STATEMENT OF CONSIDERATIONS

CLASS WAIVER OF THE GOVERNMENT'S U.S. AND FOREIGN PATENT RIGHTS TO THE REGENTS OF THE UNIVERSITY OF CALIFORNIA OR TO INVENTOR EMPLOYEES 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)-96-0015

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 (hereinafter "Stevenson-Wydler," 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.

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). The Patent Rights Clauses of the LANL and LLNL Prime Contracts (LANL and LLNL Art. XII, Clause (c)(3)) require the Regents to elect in writing whether or not to retain title within two years of disclosure of the invention to DOE.

DOE has exercised its statutory right to exclude certain categories of LANL and LLNL inventions from automatic ownership by the Regents. This exclusion currently includes weapons-related 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 the LANL and LLNL Prime Contracts (LANL and LLNL Art. XII, Clause (b)).

By W(C)92-002 (hereinafter "DP Class Waiver"), the Assistant Chief Counsel for Intellectual Property (hereinafter "Patent Counsel") at both the Albuquerque and Oakland Operations Offices were delegated the authority to approve election by the Regents of weapons-funded inventions in which a waiver of Government rights is requested during the two-year period for election set forth in the LANL and LLNL M&O contracts, respectively. The approvals are subject to the prior written concurrence of a designated Defense Programs Military Applications Field Program Official located at the Albuquerque and Oakland Operations Offices, respectively.

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 Contracts which either were directly electable by the Regents under the Prime Contract or were electable under the election conditions of Class Waiver W(C)92-002, but for which a request for waiver of Government rights is submitted after expiration of the two-year contractual period for making such election.

The scope of this waiver also includes those electable subject inventions for which the Regents have indicated in writing that they do not desire to take title and for which an inventor employee of LANL or LLNL, with the permission of the Regents, seeks title as follows: Non-Defense Programs funded inventions in which an inventor employee has requested a waiver of Government rights after expiration of the two-year contractual period for election, and Defense Programs funded inventions in which an inventor employee has requested waiver of Government rights during or after the two-year contractual period for election.

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 1954, as amended, or Executive Order 12958; (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 or a designee.

Because this waiver includes inventions for which the two-year contractual period for election has expired, the invention may not be available for waiver due to licensing and related activities carried out by the Assistant for Licensing of the Office of Assistant General Counsel for Technology Transfer and Intellectual Property at DOE Headquarters in Washington, D.C. In order to assess any prior commitments or on-going negotiations for licenses and related activities in DOE-owned patents, Patent Counsel will confer with the Assistant for Licensing to determine the availability of any invention for application of this waiver.

This waiver of the Government's rights in inventions as set forth herein is subject to the Government's retention of: (1) a non-exclusive, 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 (LANL and LLNL Art. XII, Paragraph (j)), 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.

During the contractual period for election, because many of these inventions are founded upon basic or advanced research, the commercial potential or commercial interest in an invention sometimes may appear to be limited, or be only of significant value far into the future, or may not be readily ascertainable. When resources are limited, such inventions may not be elected. The resources are understandably devoted to inventions in which the perceived commercial potential is greatest or the return on investment is more immediate. However, initial evaluation may be found to be incorrect, or related or subsequent developments may improve the commercial prospects for the invention, or the invention may become useful as a part of a larger technology portfolio. Therefore, recognition of greater commercial potential for the invention may occur after expiration of the period for requesting election under the M&O Contracts and the DP Class Waiver W(C)92-002.

Unless DOE has made a prior commitment of the invention, or is pursuing licensing, commercialization or development of the invention or related technology in a manner that is incompatible with waiver of the Government's rights in such identified inventions as set forth herein, a 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 other inventions in which the Regents have title, thereby enhancing the movement of the waived inventions to the commercial marketplace.

Furthermore, the grant of the Class Waiver as set forth herein will enable DOE to take further advantage of the technology transfer capabilities of LANL and LLNL as evidenced by the substantial local investment of resources.

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

1. Report the invention to DOE pursuant to the LLNL/LANL 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;

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;

5. Represent, that LANL/LLNL will comply with the Technology Transfer Clause of its Prime Contract, and

6. Represent that LANL/LLNL will attempt to commercialize the invention through its licensees within five years from the time the waiver is effective.

