

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 (CRADA'S) ENTERED INTO BY UT-BATTELLE, LLC UNDER ITS MANAGEMENT AND OPERATING CONTRACT DE-AC05-00OR22725; W(C)00-002; ORO-753

The Department of Energy (DOE) considers its Government-owned, Contractor-operated (GOCOs) laboratories, such as the Oak Ridge National Laboratory (ORNL), national resources capable of providing significant contributions to the development of new products and processes, job creation, skill enhancement 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 was to promote technology transfer between GOCOs and the private sector and to enhance collaboration between universities, the private sector, and GOCOs in order to foster the development of technologies in areas of significant economic potential. The Conference Report noted that it was the intent of the Conferees that the GOCO Laboratory Managers be granted authority to facilitate technology transfer to the fullest extent authorized by law.

The Act amended the Stevenson-Wydler Technology Transfer Innovation Act of 1980 (Public Law 96-480, as amended) in a number of major ways. First, the Act extended, upon agency approval, to GOCOs, the same authority earlier provided in Section 12 of Stevenson-Wydler for Government-Operated Federal Laboratories (GOGOs) to enter into Cooperative Research and Development Agreements (CRADAs) with one or more non-Federal parties.

Second, the Act required that the GOCOs' operating contracts be modified, to the extent not already included, to establish technology transfer as a mission for the laboratories. The term "Laboratory" as set forth in the Act includes for purposes of this Class Waiver any of the facilities that UT-Battelle, LLC (UT-Battelle) manages and operates under DOE Prime Contract No. DE-AC05-00OR22725 (hereinafter the 22725 Contract).

The Act defined 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 no 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.

Advance Waiver of CRADA Inventions of UT-Battelle, LLC

The scope of this class waiver is directed to the class of inventions which comprises subject inventions made by employees of UT-Battelle in the performance of work under a CRADA entered into pursuant to the 22725 Contract in conformance with the Act.

The waiver is consistent with the objectives and considerations of DOE's waiver regulations. It is believed that the waiver of the Government's rights in inventions made by UT-Battelle 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 time practicable.

The waiver will permit UT-Battelle to negotiate with prospective CRADA participants or others in a position of having rights to inventions of employees, as is normally the case in the private sector. The actual disposition of rights in intellectual property will be negotiated at business length based upon the equities and commitments of the participants and UT-Battelle.

Under the 22725 Contract, UT-Battelle is committed to moving waived subject inventions into the commercial marketplace in an expeditious manner. The waiver of rights to CRADA inventions of its employees will provide UT-Battelle with a position to negotiate with prospective CRADA participants and facilitate moving the results of any CRADA toward commercialization. The success in negotiating rights under CRADAs and in achieving commercial utilization of CRADA inventions will be factors in evaluating UT-Battelle's performance in meeting its licensing and technology transfer mission under the 22725 Contract.

Implementation of this class waiver to the CRADA inventions of UT-Battelle is by a simple procedure which requires the following:

- (1) UT-Battelle reporting the invention within the times specified in the 22725 Contract;
- (2) UT-Battelle electing in writing to retain title to the invention within the times specified in the 22725 Contract; and
- (3) UT-Battelle identifying the invention as a subject invention under a CRADA together with the identity and other particulars of the CRADA, and information with respect to the payment of the costs of prosecuting and maintaining any patent application(s) or patent(s) on the waived invention.

After review of the invention and relevant facts, Patent Counsel will certify whether the

waiver is applicable to the invention.

The scope of the Class Waiver of CRADA inventions of UT-Battelle does not include 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 disclosures or suggestion would be detrimental to national security or relate to naval nuclear propulsion program; (2) fall within or are covered by any exceptional circumstance determination issued by DOE; (3) relate to subject matter that is classified or sensitive under Section 148 of the Atomic Energy Act of 1954, as amended; (4) come within the ambit of international agreements or treaties in existence at the time of execution of the contract modification effecting this class waiver in the 22725 Contract, or future international agreements or treaties, provided UT-Battelle is formally advised in writing of the existence of such agreements prior to the reporting of inventions to DOE by UT-Battelle; (5) are subject inventions covered by existing or future Class Waivers granted to third parties by DOE, such as "Work for Others, "Metals Initiative", etc., or (6) fall within any further exceptions that may, in the national interest, be designated by the Secretary and are added by unilateral amendment by DOE to the 22725 Contract. This Class Waiver does not include inventions of subcontractors under the 22725 Contract.

