

## STATEMENT OF CONSIDERATIONS

### CLASS WAIVER W(C) 2020-002 OF PATENT RIGHTS TO INVENTIONS MADE UNDER THE OFFICE OF NUCLEAR ENERGY (NE) FUNDING OPPORTUNITY ANNOUNCEMENTS RELEASED DURING OR AFTER FISCAL YEAR 2020

This is a class patent waiver of the Government's right to title in inventions conceived or made by a domestic large business<sup>1</sup> in the course of or under an NE funding agreement. The waiver applies to funding agreements selected through a funding opportunity announcement ("FOA") or request for proposal (RFP) released by NE during or after fiscal year 2020. The waiver is effective as the date of signature by the Assistant General Counsel for Technology Transfer and Intellectual Property. The waiver will automatically renew the first day of each successive fiscal year unless cancelled or superseded by the Assistant General Counsel for Technology Transfer and Intellectual Property at the written request of the Assistant Secretary for the Office of Nuclear Energy.

The waiver is subject to a Government license, march-in rights, and preference for U.S. industry provisions set out in 35 U.S.C. §§ 202-204. The waiver is further subject to a U.S. competitiveness provision that requires products embodying any waived invention or produced through the use of any waived invention be manufactured substantially in the United States or a U.S. manufacturing plan that provides legally binding measurable commitments by the domestic large business to support U.S. manufacturing of the technologies related to the NE funding agreement when approved by the Assistant Secretary for Nuclear Energy, the Acting Assistant Secretary, or the cognizant Deputy Assistant Secretary in consultation with the cognizant DOE Patent Counsel. The cognizant Deputy Assistant Secretary or higher, in consultation with DOE Patent Counsel, may choose whether to apply this class patent waiver to a particular Funding Opportunity Announcement, Request for Proposal, and/or a particular award, contract or other transaction.

DOE takes title to inventions conceived or made by a domestic large business, unless DOE waives its right to title. A patent waiver is warranted when it is determined that the interests of the United States and the general public will best be served with the patent waiver. When making such a determination, DOE should have the following objectives: (1) make the benefits of the energy research, development and demonstration program funded by NE widely available to the public in the shortest time; (2) promote the commercialization of NE funded inventions; (3) encourage participation in programs funded by NE; and (4) encourage competition.

DOE may grant an advance patent waiver for a particular contractor<sup>2</sup> or a class patent waiver for a class of contractors. A class patent waiver is appropriate when all members of a particular class would likely qualify for an advance patent waiver. As demonstrated below, domestic large businesses performing work under an NE funding agreement constitute a class of contractors in which all of the members would likely qualify for an advance patent waiver.

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<sup>1</sup> A "domestic large business," as used in this class patent waiver, is any for-profit entity that does not qualify as a "small business" under Bayh-Dole and is incorporated or otherwise formed under the laws of a particular State or territory of the United States. For contractors that do not meet the definition of domestic large business, but where the considerations discussed in this class waiver otherwise apply, the Assistant General Counsel for Technology Transfer and Intellectual Property may grant rights under this waiver with the concurrence of NE.

<sup>2</sup> The term "contractor" includes all participants under NE financial assistance agreements, including grants and cooperative agreements.

The DOE patent waiver regulations provide a list of considerations that must be used when determining whether an advance patent waiver will best serve the interests of the United States and the general public. The following is a list of those considerations along with an analysis on how each consideration applies to a domestic large business performing work under an NE funding agreement:

- (a) The extent to which the participation of the contractor (referred to as “recipient” in NE awards) will expedite the attainment of the purposes of the program.

NE issues FOAs for work in areas that the program has determined will advance nuclear power to meet the nation's energy, environmental, and national security needs by enhancing the long-term viability and competitiveness of the existing U.S. reactor fleet, developing an advanced reactor pipeline, and/or implementing and maintaining national strategic fuel cycle and supply chain infrastructure so that the technology will be more broadly adopted and used across the U.S.

The funding program selects the recipients through a competitive process based on the merit criteria set forth in the FOA. Specifically, the program selects each recipient based on the determination that the recipient is most likely to achieve the purpose of the FOA compared to the other organizations that applied for funding. In unique circumstances, NE may also determine that a domestic large business competitively selected under a FOA merits additional support on a non-competitive basis. In both competitive and non-competitive circumstances, the participation of a particular domestic large business is determined by NE to be the best means of attaining the program's purposes.

