Department of Energy
Washington, DC 20585

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DETERMINATION OF EXCEPTIONAL CIRCUMSTANCES UNDER THE BAYH-DOLE ACT FOR THE OFFICE OF CYBERSECURITY, ENERGY SECURITY, AND EMERGENCY RESPONSE

Under the Bayh-Dole Act, 35 U.S.C. 200-12 ("Bayh-Dole" or "the Act"), Federal agencies may determine that "exceptional circumstances" exist such that a modification in the patent rights disposition provided under the Act would better promote its objectives. The Department of Energy ("DOE") has determined that exceptional circumstances exist for disposition of patent rights arising under research, development, demonstration, and market transformation projects involving cybersecurity, energy security, and emergency response technologies that secure the nation's energy infrastructure from energy disruptions from cybersecurity incidents to better enable DOE to prevent, mitigate, respond to, and facilitate recovery from these energy disruptions.

These technologies include next generation tools and technologies that are expected to become widely adopted throughout the energy sector to reduce the risk that a cyber incident could disrupt energy delivery and to allow any such disruptions to be removed quickly. The energy sector includes electricity and oil and natural gas delivery systems. Some of these technologies could include improvements to industrial control systems, Artificial Intelligence and quantum computing advancements for system resiliency and security, and tools for bringing offline systems back online quickly.

To better meet the objectives of the Act, which include the goal of promoting commercialization of inventions by United States industry and labor while ensuring the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government, DOE proposes to take an expanded Government license in certain federally supported inventions and the use of Commercialization Plans and U.S. Manufacturing Plans in funding agreements that support research, development, demonstration, and market transformation projects involving cybersecurity, energy security, and emergency response technologies. The expanded Government license will allow DOE to best ensure widespread adoption of portions of subject invention technologies especially within the U.S energy delivery sector thus providing a minimum level of cybersecurity throughout that sector and assisting in first responder efforts to bring the grid back online after a cyber event. The Commercialization Plans and U.S. Manufacturing Plans will provide specific and measurable commitments by awardees to bring their subject inventions to market and to substantially manufacture their subject inventions in the United States. Commercialization Plans and U.S. Manufacturing Plans may be used by DOE during its evaluation and selection process under a Funding Opportunity Announcement (FOA) and, if required by the FOA, will be formally incorporated into funding agreements following award negotiations. DOE may implement these proposed deviations from the Act and require the expanded Government license and submission of Plans by all types of applicants, including large businesses, small businesses, and non-profit organizations. Once incorporated into a funding agreement, the accepted proposals from the FOA application may be enforced, among other possible remedies, through forfeiture of rights to subject inventions.

I. *The Policy Objectives of the Bayh-Dole Act: ensuring that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government, promoting utilization of inventions arising from federally supported research or development, and promoting domestic manufacture of products derived from federally supported research.*

As noted in a 1998 report from the Government Accountability Office, the patent policies prior to 1980 resulted in "fewer than 5% of the 28,000 patents being held by federal agencies had been licensed, compared with 25 percent to 30 percent of the small number of federal patents for which the government had allowed companies to retain title to the invention."[1] The Act was intended to provide a more uniform patent policy for federally-funded inventions so that more contractors would retain title to the inventions and have a greater incentive to commercialize, e.g., license, a greater percentage of federally-funded inventions.

Other fundamental objectives of the Act are to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and to promote utilization of inventions arising from federally-funded research of inventions.[2] To give the Government sufficient rights, the Act provides a path for certain non-profit organizations and domestic small businesses who are recipients of a funding agreement ("Bayh-Dole entities") to elect title to any subject inventions while giving the funding Federal agency, among other Government rights, a non-exclusive license to the subject invention.[3] Rights to inventions that contractors, subcontractors, as well as recipients and subrecipients of grants and cooperative agreements ("funding recipients") conceive or first actually reduce to practice in performance of work under a funding agreement ("subject inventions") are governed by the Act and the federal regulations that implement the Act.[4] A "funding agreement" is "any contract, grant, or cooperative agreement entered into by any Federal agency...and any contractor for the performance of experimental, developmental, or research work funded in whole or in part by the Federal Government."[5] In order to comply with the Act, Federal agencies are required to use a standard patent rights clause for funding agreements with Bayh-Dole entities that set out the requirements for securing title.[6]

