

STATEMENT OF CONSIDERATIONS

CLASS WAIVER OF THE GOVERNMENT'S U.S. AND FOREIGN PATENT RIGHTS IN CERTAIN IDENTIFIED INVENTIONS TO JEFFERSON SCIENCE ASSOCIATES, LLC (JSA), MADE AND TO BE MADE IN THE COURSE OF OR UNDER CONTRACT DE-AC05-060R23177 WITH THE DEPARTMENT OF ENERGY (DOE) FOR THE MANAGEMENT AND OPERATION OF THE THOMAS JEFFERSON NATIONAL ACCELERATOR FACILITY, INCLUDING A CLASS ADVANCE WAIVER OF TITLE TO INVENTIONS MADE IN THE PERFORMANCE OF COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENTS (CRADAS) ENTERED INTO BY JSA, PURSUANT TO CONTRACT DE-AC05-060R23177 WITH DOE.

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Background

The Department of Energy (DOE) awarded Prime Contract No. DE-AC05-060R23177 (Prime Contract) to Jefferson Science Associates, LLC (JSA) for management and operation of the Thomas Jefferson National Accelerator Facility (TJNAF) on April 14, 2006. JSA is organized as a non-profit limited liability company whose members comprise the Southeastern Universities Research Association (SURA) and the Computer Sciences Corporation (CSC).

The Thomas Jefferson National Accelerator Facility (TJNAF) comprises Government owned, Contractor-operated facilities located near Newport News, Virginia. As a user facility for scientists worldwide, TJNAF's primary mission is to conduct basic research of the atom's nucleus at the quark level. TJNAF has a remarkable record of scientific and technical accomplishments since its inception in 1984. This success is due, in part, to the unique contractual relationship that exists between DOE and its management and operating (M&O) contractors by way of the dedication of both technical and administrative skills of private organizations to a significant Federal mission in a close, long-term, cooperative relationship.

The National Competitiveness Technology Transfer Act of 1989, section 3133 (d) Public Law 101-189, required DOE to include in appropriate contracts for the operation of a Government-owned laboratory operated under contract by a non-Federal entity, contract provisions to establish technology transfer as a mission of the laboratory. DOE's implementation of this requirement is found at DEAR 970.2770, which dates from 1995 and includes provisions assuring that such M&O contractors hold title to most new inventions made at the laboratory with federal funding. DOE's nonprofit M&O contractors have the right to retain title to inventions made in the performance of their prime contract with DOE pursuant to Title 35 U.S.C. 202 (P.L.96-517), as amended by P.L. 98-620, other than those inventions excluded by Section 202(a)(ii-iv) and to the extent necessary to enable the Government to comply with Treaties and International Agreements.

In 1983, President Reagan's Memorandum on Government Patent Policy was promulgated, directing that:

To the extent permitted by law, agency policy with respect to the disposition of any invention made in the performance of a federally-funded research and development contract, grant or cooperative agreement award shall be the same or substantially the same as applied to small business firms and nonprofit organizations under Chapter 38, Title 35 of the United States Code.

Executive Order 12591, dated April 10, 1987, further provided that the head of each Executive department and agency promote the commercialization, in accord with the Memorandum on Government Patent Policy, of patentable results of federally funded research by granting to all contractors, regardless of size, the title to patents made in whole or in part with Federal funds, in exchange for royalty-free use by or on behalf of the Government.

DOE has considered the impact of these statutes and directives on patent policy with respect to non-profit business contractors, including its M&O contractors, and determined that Section 152 of the Atomic Energy Act of 1954 (42 U.S.C. 2182), as amended, and Section 9 of the Federal Non-Nuclear Energy Research and Development Act of 1974 (42 U.S.C. 5908), precluded DOE from automatically granting title to its large for-profit contractors.

With the overall goal of incorporating the research, development and demonstration results from all M&O contracts, including the TJNAF's Prime Contract, into the mainstream of American commerce in the most expeditious manner consistent with the National Competitiveness Technology Transfer Act of 1989, the President's Memorandum, as referenced in Executive Order 12591 dated April 10, 1987, and in accordance with the authority of Section 152 and Section 9, above, it was decided by DOE to be in the best interest of the United States and the general public to grant individual Class Waivers for each M&O contractor authorized to conduct technology transfer activities to certain identified inventions made under their Prime Contracts and a Class Advance Waiver of inventions made by a Participant under a CRADA, to Participants. Class waivers of this nature exist for all appropriate M&O contractors.

If such Class Waivers were not granted, DOE's non-profit M&O contractors would have to file identified waiver petitions on inventions made in the performance of a Prime Contract in order to obtain title to such inventions in furtherance of their technology transfer mission. Such a process would impose a substantial front end administrative burden, both on the Government and on the contractor, in preparing and processing such individual waiver petitions.

