



Department of Energy
Washington, DC 20585

DEPARTMENT OF ENERGY DETERMINATION OF EXCEPTIONAL CIRCUMSTANCES UNDER THE BAYH-DOLE ACT TO FURTHER PROMOTE DOMESTIC MANUFACTURE OF DOE SCIENCE AND ENERGY TECHNOLOGIES

“The United States needs resilient, diverse, and secure supply chains to ensure our economic prosperity and national security.”¹ Therefore, in order to “revitalize and rebuild domestic manufacturing capability”² as directed by E.O. 14017 of Feb. 24, 2021,³ and pursuant to the Bayh-Dole Act, 35 U.S.C. §§ 200-12 (“Bayh-Dole”), the United States (U.S.) Department of Energy (DOE) has determined that exceptional circumstances exist requiring increased domestic manufacturing requirements for DOE Science and Energy Technologies⁴ to better promote the policy and objectives of Bayh-Dole and to ensure America’s security and prosperity by addressing the country’s energy, environmental, and nuclear challenges through transformative science and technology solutions.

The U.S. Competitiveness Provision described herein calls for increased domestic manufacturing to promote commercialization of DOE Science and Energy Technologies by U.S. industry and labor, and provides stronger support for U.S. national security and economic interests⁵ while also maintaining the important core rights of small business firms and nonprofit organizations to retain ownership and commercialize their federally-funded inventions. The U.S. Competitiveness Provision is narrowly tailored to provide for substantial U.S. manufacturing as a starting point in return for DOE funding, while still providing flexibility for waivers, modifications, and alternative commitments to the U.S.

¹ E.O. 14017 of Feb 24, 2021 § 1.

² Id.

³ The Administration reaffirmed this policy in E.O. 14005, Jan. 25, 2021, *Ensure the Future Is Made in All of America by All of America’s Workers*: “It is the policy of my Administration that the United States Government should, consistent with applicable law, use terms and conditions of Federal financial assistance awards and Federal procurements to maximize the use of goods, products, and materials produced in, and services offered in, the United States.”

⁴ For the purpose of this determination, DOE Science and Energy Technologies include any Subject Invention as defined by Bayh-Dole, conceived or first actually reduced in the performance of work under a DOE funding agreement issued by one or more DOE programs under the cognizance of DOE’s Under Secretary of Science, Under Secretary of Energy, combined Under Secretary of Science and Energy, or the Advanced Research Project Agency-Energy (ARPA-E), such programs hereafter referred to as collectively as “DOE’s Science and Energy programs.”

⁵ “[S]ufficient rights in federally supported inventions to meet the needs of the Government” is specifically identified as a policy and objective of Bayh-Dole. See 35 U.S.C. § 200.

economy, broad deployment and effective commercialization. This narrowly-tailored U.S. Competitiveness Provision allows DOE to promote the policy and objectives of Bayh-Dole in light of the exceptional circumstances that now exist and further the Department's efforts to create good-paying, American jobs to address energy and climate challenges while also enhancing national security and securing U.S. supply chains.

It is vital to America's security and prosperity that DOE's multi-billion-dollar R&D investments cultivate new research and development ecosystems, manufacturing capabilities and industries, and supply chains within the U.S. DOE has a broad mission to "ensure America's security and prosperity by addressing its energy, environmental and nuclear challenges through transformative science" and "to carry out the planning, coordination, support, and management of a balanced and comprehensive energy research and development program" including "assessing the requirements for energy research and development" and "developing priorities necessary to meet those requirements."⁶ As the global market has drastically changed since the enactment of Bayh-Dole in 1980, DOE is implementing the U.S. Competitiveness Provision in funding agreements to nonprofit organizations and small business firms to better ensure DOE's investment benefits U.S. manufacturing, industry, and labor.

The U.S. Competitiveness Provision imposed by this Determination of Exceptional Circumstances (DEC) will be formally incorporated into funding agreements with Contractors⁷ and once incorporated into a funding agreement, may be enforced, among other possible remedies, through forfeiture of rights to subject inventions. Except for the requirement of manufacture substantially in the United States and the corresponding enforcement mechanism, the patent rights granted to small business firms and nonprofit organizations under Bayh-Dole remain the same.

In accordance with 37 C.F.R. § 401.3(e), DOE makes the following DEC, including a supporting statement of facts and analysis.

