

## STATEMENT OF CONSIDERATIONS

CLASS WAIVER OF THE GOVERNMENT'S U.S. AND FOREIGN  
PATENT RIGHTS TO THE REGENTS OF THE UNIVERSITY OF  
CALIFORNIA IN CERTAIN IDENTIFIED INVENTIONS MADE IN THE  
COURSE OF OR UNDER THE DEPARTMENT OF ENERGY'S  
MANAGEMENT AND OPERATING CONTRACTS NOS. W-7405-ENG-36  
AND W-7405-ENG-48 WITH THE REGENTS OF THE UNIVERSITY OF  
CALIFORNIA, W(C)-92-002

### Background

Los Alamos National Laboratory (LANL) and Lawrence Livermore National Laboratory (LLNL) are owned by the U.S. Government and operated by the Regents of the University of California (hereinafter Regents) under the above-identified Prime Contracts with the Department of Energy (DOE).

DOE considers its Government-Owned, Contractor-Operated (GOCO) laboratories, such as LANL and LLNL, national resources capable of providing significant contribution to the development of new products and processes, the creation of jobs, the enhancement of the skill level of the U.S. labor force, and improved U.S. competitiveness.

Congress, recognizing this unique aspect of GOCO laboratories, enacted the National Competitiveness Technology Transfer Act of 1989, hereinafter "Act," (Public Law 101-189). The purpose of the Act is to promote technology transfer between GOCOs and the private sector in the U.S. and to enhance collaboration between universities, the private sector, and the GOCOs in order to foster the development of technologies in areas of significant economic potential.

The Act amended the Stevenson-Wydler Technology Innovation Act of 1980 (Public Law 96-480), as amended, in two major aspects. First, the Act extended to GOCOs, upon agency approval, the authority earlier specified in Section 12 of Stevenson-Wydler for Government-Operated Federal Laboratories (GOGOs) to enter into Cooperative Research and Development Agreements (CRADAs) on behalf of the agency with one or more non-Federal parties (hereinafter "Participant").

Second, the Act required that the agency formalize an agreement with the GOCOs to establish technology transfer including CRADAs as a mission for the GOCOs and to describe the respective obligations and responsibilities of the agency and the GOCOs with respect to the Act and Section 12 of Stevenson Wydler.

Currently, DOE's nonprofit management and operating (M&O) contractors such as the Regents have the right to retain title to inventions made in the performance of their prime contracts with DOE pursuant to Title 35 U.S.C. 202 (Public Law 96-517), as amended by Public Law 98-620, other than those inventions excluded by 35 U.S.C. 202(a)(ii-iv).

DOE has exercised its statutory right to exclude certain categories of LANL or LLNL inventions from automatic ownership by the Regents. This exclusion currently includes weapons funded inventions, Naval Nuclear Propulsion Program inventions, inventions subject to DOE exceptional circumstance determinations, inventions covered by treaties or international agreements and inventions covered by existing or future Class Waivers granted to third parties by DOE. This DOE exclusion is set forth in the Patent Rights clauses of Appendices of the LANL and LLNL Prime Contracts (Clause 35, paragraph b and Appendix G of LANL Prime contract; Clause 34, paragraph b and Appendix F of LLNL Prime Contract).

#### Scope of Waiver

The scope of this Class Waiver is directed to subject inventions made by employees of LANL or LLNL in the performance of work under the LANL or LLNL Prime Contract which are weapons related inventions, but which do not principally relate to weapons or inherently disclose or suggest a weapons application where such disclosure or suggestion would be detrimental to national security.

Excluded from the scope of this Class Waiver are inventions which (1) fall within DOE'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; relate to naval nuclear propulsion; relate to uranium enrichment (including isotope separation); relate to storage and disposal of civilian high level nuclear waste or spent nuclear fuel; (2) relate to subject matter which is classified or sensitive under Section 148 of the Atomic Energy Act of 1954, as amended; (3) come within the ambit of international agreements or treaties; (4) are subject inventions covered by existing or future Class Waivers granted to third parties by DOE, such as "Work for Others" or "CRADAs"; or (5) are within any further exceptions that may, in the national interest, be unilaterally designated by the Secretary of Energy. In addition, this waiver shall not apply to inventions of subcontractors under the LANL or LLNL Prime Contract, nor shall it apply to any invention existing at the time of approval of this waiver which DOE has already advertised as being available for licensing from DOE.

