SUPPORTING STATEMENT

U.S. Department of Commerce

National Institute of Standards and Technology

Domestic Manufacturing Waiver Form

OMB Control No. 0693-XXXX

SUPPORTING STATEMENT PART A

Abstract

The Bayh-Dole Act (35 USC 18) and its implementing regulations (37 CFR 401) allow for recipients of federal research funding (Contractors) to retain ownership of inventions developed under federal funding agreements. In exchange, the government retains certain rights to the invention, including a world-wide right to use by or on behalf of the U.S. government. The law also requires the Contractor to obtain permission for certain actions and fulfill reporting requirements. One such requirement under the Bayh-Dole Act is that Contractors (as defined in the statute and regulations) shall not grant "the exclusive right to use or sell any subject invention in the United States unless such person agrees that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States." However, the law allows an agency to waive this requirement if a Contractor has shown that "reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacturing is not commercially feasible."

Pursuant to Executive Order 14104, NIST was directed to consult with the Interagency Working Group for Bayh-Dole to create a set of common questions to be used by all agencies as an application to apply for waivers of the domestic manufacturing requirement under the Bayh-Dole Act.

Justification

1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection. Attach a copy of the appropriate section of each statute and regulation mandating or authorizing the collection of information.

The Bayh-Dole Act (35 USC 18) and its implementing regulations (37 CFR 401) only allow agencies the authority to waive a Contractor's domestic manufacturing obligations if it is shown that reasonable but unsuccessful efforts have been made to grant similar licenses to those likely to manufacture in the United States or that domestic manufacturing is not commercially feasible. In order to make these determinations, agencies need to collect certain information from the Contractors.

Executive Order 14104 directed NIST to consult with the Interagency Working Group in developing common waiver application questions to be used by all agencies (EO 14104, Section 7(e)). The EO also states certain questions to asked, including how the waiver will be used, why it is important for the subject invention to be brought to market, potential economic and national security impacts, benefits that will accrue to domestic manufacturing and the United States if the subject invention were brought to market, whether the license is exclusive or non-exclusive, and certain conditions under which the subject invention would be manufactured.

2. Indicate how, by whom, and for what purpose the information is to be used. Except for a new collection, indicate the actual use the agency has made of the information received from the current collection.

The table below details the information/data fields being requested and the needs or uses for collection of this piece of information.

Item No.	Question	Needs/Uses
1	Contractor/Petitioner Organization	- Used by agencies to identify the party(ies) who are requesting the waiver
2	Contractor/Petitioner Organization Address	- Used by agencies to identify the party(ies) who are requesting the waiver
3	Contractor/Petitioner Point of Contact including Name, Email Address, and Phone Number	- Used by agencies to know who to contact with additional questions or follow-ups to the waiver request
4	Primary Contact (if different from above) or Additional Point of Contact including Name, Email Address, Phone Number, and the Name of the Party the Additional Contact Represents	- Allows contractor to designate another point of contact and give agencies authorization to speak with those parties about the waiver form
5	Invention Report Number(s)	- Used by agencies to identify invention and associated Bayh-Dole/iEdison that are associated with the request
6	Primary Funding Agency	- Used by agencies to identify the agency designated to take the lead in receiving Bayh-Dole/iEdison related reporting
7	Other Funding Agency(ies)	- Used by agencies to identify any other agency that supported the conception or first actual reduction to practice of the invention
8	Agreement Number(s)	- Used by agencies to identify funding agreements and programs that supported the conception or first actual reduction to practice of the invention
9	Invention Title(s)	- Used by agencies to identify inventions associated with the waiver request
10	Invention Docket Number(s)	- Used by agencies to identify inventions and invention records associated with the request as some inventions have similar titles but docket numbers are often unique.
11	Patent Docket Number(s)	- Used by agencies to identify patents and patent records associated with the request
12	Patent Applications and Patent Numbers included in request	- Used by agencies to confirm any and all patents associated with the waiver request

