

STATEMENT OF CONSIDERATIONS

CLASS WAIVER OF THE GOVERNMENT'S DOMESTIC AND FOREIGN PATENT RIGHTS AND ALLOCATION OF DATA RIGHTS ARISING FROM THE USE OF DOE FACILITIES AND FACILITY CONTRACTORS BY OR FOR THIRD PARTY FUNDING SPONSORS UNDER AGREEMENTS FOR COMMERCIALIZING TECHNOLOGY (ACT): DOE WAIVER NO. W(C)-2011-013

Introduction

The Department of Energy (and its predecessor agencies) (collectively, "DOE" or "Department") considers each of its DOE Facilities (i.e., National Laboratories, single-purpose research facilities, and other Department facilities, hereinafter referred to individually as "Facility" or collectively as "Facilities") to be a unique and valuable national resource that should be made available to the extent feasible for non-Federal research and development activities and related technical services for third-party non-Federal funding sponsors.

Over the years, DOE has developed a number of technology transfer mechanisms that enable third-party sponsors to access DOE Facilities and expertise. These mechanisms have enabled DOE Facilities to work with businesses and academia on research and development efforts that have generated significant scientific and technological advances, spawned new businesses, and supported the creation of new industries and jobs. Building upon this successful history, the Department recently authorized a new contractual mechanism entitled "Agreements for Commercializing Technology" (ACT)¹ that complements DOE's current technology transfer mechanisms and will enable DOE Facilities to engage with the private sector in mission compatible areas using terms that are more consistent with industry practices. ACT, combined with the Department's existing technology transfer mechanisms like Work for Others Agreements (WFOs), Cooperative Research and Development Agreements (CRADAs), and User Facility Agreements, will further accelerate the movement of technology from Facilities to the marketplace and better enable the United States to compete in the global economy of the 21st century.

Under ACT, DOE authorizes its contractors that manage and operate Facilities on behalf of DOE (Facility Contractors) to conduct third-party sponsored research for the purpose of furthering the Department's technology transfer mission. Facility Contractors act as stewards of their respective Federally Funded Research and Development Centers (FFRDCs) in almost all situations, such as entering into and carrying out WFOs, CRADAs, and User Agreements. In certain well-defined situations, such as Privately-Funded Technology Transfer (PFTT) and the new ACT mechanism, Facility Contractors are permitted to act in their private capacity (Contractors-P). In exchange for assuming some of the risks and liabilities normally borne by private parties sponsoring research at DOE Facilities, and/or offering other private consideration, Contractors-P will be authorized to negotiate and execute ACT agreements² with a funding ACT Participant(s) using terms that may be more consistent with private sector agreements.

This Class Waiver applies only to work performed under ACT transactions with non-Federal funds and which is not within the scope of another Federally-funded contract or award (other than an M&O Contract). This Class Waiver enables Contractors-P and the other ACT Participant(s)³ (hereinafter referred to individually as "Party" or collectively as "Parties") to negotiate more flexible intellectual property (IP) terms

¹ See, Secretarial Memorandum entitled "Agreements Commercializing Technology (ACT) Contracting Vehicle" and dated October 21, 2011.

² An ACT transaction includes an ACT agreement entered into between Contractor-P and other ACT Participant(s), and the Management and Operating (M&O) Contract provisions that govern work to be performed at the Facility under the scope of the applicable M&O Contract.

³ "ACT Participant(s)" means a signatory to an ACT agreement that is a non-Federal entity, including contractor-P.

concerning which Party has the first option to own the IP (i.e., the designation of an IP Lead, which can be either the Contractor-P or another ACT Participant) and alternatives as to the rights the Government retains. Once an IP Lead is designated for an ACT transaction, the Parties will have the flexibility to further allocate IP rights between or amongst each other as described below. This flexible IP approach will allow the Parties to capitalize on the combined resources and expertise of ACT Participants and Facility Contractors to help accelerate the movement of technology to the marketplace.

Scope of this Class Waiver

This Class Waiver provides a waiver of DOE rights to Subject Inventions developed under ACT transactions with ACT Participants that engage Facilities for research and development and related technical services to be performed by Facility Contractors or subcontractors. This Class Waiver is granted under the authority of the Atomic Energy Act of 1954, as amended (42 U.S.C. § 2182) and Section 9 of the Federal Nonnuclear Energy Research and Development Act of 1974 (42 U.S.C. § 5908) and the regulations at 10 CFR Part 784 promulgated thereunder.