Excluded from the scope of this Class Waiver are inventions which:

- (1) Fall within DOEINNSA'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;
- (2) Relate to the Naval Nuclear Propulsion Program; Relate to the Uranium Enrichment (including Isotope Separation) Program;
- (3) Are classified or sensitive under Section 148 of the Atomic Energy Act of 1954, as amended;
- (4) Are included in international agreements or treaties to the extent necessary to implement the treaty or international agreement;
- (5) Are covered by existing or future Class Waivers granted to third parties by DOE such as "Work for Others" or "User Facilities"; and
- (6) Fall within any further exceptions that may, in the national interest, be unilaterally designated by the Secretary or his designee.

For inventions relating to Federal storage and disposal of civilian high-level nuclear waste and spent nuclear fuels, JSA's right to elect title is subject to the reservation in DOE of the right to require nonexclusive, nontransferable royalty-free licensing to any organization, such as a utility, that is contributing to the costs of activities relating to such storage and disposal.

This Class Waiver does not include inventions of subcontractors under the Prime Contract. It does apply to inventions of laboratory employees made under an agreement, such as a Work for Others agreement where the a third party sponsor having the right to elect title to a laboratory employee invention, decides not to elect to retain title to the laboratory employee invention. It also applies to laboratory employee inventions, where DOE determines that a class waiver that would normally grant a Work for Others sponsor or user the right to elect title to a laboratory employee invention does not apply and no other exception to the M&O contractor obtaining title applies.

Identified Invention Waiver to JSA

In one particular, the scope of the Class Waiver is directed to and includes U.S. and foreign patent rights to identified subject inventions made in the performance of the Prime Contract for TJNAF managed by JSA. Many of the inventions made under the Prime Contract would require additional development before they can be made available in the commercial marketplace. Additionally, many of these inventions are conceptual in nature and are on a laboratory 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 research and development 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.

A Class Waiver of the Government's rights in identified inventions as set forth herein will create sufficient exclusive rights in those inventions to bring forth private venture 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 M&O Contractor's Prime Contract, JSA is authorized to carry out technical liaison with universities, the private sector and other Federal facilities in connection with Cooperative Agreements of the Department and CRADAs 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, JSA will be able, where appropriate, to enhance the movement of the waived inventions to the commercial marketplace.

Furthermore, the grant of a Class Waiver of identified inventions as set forth herein will enable DOE to take advantage of the technology transfer capabilities of JSA. Permitting JSA to retain title to a broad range of important inventions, except those imbued with the national interest, should further enhance the technology transfer initiatives of DOE through JSA's Prime Contract.

JSA has agreed to attempt to commercialize the waived inventions within five years from the time the waiver is effective. This commitment to early commercialization by JSA will best promote the commercial utilization of such inventions and make the benefits of the research effort conducted under the Prime Contract widely available to the public in the shortest practicable time, consistent with the objectives and considerations of DOE's waiver regulations.

Class Waiver for the Benefit of JSA After Lapse of Two-Year Election Time Limit and for Inventor Employees

In a second particular, the scope of this Class Waiver is directed to and includes U.S. and foreign patent rights to identified subject inventions made in the performance of the Prime Contract for TJNAF managed by JSA that were electable under the conditions set forth above, but for which a request for waiver of Government rights is submitted after the expiration of the two-year period for making such an election.

The scope of this waiver also includes those electable subject inventions that JSA has previously indicated, in writing or otherwise, that they do not desire to take title and for which an inventor employee of JSA, with permission of JSA, seeks title. A waiver of such inventions to inventor employees shall be at the discretion of the DOE Patent

Counsel responsible for administration of the JSA Prime Contract based on the employee having sufficient plans and intents to commercialize the invention.

Because this waiver includes inventions in which the two-year period of election has expired, the invention may not be available for waiver due to licensing and related activities carried out by 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, the DOE Patent Counsel or designee will confer with said Office to determine the availability of any invention for application of this waiver.

Furthermore, if DOE has expended Federal funds to patent or pay any fees in relation to an invention that JSA is seeking title under this waiver, the DOE Patent Counsel, in his or her discretion, may require JSA to reimburse DOE, in some fashion, for these expenditures before approving JSA's waiver request.

Implementation of this waiver where JSA is obtaining title

Implementation of this Class Waiver, to the extent it benefits JSA, is to be by a simple procedure that requires:

- (1) JSA reporting of the invention pursuant to the Prime Contract and identifying the cognizant DOE program official in the invention disclosure;
- (2) JSA electing in writing to retain title to the invention at the time of disclosure or within two years of disclosure;
- (3) Representation after reasonable internal inquiry that the invention falls within this Class Waiver;
- (4) Representation to its best knowledge and belief and after reasonable internal inquiry that the invention does not fall within international agreements or treaties of the Government; and
- (5) Representation that JSA will attempt to commercialize the invention through its licensees within five years from the time the waiver is effective.