II. *The patent rights provided by the Act may be modified to better promote the objectives of the Act when an agency determines that "exceptional circumstances" exist.*

A Federal agency may restrict, eliminate, or otherwise modify rights provided to Bayh-Dole entities and

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1 "Technology Transfer: Administration of the Bayh-Dole Act by Research Universities", Government Accountability Office report to Congress GAO-RCED-98-126 (May 1998).

2 35 U.S.C. § 200(a).

3 35 U.S.C. § 200(c)(4).

4 35 U.S.C. §§ 200-212; 37 C.F.R. Part 401.

5 35 U.S.C. § 201(b).

6 37 C.F.R. § 401.3(a).

implemented through the standard patent rights clause in "exceptional circumstances" when the Federal agency determines that a restriction, elimination, or modification of the rights and requirements provided by the Act would better promote the Act's objectives.[7] The degree or scope of the modification should only be to the extent necessary to address the exceptional circumstances.[8]

III. *DOE has determined that exceptional circumstances exist because the Act's objectives of the Government obtaining sufficient rights in federally supported inventions to meet the needs of the Government, promoting utilization of inventions arising from federally supported research or development, and promoting U.S. manufacturing of federally-funded research and are not fully being met with respect to cybersecurity, energy security, and emergency response technologies.*

a. *The U.S. has made and continues to make significant investments in cybersecurity, energy security, and emergency response technologies through DOE.*

Since 2010, DOE has invested more than $240 million in cybersecurity research, development, and demonstration projects that have yielded more than 35 new tools.[9] The investments by DOE are now made primarily through DOE's Office of Cybersecurity, Energy Security, and Emergency Response (CESER). This office was created in 2018 to provide a single DOE office to coordinate and addresses emerging cybersecurity threats while protecting the reliable flow of energy to Americans today by improving energy infrastructure security and supporting the Department of Energy's (DOE) national security mission through supporting preparedness and response activities to natural and man-made threats. To ensure that appropriate advancements in cybersecurity, energy security, and emergency response preparedness technologies are made, CESER partners with business, industry, universities, national laboratories, consumers, federal energy managers, inventors, states, and tribes to research, develop, and advance cybersecurity, energy security, and emergency response preparedness technologies. Further, DOE is the Sector-Specific Agency to secure the national critical energy infrastructure from incapacitation and destruction against both physical and cyber threats.[10]

b. *Despite DOE's significant investment in cybersecurity, energy security, and emergency response technologies research, development, and deployment, significant national security concerns remain about the cybersecurity and resiliency of U.S. infrastructure.*

Notwithstanding DOE's leadership in research, development, and demonstration of cybersecurity, energy security, and emergency response technologies, the threat from cyberattacks continues to grow. A 2019 report from the Government Accountability Office found that the grid is becoming more vulnerable to

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7 35 U.S.C. § 202(a)(ii); 37 C.F.R. § 401.3(a).

8 37 C.F.R. § 401.3(b).

9 https://www.energy.gov/ceser/activities/cybersecurity-critical-energy-infrastructure/cybersecurity-research-development-and last accessed November 1, 2019.

10 Presidential Policy Directive 21, pp. 2, 11 (2013).

cyberattacks.[11] While to date, no cyberattack has been reported to have disrupted U.S. energy delivery, such cyberattacks are occurring more frequently and with greater sophistication.[12] For example, in August 2019, a spear-phishing campaign targeted various public utilities, ostensibly from a foreign state actor.[13] Other countries have not been as able as the U.S. to withstand such attacks; in 2015 and 2016, cyberattacks were able to take portions of Ukraine's electric grid offline.[14]