- (b) The extent to which a waiver of all or any part of such rights in any or all fields of technology is needed to secure the participation of the particular contractor.

Waiving patent rights encourages participation in NE funded research, development and demonstration projects. With patent rights, an organization is more likely to invest (*e.g.*, cost share) in research, development and demonstration projects that may lead to valuable inventions.

Congress recognized the value of patent rights with the passage of the Bayh-Dole Act, 35 U.S.C. §§ 200-212 (“Bayh-Dole”). One of the objectives of Bayh-Dole was to encourage participation in federally funded research, development and demonstration projects. Congress understood that more organizations would participate in federally funded research, development and demonstration projects when the organizations can own the rights to the inventions conceived or first actually reduced to practice in performance of the work under a funding agreement (referred to as “subject inventions”). Therefore, Bayh-Dole requires that funding agencies generally allow domestic small businesses and non-profit organizations the right to retain title to their subject inventions. Bayh-Dole was extended to all types of contractors, including domestic large businesses, under Executive Order 12591, to the extent permitted by law.

Section 2 of the Atomic Energy Act (42 U.S.C. § 2182), however, provides that title to any invention or discovery useful in the production or utilization of special nuclear material or atomic energy made or conceived in the course of or under any contract, subcontract, or arrangement entered into with or for the benefit of the DOE vests with DOE unless title is waived. For any contract, subcontract, or arrangement not covered by the Atomic Energy Act, section 9 of the Federal Non-nuclear Research and Development Act of 1974 (42 U.S.C. § 5908) also provides that title to subject inventions vests with DOE unless title is waived.

Because of these provisions, the Executive Order does not extend Bayh-Dole to domestic large businesses under NE funding agreements and the right for large businesses to retain title to subject inventions must be granted through the patent waiver process. Nevertheless, the same policy reasoning behind Bayh-Dole and the Executive Order applies here to domestic large businesses (*i.e.*, allowing large businesses to take title to their subject inventions will encourage their participation) under NE funding agreements. Therefore, granting a patent waiver encourages the participation of domestic large businesses.

- (c) The extent to which the work to be performed under the contract is useful in the production or utilization of special nuclear material or atomic energy.

NE funding agreements often cover work which is useful in the production or utilization of special nuclear material or atomic energy.

- (d) The extent to which the contractor's commercial position may expedite utilization of the research, development, and demonstration results.

The utilization of the research, development, and demonstration results is more likely expedited with a domestic large business having patent rights instead of the Government retaining the patent rights. With the patent rights, the domestic large business is more likely to be able and willing to make the necessary investment to commercialize the results.

In order to progress the technology beyond research, development and demonstration to commercialization, a business must make a significant investment in time, equipment and other resources. The investment is not guaranteed due to the risk associated with being the first one to introduce a new technology to the marketplace. A business is less likely to make the investment and accept the risks if it does not have the patent protection to prevent its competitors from copying the technology if and once the business establishes a market for the new technology.

Congress recognized that federally funded technology was more likely to be utilized and commercialized when the organizations that made the inventions had the patent rights to the inventions with the passage of Bayh-Dole. Congress passed Bayh-Dole, in part, to promote the utilization of federally funded inventions by domestic small businesses and non-profit organizations. Executive Order 12591 implicitly recognized that the same policy considerations behind Bayh-Dole also apply to large business contractors. This same reasoning also applies to domestic large businesses under NE funding agreements.

- (e) The extent to which the Government has contributed to the field of technology to be funded under the contract.

The Government has made significant and strategic contributions to nuclear energy technologies. Although the Government's contributions have been important, the contributions by private industry have been significant as well. In addition to cost share provided under a particular funding agreement, it is typical that the work of the funding agreement relies significantly on past investments made by a domestic large business and will rely on future investments from the domestic large business in order to commercialize the technology.

- (f) The purpose and nature of the contract, including the intended use of the results developed thereunder.

NE funding agreements selected through an NE FOA are financial assistance instruments. The principal purpose of financial assistance is to transfer a thing of value to a recipient to carry out a public purpose of support or stimulation authorized by law rather than acquiring property or services for the direct benefit or use of the U.S. government. The purpose of the NE funding agreements is to increase performance or lower the cost associated with advancing nuclear power technologies to meet the nation's energy, environmental, and national security needs so that these technologies are more broadly adopted and used across the U.S. Granting a waiver encourages participation and supports commercialization of the technologies. Therefore, granting a waiver is consistent with the purpose of the NE funding agreements.

