

## STATEMENT OF CONSIDERATIONS

### CLASS WAIVER OF PATENT RIGHTS TO INVENTIONS MADE UNDER CERTAIN OFFICE OF SCIENCE FUNDING OPPORTUNITY ANNOUNCEMENTS RELEASED DURING OR AFTER FISCAL YEAR 2022 W(C) 2022-01

This is a class patent waiver of the Government's right to title in inventions made or conceived by a domestic large business in the course of or under a financial assistance (FA) agreement released by the Office of Science (SC) selected through a funding opportunity announcement (FOA) released by SC during or after fiscal year 2022. The waiver is granted in extendable one (1) year terms beginning the first day of fiscal year 2022 and will be automatically extended at the beginning of each subsequent fiscal year unless cancelled or superseded by the Assistant General Counsel for Technology Transfer and Intellectual Property. To ensure appropriate program cognizance, each year, approximately 60 days prior to the beginning of the next fiscal year, a memo similar to the one in Attachment B, will be sent to SC providing notice that the class waiver will renew on October 1, unless objected to by the Director for the Office of Science.

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 and is not owned, controlled, or influenced by a foreign government, agency, firm, corporation or person. The requirement that the recipient, or subrecipient at any tier be a domestic entity may be waived by DOE Patent Counsel with program concurrence after a risk-based analysis (in coordination with the Office of Counterintelligence as appropriate). 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.

DOE takes title to inventions made or conceived by a 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 research, development and demonstration program funded by SC widely available to the public in the shortest time; (2) promote the commercialization of SC-funded inventions; (3) encourage participation in the programs funded by SC; and (4) encourage competition.

DOE may grant an advance patent waiver for a particular recipient or a class patent waiver for a class of recipients. 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 a SC FA agreement constitute a class of recipients in which all of the members would likely qualify for an advance patent waiver.

The DOE patent waiver regulations provide a list of considerations that must be addressed 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 a SC FA agreement:

- (a) The extent to which the participation of the recipient will expedite the attainment of the purposes of the program.

Each SC program issues FOAs for work in areas that the program has determined will help deliver scientific discoveries and major scientific tools to transform our understanding of nature and advance the energy, economic, and national security of the United States.

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 entities that applied for funding. Therefore, the participation of a particular domestic large business was determined by the funding program 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 recipient.

Waiving patent rights encourages participation in SC 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 recipients, including domestic large businesses, under Executive Order 12591 ("Executive Order"), to the extent permitted by law. However, Section 9 of the Federal Non-nuclear Energy Research and Development Act of 1974 (42 U.S.C. § 5908) provides that title to subject inventions vests with DOE unless title is waived. Because of this provision, the Executive Order does not extend Bayh-Dole to domestic large businesses under SC FA agreements and so the right for large businesses to retain title to subject inventions must be granted through the patent waiver process. Nonetheless, 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 SC FA 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 FA agreement is useful in the production or utilization of special nuclear material or atomic energy.

SC programs are focused on basic research in physics, materials science, chemistry, and bioscience. Some SC funded projects are specifically aimed at improving nuclear energy technologies. However, in the unlikely event that the work under a SC FA agreement would be useful in the production or utilization of special nuclear material or atomic energy, the SC FOA will include a statement that this SC class patent waiver does not apply. A domestic large business working under a SC FOA excluded from this class patent waiver may later petition for an advanced or identified patent waiver.

- (d) The extent to which the recipient'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 its subject inventions.

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 when 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 recipients. This same reasoning also applies to domestic large businesses under SC FA agreements.

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

The Government has made significant and strategic contributions to core research in physics, materials science, chemistry, and bioscience. 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 FA agreement, it

is typical that the work under the 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 FA agreement, including the intended use of the results developed thereunder.

SC agreements selected through a 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 purposes of the SC FA agreements help the United States deliver scientific discoveries and major scientific tools to transform our understanding of nature and advance the energy, economic, and national security of 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 SC FA agreements.

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

In order to avail itself of this waiver, the domestic large business must provide at least 20% cost share. 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 FA agreement related to the technology being developed under the SC agreement. The past and anticipated future investment varies with the domestic large business. However, based on past patent waiver requests, it is typical that the work to be done under a FA 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 FA agreement. In any event, patent waivers are subject to march-in rights that would require licensing the subject inventions to others if the large business fails to make reasonable commercialization efforts.

- (h) The extent to which the field of technology to be funded under the FA agreement has been developed at the recipient'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, and additionally, to further fund the field of technology at its private expense.

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

A particular large business may receive additional federal funding related to technology developed under a SC FA agreement. However, it would be unusual for the Government to conduct any commercialization efforts on a technology developed by a large business under a SC FA agreement without the entity that developed the technology. Furthermore, as recognized by Bayh-Dole, any effort to commercialize a technology is most effective when the commercialization is done by the entity that developed the technology.

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

The purpose of SC FA agreements is to produce scientific discoveries and major scientific tools. The production of scientific discoveries and major scientific tools would indirectly benefit the public health, safety and welfare by increasing our understanding of nature and expediting the development of technologies, both of which would provide the building blocks for innovations that serve the public. Granting a waiver should expedite these scientific discoveries and development of scientific tools. Therefore, granting a waiver is in the interest of public health, safety and welfare.

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

Scientific research in the basic physical sciences is highly competitive as are the global markets for the technologies resulting from said research. Commercial viability is possible through the competition among researchers and technologies. Moreover, even within a particular type of research and technology, there are typically several different approaches and systems competing among themselves. 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 impact the other solutions already in the market, a patent waiver supports competition in scientific research and discoveries resulting therefrom.

- (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 recipient 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 patent waiver will be subject to the standard U.S. competitiveness provision.