In recognition of these ongoing and increasing threats, Congress has provided legislation to provide various Government Departments and Agencies the ability to improve the Government response to cyber threats. For example, in 2015, the FAST Act was passed to enhance the ability of the Government Departments and Agencies to protect and enhance the security and resilience of U.S. cybersecurity, emergency communications, and critical infrastructure, including energy infrastructure.[15] Congress continues to introduce a significant amount of legislation to provide additional authority and resources to Government agencies, including DOE, to prepare for, prevent, and address cyberattacks. In the 116th Congress alone, over 150 bills related to improving the nation's cybersecurity have been introduced.[16]

c. *National security interests support the need to accelerate the level of U.S. manufacturing from DOE's investments in cybersecurity, energy security, and emergency response technologies beyond DOE's general Congressional requirements for improving U.S. Manufacturing.*

In the accompanying House Report for the 2013 Energy and Water Appropriations Bill, the Committee on Appropriations identified the specific need for DOE to take a leadership role in improving U.S. manufacturing and domestic intellectual property retention. The Committee requested that DOE examine what authorities are available to control intellectual property, specifically including Act.

Furthermore, U.S. national security interests are supported by having a U.S.-based supply chain for the equipment and components of that equipment used in the nation's energy delivery systems. In 2018, credible allegations of tampering with circuit boards assembled overseas by including a specialized and difficult to discover chip that gave foreign entities unauthorized access to the data from the final assembled equipment.[17]

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11 "Critical Infrastructure Protection: Actions Needed to Address Significant Cybersecurity Risks Facing the Electric Grid", U.S. Government Accountability Office Report to Congress, August 2019.

12 Id. At 16.

13 "Chinese State Hackers Suspected of Malicious Cyber Attack on U.S. Utilities", Zak Doffman, Forbes, August 3, 2019.

14 "Ukraine power cut 'was cyber-attack'", BBC News, January 11, 2017 (www.bbc.com/new/technology-38573074 last accessed November 1, 2019).

15 Fixing America's Surface Transportation Act ("FAST Act"), P.L. 114-94 (December 2015). The energy-specific provisions including authorities to DOE are in Division F – Energy Security, Section 61001 et seq.

16 www.congress.gov last accessed November 1, 2019.

17 Robertson, Jordan and Riley, Michael, "The Big Hack: How China Used a Tiny Chip to Infiltrate U.S. Companies", Bloomberg Businessweek, October 4, 2018.

It is critical that cybersecurity, energy security, and emergency response technologies funded by DOE support manufacturing in the U.S., particularly in view of the necessity of creating and maintaining jobs, including manufacturing jobs, in the U.S. as well as the national security need for having a clean, reliable, and trusted supply chain. If the U.S. cannot maintain a manufacturing base for cybersecurity, energy security, and emergency response technologies, then it will remain dependent on foreign sources to supply components and equipment for energy delivery systems and fail to achieve economic, energy, and national security.

IV. CESER may take an expanded Government license in a designated portion of inventions resulting from federally-funded research.

DOE proposes to take an expanded Government license in certain federally supported inventions to further the national security needs of the Government. The expanded Government license will allow DOE to ensure widespread adoption of portions of subject inventions in certain cybersecurity, energy security, and emergency response technologies. The expanded Government license will allow DOE to best ensure widespread adoption of portions of these subject invention technologies especially within the U.S energy delivery sector thus providing a minimum level of cybersecurity throughout that sector and assisting in first responder efforts to bring the grid back online after an event.

The technical solutions proposed by applicants to a CESER FOA are anticipated to have two components: a Baseline Technology and a Specific Implementation Technology that utilizes the Baseline Technology and provides additional functionalities. Both aspects of the technical solutions will be federally-funded technologies. The Baseline Technology will provide a minimum level of functionality that solves a technical problem, while the Specific Implementation Technology will incorporate the Baseline Technology and include additional functionality for specific energy sector end-use applications. The applicant will have the ability to retain ownership in both the Baseline and Specific Implementation Technologies. DOE, at its discretion, will retain an expanded Government license in the Baseline Technology to ensure that the Baseline Technology will be made broadly available to the relevant industry on reasonable terms. For the Specific Implementation Technology, standard government rights under the Act will attach.

