STATEMENT OF CONSIDERATIONS

CLASS WAIVER OF U.S. AND FOREIGN PATENT RIGHTS IN INVENTIONS MADE BY INFORMAL COLLABORATORS WORKING WITH EMPLOYEES OF DEPARTMENT OF ENERGY OFFICE OF SCIENCE NATIONAL LABORATORIES DURING THE PERFORMANCE OF WORK UNDER THEIR DOE PRIME CONTRACTS; W(C) 2012-008 [ORO-810]

As a leading program office of the Department of Energy (DOE), the Office of Science (SC) supports a diverse portfolio of research that advances the science needed for revolutionary energy breakthroughs, seeks to unravel nature's deepest mysteries, and provides the Nation's researchers with the most advanced large-scale tools of modern science. SC manages this research portfolio through six core program offices: Advanced Scientific Computing Research, Basic Energy Sciences, Biological and Environmental Research, Fusion Energy Sciences, High Energy Physics, and Nuclear Physics. SC is also the steward of 10 of the 17 DOE laboratories (DOE SC Laboratories) which provide essential support to the missions of the DOE SC science programs:

Ames Laboratory (Contract No. DE-AC02-07CH11358)

Argonne National Laboratory (Contract No. DE-AC02-06CH11357)

Brookhaven National Laboratory (Contract No. DE-AC02-98CH10880)

Fermi National Accelerator Laboratory (Contract No. DE-AC02-07CHI1359)

Lawrence Berkeley National Laboratory (Contract No. DE-ACO2 05CH11231)

Oak Ridge National Laboratory (Contract No. DE-AC05-000R22725)

Pacific Northwest National Laboratory (Contract No. DE-AC05-76RL01830)

Princeton Plasma Physics Laboratory (Contract No.DE-AC02-09CH11466)

SLAC National Accelerator Laboratory (Contract No. DE-AC02-76SF00515)

Thomas Jefferson National Accelerator Facility (Contract No. DE-AC05-06OR23177)

DOE regards these Government-owned, Contractor-operated laboratories as Important 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. Because of the DOE SC Laboratories' unique resources and expertise, the public frequently engages with the laboratories' scientists and facilities via a number of agreement types, including Cooperative Research and Development Agreements (CRADAs), Work for Others (WFOs), and User Agreements (UAs). In addition to employing an extensive research staff, the DOE SC Laboratories host thousands of users and visiting scientists annually and operate numerous user facilities providing researchers with the most advanced tools of modern science. Scientists and engineers not working under a CRADA, WFO, or UA who come to work at the DOE SC Laboratories' facilities execute an Entrance Agreement which governs safety and security, export control, protection of proprietary information, and intellectual

property rights.¹ Thus, in most situations when DOE SC Laboratories' scientists collaborate with outside entities, intellectual property rights are expressly addressed. However, when no formal agreement is in place between the laboratories and collaborating scientists, the question of which entity or person retains rights to inventions is often difficult to answer.

Section 9 of the Federal Nonnuclear Energy Research and Development Act of 1974 (42 U.S.C § 5908)

Section 9 of the Federal Nonnuclear Energy Research and Development Act of 1974 (Section 9) provides that title to any inventions conceived or first actually reduced to practice under any DOE "contract" vests in the United States, except where the Bayh-Dole Act² provides otherwise for nonprofit or small business organizations. As used in Section 9, "contract" means "any contract, grant, agreement, understanding, or other arrangement which includes research, development, or demonstration work." [Emphasis added.] Without clear legislative history or case law that defines the terms, "understandings" and "arrangements," these terms can be interpreted quite broadly, casting a cloud on rights to inventions in a variety of circumstances. Arguably, Section 9 applies to inventions that arise out of a long-term collaborative relationship between a DOE SC Laboratory employee and a third party colleague. In the extreme, Section 9 may even apply when an invention results from a mere conversation between a scientist and a DOE SC Laboratory employee. Absent guiding regulations or rules, the interpretation and application of Section 9 across the DOE complex has been inconsistent. Accordingly, in view of the inconsistent application and ambiguous scope of Section 9, a class waiver is needed to clarify rights to inventions in certain specific situations as discussed in this Statement of Considerations.

Advance Waiver of Subject Inventions of Informal Collaborators

This class waiver is directed to the class of inventions which comprises subject inventions made by "Informal Collaborators" jointly with a DOE SC Laboratory employee(s) during the performance of work under any of the above listed DOE SC Laboratories prime contracts and waives rights³ to such class of inventions to the "Informal Collaborator." As used herein, "Informal Collaborator" means a third party person who collaborates with a DOE SC Laboratory employee(s) and makes a joint invention with the DOE SC Laboratory employee(s) without any official contractual agreement in place. The term does <u>not</u> include third-party scientists that visit a DOE SC Laboratory to work on site and execute an Entrance Agreement, User Agreement, CRADA, or WFO.

¹ The Entrance Agreement provides that DOE SC Laboratories will own rights to any inventions made by the visiting scientist as set forth in DOE Class Waiver W(C)-90-014 ("Employee-Like" Waiver).

² 35 U.S.C. § 200 et seq.

³ The term, "rights" used herein means the undivided rights of the informal collaborator. Under patent law and unless otherwise agreed to, joint inventors have equal, undivided rights to "make, use, offer to sell, or sell the patented invention within the United States, or import the patented invention into the United States, without the consent of and without accounting to the other owners." 35 USC § 262.

