

STATEMENT OF CONSIDERATIONS

CLASS WAIVER OF THE GOVERNMENT'S U.S. AND FOREIGN PATENT RIGHTS IN INVENTIONS MADE IN THE PERFORMANCE OF COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENTS ENTERED INTO BY THE REGENTS OF THE UNIVERSITY OF CALIFORNIA UNDER MANAGEMENT AND OPERATING CONTRACTS NOS. W-7405-ENG-36 AND W-7405-ENG-48 BETWEEN THE DEPARTMENT OF ENERGY AND THE REGENTS OF THE UNIVERSITY OF CALIFORNIA [W(C)-91-002; AL ____; SAN ____]

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 contract 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, creation of jobs, enhancement of the skill level of the U.S. labor force, and in 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 this Act was 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 a number of 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 operating contractor to establish technology transfer including CRADAs as a mission for the laboratories and to describe the respective obligations and responsibilities of the Agency and the laboratories with respect thereto.

The Act defined a CRADA as:

Any agreement between one or more Federal laboratories and one or more non-Federal parties under which the Government, through its laboratories, provides personnel, services, facilities, equipment or other resources with or without reimbursement (but not funds to non-Federal parties) and the non-Federal parties provide funds, personnel, services, facilities, equipment, or other resources toward the conduct

of specified research or development efforts which are consistent with the missions of the laboratory.

Excluded from this type of agreement are procurement contracts, grants, or cooperative agreements as these terms are used in Sections 6303, 6304, and 6305 of Title 31.

The term "Laboratory" as set forth in the Act includes, for purposes of this Class Waiver, all facilities managed and operated by the Regents under DOE Contracts Nos. W-7405-ENG-36 and W-7405-ENG-48.

Identified Invention Waiver to the Regents of the University of California

In one particular, the scope of this Class Waiver is directed to the class of identified inventions which comprises subject inventions made by employees of the University of California (hereinafter "contractor CRADA inventions") in the performance of work under a CRADA, executed by the Regents under the LANL and LLNL management and operating (M&O) contracts, pursuant to the Act.

This Class Waiver grants to the Regents, in advance, title to certain inventions to be made by LANL or LLNL employees in the course of DOE authorized CRADAs, which inventions would, prior to this class waiver, be owned by the U.S. Government and subject to DOE's identified invention waiver process, as set forth in Appendix ____ of the LANL contract or Appendix F of the LLNL contract (copies attached). As stated below, certain categories of CRADA inventions are excluded from this Class Waiver.

This waiver is consistent with the objectives and considerations of DOE's waiver regulations. It is believed that the waiver to the Regents of the Government's rights in LANL and LLNL employee inventions made in the performance of work under a CRADA will best promote the commercial utilization of such inventions and make the benefits of the cooperative research effort widely available to the public in the shortest practicable time.

Further, the waiver of the Government's rights in such inventions will enable DOE to take advantage of the technology transfer capability of the University of California (UC). UC has for many years maintained an established technology transfer organization (with authority under the Stevenson-Wydler Technology Innovation Act of 1980) and that organization is fully staffed and functioning.

The waiver to the Regents of LANL and LLNL employee CRADA inventions is believed to be further justified in that the performance of the CRADA by LANL or LLNL and licensing associated therewith will enhance the movement of such waived inventions to the commercial marketplace, especially where LANL or LLNL inventions will normally be combined (through license arrangements with cost share participants or other entities) with participant's technology that has commercial value for purposes of commercialization. It is expected that such license arrangements will contain commercialization incentives that will enhance the waived inventions with a view toward early commercialization.

Implementation of this Class Waiver to the identified inventions of LANL and LLNL is to be by a simple procedure which requires:

1. LANL or LLNL reporting of the invention as required in the LANL or LLNL M&O Contract; and
2. LANL or LLNL electing in writing for the Regents whether or not to retain title to the invention at the time of disclosure or within two years of disclosure, subject to the right of DOE Patent Counsel to proceed with obtaining patent protection where it appears such patent protection might be lost due to a statutory bar.

After review of the invention and relevant facts, DOE Patent Counsel will promptly determine whether the waiver is applicable to the invention.