"Subject Invention" means any invention or discovery of the Contractor, either as Facility Contractor or Contractor-P, or, to the extent another ACT Participant or a Facility subcontractor is performing any work under an ACT transaction, of the ACT Participant or Facility subcontractor respectively, conceived in the course of, or under an ACT transaction or, in the case of an invention previously conceived by the Contractor-P, ACT Participant or Facility subcontractor, first actually reduced to practice in the course of or under an ACT transaction.

Since Facility subcontracts awarded under an ACT transaction (ACT subcontract) are funded with the private funds of the ACT Participants, the Bayh-Dole Act does not apply and the Department takes title to inventions made under such subcontracts unless waived. In consideration that the work is being funded with the private funds of the ACT Participants, and in order to allow the Parties to consolidate title to inventions made under privately funded ACT agreements, DOE waives its title in any Subject Invention made under an ACT subcontract to the IP Lead, subject to the terms and conditions of this Class Waiver.

Facilities should continue to follow established procedures for performing Federally funded WFOs, CRADAs, and User Agreements as specified in their M&O contracts with DOE.

The waiver of title to the IP Lead shall be automatic, and granted without a request or petition by the IP Lead, upon a determination from DOE/NNSA field Patent Counsel that:¹

- (1) The work to be performed under the ACT transaction is not covered by another contract or arrangement falling under DOE's statutory patent policy, and is not of sufficient interest to the DOE programmatic mission responsibility to justify DOE supporting the work in whole or in part with direct program funding;
- (2) Appropriate cost reimbursement is being provided for the services performed and/or facilities used as set forth in this Class Waiver;

¹ Since these four determinations are based on information supplied by Facility Contractors, DOE/NNSA field Patent Counsel may, at their discretion, authorize the Facility Contractor to make determinations (1), (2), (3) and (4).

- (3) The terms and conditions for the ACT agreement comply with this Class Waiver and instructions for its implementation as issued by the Assistant General Counsel for Technology Transfer and Intellectual Property (CC-62); and
- (4) The work does not involve Federal funds or fall within the scope of a Federally-funded contract or award (excluding an M&O contract for a Facility).

In most ACT transactions title to inventions will be waived to the IP Lead, however, there are certain situations where waiver of title to inventions to the IP Lead may be denied including: (1) where one of the identified exceptions (see next section) applies; or (2) because the Department, acting through the Contracting Officer and based on a determination of DOE/NNSA field Patent Counsel, finds that in a particular ACT transaction it is not in the best interest of the Government and the general public to allow the IP Lead to retain title to Subject Inventions developed under the proposed ACT transaction. This Class Waiver does not affect the Class Waivers covering CRADAs, WFOs, PROPRIETARY USER AGREEMENTS or NON-PROPRIETARY USER AGREEMENTS.

Identified Exceptions to the Class Waiver

DOE has identified several fact patterns where waiver of title to the IP Lead should be denied or would not apply. They are:

- (a) When any Subject Invention that might be made would be a research tool, (e.g., a transgenic animal etc.), and there is a Departmental and public interest in having the tool available to many potential research and commercial organizations;
- (b) When ACT Participants are either foreign-owned or -controlled or are sponsoring research on behalf of a foreign entity. However, this Class Waiver may apply to an ACT transaction under such circumstances with approval by the DOE/NNSA field Patent Counsel and with the concurrence of the cognizant Field Office or Headquarters program official; and
- (c) When any Federal funding is used to fund a project either directly from a Federal Agency or indirectly through a third-party recipient of Federal funds or falls within the scope of a Federally-funded contract or award (excluding an M&O contract for a Facility).

In providing advice to the Contracting Officer, DOE/NNSA field Patent Counsel is the final determiner that an exception to this Class Waiver should apply. With concurrence of DOE/NNSA field Patent Counsel, the Contracting Officer may delegate to the Facility Contractor the authority to determine whether fact pattern (a) or (c) exists. Whenever fact pattern (b) is believed to exist, DOE field Patent Counsel must approve the disposition of invention rights. Determinations regarding (a) are not mandatory and are judgment calls that should be made by balancing the needs of the Parties and the Department.