This waiver of the Government's rights in 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 March-In Rights provisions of the LANL and LLNL Prime Contracts (Clause 35, paragraph C of the LANL Prime Contract; Clause 34, paragraph C of the LLNL Contract, as well as the additional March-In Right set forth in the attachment to this Statement of Considerations..

### Analysis

Most inventions made under the LANL or LLNL Prime Contract require additional development before they can be made available in the commercial marketplace. This is because many of the inventions made by LANL or LLNL are founded upon basic or advanced research. Additionally, many of these inventions are conceptual in nature and are on a laboratory or proof-of-principle scale. Scale-up to a commercial size demonstration of the inventive concept is often a prerequisite to negotiating royalty-bearing licenses. Finally, many of the inventions arising out of DOE's weapons research will require substantial capital in order to translate the inventions into commercial reality; such costs, for example, include further engineering, design, start-up and marketing.

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

Additionally, under the authority of the Act, LANL and LLNL are authorized to enter into CRADAs with universities, the private sector and other Federal laboratories 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, LANL and LLNL will be able to combine, where appropriate, these waived inventions with those waived under the separately issued Class Waiver for CRADAs through license agreements with cost-sharing Participants under the CRADAs, thereby enhancing the movement of the waived inventions to the commercial marketplace.

Furthermore, the grant of the Class Waiver of identified inventions as set forth herein will enable DOE to take further advantage of the technology transfer capabilities of LANL and LLNL.

As a condition of this waiver, LLNL and LANL must agree to attempt to commercialize the waived inventions within five years from the time the waiver is effective. This commitment to early commercialization will best promote the commercial utilization of

such inventions and make the benefits of the research effort conducted under the Prime Contracts widely available to the public in the shortest practicable time, consistent with the objectives and considerations of DOE's waiver regulations.

To implement this Class Waiver LANL/LLNL will be required to:

1. Report the invention to DOE pursuant to the LANL/LLNL Prime Contract obligation, including identification of the cognizant DOE program official in the invention disclosure;
2. Elect in writing whether or not to retain title to the invention within two years of disclosure;
3. Represent, after reasonable LANL/LLNL inquiry, that the invention falls within the scope of this Class Waiver and that the invention does not principally relate to weapons or inherently disclose or suggest a weapons application where such disclosure or suggestion would be detrimental to national security;
4. Represent, after reasonable LANL/LLNL inquiry and to the best of LANL's or LLNL's knowledge and belief, that the invention is not covered by a treaty or international agreement; and
5. Represent that LANL/LLNL 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 Assistant Chief Counsel for Intellectual Property, Albuquerque or San Francisco Operations Office as appropriate (herein Patent Counsel) will certify whether the waiver is applicable to the invention.

Except as hereinafter provided with respect to DOE's Defense Programs funded inventions, the election for inventions shall become effective sixty (60) days after receipt by Patent Counsel, unless the Patent Counsel shall return the election with reasons for failure to accept the election, as set forth in this Class Waiver or Patent Counsel makes a request for a one-time extension of thirty (30) days.

As noted above, the scope of this Class Waiver does not include two types of DOE Defense Programs funded inventions: (1) inventions which fall within DOE'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 and (2) inventions which relate to subject matter that is classified or sensitive under Section 148 of the Atomic Energy Act of 1954, as amended. These inventions are, accordingly, not available for

election under this Class Waiver and if LLNL and LANL desire greater rights in these inventions, then identified waiver petitions must be pursued.

It is recognized that significant research under the Prime Contracts is funded by DOE's Weapons Programs which results in valuable patentable technology. It is further noted that the ownership of such patentable technology by LANL/LLNL would not necessarily compromise national security or DOE's program or patent position if appropriate safeguards are applied.