- I. The patent rights provided by Bayh-Dole may be modified to better promote the objectives of the Act when an agency determines that "exceptional circumstances" exist.
 - a. *Bayh-Dole provides a standard set of patent rights to certain nonprofit and small business firm recipients of federal funds under a funding agreement.*

Rights to inventions that Contractors conceive or first actually reduce to practice in performance of work under a funding agreement ("subject inventions") are governed by Bayh-

⁶ 42 U.S.C. §7112(5).

⁷ Contractor means any person, small business firm, or nonprofit organization that is a party to a funding agreement as defined by 35 USC § 201(b).

Dole and the federal regulations that implement Bayh-Dole.⁸ A "funding agreement" is "any contract, grant, or cooperative agreement entered into between 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."⁹

Bayh-Dole allows certain nonprofit organizations and small business firms that are recipients of a funding agreement to elect title to their subject inventions subject to limited government rights, and further provides that the recipients must comply with certain disclosure, patent prosecution, and other requirements.¹⁰

- b. Standard patent rights under Bayh-Dole may be modified when "exceptional circumstances" exist and a modification would better promote the Act's objectives.*

A federal agency may restrict, eliminate, or otherwise modify rights provided to nonprofit organizations and small business firms in "exceptional circumstances" when the federal agency determines that a restriction, elimination, or modification of the rights and requirements provided by Bayh-Dole would better promote the Act's objectives.¹¹ The degree or scope of the modification should only be to the extent necessary to address the exceptional circumstances.¹²

II. Promoting domestic manufacture of products derived from federally-funded research is a primary objective of Bayh-Dole.

A fundamental policy and objective of Bayh-Dole is to promote United States manufacturing by encouraging the domestic manufacture of products derived from federally-funded research. Thus, Bayh-Dole seeks "to promote the commercialization and public availability of inventions made in the United States by United States industry and labor."¹³ This policy set by Congress is directed to "inventions" and is not limited to a particular technology, consistent with this DEC.

Bayh-Dole was enacted in 1980, in part, to address a growing concern regarding the ability of U.S. manufacturing to compete in an increasingly global marketplace. The House of Representatives Report filed by the Judiciary Committee when Bayh-Dole was presented to Congress identified the need for legislation to address the "failure of American industry to

⁸ 35 U.S.C. §§ 200-21; 37 C.F.R. § 401.

⁹ 35 U.S.C. § 201(b).

¹⁰ Bayh-Dole does not provide large business contractors and recipients the right to elect title to subject inventions under DOE statutory authorities. 42 U.S.C. §§ 2181 and 5908. Bayh-Dole also does not apply to Technology Investment Agreements under DOE's Other Transactions Authority. 42 U.S.C. § 7256.

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

¹² 37 C.F.R. § 401.3(b).

¹³ 35 U.S.C. §200.

keep pace with the increased productivity of foreign competitors."¹⁴ Bayh-Dole's passage was spurred in part by the President's Advisory Committee on Industrial Innovation, convened in 1978 to study the possibilities for encouraging increased productivity in the United States. Chief among the recommendations of the committee was a legislative proposal to promote industrial innovation through the commercial manufacture of federally-funded technologies. The legislative proposal led to Bayh-Dole.¹⁵

III. DOE has determined that exceptional circumstances exist and Bayh-Dole's objective of promoting United States manufacturing and commercialization of products and processes resulting from federally-funded research is not fully being met with respect to DOE Science and Energy Technologies

a. Exceptional circumstances are present

As noted above, one of Bayh-Dole's primary goals is to promote the commercialization of federally-funded technologies by U.S. industry and labor while ensuring that the Government obtains sufficient rights in federally-funded subject inventions to meet the needs of the Government.¹⁶ Unfortunately, this goal has often not been realized as we have seen the manufacturing for countless federally-funded technologies (ranging from solar technologies to semiconductors to energy storage) increasingly offshored to locations other than the United States over the past several decades since passage of Bayh-Dole. As explained in more detail below, the resulting erosion of the U.S. manufacturing base and its associated manufacturing jobs, combined with the urgent need to secure U.S. supply chains for a wide-range of technologies has created an exceptional circumstance requiring urgent action. This urgent circumstance is further exacerbated by the fact that several areas of science and technology are going through disruptions that could rapidly shift the balance of global power in the 21st Century. Since many (if not all) of these disruptive areas are funded by DOE, and since it is often impossible to predict the next disruption, the Department has determined that issuing a DEC for DOE's Science and Energy Technologies will better ensure current and future technologies are best positioned to be commercialized by U.S. industry and labor, preserving U.S. economic leadership. This action will allow the Department to harness its experimental, research, development, and demonstration funding to help revitalize domestic manufacturing, secure U.S. supply chains, and create good-quality American Jobs.