Designation of an IP Lead

The Parties will designate an IP Lead for each ACT transaction prior to submission of an ACT proposal package to the Contracting Officer. The IP Lead will be the Party that initially receives the right to own

Subject Inventions as allowed under this Class Waiver, and that assumes responsibility for further allocation of rights in Subject Inventions and other IP made under an ACT agreement (ACT IP) among the Parties. Instead of having title to Subject Inventions automatically flow to either the Contractor-P or other ACT Participants under this Class Waiver, the Parties will have the flexibility to jointly determine the optimum allocation of rights to Subject Inventions and other ACT IP for a particular transaction, including the designation of an IP Lead. The IP Lead may be the Contractor-P or another ACT Participant, however the IP Lead must be a Party to the ACT agreement.

Once the Parties have designated an IP Lead, the Parties will have the flexibility to further allocate IP between or among themselves.⁵ When requested by the Contracting Officer, the allocation of ACT IP rights must be described in a formal IP Management Plan that will be submitted to the Contracting Officer as part of an ACT approval package. An IP Management Plan shall, at a minimum, set forth the proposed allocation of ACT IP rights, and the proposed income and royalty sharing allocations, between or among the Parties.

Allocation of Intellectual Property Rights Under the Waiver

Waiver to the IP Lead Granted: Subject to the terms and conditions described herein (including appendices) or other guidance issued by DOE's Assistant General Counsel for Technology Transfer and Intellectual Property, this Class Waiver waives Government title to Subject Inventions to the designated IP Lead for each ACT transaction. The IP Lead and the other Parties can then allocate the rights to the Subject Inventions between or among themselves as they determine to be appropriate in an ACT agreement or consistent with any IP management plan, if any, for commercialization of the underlying technology. Where appropriate, the filing of patent applications is subject to DOE and other Government security regulations and requirements.

If the IP Lead does not elect to retain title to a Subject Invention, another ACT Participant may elect title to the Subject Invention within the same time period for election subject to the same requirements applicable to the IP Lead. If the IP Lead or other ACT Participant does not elect to retain title to a Subject Invention, or if the IP Lead or other party responsible for the prosecution or maintenance of a Subject Invention discontinues the filing or prosecution of a previously-elected Subject Invention or decides not to pay a maintenance fee covering a Subject Invention, the Facility Contractor will have the secondary right to take title to such inventions subject to the terms and conditions of the M&O Contract governing the right of the Facility Contractor to elect title to inventions. Where the IP Lead or other responsible party decides to discontinue filing or prosecution or suspend payment of maintenance fees, title may be offered to other interested ACT Participants before transferring title to the Facility Contractor. However, the IP Lead shall ensure that title is transferred to the Facility Contractor in a timely fashion so as to preserve any patent rights in the inventions.

Waiver to the IP Lead Denied: When waiver of title to Subject Inventions to the IP Lead has been denied (i.e., determined that an exception applies), this Waiver grants to the Facility Contractor the right to elect title to any of its Subject Inventions not otherwise reserved for DOE (e.g., inventions subject to a Bayh-Dole exceptional circumstance), subject to the terms and conditions of the Prime Contract governing the right of the Facility Contractor to elect title to inventions. (See, attached Appendix B). If a waiver of rights to the IP Lead is denied, this Class Waiver grants to the ACT Participants and Facility subcontractors the right to elect title to their own Subject Inventions, subject to the requirement to report inventions to DOE, the standard

⁵ Subject to the terms and conditions described herein (including appendices) or other guidance issued by DOE's Assistant General Counsel for Technology Transfer and Intellectual Property

Government Use License, and U.S. Preference (35 U.S.C. § 204), and such other conditions consistent with DOE patent waiver policy.

DOE shall retain title to any Subject Invention that is not retained by any one of the Parties, Facility subcontractors or the Facility Contractor and for any Subject Invention that constitutes a research tool.

In reporting Subject Inventions, the Parties shall identify the ACT agreement under which the Subject Invention was made and specify the rights (in both Subject Inventions and generated data) that have been reserved by the Government pursuant to this Class Waiver, and must otherwise be consistent with applicable laws and DOE policies.

Organizational Conflicts of Interest (OCI)

Facility Contractors shall conduct ACT in a manner that minimizes even the appearance of conflicts of interest and avoids or mitigates actual conflicts of interest with the Facility Contractor's functions under its M&O Contract with the Department. The Department conditions the application of this Class Waiver on the Facility Contractor's compliance with OCI requirements.

Government License to Subject Inventions

Under this Class Waiver, the Government will typically retain the standard Government Use License, which is a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced by or on behalf of the United States, any Subject Invention throughout the world.

Alternatively, the Parties may seek, subject to (a) and (b) below, for application of a narrowed Government Use License ("Government R&D License") for research and development purposes only. The Government R&D License grants to the Government, for R&D purposes only⁶, a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States, any Subject Invention throughout the world.