After review of the invention disclosure and relevant facts, the DOE Patent Counsel, or other staff member of the Office of DOE Patent Counsel designated by said DOE Patent Counsel, will certify whether the waiver is applicable to the invention. Except as hereinafter provided with respect to inventions funded by or through DOE/NNSA's Defense Programs, herein "DP-funded inventions", the election for inventions shall become effective sixty (60) days after receipt by DOE Patent Counsel, unless the DOE Patent Counsel shall return the election with reasons for failure to accept the election, as set forth in this Class Waiver, or DOE Patent Counsel elects for a one- time extension of thirty (30) days.

It is recognized that significant research and development under the Prime Contract is funded by DOE that result in valuable patentable technology. It is further noted that the ownership of such patentable technology by JSA, in all instances, would not compromise national security or DOE's program or patent position by application of appropriate safeguards.

The fact that certain inventions arising under DOE/NNSA's funding 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 this sensitive program, as specifically prescribed in 48 C.F.R. 927.370.

With regard to any invention that JSA reports with an election to retain title, JSA shall, to its best knowledge or belief, provide to DOE 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 Programs or other defense activities of the DOE/NNSA, 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/NNSA 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/NNSA; and
- (4) Whether there is any Export Controlled information or material present and, if so, how such information or material will be protected.

Additionally, JSA shall provide a statement of any safeguards it proposes to protect national security while commercializing the subject matter of the invention.

All elections of DP-funded inventions shall be subject to the independent concurrence of a designated DOE Program Official, in addition to the approval of the DOE Patent Counsel. The DOE Patent Counsel shall base the approval determination on the written election and any notifications provided in paragraph (J), of the Technology Transfer Mission Clause of the subject Prime Contract as of the date of approval of this Waiver. The concurrence of the designated DOE Program Official shall be based on a review of the national security impact of the election including the items set forth above, and the approval of such election by DOE Patent Counsel shall not be effective until such concurrence has been provided to DOE Patent Counsel. DOE shall use best efforts to provide approval and concurrence within 10 business days of the date that a complete election is received.

Furthermore, if DOE has expended federal funds to patent or pay any fees in relation to an invention that JSA is seeking title under this waiver, the DOE Patent Counsel, in his or her discretion, may require JSA to reimburse DOE, in some fashion, for these expenditures before approving JSA' waiver request.

This waiver of the Government's rights in TJNAF 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 inventions throughout the world, and (2) march-in rights in accordance with the attachment hereto entitled "March-In Rights."

This Class Waiver is implemented in conjunction with the implementation of technology transfer as a mission under the Prime Contract. Therefore, this Class Waiver is effective as of the effective date of the Prime Contract and shall apply to any subject inventions reported to DOE which may have been subject inventions under predecessor contracts for operation of TJNAF.

Class Advance Waiver to CA 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, or persons acting on behalf of Participants under the class of CRADAs entered into by Participants with JSA under the Prime Contract, pursuant to the Technology Transfer mission of the DOE. 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 CRADAs are intended to be covered by this Class Waiver.

With respect to the advance Class Waiver to the class of CRADAs above, it is expected that JSA 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 Class Advance 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 JSA 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 Class Advance Waiver is to be by execution of the CRADA by the DOE. Participants' cost of filing and maintaining any patent application(s) or patent(s) on their inventions will be at Participant's private expense.

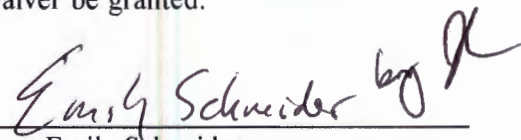
It is expected that in negotiating the commercialization rights to the waived inventions (including background inventions owned by the parties, if any), JSA and the Participant will be guided by their respective equities, the small business status of the Participant, if applicable, and the overall objective of attempting to secure the most expeditious commercialization route for moving the technology from the research state to the marketplace.

This Class Advance Waiver of the Government's rights in inventions to Participant, as set forth herein is subject to (1) the Government's retention of 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, (2) a preference for United States industries as set forth in 35 U.S.C. 204, (3) march-in rights comparable to those set out in 35 U.S.C. 203, and (4) the provisions of the Prime Contract with DOE, including the Patent Rights, Rights in Data, and Technology Transfer Mission clauses.

Summary

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 JSA or 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 statutory objectives to be obtained and the factors to be considered under DOE's statutory waiver policy, and the objectives of 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.




Emily Schneider
Chief Patent Counsel
Oak Ridge 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. This waiver shall not affect any waiver previously granted.

CONCURRENCE:

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APPROVAL:


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Transfer and Intellectual Property