The urgent and exceptional nature of the economic security challenges the U.S. faces, which supports DOE's determination, was recently confirmed in the Worldwide Threat Assessment of the U.S. Intelligence Community, dated April 9, 2021.¹⁷ The assessment describes that,

¹⁴ H.R. REP. 96-1307, 1. 1980 U.S.C.C.A.N. 6460, 6460 ("Need for the Legislation: Many analysts of the U.S. economy have warned that the roots of the current recession lie in a longer term economic malaise which arises out of a failure of American industry to keep pace with the increased productivity of foreign competitors.").

¹⁵ *Id.* at 6462. See U.S. DEPT. OF COMMERCE, ADVISORY COMMITTEE ON INDUSTRIAL INNOVATION: FINAL REPORT (Sept. 1979).

¹⁶ 35 U.S.C. §200.

¹⁷ 2021-04-09 Final ATA 2021 Unclassified Report - rev 2.pdf (senate.gov).

in emerging technologies, decades of investment and effort by multiple countries have precipitated what DOE considers a potential tipping point of “a more level playing field” to increasingly challenge U.S. leadership in these areas, primarily by China. “We anticipate that with a more level playing field, new technological developments will increasingly emerge from multiple countries and with less warning” and that “advances in technologies such as computing, biotechnology, artificial intelligence, and manufacturing warrant extra attention to anticipate the trajectories of emerging technologies and understand their implications for security.” This DEC provides an important tool for DOE to not only ensure domestic impact but also to provide “extra attention” or oversight of the constantly changing introduction, trajectories, and implications of emerging technologies which may now arrive more quickly and with less warning. The U.S. Competitiveness Provision better ensures an open dialogue between DOE and its partners to anticipate breakthroughs and help steer their impact and job creation in the U.S. This U.S. manufacturing and oversight tool is needed to best position our nation to anticipate and advance U.S. economic interests.¹⁸

As DOE deepens its collaboration with the research community to accelerate science, energy, environmental and nuclear science and technology solutions, it needs to maintain a full awareness of the potential security threats posed by exploited U.S. intellectual property and products, and to implement mitigation strategies to stop the unintended leakage of proprietary research and technology to foreign competitors. This is essential not only to avert national security risks but also to create an environment in which U.S. companies feel more secure in realizing the benefits of their labors.

New action is needed to promote these important ends given the exceptional circumstances that exist today. Challenges with U.S. manufacturing were noted in a 2017 publication funded by the National Institute of Standards and Technology (NIST)¹⁹ which states:

Since 2001, the year China joined the World Trade Organization, the United States has lost nearly one-third of its manufacturing jobs and the workers employed in manufacturing has declined to 12 million.²⁰ Since then, China has become the world’s factory, now accounting for nearly half of global manufacturing output. Dense networks of diverse suppliers in virtually every industry, combined with

¹⁸ The assessment describes the challenges China presents: “China has a goal of achieving leadership in various emerging technology fields by 2030. China stands out as the primary strategic competitor to the U.S. because it has a well-resourced and comprehensive strategy to acquire and use technology to advance its national goals, including technology transfers and intelligence gathering through a Military-Civil Fusion Policy and a National Intelligence Law requiring all Chinese entities to share technology and information with military, intelligence and security services.” This DEC serves as an important safeguard to help protect against such forced technology transfer aimed at achieving China’s 2030 goal.

¹⁹ ENSURING AMERICAN MANUFACTURING LEADERSHIP THROUGH NEXT-GENERATION SUPPLY CHAINS JUNE 2017 REPORT NUMBER: MF-TR-2017-0201 available at <https://www.nist.gov/system/files/documents/2017/07/07/supply-chain-digital-final-june-2017.pdf>

²⁰ As reported “the number of U.S. manufacturing jobs peaked in 1979 at 19.5 million; in March 2017, manufacturing employment was 12.4 million, a decline of more than 36 percent.”

extensive government support, make China the world leader in manufacturing value-added. The capability has become so great that many American startups, and even established companies, often assume that China is where manufacturing is done. Meanwhile, technically advanced, high-wage nations such as Germany and Japan have maintained strong manufacturing sectors.²¹

The 2017 NIST publication also provides the following conclusion:

The national challenge is moving from the current situation, in which foreign suppliers are too frequently the default choice and many domestic suppliers have weak capabilities or no longer exist, to an innovative future supported by vibrant supply chains in which U.S. manufacturers compete globally based on innovation and unique domestic production capabilities.²²

The U.S. Competitiveness Provision will ensure that taxpayer-funded DOE Science and Energy Technologies create jobs here in the U.S. and help mitigate the increasing threat of exploitation by foreign adversaries and competitors. The Director of the Federal Bureau of Investigation testified in September 2020 before a U.S. Senate Committee that “[t]he greatest long-term threat to our nation’s information and intellectual property and to our economic vitality is the counterintelligence and economic espionage threat from China. It is a threat to our economic security and by extension, to our national security.”