- (a) Any use of the Government R&D License must be accompanied by expanded Government access to data generated under the ACT transaction. Specifically, if an ACT transaction is to include a patent rights clause having the narrower Government R&D License, then the proprietary data clause must be replaced with a "Protected ACT Information" data clause (see attached Appendix C) that limits the period of protection for generated data to no more than five (5) years.⁷ Subject to DOE/NNSA field Patent Counsel approval and the mutual agreement of the Parties, the period of protection for Protected ACT Information may be extended for one extension term that is no more five (5) years in duration and which begins immediately upon expiration of the initial period of protection.

⁶ R&D purpose includes all research, development and demonstration activities by or on behalf of the Government, including uses at Federal Facilities to perform work under privately-sponsored agreements.

⁷ See. Secretarial Memorandum entitled "Agreements Commercializing Technology (ACT) Contracting Vehicle" and dated October 21, 2011, approving increased flexibility in Government Rights.

- (b) The application of the Government R&D License requires approval by DOE/NNSA field Patent Counsel after consulting with the cognizant DOE Program Office because application of the narrower Government R&D License may affect ongoing programs at either DOE or another Federal Agency.⁸

The Government R&D License will not be allowed for ACT transactions related to national security.⁹ Special attention also should be given to proposed ACT transactions involving environmental management programs, or in situations where the ACT transaction involves work to be performed for the Facility Contractor, Facility Contractor's parent, member, subsidiary, or other entity in which the Facility Contractor, Facility Contractor's parent, member or subsidiary has an equity interest. The foregoing examples of special circumstances are not exhaustive.

The Allocation of Data Rights

Greater Data Rights for Generated Data: DOE has traditionally allowed Sponsors in Non-Federal WFO agreements to designate generated data by most Facilities as "Proprietary Data" as long as the funding is not from a Federal source (referred to herein as "enhanced data protection"). Unless prohibited or limited by this Class Waiver, DOE authorizes the same enhanced data protection for data generated under ACT transactions.

Enhanced data protection is not appropriate or warranted in a number of situations, even where the full Government Use License is retained for Subject Inventions. In those cases, this Class Waiver allows the flexibility to negotiate greater data rights. Specifically, the applicability of enhanced data protection, including proprietary or protected data protection to foreign ACT Participants is not automatic and requires approval from DOE/NNSA field Patent Counsel with input from the applicable HQ Program Office as appropriate.

Other situations in which enhanced data protection may not be appropriate or warranted are: (1) ACT Participant(s) is/are not providing proprietary information or material to the Facility; (2) the ACT Participant(s) is/are not likely to use the results of the work for commercial activity or is an institution that does not want to assert proprietary rights in the data to the exclusion of any rights in the Government; (3) the ACT Participant(s) cannot show that the primary use of the data will be in the United States rather than in a foreign country; (4) the ACT Statement of Work is directly related to specific ongoing projects (this is an instance where perhaps 5-year protection might be appropriate); (5) the ACT Statement of Work requires only a paper study and is not directed to a particular commercial product of the ACT Participant(s) (this is an instance where unlimited data rights in the Government might be appropriate); (6) per this Class Waiver, title to some of the Subject Inventions remains at the Facility pursuant to the M&O Contract; (7) any benefit to the U.S. Government would be lost by the removal of the data from the Facility. As previously noted, if an ACT transaction includes the narrower Government R&D License for Subject Inventions, then the proprietary data clause must be replaced with a "Protected ACT Information" data clause (See, Appendix C) that limits the period of protection for generated data to no more than five (5) years unless extended as previously described.

⁸ DOE program offices may grant blanket approvals or issue blanket denials for the use of the Government R&D License in certain program areas.

⁹ The scope of subject matter that will not be eligible for performance under an ACT transaction on the basis of this national security exclusion will be described in guidance issued by cognizant Program Offices.

DOE recognizes that some Facility Contractors have a policy prohibiting the protection of Facility Technical Data and provides alternate language to comply with this policy. Nothing in this Class Waiver shall prevent a Facility Contractor from applying the same policy for ACT transactions.

Greater Data Rights for Government and Facility: Before an ACT transaction is entered into, the Facility Contractor or the Department may require that greater data rights be obtained for the Government or the Facility. The data rights acquired by the Government/Facility depend on the circumstances, and can range from unlimited rights to some lesser level of protection, such as a period of protection (e.g., five (5) years), or having only part of the data being proprietary to one of the Parties. The Department or the Facility Contractor can also obtain greater rights in copyright, especially where the transaction covers work that is derivative of prior work at the DOE Facility.