Although this class waiver generally excludes the above exceptional circumstance inventions relating to uranium enrichment as well as subject matter which is classified or sensitive, the Department has previously granted class waivers (W(C)-96-006; W(C)-98-004) involving inorganic membrane technology to major prime contractors in order to further the Department's program to commercialize that technology (originally developed as part of the gaseous diffusion process for uranium enrichment) by developing unclassified products which could be sold commercially. Several such unclassified inorganic membrane products have been developed to date although the process for manufacture of those products remains classified. During the course of the 22725 Contract, UT Battelle anticipates collaborating with participants and the other major prime contractor in the development of an improved inorganic membrane product. Accordingly, in order to promote commercialization by licensing of any invention made by UT-Battelle under CRADAs, this waiver is intended to apply to inorganic membrane inventions notwithstanding the uranium enrichment and classification exceptions identified above.

This waiver of the Government's rights in inorganic membrane inventions is subject to the Government's retention of: (1) a non-exclusive, non-transferable, irrevocable, paid-up license to practice or to have practiced the waived inventions for or on behalf of the United States, (2) an irrevocable, paid-up, exclusive license (i.e. exclusive as against the owner) in the field-of-use of uranium enrichment with the exclusive right to grant sublicenses in the field-of-use and (3) March-in-Rights. In addition, special policies were adopted in previous inorganic membrane class waivers limiting the total royalty share (from inorganic membrane inventions) for any one person to \$150,000 per year. A similar limit would apply to this waiver. Further, in view of the unique quality and nature of the waiver as it applies to inorganic membrane inventions, DOE will also retain the right to review the waiver and

revoke or modify it if deemed necessary. In order to avoid chilling current license negotiations with potential licensees and to protect licensee investments in commercialization activities, future modifications or revocation of the waiver would not adversely impact any options/license agreements effective at the time of such modification or revocation. Finally, any commercialization efforts related to the inorganic membrane technology would be subject to the security and classification provisions as set forth in the CRADA document.

Advance Waiver to CRADA Participant Inventions

In accordance with 15 USC 3710a(b)(2) which states “the laboratory shall ensure that a collaborating party may retain title to any invention made solely by its employee” in exchange for the retained Government license, the scope of this Class Waiver is also directed to the class of inventions made by employees of, or persons acting on behalf of, participants under CRADAs entered into with UT-Battelle in conformance with the Act. 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 participant in a CRADA are intended to be covered by this Class Waiver.

With respect to this advance Class Waiver, it is expected that UT-Battelle 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 waiver is seen to be an extension of existing DOE patent waiver policy which recognizes that substantial cost-sharing by participants as an indication of commitment by the participants to advance the technology and effect commercial utilization. Additionally, work being performed under CRADAs is typically driven by the needs of the participant and is likely to 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.

It is believed that the technology transfer will be enhanced by UT-Battelle and CRADA participants being able to offer for commercialization subject inventions to which they hold title, together with other related inventions and intellectual property that they may have.

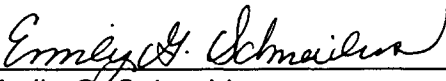
Implementation of this advance Class Waiver is to be by execution of a DOE approved CRADA. This waiver is effective as of the initiation date of the 22725 Contract. Participants' cost of filing and maintaining any patent application(s) or patent(s) on their inventions will be at private expense.

Additionally, in accordance with the policy set out in 15 U.S.C. 3710a, UT-Battelle will ensure that the participant has the option to choose an exclusive license for a pre-negotiated field of use for any waived inventions. It is also expected that in negotiating rights to any waived inventions (including background inventions owned by the parties if any), UT-Battelle 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 securing the most expeditious route for moving the technology from research and development to the marketplace. It is also recognized that the parties, in order to achieve the above objectives, may allocate title or other rights to the waived inventions among themselves as they deem appropriate during the course of the CRADA. When the allocation or division of rights is through good faith negotiation for commercialization purposes, the fact that each party may not own the subject CRADA inventions that it makes will not be a basis for disapproval of the CRADA.

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, and (2) march-in rights (comparable to those set out in 35 U.S.C. 203).

The grant of this Class Waiver should not adversely affect 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 utilization or the efforts at obtaining utilization of any waived inventions. Also, if a participant is not making reasonable efforts to utilize a waived invention, DOE can exercise its march-in rights and require licensing of the invention.

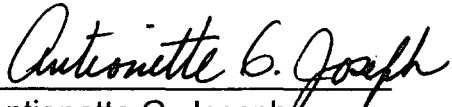
Accordingly, in view of the objectives and considerations set forth in DOE's statutory waiver policy, the objectives of Public Law 101-189, and Executive Order 12591, all of which have been considered, it is recommended that this Class Waiver be granted.



Emily G. Schneider
Assistant Chief Counsel for
Intellectual Property
Date 9/7/2000

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 a waiver of U.S. and foreign patent rights as set forth herein and therefore, the waiver is granted subject to the terms of the 22725 Contract. This waiver shall not affect any waiver previously granted.

CONCURRENCE:



Antionette G. Joseph
Director
Laboratory Policy
Office of Science

Date: Dec 15, 2000

APPROVAL:



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

Date: 1-2-01