As a condition of this waiver, each inventor employee or group of inventor employees seeking waiver of inventions not elected by the Regents must submit a summary plan of commercialization and agree to be subject to the requirements/provisions of 35 U.S.C. SS 202-204, to abide by the U.S. competitiveness provision of the effective Laboratory Prime Contract, to use best efforts to license the subject invention within two years, and to commercialize the subject invention within three years from the date that the waiver is granted, subject to two-year extensions that may be granted. Further, each inventor employee or group of inventor employees will be required to reimburse DOE for its costs, if any, associated with the filing and prosecuting of a patent application on the invention. In cases of joint invention where all inventors are not seeking waiver, the inventor employee(s) seeking waiver must notify the other inventors, including non-employee inventors, if any, of the request for waiver and that any objections must be provided to local Patent Counsel within two weeks of such notice. The waiver of the invention to co-inventor employee(s) will not affect any non-employee inventor's rights in the invention.

After review of the invention disclosure and relevant facts, the Patent Counsel at the Albuquerque or Oakland Operations Office, as appropriate, will certify whether the waiver is applicable to the invention.

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, or Executive Order 12958. 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 these sensitive programs, 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 and elects to retain title, or an inventing employee requests waiver, LLNL, LANL, or the inventor employee(s), shall, to its best knowledge or belief, provide to Patent Counsel 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, LANL, or the inventor employee(s) 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 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 and LLNL Art. XII, Clause 11). 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.

For such inventions falling within the scope of this Class Waiver and which DOE has advertised as being available for licensing or for which DOE is actively pursuing commercialization or development of the inventions or related technology, DOE may at its discretion conclude that the interests of the Government are best served by disapproval of the election.

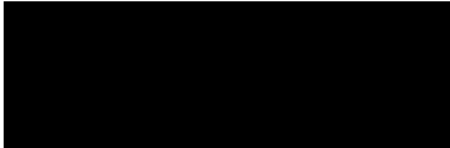
DOE shall use its best efforts to provide approval and concurrence within ninety days of the date the complete election is received, and, if the election is disapproved, to respond with reasons for disapproval within ninety days of the date the complete election is received.

In the interim, pending the grant of the Class Waiver, LANL/LLNL and inventor employees have 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 untimely 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 waiver request is pending as of the effective date of this Class Waiver.

The grant of this Class Waiver should not result in adverse effects on competition or market concentration. 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.

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.

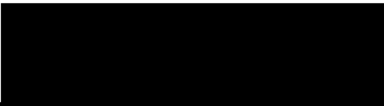


James H. Chafin
Chief Patent Counsel
Albuquerque Operations Office

James M. Hanley
Chief Patent Counsel
Oakland Operations Office

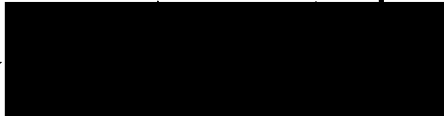
Based on the foregoing Statement of Considerations, it is determined that the interest of the United States and the general public will best be served by waiver of the United States and foreign patent rights as set forth herein to the Regents and, therefore, the waiver is granted subject to the terms of the Prime Contracts W-7405-ENG-36 and W-7405-ENG-48. This waiver shall not affect any waiver previously granted.

CONCURRENCE:



Victor H. Reis
Assistant Secretary
for Defense Programs

Date: 10-30-96



Diane E. Bird
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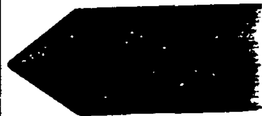
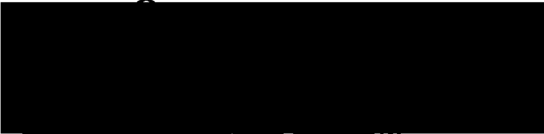


APPROVAL:



Paul A. Gottlieb
Assistant General Counsel
for Technology Transfer and
Intellectual Property

March-In Rights

LANL/LLNL agrees that, with respect to any Subject Invention in which it has acquired title, DOE has the right at the end of the 5 year period in which LANL/LLNL has agreed to attempt to commercialize the invention set forth in the Statement of Considerations hereof to request LANL/LLNL to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant(s) upon terms that are reasonable under the circumstances, provided such grant does not cause a termination of any licensee's right to use the invention; and, if LANL/LLNL refuses such request, to grant such a license itself, if DOE determines that LANL/LLNL has not made a satisfactory demonstration that it or its licensee(s) is actively pursuing such commercialization.

Before requesting licensing under the preceding paragraph, DOE shall furnish LANL/LLNL a written notice of its intentions to request LANL/LLNL to grant the stated license, and LANL/LLNL shall be allowed 30 days (or such longer period as may be authorized by the Contracting Officer for good cause shown in writing by LANL/LLNL) after such notice to show cause why the license should not be granted.