DOE seeks to address these challenges by securing U.S.-based supply chains for DOE Science and Energy Technologies, which in turn protects U.S. economic and national security interests. Without a secure supply chain, for example, secure communications, advanced computing and next generation technologies like advanced energy storage technologies could be significantly compromised. The U.S. Competitiveness Provision safeguard helps cultivate and grow emerging supply chains and jobs in the U.S. at this critical point when U.S. economic leadership is increasingly challenged and emerging breakthroughs appear with little notice and new supply chains and related R&D ecosystems quickly begin to form around them.

b. In light of such exceptional circumstances, DOE has determined that the carefully tailored U.S. Competitiveness Provision will better promote Bayh-Dole's policy and objectives

Over the past 8 years, DOE has determined that requiring enhanced U.S. manufacturing for select programs and technologies more effectively achieves the objectives of Bayh-Dole and DOE’s mission, while ensuring that small business firms and nonprofit organizations retain

²¹ As reported “According to the World Bank, manufacturing value added as a percentage of GDP in 2015 was 23% in Germany, 18% in Japan, 12% in the United States, and more than 30% in China. See <http://data.worldbank.org/indicator/NV.IND.MANF.ZS>.”

²² Id.

the right to elect title to their subject inventions. While program and technology-specific DEC's issued by the Department over that time period have acted as a stopgap, and will remain in place, the Department has determined that exceptional circumstances now exist for a wider-range of DOE-funded technologies. Therefore, through this DEC, DOE invokes its authority to include the U.S. Competitiveness Provision, attached as Appendix A, in any DOE Funding Opportunity Announcement (FOA), solicitation, announcement, notice, or specific funding agreement for DOE Science and Energy Technologies, including but not limited to, financial assistance transactions, acquisition contracts and laboratory or facility management and operating contracts. The U.S. Competitiveness Provision requires that any products embodying a subject invention or produced through the use of a subject invention be manufactured substantially in the United States unless otherwise approved by DOE. If this provision is breached, DOE may then obtain title to subject inventions. Like the previously issued DEC's, this DEC is also narrowly tailored such that except for the addition of the U.S. Competitiveness Provision and its corresponding enforcement mechanism, the patent rights granted to certain funding recipients under Bayh-Dole remain the same.

- i. DOE makes significant investments in science, energy, environmental, and nuclear science and technology solutions and continued U.S. competitiveness is necessary to protect U.S. national and economic security interests.

The importance of having DOE Science and Energy Technologies manufactured by U.S. industry and labor has never been greater. DOE invests billions of dollars a year in science, energy, environmental and nuclear science and technology solutions to ensure continued U.S. leadership in these fields. DOE efforts include a broad range of science, energy, environmental and nuclear science and technology solutions to advance DOE's mission. The National Strategy for critical and emerging technologies (C&ET) stressed the importance of promoting the national security innovation base (NSIB) including a priority action to "[s]upport the development of a robust NSIB, to include academic institutions, laboratories, supporting infrastructure, venture funding, supporting businesses, and industry."²³ The strategy also stated that one way to "maintain and improve American leadership in C&ET is to protect our technology advantage both domestically and in conjunction with like-minded allies and partners." The strategy identifies various priority actions in this area including those which: (1) "[e]nsure that competitors do not use illicit means to acquire United States intellectual property, research, development, or technologies"; and (2) "[e]nsure secure supply chains, and encourage allies and partners to do the same." Ensuring secure supply chains continues to be a priority for the U.S.²⁴

²³ *National Strategy for Critical and Emerging Technologies*, p. 7 (October 2020).

