

STATEMENT OF CONSIDERATIONS

CLASS WAIVER OF THE GOVERNMENT'S U.S. AND FOREIGN PATENT RIGHTS IN INVENTIONS MADE BY PARTICIPANTS IN THE PERFORMANCE OF COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENTS ENTERED INTO BY LOVELACE MEDICAL FOUNDATION AND THE LOVELACE BIOMEDICAL AND ENVIRONMENTAL RESEARCH INSTITUTE, INC. (LOVELACE) PURSUANT TO MANAGEMENT AND OPERATING CONTRACT NO. DE-AC04-76EV01013 - W(C)90-005

The Department of Energy (DOE) considers its Government-Owned, Contractor-Operated (GOCOs) laboratories, such as the Inhalation Toxicology Research Institute (ITRI), national resources capable of providing significant contribution to the development of new products and processes, creating new jobs, enhancing the skill level of the U.S. labor force, and improving 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 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 GOCO laboratories, 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) with one or more non-Federal parties (hereinafter "Participant").

Second, the Act required that the GOCOs' operating contracts be modified, to establish technology transfer including CRADAs as a mission for the laboratories. The term "Laboratory" as set forth in the Act includes, for purposes of this Class Waiver, the facility (ITRI) that Lovelace manages and operates under DOE prime Contract No. DE-AC04-76EV01013 (hereinafter Lovelace M&O contract).

The Act defines 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.

Class Advance Waiver to Participant's Inventions

The scope of this Class Waiver is directed to an advance waiver to the participant of inventions made by employees of, or persons acting on behalf of participant, under the class of CRADAs entered into by participant with Lovelace under the Lovelace M&O 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 this Class Waiver. Lovelace, on the other hand, subject to its M&O contract, may elect title to inventions of its employees.

With respect to the advance Class Waiver to the class of CRADAs under the Act, it is expected that Lovelace will negotiate agreements that provide for a substantial cost sharing of the joint research effort by the participant, 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 participant is an indication of commitment by the participant to advance the technology and effect commercial utilization. Additionally, the work being performed under CRADAs will typically be driven by participant's 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 participant under CRADAs to the participant 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 Lovelace 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 AL approved CRADA. Participant's cost of filing and maintaining any patent application(s) or patent(s) on its 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), Lovelace 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 Lovelace 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 does not include inventions which:

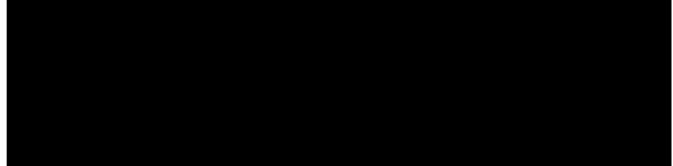
1. Relate to subject matter that is classified or sensitive under section 148 of the Atomic Energy Act of 1954, as amended, or which fall within DOE's weapons programs, wherein such inventions principally relate to weapons or inherently disclosure or suggest an application where such disclosure or suggestion would be detrimental to national security;
2. Arise out of naval nuclear propulsion program;
3. Arise out of uranium enrichment (including isotope separation) program;
4. Relate to storage and disposal of civilian high level nuclear waste or spent nuclear fuels; or
5. 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 to participant, 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 throughout the world, and (2) march-in rights comparable to those set out in 35 U.S.C. 203.

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 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.



Patent Counsel
Albuquerque Operations Office

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:

APPROVED:

James F. Decker
Acting Director, Office of
Energy Research
Date: _____

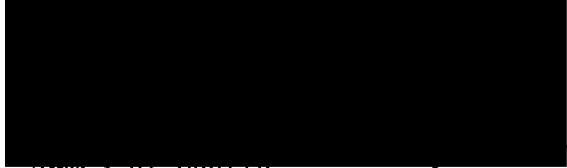
Richard E. Constant
Assistant General Counsel
for Patents
Date: _____



Linda G. Stuntz
Deputy Undersecretary for
Policy, Planning and Analysis
Date: 8/20/90

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CONCURRENCE:

APPROVED:


James F. Decker
Acting Director, Office of
Energy Research

Date: 8/24/90

for Richard E. Constant
Assistant General Counsel
for Patents

Date: 8/28/90

Linda G. Stuntz
Deputy Under Secretary for
Policy, Planning and Analysis
Date: _____