The fact that certain inventions arising under DOE's Weapons Programs 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 arising under or funded by DOE's Weapons Programs which LLNL or LANL reports with an election to retain title, LLNL or LANL shall, to its best knowledge or belief, provide to Patent Counsel and to a designated Defense Programs Military Application Field Program Official a supporting statement with reasons, addressing:

- (1) Whether National Security will 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 or the Nuclear Weapons Program or other defense activities of DOE, for which dissemination is controlled under Federal statutes and regulations, will be released to unauthorized persons;
- (3) Whether failure to assert such a claim (i.e., failure by DOE to retain title to a subject invention) will adversely affect the operation of the Naval Nuclear Propulsion Program or the Nuclear Weapons Program or other defense activities of the DOE; and
- (4) Whether there is any Export Controlled material present and, if so, how such material will be protected.

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

The election for Defense Programs' funded inventions covered by the Class Waiver shall be subject to the independent concurrence of a designated Defense Programs Military Applications Field Program Official, in addition to the approval of the Patent Counsel. The Patent Counsel shall base the approval

determination on the written election and any notifications provided in Part One, paragraph J, of the Technology Transfer Clause of the LANL or LLNL Prime Contract (LANL Clause No. 68 LLNL Clause No. 66). The concurrence of the designated Defense Programs Military Applications Field Program Official shall be based on a review of the election including the items set forth above, and the approval of such election by Patent Counsel shall not be effective until such concurrence has been provided to Patent Counsel. DOE shall use its best efforts to provide approval and concurrence within 90 days of the date the complete election is received.

In the interim, pending the grant of the Class Waiver, LANL/LLNL has submitted a number of identified waiver petitions on subject inventions. These inventions are of importance to the commercialization efforts of LLNL and LANL under their Technology Transfer Programs. An expedited processing of these timely submitted waiver petitions, such as would be effectuated by inclusion in this Class Patent Waiver grant, is highly desirable and would greatly reduce the paper work associated with processing each such waiver on a case-by-case basis. Accordingly, the scope of this Class Waiver shall include inventions made by LLNL and LANL employees on which a timely filed waiver request is pending as of the effective date of this Class Waiver. Further, this Class Waiver shall not apply to any invention existing at the time of approval of this waiver which DOE has advertised as being available for licensing.

This waiver of the Government's rights in 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 invention throughout the world, and (2) march-in rights in accordance with the previously recited March-In Rights provisions of the LANL and LLNL Prime Contracts and the attachment hereto entitled "March-In Rights."

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 DOE 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 LLNL or LANL is not making reasonable efforts to utilize a waived invention, DOE 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 DOE's statutory waiver policy, the objectives of Public Law 101-189, and 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]  
James H. Charlin  
Chief Patent Counsel  
Albuquerque Operations Office

[REDACTED]  
James Hanley  
Chief Patent Counsel  
San Francisco Operations  
Office

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 the United States and foreign patent rights as set forth herein to the Regents and, therefore, the waiver is granted subject to the terms of the Prime Contracts W-7405-ENG-36 and W-7405-ENG-48 and the Technology Transfer Clauses of the LANL and LLNL contracts to implement this Class Waiver. This waiver shall not affect any waiver previously granted.

CONCURRENCE:

[REDACTED]  
Linda G. Stuntz  
Deputy Undersecretary  
for Policy, Planning  
and Analysis

Date: January 27, 1992

CONCURRENCE:

\_\_\_\_\_  
Richard A. Claytor  
Assistant Secretary  
for Defense Programs

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

APPROVAL:

\_\_\_\_\_  
Richard E. Constant  
Assistant General Counsel  
for Intellectual Property

[REDACTED]  
James H. Chafin  
Chief Patent Counsel  
Albuquerque Operations Office

[REDACTED]  
James Hanley  
Chief Patent Counsel  
San Francisco Operations  
Office

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 the United States and foreign patent rights as set forth herein to the Regents and, therefore, the waiver is granted subject to the terms of the Prime Contracts W-7405-ENG-36 and W-7405-ENG-48 and the Technology Transfer Clauses of the LANL and LLNL contracts to implement this Class Waiver. This waiver shall not affect any waiver previously granted.

CONCURRENCE:

\_\_\_\_\_  
Linda G. Stuntz  
Deputy Undersecretary  
for Policy, Planning  
and Analysis

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

CONCURRENCE:

*Richard A. Claytor*  
\_\_\_\_\_  
Richard A. Claytor  
Assistant Secretary  
for Defense Programs

Date: 1/30/92

APPROVAL:

[REDACTED]  
Richard E. Constant  
Assistant General Counsel  
for Intellectual Property

1-30-92