

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 WESTINGHOUSE SAVANNAH RIVER COMPANY (WSRC), UNDER ITS MANAGEMENT AND OPERATING CONTRACT NO. DE-AC09-89SR18035

W(C)-93-009

The Department of Energy (DOE) considers its Government-owned, Contractor-operated (GOCOs) laboratories, such as WSRC, 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 United States 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. It was noted in the Conference Report that it is the intent of the Conferees that the Laboratory Manager of GOCOs be granted authority to facilitate technology transfer to the fullest extent authorized by law.

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, upon agency approval, to GOCOs 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) with one or more non-Federal parties (hereinafter Participant).

Second, the Act required the GOCOs' operating contracts be modified, to the extent not already included, to establish technology transfer as a mission for the laboratories.

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.

Expressly excluded from this type of agreement are procurement contracts 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 any of the facilities that WSRC manages and operates under the prime Contract No. DE-AC09-89SR18035 (hereinafter the 18035 Contract).

Identified Invention Waiver to WSRC

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 WSRC in the performance of work under a CRADA that it enters into under the 18035 Contract pursuant to the Act.

This waiver is consistent with the objectives and considerations of DOE's waiver regulations. It is believed that the waiver of the Government's rights to WSRC in inventions made by employees of WSRC 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 WSRC which has over the last four years established and operated a very successful limited or restricted technology transfer program which has included the location or identification of license applicants and the coordination of license applications with DOE-HQ. About 12 licensees have been so secured and about 34 additional license applications have been obtained through WSRC's efforts as explained hereinabove.

The WSRC Technology Transfer Program will, under Modification M075 of the 18035 Contract, be evaluated on its conduct of technology transfer as a mission of the Laboratory including the placement of CRADAs. This evaluation of the WSRC Technology Transfer Program serves as an additional justification for the grant of the Class Waiver as set forth herein.

Lastly, the waiver to WSRC of its employees' inventions is believed justified in that performance of the CRADA by WSRC will enhance the movement of such waived inventions to the commercial marketplace, especially where WSRC inventions will normally be combined through license arrangements with cost-shared participants (or other entities) with participants' technology that has commercial value for purposes of commercialization. It is expected that such license arrangements will contain commercialization incentives that will advance the waived inventions to early commercialization.

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

- (1) WSRC reporting of the invention within the times specified in the 18035 Contract;

- (2) **WSRC electing in writing whether or not to retain title to the invention at the time of disclosure or within one year of disclosure;**
- (3) **Representation by WSRC that the cost of prosecuting and maintaining any patent application(s) or patent(s) on its waived invention will be in accordance with the provisions of the Modification M075.**

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

Class Advance Waiver to Participants' Inventions

In another particular, the scope of this Class Waiver is directed to an Advance Waiver to the participant of inventions made by employees of participants under the class of CRADAs entered into by participants with WSRC under the 18035 Contract pursuant to 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 participants to the CRADA are intended to be covered by the Class Waiver.

With respect to the advance Class Waiver to the class of CRADAs under the Act, it is expected that WSRC 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 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 advanced 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 both WSRC 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 Advance Class Waiver is to be by execution of the Savannah River Operations Office 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), WSRC 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 WSRC or the participant should hold title to all of the inventions made under the CRADA. Where this occurs from good faith negotiation of the commercialization rights, any disposition of rights set forth in the CRADA of waived inventions other than each party owning its own inventions as provided for in this advance Class Waiver will not be a basis for disapproval by DOE of the submitted CRADA.


The scope of the Class Waiver to either the identified inventions of WSRC, or the Advance Waiver to participants under CRADAs entered into under the Act, 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 suggestions would be detrimental to national security; naval nuclear propulsion program; uranium enrichment (including isotope separation) program; storage and disposal of civilian high level nuclear waste or spent fuels; (2) relate to subject matter that is classified or sensitive under Section 148 of the Atomic Energy Act of 1954, as amended; or (3) come within the ambit of international agreements or treaties in existence at the time of execution 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 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, and (2) 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 WSRC 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.

This waiver shall not become effective until the full execution of the Modification of 18035 to include the Technology Transfer/CRADA clause package.


Harold M. Dixon
Chief Patent Counsel
Savannah River 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 United States and foreign patent rights as set forth herein and, therefore, the waiver is granted subject to the terms of the 18035 Contract as amended in Modification M075 to implement this Class waiver. This waiver shall not effect any waiver previously granted.

CONCURRENCE:


Dr. Everet Beckner
Acting Assistant Secretary
for Defense Programs

Date: 7/21/93

Lake Barrett
Acting Director, Civilian
Radioactive Waste Management

Date: _____

Roger Lewis
Director, Office of Technology
Utilization

Date: _____

CONCURRENCE:

Thomas P. Grumbly
Assistant Secretary for
Environmental Restoration
and Waste Management


Date: _____

APPROVAL:

Richard E. Constant
Assistant General Counsel
for Intellectual Property

DATE: _____

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DATE: 9/1/93