- (g) The extent to which the contractor has made or will make substantial investment of financial resources or technology developed at the contractor's private expense which will directly benefit the work to be performed under the contract.

Under NE funding agreements, domestic large businesses are usually required to meet certain cost share requirements. Specifically, under Section 988 of the Energy Policy Act of 2005, a large business is usually required to provide at least a 20% cost share for research and development activities and at least a 50% cost share for demonstration activities, unless reduced by DOE in conformance with applicable authorities.

In addition to cost share, a domestic large business will typically have made a past investment and intend to make a future investment beyond the funding agreement related to the technology subject to an NE funding agreement. The past and anticipated future investment varies from domestic large business to domestic large business. However, based on past patent waiver requests, it is typical that the work to be done under a funding agreement by a large business is built upon and benefits from a past investment by the large business (e.g., use of equipment and facilities and background intellectual property). It is also typical that a large business has the intent and capability of making future investments in promising technologies resulting from work under the funding agreement. In any event, patent waivers are subject to march-in rights that would require licensing the technologies to others if the large business fails to make reasonable efforts to utilize the technologies.

- (h) The extent to which the field of technology to be funded under the contract has been developed at the contractor's private expense.

The extent to which a large business has developed a particular technology at private expense will vary. It is typical, however, for a large business to rely on its past investments to perform the work under an award.

- (i) The extent to which the Government intends to further develop to the point of commercial utilization the results of the contract effort.

A particular large business may receive additional federal funding related to the technology subject to an NE funding agreement. However, it would be unusual for the Government to conduct any development work by itself on nuclear energy technologies related to an NE funding agreement. Any additional federal funding to a large business is likely to be made through a competitive process, in support of other NE program objectives, and subject to the

required terms and conditions for receiving federal funding (e.g., 50% cost share for demonstration activities).

- (j) The extent to which the contract objectives are concerned with the public health, public safety, or public welfare.

The purpose of the NE funding agreements is to increase performance or lower the cost associated with nuclear energy technologies so that the technologies are broadly adopted and used across the U.S. The adoption of nuclear energy technologies would indirectly benefit the public health, safety and welfare by enhancing the long-term viability and competitiveness of the existing U.S. reactor fleet, developing an advanced reactor pipeline, and/or implementing and maintaining national strategic fuel cycle and supply chain infrastructure. Granting a waiver is therefore in the interest of public health, safety and welfare.

- (k) The likely effect of the waiver on competition and market concentration.

Energy is a globally competitive market. In order to be commercially viable, nuclear energy must compete with more conventional sources of energy. Within nuclear energy, the different types of technologies (e.g., pressurized water reactors, boiling water reactors, sodium cooled reactors, and molten salt reactors) compete among themselves. Moreover, even within a particular type of technology, there are often different approaches and systems competing among themselves (e.g., small modular reactors vs. micro reactors).

Typically, a patent waiver encourages a large business to make the necessary investments needed to bring its particular technology solution to the market. A patent waiver should not have an impact on the other technology solutions in the market. By encouraging the large business to bring another technology solution to the market and not impacting the other solutions already in the market, a patent waiver supports competition in energy.

- (l) In the case of a domestic nonprofit educational institution under an agreement not governed by Chapter 18 of Title 35, United States Code, the extent to which such institution has a technology transfer capability and program approved by the Secretary or designee as being consistent with the applicable policies of this section.

This consideration is not applicable to a domestic large business.

- (m) The small business status of the contractor under an agreement not governed by Chapter 18 of Title 35, United States Code.

This consideration is not applicable to a domestic large business.

- (n) Such other considerations, such as benefit to the U.S. economy, that the Secretary or designee may deem appropriate.

Most patent waivers include a U.S. competitiveness provision that requires products embodying any waived invention or produced through the use of any waived invention be manufactured substantially in the United States. This class waiver will be subject to a U.S. competitiveness provision and/or a U.S. manufacturing plan that provides for measurable commitments to U.S. manufacturing. If DOE agrees to foreign manufacture, there will be a requirement that the

Government's support of the technology be recognized in some appropriate manner such as a legally binding Net Benefits Statement.

As shown above, a domestic large business performing work in an NE funding agreement is likely to qualify for an advance patent waiver because, based on the requisite considerations of the DOE patent waiver regulations, it best serves the interests of the U.S. and the general public. This analysis is consistent with Bayh-Dole.