²⁴ The Administration reaffirmed this policy in E.O. 14005, Jan. 25, 2021, *Ensure the Future Is Made in All of America by All of America's Workers*: "It is the policy of my Administration that the United States Government should, consistent with applicable law, use terms and conditions of Federal financial assistance awards and Federal procurements to maximize the use of goods, products, and materials produced in, and services offered in, the United States." and in E.O. 14017, February 24,

- ii. An enhanced U.S. Manufacturing requirement is necessary to meet the policy and objectives of Bayh-Dole in promoting the commercialization and public availability of inventions made in the United States by United States industry and labor and protecting national security interests.

Promoting the commercialization and public availability of inventions made in the United States by United States industry and labor is a vital policy and objective of Bayh-Dole, and exceptional circumstances today make it appropriate to promote these policies through this DEC.²⁵ The mission of DOE's research and development is to ensure America's security and prosperity by addressing its science, energy, environmental and nuclear challenges through transformative science and technology solutions.²⁶ A strong and vibrant domestic manufacturing base is essential for these objectives to be met. If the U.S. cannot maintain a manufacturing base, then it will remain dependent on foreign supplies and fail to achieve economic, energy, and national security.

Bayh-Dole recognizes that, in exceptional circumstances and other situations, agencies need the flexibility to adjust the standard disposition of rights between the Government and the Contractor if the agency decides that a different disposition would "better promote" Bayh-Dole's objectives and policies. The Act provides DECs, for example, as a tool for agencies to balance the Government's and the Contractor's rights if the circumstances are exceptional, and if an agency determines that the restriction, i.e., here, the U.S. Competitiveness Provision, will "better promote the [Act's] policy and objectives," including "to promote the commercialization and public availability of inventions made in the United States by United States industry and labor," and "to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions." In this way, the Act acknowledges that agency DECs may more effectively achieve, and, in fact, must "better promote," the objectives of Bayh-Dole in these unique circumstances compared to the standard rights disposition.

While Bayh-Dole contains a limited domestic manufacturing restriction on granting certain exclusive licenses,²⁷ DOE has determined that a broader yet flexible and tailored U.S. Competitiveness Provision balances and "better promotes" the goals of the Act and the DOE

2021, *America's Supply Chains*: More resilient supply chains are secure and diverse—facilitating greater domestic production, a range of supply, built-in redundancies, adequate stockpiles, safe and secure digital networks, and a world-class American manufacturing base and workforce. Moreover, close cooperation on resilient supply chains with allies and partners who share our values will foster collective economic and national security and strengthen the capacity to respond to international disasters and emergencies. Therefore, it is the policy of my Administration to strengthen the resilience of America's supply chains.

²⁵ 35 U.S.C. §200.

²⁶ <https://www.energy.gov/about-us>.

²⁷ 35 U.S.C. § 204 often referred to as the "U.S. Preference Clause".

mission. Given the challenges and stakes presented by the exceptional circumstances described above in emerging technologies, as well as in present and future U.S. supply chains, the Act's goals are better achieved with the U.S. Competitiveness Provision than with an exclusive license (U.S. sale and use) restriction. Entities other than exclusive U.S. rights licensees, such as Contractors and other licensees, may play decisive roles in technology commercialization and availability plans and activities. A more comprehensive yet targeted approach to U.S. manufacturing using the U.S. Competitiveness Provision is warranted in the current exceptional environment of unprecedented challenges to U.S. manufacturing and economic leadership.

The strengthened U.S. Competitiveness Provision better ensures commercialization of DOE-funded technologies by U.S. industry and labor. Furthermore, the U.S. Competitiveness Provision allows DOE review and oversight when a Contractor undergoes a change in ownership amounting to a controlling interest, or when inventions are transferred. This protects against foreign entities acquiring rights to federally-funded technologies through stock/asset purchases and bankruptcy proceedings and then moving the manufacturing of such technologies offshore. These enhancements, particularly needed in today's exceptional circumstances, allow DOE to ensure America's security and prosperity, while allowing flexibility when needed for commercialization.

To address the limitations of U.S. Preference arising out of Bayh-Dole, DOE has issued several DEC's over the past eight (8) years to protect domestic manufacturing for specific programs/technologies including.