Specifically excluded from this class waiver are (1) inventions made solely by an Informal Collaborator(s); (2) inventions which fall under Section 152 of the Atomic Energy Act; (3) inventions covered by an Exceptional Circumstance Determination; and (4) inventions covered by international or other agreements.

The objectives set forth in 10 CFR Part 784 have been examined and are discussed below. As a primary consideration, the proposed waiver makes the benefits of the energy research, development and demonstration program available to the public in the shortest practicable time and promotes commercial utilization of the invention. Without this waiver, an identified waiver petition would have to be submitted to DOE for approval *each* time an invention is jointly made by a DOE SC Laboratory employee and an Informal Collaborator. The waiver approval process is often a time consuming process for both the submitter and DOE. By having rights vest with the Informal Collaborator in advance, the DOE SC Laboratory and the Informal Collaborator can agree more quickly on how the joint invention will be protected and commercialized. Moreover, recent changes to U.S. patent law have made rapid filing of patent applications of greater importance; therefore, this waiver enhances the protection of valuable intellectual property rights and increases the licensing potential of the technology.

The proposed waiver also serves to encourage participation by private persons in DOE's energy research, development, and demonstration programs. In order to advance the fundamental R&D mission of DOE, researchers from DOE SC Laboratories (like most scientists) cooperate both informally and formally with a wide range of entities and individuals at various organizations, both in the U.S. and around the world. This waiver thus promotes an open and interactive scientific environment by removing uncertainty as to rights to any joint inventions resulting from an informal collaboration.

This waiver also enhances commercialization of the joint invention because the waiver permits the parties who own the rights to make the business decisions as to how to best commercialize the technology. For example, if the Informal Collaborator has an established commercial position, then it may be expeditious to grant the Informal Collaborator an exclusive license in the DOE SC Laboratory's undivided rights. Absent this waiver, commercialization efforts are likely hampered when an Informal Collaborator's rights are vested in DOE, which may lack the interest or acumen to optimally commercialize the invention.

In accordance with applicable federal regulations, inventions covered by this class waiver are subject to U.S. preference, march-in provisions, and the retention by the Government of a worldwide, nonexclusive, nontransferable, irrevocable, paid-up license to practice for or on behalf of the Government. It is believed that these retained rights and other requirements represent sufficient

⁴ As stated earlier, this class waiver waives the informal collaborator's undivided rights in the subject inventions to the Informal Collaborator. If there is an employment or other agreement requiring the Informal Collaborator to assign rights, then such further disposition of rights are not impacted by this waiver, except that any such assignment is subject to the retention of Government rights and other obligations set forth herein.

consideration to the Government in exchange for this waiver, given the typical absence of DOE funding or use of other Government resources in such informal arrangements.⁵

As stated above, this waiver only applies to inventions jointly made by Informal Collaborators and a DOE SC Laboratory employee(s). Third-party researchers visiting or working at DOE SC Laboratories—who have or should have executed an Entrance Agreement addressing intellectual property rights—are categorically excluded from the benefits of this class waiver. Accordingly, the waiver of rights to the Informal Collaborator shall be automatic and granted without a request or petition by the Informal Collaborator, upon a determination from DOE field patent counsel (based on information submitted by the DOE SC Laboratory) that:

- (1) The work under which the invention arose is not covered by another contract, agreement or arrangement falling under DOE's or other federal statutory patent policy;⁶
- (2) The work under which the invention arose in not covered by an international or other agreement;
- (3) The subject invention is not covered by an Exceptional Circumstance Determination;
- (4) The work under which the invention arose is not or should not be covered by an Entrance Agreement; and,
- (5) At least one DOE SC Laboratory employee is a joint inventor.

Conclusion

The disposition of patent rights described herein resolves a long standing uncertainty as to rights in inventions arising out of informal collaborations and will best encourage the utilization and further development of the technology developed at DOE SC Laboratories. Accordingly, in view of the Congressional and statutory objectives to be obtained and the factors to be considered under DOE's Statutory Patent Waiver Policy, all of which have been considered, it is determined that this Class Waiver will best serve the interests of the United States and the general public. I therefore recommend that the waiver be granted.

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⁵ These conditions are consistent with the rights retained for subject inventions arising under the Bayh-Dole Act which also does not require compliance with the stricter U.S. Competitiveness clause normally included in DOE Waivers.

⁶ e.g., WFO, CRADA, User Agreement, or agreements under 10 CFR 600 or 48 CFR, Federal Acquisition Regulations.

Pursuant to the authority provided in Section 152 of the Atomic Energy Act of 1954, as amended (42) U.S.C. § 2182), Section 9 of the Federal Nonnuclear Energy Research and Development Act of 1974, as amended (42 U.S.C. § 5908), and the implementing regulations promulgated there under for waivers of patent rights, it is concluded that it is in the best interests of the United States and the general public to grant a waiver of patent rights to the class described herein. Therefore, it is ordered that a waiver of U.S. and foreign patent rights to the class of inventors described in the foregoing Statement of Considerations is hereby granted. The waiver is limited to inventions which are conceived or first actually reduced to practice in the course of or under an informal collaboration is subject to all the limitations, terms, and conditions set forth in the foregoing Statement of Considerations. The Assistant General Counsel for Technology Transfer and Intellectual Property shall be responsible for issuing instructions for implementation of this waiver in accordance with DOE regulations for the waiver of patent rights.

CONCURRENCE:

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Office of Laboratory Policy (SC-32)



APPROVED:

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