The purpose of this dual component structure is to assure that a basic level of the technology produced under this FOA is made broadly available within the U.S. energy delivery sector to provide a minimum level of cybersecurity throughout the U.S. energy delivery sector. The applicant is then free to commercialize the Specific Implementation component of the solution with the additional functionality. Categorizing the components into Baseline Technologies and Specific Implementation Technologies will be determined during negotiations of the award post-selection, though applicants to a CESER FOA will be expected to provide preliminary categorization in their applications. The definition of an applicant's Baseline Technology will be intentionally left flexible in a FOA so that it can be negotiated after selection but prior to award of the funding agreement.

At its discretion but as specified in a CESER FOA, DOE will take the expanded Government license to promote the widespread adoption of Baseline Technologies, particularly those technologies that enhance

the ability of CESER to act as first responders and provide support to private industry or local government first responders as the Sector-Specific Agency to secure the national critical energy infrastructure from incapacitation and destruction against both physical and cyber threats. DOE may require the submission of a licensing document to fully vest these expanded Government license rights. Depending upon the technology and as either specified in a CESER FOA or negotiated in an award under the CESER FOA, the expanded Government license could include terms that allow DOE-CESER to sublicense the Baseline Technology to first responders for no fee, to sublicense to the relevant market on reasonable terms should the awardee fail to do so or otherwise meet its obligations under the Commercialization Plan (discussed below), or other terms intended to promote widespread adoption of the Baseline Technology on reasonable terms in the energy sector.

Because the expanded Government license is connected to subject inventions, the standard patent rights clause for Bayh-Dole entities will be modified accordingly. The modification would be necessary to implement and enforce the license.

V. *CESER will implement Commercialization and U.S. Manufacturing Plans to further promote the broad adoption through commercialization and U.S. manufacture of inventions resulting from federally-funded research and satisfy the national security needs of the Government.*

a. *Commercialization and U.S. Manufacturing Plans may be required under a FOA and may be used as a basis for selection.*

Depending on the nature of the FOA, CESER may require a Commercialization Plan, a U.S. Manufacturing Plan, or both ("Plans") from each applicant of the FOA as part of its application. The Plans shall apply equally to all types of applicants, including large businesses, small businesses, and non-profit organizations. Once incorporated into a funding agreement, the Plans will provide that they may be enforced, among other possible remedies, through forfeiture of rights to subject inventions. CESER may use both of these Plans to require commitments to minimum levels of commercialization and U.S. Manufacturing, where these minimum levels would be specified in the FOA.

The nature and specificity of the applicants' Plans will vary based on the FOA and the program issuing the FOA. A higher level of specificity may be required in the Plans for technologies at higher technology readiness levels due to the greater certainty surrounding the commercialization and U.S. manufacture of these technologies. Plans submitted in response to FOAs targeting technologies at high technology readiness levels or demonstration activities should include specific commitments to commercialization including metrics for the broad adoption of the technology in the relevant industry and manufacturing in the U.S.

The weight given to the Plans during the review and selection process likely will also vary based on the particular FOA and may be part of the evaluation or merit criteria. For example, the Plans may constitute 30% of the overall merit review score of the proposals. Alternatively, the Plans may be treated as a qualitative program policy fact or, thereby allowing the selecting official to give preference to applications

based on the Plans. FOAs directed to technologies at high technology readiness levels or demonstration type activities may require greater consideration of applicants' Plans.

Following selection and award negotiations, the Plans will be incorporated into the funding agreement. The funding agreement may further require that the funding recipient submit annual reports to DOE (including after expiration of the funding period) to demonstrate compliance with the Plans.

