the work being performed under CRADAs will typically be driven by Participants' needs and will most likely be of near term commercial value; hence, it is believed that the granting of the Class Advance Waiver of inventions made by Participants under CRADAs will also make the benefits of the CRADA research widely available to the public in the shortest practicable time and promote the commercial utilization of the waived inventions.

Further, it is believed that technology transfer will be enhanced by both LLNS and the CRADA Participant, as appropriate, being able to offer, for commercialization purposes, waived inventions with other related inventions and intellectual property. Implementation of the Class Advance Waiver is to be by execution of the CRADA by the Department of Energy. Participants' cost of filing and maintaining any patent applications or patents on their inventions will be at Participant's expense.

Additionally, if a CRADA Participant elects not to retain title to any subject invention under this waiver, LLNS shall have the second option to elect to retain title to such invention.

It is expected that in negotiating the commercialization rights to the waived inventions (including background inventions owned by the parties, if any), LLNS and the Participant will be guided by their respective equities, the small business status of the Participant, if applicable, and the overall objective of attempting to secure the most expeditious commercialization route for moving the technology from the research state to the marketplace.

This Class Advance Waiver of the Government's rights in inventions to Participant, as set forth herein is subject to (1) the Government's retention of a non-exclusive, non-transferable, irrevocable, paid-up license to practice or to have practiced for or on behalf of the United States the waived invention throughout the world, (2) a preference for United States industries as set forth in 35 U.S.C. § 204, (3) march-in rights comparable to those set out in 35 U.S.C. § 203, and (4) the provisions of the M&O Contract, including the Patent Rights, Rights in Data, and Technology Transfer Mission clauses.

Summary

The grant of this Class Waiver should not result in adverse effects on competition or market concentration. Waived inventions will be subject to a royalty-free license to the Government and NNSA has the right to require periodic reports on the utilization or the efforts at obtaining utilization that are being made for the waived inventions. If LLNS or Participant is not making reasonable efforts to utilize a waived invention, NNSA can exercise its march-in rights and require licensing of the invention.

Accordingly, in view of the statutory objectives to be obtained and the factors to be considered under the Department of Energy's statutory waiver policy, and the objectives of Executive Order 12591, all of which have been considered, it is recommended that this Class Waiver as set forth above will best serve the interest of the United States and the general public. It is therefore recommended that the waiver be granted.

[redacted]

Jim C. Durkis
NNSA Patent Counsel
NNSA Service Center

Based on the foregoing Statement of Considerations, it is determined that the interest of the United States and the general public will best be served by waiver of United States and foreign patent rights as set forth herein and, therefore, the waiver is granted. This waiver shall not affect any waiver previously granted.

CONCURRENCE: [redacted]

William C. Ostendorff
Principal Deputy Administrator, NNSA

Date: 8/1/08

APPROVAL: [redacted]

Paul A. Gottlieb
Assistant General Counsel for Technology Transfer and Intellectual Property, GC-62

Date: 8-07-08