- "EXCEPTIONAL CIRCUMSTANCES DETERMINATION UNDER BAYH-DOLE FOR ENERGY EFFICIENCY, RENEWABLE ENERGY, AND ADVANCED ENERGY TECHNOLOGIES" issued on September 19, 2013 for inventions in the fields of energy efficiency, renewable energy, and advanced energy technologies. This DEC relied on the development of U.S. Manufacturing Plans as discussed below, while allowing for the U.S. Competitiveness Provision.
- "DETERMINATION OF EXCEPTIONAL CIRCUMSTANCES UNDER THE BAYH-DOLE ACT FOR THE OFFICE OF CYBERSECURITY, ENERGY SECURITY, AND EMERGENCY RESPONSE" issued on January 10, 2020 for 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.
- "DETERMINATION OF EXCEPTIONAL CIRCUMSTANCES UNDER THE BAYH-DOLE ACT FOR QUANTUM INFORMATION SCIENCE TECHNOLOGIES" issued on September 16, 2020 for Quantum Information Science (QIS) technologies and applications.

DOE tailored each of these DEC's to a reasonable and flexible restriction that is far less than title forfeiture to ensure that only modifications necessary to address the exceptional circumstances or concerns which led to the use of the exception were deployed for these program-specific projects.²⁸ In view of the above and the increasingly rapid changes to the global landscape, DOE needs to avail itself of the authority provided by Bayh-Dole to address exceptional circumstances by expanding the use of the U.S. Competitiveness Provision to protect domestic manufacturing, not only to better meet the policy and objective of Bayh-Dole and fulfill its mission, but also to address the critical concerns expressed in E.O. 14017. The need for the U.S. Competitiveness Provision is particularly strong for emerging technologies which, by their nature, are cutting edge and thus not always identifiable in advance.

Even under these increasing pressures, this DEC is specifically structured so that DOE may limit its application when circumstances warrant, such as upon a determination that in individual cases, the exceptional circumstances outlined above may not be present. Even when it does apply, the U.S. Competitiveness Provision and enforcement provision are narrowly crafted without any other changes affecting Contractor rights. This DEC is permissive and allows DOE to omit the U.S. Competitiveness Provision in funding agreements. For example, DOE may decide it is not warranted to require the U.S. Competitiveness Provision in funding agreements for certain technologies, especially certain basic science technologies.

While existing program/technology specific DEC's have been successfully implemented, it has become clear to DOE that a DEC covering all of DOE's Science and Energy Programs is necessary to better achieve the policies and objectives of Bayh-Dole for DOE Science and Energy Technologies in light of the exceptional circumstances discussed. This DEC will ensure that DOE has the flexibility to require a U.S. Competitiveness Provision or U.S. Manufacturing Plan for any DOE Science or Energy Technology, thereby ensuring that DOE-funded technologies, including emerging technologies with the ability to significantly affect important national and/or economic security interests, are commercialized by U.S. industry and labor, further ensuring secure supply chains for critical and emerging technologies while furthering U.S. economic and national security interests.

Furthermore, by having consistent terms for all funding agreements where exceptional circumstances are present (including DOE funding agreements to entities other than nonprofit organizations and small business firms) the administrative burden may be significantly reduced for all parties. DOE and its partners, including nonprofit organizations and small business firms, are already familiar with the U.S. Competitiveness Provision having been successfully included for years in the above mentioned DEC's, as well as other DOE agreements. DOE has, for example, required substantial U.S. manufacturing similar to the U.S. Competitiveness Provision for decades in funding agreements with large businesses,

²⁸ 37 C.F.R. § 401.14(b).

implemented through DOE's patent waiver authorities.²⁹ This provision has protected domestic manufacturing by ensuring investment in domestic manufacturing and industry is a primary consideration. Although the substantial U.S. manufacturing requirement is typically accepted by large businesses, waivers and modifications are granted as appropriate.

For at least these reasons, the current state of domestic manufacturing for science, energy, environmental, and nuclear science and technology solutions makes clear that Bayh-Dole's policy and objective of promoting U.S. manufacture and commercial deployment of subject inventions has not been adequately achieved given the exceptional circumstances described. Therefore, the U.S. Competitiveness Provision must be deployed to protect domestic manufacturing.

- iii. Congress recognizes the need to promote U.S. Competitiveness through DOE's investment in science, energy, environmental, and nuclear science and technology solutions.

In the House Report accompanying 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 Department's research and development efforts yield several thousand patents and licenses each year, and taxpayers expect their support to result in commercialized technologies that benefit both American consumers and American industry. This expectation is not met when intellectual property that was developed with public funding is commercialized only by foreign manufacturers. *The Committee believes that intellectual property policies offer substantial opportunities to encourage domestic manufacturing without obstructing commercial efficiency, eroding the value of intellectual property, or under-mining free trade.* The technology transfer efforts of the Department should support domestic manufacturing wherever possible and DOE must take proactive steps to ensure taxpayer-funded research and development result in domestic jobs and revenues.³⁰ (emphasis added)

The Committee requested that DOE examine what authorities are available to control intellectual property, specifically including Bayh-Dole.³¹ They recognize that it is critical that technologies funded by DOE support manufacturing in the United States, particularly in view of the necessity of creating and maintaining jobs, including manufacturing jobs, in the U.S.