Once the Plans are incorporated into the funding agreement, the funding agreement terms and conditions will further provide for the remedies upon breach of the Plans. Individual FOAs, for example, may specify remedies such as a penalty payment to DOE equal to the amount of funding originally provided by DOE to the funding recipient, with or without interest. Remedies may also include a loss of all rights to subject inventions by the funding recipient, including title reverting back to DOE if the funding recipient had title to the subject inventions.

b. Commercialization Plans

The Commercialization Plan will represent the applicant's measurable commitment to support U.S. industry with the technologies related to its CESER funding agreement. CESER may require, among other specific information, that Commercialization Plans include metrics related to goals for distribution to the relevant market, licensing, commercial production, and job creation related to both the Baseline Technology and the Specific Implementation Technology. Commercialization Plans for lower readiness technologies may be less specific and aimed more at how the applicant intends to bring the technology to an appropriate readiness level for commercialization. Commercialization Plans will be subject to review and acceptance by both CESER personnel and DOE Patent Counsel.

In many circumstances, the technologies being developed under any particular FOA may utilize Background Technology. This term refers to existing technology and Intellectual Property (IP) that was developed prior to the FOA and is owned by the applicant or the applicant has a license to use the technology. Background Technology may be brought into the project by the applicant and may be used, modified or advanced with project funds under an award resulting from the FOA. In such cases, CESER may require that the Commercialization Plan include information regarding how the applicant will make the Background Technology available to users of the FOA-developed technology.

Another aspect of the Commercialization Plan will be a requirement to update CESER in the annual report demonstrating compliance with the Plans when a funding recipient develops a new technology that improves upon or replaces the FOA-developed technology. While DOE may not necessarily have rights to the new technology, such information about potential vulnerabilities or obsolescence is necessary to support CESER's mission, especially as the Sector-Specific Agency to secure the national critical energy infrastructure from incapacitation and destruction against both physical and cyber threats.

c. U.S. Manufacturing Plans

The U.S. Manufacturing Plan will represent the applicant's measurable commitment to support U.S.

manufacturing of the technologies related to its CESER funding agreement. For example, the Plans may specify products related to the funding agreement that will be manufactured in the U.S., identify investments in U.S. facilities to support product manufacture, or identify how the applicant intends to secure components free from potential cyber-related interference when those components are to be incorporated into a U.S.-assembled article of manufacture. U.S. Manufacturing Plans submitted in response to FOAs directed at technologies at lower technology readiness levels may have fewer specific manufacturing details and may focus more on licensing and other strategies to promote U.S. manufacturing and the creation of manufacturing jobs. U.S. Manufacturing Plans will be subject to review and acceptance by both CESER personnel and DOE Patent Counsel.

d. The standard patent rights clause will be modified to allow the Plans to be enforceable and to serve as a basis for selection and continuation.

To the extent that the Plans are connected to subject inventions or that the remedy for a breach of the Plans are connected to subject inventions (e.g., title reverts back to DOE), the standard patent rights clause for Bayh-Dole entities will be modified accordingly. The modification would be necessary to implement and enforce the Plans proposed by the Bayh-Dole entity and was in part the purpose for selecting the Bayh-Dole entity's proposal.

e. Waivers and modifications are available.

The funding recipient, including any Bayh-Dole entity, may request a waiver or modification of the Plans from DOE upon a satisfactory showing that the original Plan is no longer economically feasible and where the funding recipient can demonstrate an alternate net benefit to the U.S. economy notwithstanding the requested waiver or modification.

Except for the expanded Government license, the Plans proposed by the applicant, and the enforcement mechanism, the patent rights of funding recipients granted by the Act remain the same.

IV. Conclusion

DOE has determined that exceptional circumstances exist for cybersecurity, energy security, and emergency response technologies. The expanded Government license, Commercialization Plan, and U.S. Manufacturing Plan strategy described herein would better promote the objectives of the Act by providing stronger support to U.S. national security, commercialization of federally supported inventions, U.S. industry, and U.S. manufacturing. Moreover, DOE is not imposing additional restrictions, requirements, or modifications from the standard patent rights clause beyond what is necessary to address the exceptional circumstances.

Any Bayh-Dole entity affected by this determination of exceptional circumstances has the right, and will be informed of that right, to appeal it.

Approved: _____ Date: 12/17/19

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