Elimination of March-In Rights

This Class Waiver does not apply the Government's march-in rights to Subject Inventions, subject to the exception below where title is retained by the Facility Contractor instead of Contractor-P. Although rarely, if ever exercised, these rights were often perceived as a barrier to access by industry and were not statutorily mandated in the case of a Sponsor privately funding WFO work at a Facility. The decision to not apply march-in rights to ACT Subject Inventions elected by the IP Lead aims to maximize the availability of DOE Facilities to funding sponsors who have made substantial private investment in proprietary technology and to enhance the potential for such technology to be further commercialized. Because the Government still retains a Government license in any Subject Inventions, the Government's interests are believed to be adequately protected in the absence of such march-in rights. All Subject Inventions will continue to be subject to the requirements of the U.S. Preference clause pursuant to 35 U.S.C. § 204.

Subject Inventions that revert to the Facility Contractor and are elected under the applicable M&O Contract will be governed by the provisions of the applicable M&O Contract

Intellectual Property Terms for ACT Transactions¹⁰

When it has been determined that waiver of title to Subject Inventions to the IP Lead is appropriate, work performed under an ACT transaction will be pursuant to the standard intellectual property terms and conditions attached hereto as Appendix A.

In situations where waiver of title to Subject Inventions to the IP Lead has been denied (e.g., due to the application of one of the exceptions to this Class Waiver), the work performed under an ACT transaction will be pursuant to the intellectual property terms attached hereto as Appendix B.

When it has been determined that waiver of title to Subject Inventions to the IP Lead is appropriate and the Parties have been granted a request to incorporate the limited Government R&D License for Subject

¹⁰ For ACT transactions where no research, development, or demonstration is to be conducted in performance of the Scope of Work, the patent rights clause may be reserved. The Facility Contractor must timely notify local DOE/NNSA field Patent Counsel before entering into an ACT agreement of its intent to reserve the patent rights clause. Failure to include the applicable patent provisions may result in Government ownership of Subject Inventions.

Inventions, work performed under an ACT transaction will be pursuant to the alternate intellectual property terms and conditions attached hereto as Appendix C.

With not less than thirty (30) days notice to Facility Contractors, the DOE Assistant General Counsel for Technology Transfer and Intellectual Property may periodically update the terms found in Appendices A, B, and C by issuing administrative updates to this Class Waiver. A Facility Contractor may utilize local variants of these terms and conditions as long as DOE/NNSA field Patent Counsel has determined in writing that such terms are the legal equivalent.

Subject to a reserved Government Use License as appropriate, the Parties may assert copyright to any data generated within the scope of an ACT transaction and exercise discretion in allocating such copyright rights between the Parties.

Commercialization of ACT IP by the Facility Contractor

If appropriate under the terms of this Class Waiver:

Either Contractor-P or another ACT Participant may be designated as the IP Lead under an ACT transaction and commercialize ACT IP using its private funds, where no costs for patenting, licensing and marketing the ACT IP will be allowable under the applicable M&O Contract. The Contractor-P will share royalties collected as a result of commercializing ACT IP with inventors in accordance with paragraph (h) of the Technology Transfer Mission clause of the applicable M&O Contract.

If the Facility Contractor receives ownership or license rights to ACT IP, then the ACT IP will be treated as other Subject Inventions or data under the applicable M&O Contract and the costs associated with patenting, licensing and marketing such ACT IP may be allowable.

Conclusion

Providing the disposition of intellectual property rights described herein will best encourage the utilization and further development of the technology developed at DOE Facilities. Accordingly, this Class Waiver is consistent with the objectives and considerations of DOE's waiver regulations set forth in 10 CFR 784.

The Assistant General Counsel for Technology Transfer and Intellectual Property shall be responsible for issuing instructions for implementation of this Class Waiver in accordance with DOE regulations for the waiver of patent rights.



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DOE Chicago Office

Date: 3/13/2012

Based on the foregoing Statement of Considerations, it is determined that the interests of the United States and the general public will be served by a waiver of patent rights of the scope determined above, and, therefore, the waiver is granted.

CONCURRENCE:

[Handwritten initials]



Under Secretary for Science

Under Secretary for Energy

Date: 5/1/12

Date: MAY 1, 2012



Under Secretary for Nuclear Security

Date: 5/1/12

APPROVAL:



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Date: May 3, 2012