Advance Class Waiver to Participants' Inventions

In another particular the scope of this Class Waiver is directed to an advance waiver to the participants of inventions made by employees of, or persons acting on behalf of, participants under the class of CRADAs entered into by participants with LANL or LLNL under the LANL or LLNL M&O Contract pursuant to the Act. Since CRADAs do not fall within the definition of "funding agreements" of Public Law 96-517, as amended, the patent policy set forth therein as applicable to small businesses and non-profit organizations does not apply to CRADA participants. However, since the M&O contractor (GOCO) enters into the CRADA on behalf of the Agency, the CRADA amounts to "an arrangement" within the meaning of the Atomic Energy Act of 1954, as amended, (42 USC 2182) and the Federal Nonnuclear Act of 1974 (42 USC 5908). Hence, inventions made by any small business, non-profit organization or for-profit large business participants to a CRADA are intended to be covered by this Class Waiver.

With respect to the advance Class Waiver to the class of joint research arrangements identified as CRADAs under the Act, it is expected that LANL and LLNL will negotiate agreements that provide for 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 existing DOE 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 advance Class 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 LANL, LLNL and the CRADA participant, as appropriate, being able to offer, for commercialization purposes, a package of technology including waived inventions and other related inventions and intellectual property.

Implementation of the advance Class Waiver is to be by execution of the DOE Operations Office (AL or SAN) approved CRADA. Participants' cost of filing and maintaining any patent application(s) or patent(s) on their inventions will be at private expense.

It is expected that in negotiating the commercialization rights to the waived inventions (including background inventions owned by the parties, if any), LANL, LLNL and the participant will be guided by the respective equities of the parties, 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 stage to the marketplace. Hence, it is recognized that the parties may conclude, in order to achieve the above objectives, that either the DOE laboratory or the participant should hold title to all of the inventions made under a CRADA. Where this occurs and results from good faith negotiation between the parties of invention commercialization rights, a disposition in the CRADA of rights to waived inventions, other than each party owning its own inventions as provided for in this advance Class Waiver, will not be a basis for DOE disapproval of the submitted CRADA.

Exclusions from Class Waiver

The scope of the Class Waiver to the identified inventions of LANL, LLNL or the advance waiver to participants under CRADAs entered into under the Act does not include inventions which:

1. Relate to subject matter that is classified or sensitive under Section 148 of the Atomic Energy Act of 1954, as amended, or which falls within DOE's weapons programs, wherein such inventions inherently disclose or suggest a weapons application where such disclosure or suggestion would be detrimental to national security;
2. Arise out of DOE's naval nuclear propulsion program;
3. Arise out of DOE's uranium enrichment program (including isotope separation);
4. Arise out of DOE's program for storage and disposal of civilian high level nuclear waste or spent nuclear fuels;
5. Arise out of DOE's steel initiative program;
6. Come within the ambit of international agreements or treaties in existence at the time of execution of the CRADA; or
7. Are covered by an exceptional circumstance determination made by DOE prior to the date of execution of the CRADA.

This waiver of the Government's rights in inventions, in the first case to the Regents, and in the second case to participants, as set forth herein is subject to the Government's retention of (1) 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 inventions throughout the world, and (2) march-in rights comparable to those set out in 35 USC 203.

Conclusion/Recommendation

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 the Regents or participant is not making reasonable efforts to utilize a waived invention, DOE can exercise its march-in right 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.

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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 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 H. Young
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Date: 2/5/91

Bryan A. Siebert, Director
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Date: _____

Linda G. Stuntz
Deputy Undersecretary for
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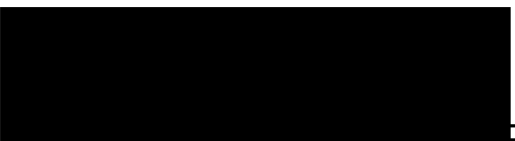
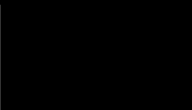
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Date: 1/28/91

Bryan A. Siebert, Director
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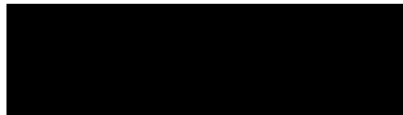

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