²⁹ e.g., 10 CFR § 784 et seq.

³⁰ H. Rept. 112-462 - ENERGY AND WATER DEVELOPMENT APPROPRIATIONS BILL, 2013 at page 81.

³¹ *Id.*

IV. DOE may require the U.S. Competitiveness commitment to help maintain U.S. competitiveness and leadership in science, energy, environmental, and nuclear science and technology solutions.

a. DOE may incorporate the U.S. Competitiveness Provision in any DOE FOA, solicitation, announcement, notice, or specific funding agreement.

DOE may require incorporation of the U.S. Competitiveness Provision in Appendix A for funding agreements issued to Contractors as designated in any DOE Science and Energy Technology FOA, solicitation, announcement, notice, or specific funding agreement, including but not limited to, financial assistance transactions, acquisition contracts, and laboratory or facility management and operating contracts (e.g. DOE Acquisition Letter). The U.S. Competitiveness Provision requires 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 Contractor can show to the satisfaction of the DOE that it is not commercially feasible. A similar provision is already incorporated into large-business funding agreements through the DOE's patent waiver process.

Additionally, for funding agreements in existence prior to approval of this DEC, 37 CFR § 401.3(d) authorizes DOE to negotiate the insertion of the U.S. Competitiveness provision described in Appendix A task-orders/modifications added to a funding agreement after the initial award, including, but not limited to, contracts for the management and operation of DOE's National Laboratories.

Prioritizing U.S. manufacture will help ensure that essential science, energy, environmental and nuclear science and technology solutions will be manufactured and deployed in the U.S., providing not only valuable economic benefit to the U.S. but also ensuring that the U.S. has key production and workforce capabilities to protect our national security interests and critical national economic interests, for example, as described in the National Strategy for Critical and Emerging Technologies, the National Strategic Overview for Quantum Information Science, and the National Quantum Initiative Act, while also providing the flexibility necessary to ensure a research environment conducive to discovery and collaboration. DOE has determined that the U.S. Competitiveness Provision is necessary.

b. The U.S. Competitiveness Provision will be enforceable to protect the nation's interests.

DOE will amend the patent clause of any funding agreement for DOE Science and Energy Technologies including the U.S. Competitive Provision to grant DOE the right to obtain title to the subject invention (e.g., title reverts back to DOE) if a Contractor fails to comply with the requirement to substantially manufacture a subject invention in the U.S., absent any DOE-approved waiver or modification. This right to obtain title for a breach of the U.S. Competitiveness Provision will provide DOE a quick and effective enforcement mechanism similar to other available remedies under Bayh-Dole.

c. *Waivers and modifications are available.*

Recognizing the need for flexibility, DOE will accept applications from Contractors for a waiver or modification of the requirements under the U.S. Competitiveness Provision. All applications for a waiver or modification will be considered. DOE expects to modify the U.S. Competitiveness Provision in certain situations. This DEC authorizes modification of the U.S. Competitiveness Provision to reduce requirements when doing so will facilitate or promote commercialization. For example, DOE may authorize certain technologies or products be manufactured outside the U.S. in certain quantities, fields of use, or for certain time periods. Additionally, administrative changes may be made to the U.S. Competitiveness Provision, for example to clarify funding agreement requirements, provide contact information, or to reduce requirements of the provision as appropriate.

Any waiver or modification of the U.S. Competitiveness Provision must consider the factors described below as well as substantial U.S. economic benefits. DOE, in its sole discretion, through the cognizant DOE funding program, and with the concurrence of the DOE Assistant General Counsel for Technology Transfer and Intellectual Property (GC-62), may grant such waiver or modification requests. GC-62 may delegate such concurrence approvals to DOE Field Patent Counsel as the Assistant General Counsel for Technology Transfer and Intellectual Property deems appropriate. DOE offices will be encouraged to provide funding agreement specific information for the waiver process including contact information for local field patent counsel and program approval information. Contractors may address in writing to DOE, and DOE may consider, the following factors in such requests, for example:

- (1) the extent to which the request supports the objectives of DOE's mission;
- (2) the commercial feasibility of manufacturing the subject invention in the U.S., including the feasibility of developing all or part of the related supply chain(s) in the U.S.;
- (3) any reasonable efforts to substantially manufacture the subject invention in the U.S., including licensing U.S. firms for manufacturing;
- (4) legally enforceable commitments proposed by the recipient to provide alternative benefits to the U.S. economy and industrial competitiveness preferably related to the commercial use of the subject invention, e.g., direct or indirect investment in U.S.-based plant and equipment, creation of high-quality U.S.-based jobs, and further domestic development of the subject invention technology;
- (5) the geographic, technological, commercial, and temporal scope of the requested waiver compared to any proposed contractual or other benefits;
- (6) agreement by the Contractor to provide at least a non-exclusive license with commercially reasonable terms to any Contractor agreeing to the U.S. Competitiveness Provision; and
- (7) any other such factors that may be relevant.

DOE may also consider whether such requests present any risk of unauthorized or other transfer of subject invention rights or information which may result in a loss of benefits to the U.S. economy or other harm to U.S. competitive or economic interests. DOE funding programs may issue their own guidance on waiver or modification requests, which may or may not include the above factors, through FOA, solicitation or other announcement language, program-specific waiver forms, or other mechanisms. Therefore, this narrowly-tailored U.S. Competitiveness Provision protects the nation's interests, while having streamlined flexibility to balance U.S. manufacturing interests with commercialization interests when the technology is ready for commercialization.

These considerations must be made expeditiously to facilitate commercialization. Therefore, DOE plans to issue internal instructions for the collection, review, and timely response to requests to waive or modify the U.S. Competitiveness Provision. Additionally, DOE may leverage upcoming updates to the iEdison invention reporting and patent tracking system to allow for electronic receipt of requests for waivers of U.S. manufacturing, thereby facilitating Contractor applications for waivers or modifications.

The cognizant DOE funding program, with the concurrence of the DOE Assistant General Counsel for Technology Transfer and Intellectual Property (GC-62) may waive or modify the U.S. Competitiveness Provision for a particular award or a class of awards as necessary to accommodate effective commercialization. GC-62 may delegate his/her authority to DOE field Patent Counsel. Depending on the nature of the FOA, solicitation, or other announcement, DOE may require or allow a U.S. Manufacturing Plan from each applicant as part of its application in addition to or, if the cognizant program office approves, in lieu of the U.S. Competitiveness Provision. The U.S. Manufacturing Plan will represent the applicant's measurable commitment to support U.S. manufacturing of the technologies resulting from any subsequent DOE funding agreement. The U.S. Manufacturing Plan requirement shall apply equally to all types of applicants, including large businesses, small business firms, and nonprofit organizations. Once incorporated into a funding agreement, the U.S. Manufacturing Plan will provide that it may be enforced, among other possible remedies, through forfeiture of rights to subject inventions.

V. Conclusion

DOE has determined that exceptional circumstances exist for DOE Science and Energy Technologies. Enabling use of the U.S. Competitiveness Provision described herein via this comprehensive DEC will better promote the objectives of Bayh-Dole in light of those circumstances by providing stronger support to U.S. economic and national security, commercialization of federally-supported inventions, U.S. industry, labor, and U.S. manufacturing. Moreover, this narrowly-tailored DEC does not impose 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 to appeal it.³²

Other DOE program offices may approve this DEC by signature of this approval page by the cognizant Under Secretary or Head of Departmental Element including additional supporting information, if any, with written notification to the Secretary and a copy to the Assistant General Counsel for Technology Transfer and Intellectual Property.

Approved:  Date: June 3, 2021
KATHLEEN HOGAN
ACTING UNDER SECRETARY FOR
SCIENCE AND ENERGY

Approved:  Date: June 3, 2021
JENNIFER GERBI
ACTING DIRECTOR
ARPA-E

Approved: _____ Date: _____
JOHN T. LUCAS
DEPUTY GENERAL COUNSEL
FOR TRANSACTIONS,
TECHNOLOGY, & CONTRACTOR
HUMAN RESOURCES

³² See 35 U.S.C. § 202(b)(3); 37 C.F.R. § 401.4.

Appendix A

U. S. Competitiveness

The Contractor 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 Contractor 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 Contractor 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 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 assignment, license, or other transfer of rights in the subject invention(s) is/are suspended until approved in writing by DOE. The Contractor 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 Contractor will include this paragraph in all subawards/contracts, regardless of tier, for experimental, developmental or research work.

(End of clause)