Domestic large businesses working under awards made under competitive funding opportunity announcement by the DOE Office of Nuclear Energy released during or after FY 2020 would qualify for this advance patent waiver, unless otherwise specified by the Contracting Officer.

This class patent waiver shall be subject to DOE's standard patent waiver terms and conditions including the usual Government license, march-in rights, and preference for U.S. industry provisions set out in 35 U.S.C. §§ 202-204. The class waiver also includes the following U.S. Competitiveness provision:


The Contractor agrees that any products embodying any waived invention or produced through the use of any waived invention will be manufactured substantially in the United States unless the Contractor can show to the satisfaction of the DOE that it is not commercially feasible to do so. In the event the DOE agrees to foreign manufacture, there will be a requirement that the Government's support of the technology be recognized in some appropriate manner, e.g., recoupment of the Government's investment, etc. The Contractor agrees to make the above conditions binding on any assignee or licensee or any entity otherwise acquiring rights to any waived invention, including subsequent assignees or licensees. Should the Contractor or other such entity receiving rights in the invention(s): (1) undergo a change in ownership amounting to a controlling interest, or (2) sell, assign, or otherwise transfer title or exclusive rights in the invention (s), then the waiver, assignment, license, or other transfer of rights in the waived invention(s) is/are suspended until approved in writing by the DOE. Approval of any such change in ownership or transfer of title or exclusive rights in the inventions, or any modification of this provision, including foreign manufacture, shall require the concurrence of the Assistant Secretary for Nuclear Energy, the Acting Assistant Secretary, or the cognizant Principal Deputy Assistant Secretary.

If a recipient fails to satisfy the U.S. competitiveness provision the recipient shall forfeit and assign all rights to all waived inventions to which this waiver applies to DOE.

NE may require applicants to its FOAs to submit U.S. manufacturing plans as part of their proposals. A U.S. manufacturing plan represents an applicant's measurable commitment to support U.S. manufacturing of the technologies related to its potential NE funding agreement. The nature and specificity of the applicants' U.S. manufacturing plans will vary based on the FOA and the program issuing the FOA. The weight given to the U.S. manufacturing plans during the review and selection process will also vary based on the particular FOA and may be part of the evaluation or merit criteria. The DOE Patent Counsel supporting the FOA, in consultation with the responsible program/office official for the FOA, may agree to use the U.S. manufacturing plan in lieu of the U.S. competitiveness provision for a particular domestic large business when the funding program/office official, in consultation with the cognizant DOE Patent Counsel, determines that the U.S. manufacturing plan provides adequate and enforceable support to the U.S. manufacturing of the technology related to the NE funding agreement.

This class patent waiver is available to any domestic large business that (1) is a recipient, or subrecipient at any tier, to a funding agreement issued under an NE FOA released during or after FY 2020 or a subcontractor to a DOE national laboratory for work on a project selected under an NE FOA released during or after FY 2020 and (2) is providing at least the statutory minimum cost share for the work assigned to it under the funding agreement or project (*i.e.*, at least 20% for research and development activities and at least 50% for demonstration activities, even when a domestic large business would have otherwise qualified for a cost share waiver). NE may also decide to apply this class waiver to non-domestic entities and/or those awardees/contractors that provide less than the statutorily required cost share if NE decides it is in the best interest of NE's mission to do so, however, application of the waiver to such entities shall require the written concurrence of the cognizant Deputy Assistant Secretary or higher. However, if a recipient or subrecipient fails to meet or maintain the required minimum cost share required under an NE FOA, the recipient shall forfeit and assign all rights to all waived inventions to which this waiver applies to DOE.


Considering the foregoing, and in view of the statutory objectives to be obtained and the factors to be considered under DOE's statutory waiver policy, all of which have been considered, it has been determined that this class waiver as set forth above will best serve the interest of the United States and the general public. It is recommended that the waiver be granted.

  
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Dan Park  
DOE Patent Counsel

Date: 7/29/20



Based upon the foregoing Statement of Considerations, it is determined that the interests of the United States and the general public will best be served by a waiver of the 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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Dr. Rita Baranwal  
Assistant Secretary  
Office of Nuclear Energy

Date: July 29, 2020

APPROVAL:

  
  
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Brian Lally  
Assistant General Counsel for  
Technology, Transfer, and  
Intellectual Property

Date: 7/29/20