Historically, DOE has agreed to the proposition that domestic large businesses qualify for advance patent waivers under FA agreements because the objectives and considerations set forth in the DOE patent waiver regulations are usually met by domestic large businesses. For example, the Office of Energy Efficiency and Renewable Energy (EERE) has allowed large businesses funded by an EERE FA to retain title to their inventions since 2013, subject to the obligations listed below, for example, see DOE waiver number W(C) 2013-001 and W(C) 2016-004. The Advanced Research Projects Agency-Energy (ARPA-E) has also allowed large businesses funded by an EERE FA to retain title to their inventions since 2013, subject to the obligations listed below, for example, see DOE waiver number W(C) 2013-010 and W(C) 2016-004. Moreover, SC has issued similar Class Patent Waivers for Quantum Information Science and its Technology Applications (W(C)2020-001). DOE's past practice is consistent with the above analysis that domestic large businesses working under a cost-shared financial assistance agreement made as a result of a SC FOA released during or after fiscal year 2022 would qualify for advanced patent waivers with DOE's standard patent waiver terms, including the U.S. Competitiveness clause requiring substantial U.S. manufacture.

This class patent waiver shall be subject to the terms and conditions that follow this statement of considerations. The terms and conditions include the usual Government license, march-in rights, and preference for U.S. industry provisions set out in 35 U.S.C. §§ 202-204. The terms and conditions may be periodically updated by the Assistant General Counsel for Technology Transfer and Intellectual Property. The class patent waiver also includes the following U.S. Competitiveness clause. The following U.S. Competitiveness clause requires substantial U.S. manufacturing for any products embodying any subject invention or produced through the use of any subject invention without any locality limitations (worldwide). The following U.S. Competitiveness clause applies to all licenses (including exclusive and non-exclusive). Additionally, the following U.S. Competitiveness clause, requires DOE approval in writing if any entity receiving rights in any subject 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).

The Recipient agrees that any products embodying any subject invention or produced through the use of any subject invention will be manufactured substantially in the United States unless the Recipient can show to the satisfaction of DOE that it is not commercially feasible. In the event 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., alternative binding commitments to provide an overall net benefit to the U.S. economy. The Recipient agrees that it will not license, assign or otherwise transfer any subject invention to any entity, at any tier, unless that entity agrees to these same requirements. Should the Recipient 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 assignment, license, or other transfer of rights in the subject invention(s) is/are suspended until approved in writing by DOE. The Recipient and any successor assignee will convey to DOE, upon written request from DOE, title to any subject invention, upon a breach of this paragraph. The Recipient will include this paragraph in all subawards/contracts, regardless of tier, for experimental, developmental or research work.

Any waiver or modification of the U.S. Competitiveness clause will be subject to paragraph (u) which requires DOE to determine “(1) the Recipient (or any entity subject to paragraph (t) ) has demonstrated, with quantifiable data, that manufacturing in the United States is not commercially feasible and (2) a waiver or modification would best serve the interests of the United States and the general public”. Additionally, any such waiver will be consistent with DOE’s manufacturing policies, for example at <https://www.energy.gov/gc/us-manufacturing>.

The terms and conditions of this class patent waiver are the standard terms and conditions used in DOE advance patent waivers except that the recipient does not retain any rights to a subject invention in the event that the above U.S. Competitiveness clause or the subject invention utilization reporting requirement is breached.

In the unlikely event that this class patent waiver will not best serve the interests of the United States and the general public for work under a particular SC FOA, as described above and in the DOE patent waiver regulations, the SC FOA will include a statement that the SC class patent waiver does not apply. A domestic large business working under a SC FOA excluded from this class patent waiver may later petition for an advanced or identified patent waiver.

Unless otherwise specified in a SC FOA, this class patent waiver is automatic and available to any domestic large business that (1) is a recipient, or subrecipient at any tier, to a FA agreement issued under a SC FOA released during or after fiscal year 2022, (2) is providing at least 20% cost share from non-federal sources for the work assigned to it under their funding agreement, and (3) accepts the terms and conditions of this class patent waiver. A large business, whether a recipient or sub-recipient, that does not accept the terms of this waiver, or is otherwise ineligible (*e.g.*, specifically excluded in the SC FOA, insufficient cost share, or is owned, controlled, or influenced by a foreign government, agency, firm, corporation or person), may petition for an advanced or identified patent waiver. The requirement that the recipient, or subrecipient at any tier be a domestic entity may be waived by DOE Patent Counsel with program concurrence after a risk-based analysis (in coordination with the Office of Counterintelligence as appropriate).

Unless otherwise specified in a SC FOA or instructed by DOE Patent Counsel, this class patent waiver shall be incorporated into each FA agreement issued under a SC FOA released during or after fiscal year 2022 to a domestic large business that is providing at least 20% cost share for the work assigned to it under the funding agreement. Unless otherwise specified in the SC FOA or instructed by DOE Patent Counsel, this class patent waiver shall also apply to any domestic large business who is a sub-recipient (at any tier), including a sub recipient to a DOE Laboratory, of such a FA agreement. The sub-recipient must accept the terms and conditions of the class patent waiver and provide at least 20% cost share for the work assigned to it under the funding agreement.

The requirement that the subrecipient be a domestic entity may be waived by DOE Patent Counsel with program concurrence after a risk-based analysis (in coordination with the Office of Counterintelligence as appropriate).

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 patent waiver as set forth above will best serve the interests of the United States and the general public. It is recommended that the waiver be granted.



Michael J. Dobbs  
Deputy Chief Counsel  
Intellectual Property Law

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:

APPROVAL:



Asmeret Asefaw Berhe  
Director  
Office of Science



Brian J. Lally  
Assistant General Counsel  
Technology, Transfer, and  
Intellectual Property, GC- 62