13	Name of Licensee or Proposed Licensee	- Used by agencies to identify to whom the invention is being licensed to give rise to the waiver request
14	Names of any Sub-Licensees	- Used by agencies to identify to whom the invention is may have been sub-licensed to in order to identify all parties involved
15	Business Address of Licensee	- Used by agencies to identify to whom the invention is being licensed to give rise to the waiver request and where they are located which may have economic impact in regards to jobs, etc.
16	Exclusive or Non-Exclusive License	- Used by agencies to identify the breadth of rights afforded in the license agreement - Required under EO 14104
17	Fields of use to which the license is or could be restricted	- Used by agencies to identify the breadth of rights afforded in the license agreement
18	What is the scope of rights given (e.g., U.S> versus worldwide use and sales)?	- Used by agencies to identify the breadth of rights afforded in the license agreement
19	Describe the technology, including products to be manufactured or specific processes implementing the subject invention.	- Used by agencies to understand the invention and what resulting products will be
20	Describe the current stage of development of the subject invention and any development milestone plans necessary for manufacturing and commercialization.	- Used by agencies to understand where inventions are in the development process and how soon they may be brought to market
21	What are the manufacturing plans for the subject invention. Describe any hurdles (manufacturing or otherwise) to be overcome to make the technology practical as well as the projected manufacturing start date.	- Used by agencies to understand the process for manufacturing the invention and potential issues and/or difficulties that may arise
22	Discuss the factors that make domestic manufacture not commercially feasible, including: a. Implications of substantially manufacturing in the U.S. on commercial adoption risks, including those related to the value proposition for the technology to meet the market demand, market acceptance and risks posed by existing players in the global competitive landscape, resource maturity and the domestic and global inputs needed to produce the technology, and societal, non-economic risks that may hinder deployment b. The relative costs of U.S. and foreign manufacturing c. Manufacturing capabilities within the U.S. d. The efforts made to locate, develop, or contract for such manufacturing capabilities, including any previous efforts to manufacture the subject invention(s) in the U.S. e. Approximately how much additional time, funding, and/or other factors that would be necessary in order to make U.S. manufacturing commercially feasible f. Any other circumstances that make foreign manufacture necessary	- Used by agencies to understand the scope and nature of the domestic and foreign manufacturing capabilities related to this specific invention(s) and product(s)
23	Identify any companies, including contract companies, that	- Used by agencies to understand the entities are

	would be manufacturing the subject invention(s) (if other than the Contractor/Petitioner, Licensee, or a subsidiary of either one). Do any of those companies, including contract companies, have manufacturing locations within the U.S.?	may manufacture the product(s) and their U.S. presence (if any)
24	Has the Hollings Manufacturing Extension Partnership (MEP) or similar organizations been consulted to identify domestic manufacturers for the product?	- Used by agencies to understand the degree to which contractors attempted to find domestic manufacturers
25	Is there any product embodying the subject invention or produced through the use of the subject invention manufactured in the U.S., or alternatively, is there any U.S. content used in manufacturing the product(s)? Please describe the scale of U.S. manufacturing (i.e., quantities of U.S. product(s) or content).	- Used by agencies to understand whether any products or any part of a product will be manufactured in the United States to understand the scope of benefit to United States' manufacturing and economy.
26	Where would the proposed manufacturing facility be located (city and country)?	- Used by agencies to understand where the Contractor and/or licensee propose manufacturing to take place
27	If the location(s) of current or proposed manufacturing facility(ies) is/are not in an allied or partner country (e.g., Canada, Mexico, South Korea, Japan, the UK, EU countries, those with a free trade agreement as identified by the U.S. Trade Representative (USTR) in official USTR publications or public announcements such as on Free Trade Agreements | United States Trade Representative (ustr.gov)), has there been any effort to locate manufacturing facilities in such jurisdictions? If yes, please provide details of such efforts.	- Used by agencies to understand the nature of the location of the proposed manufacturing and whether the country is one with which the United States has an allyship or partnership
28	Is the proposed manufacturing facility new or an existing facility?	- Used by agencies to understand whether an existing manufacturing facility is proposed or one where investment went into the creation of a new facility that might have also been created in the United States
29	For any step in the manufacturing process that would occur outside of the United States, describe the conditions under which the subject invention will be manufactured abroad (including unionization of workplaces, health and safety standards, labor and wage laws, and environmental impacts).	- Used by agencies to understand the nature of the proposed manufacturing location. - Required under EO 14104
30	What is the mechanism(s) by which the company manufacturing the product will acquire the necessary rights to the subject invention to manufacture the products (e.g., license, exclusive license, assignment)?	- Used by agencies to understand the nature of the agreement, particularly if it is not a license
31	How will the know-how to manufacture be transferred (e.g., Licensee's employee or other knowledge being provided)?	- Used by agencies to understand whether and how additional information is being transferred in relation to the invention
32	How will the Contractor/Petitioner monitor and oversee compliance with the terms of a waiver, if approved, including the manufacturing and distribution of the products? Please specify the legal mechanism(s) used by the Contractor/Petitioner and/or Licensee to enforce (e.g., license, exclusive license, assignment) in your response.	- Used by agencies to understand how a waiver, if granted would be monitored to ensure compliance and ensure that the Contractor/Petitioner has a plan in regards to monitoring and compliance
33	Describe all reasonable but unsuccessful efforts made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States. This may include past marketing strategies and efforts for the technology, including the number of companies contacted, the methods used for marketing and contacting companies, the types of licenses and terms offered to potential licensees,	- Used by agencies to determine whether and to what degree reasonable but unsuccessful efforts were taken to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States

	comparison of terms offered to potential foreign licensee and those offered to U.S. companies, and the responses of companies to marketing efforts.	
34	Describe the market size and geographic distribution potential of the technology.	- Used by agencies to determine potential impact of the technology and resulting product(s) and its need in the marketplace
35	Discuss the significance of the technology, including the availability of alternative products, the size of intended patient populations (if applicable), whether requiring U.S. manufacture will delay entry of the product into the U.S. market, and the effect any such delay may have on U.S. public health.	- Used by agencies to determine potential impact of the technology and resulting product(s) and its need in the marketplace
36	Identify any value or benefit to the United States of the technology even if it would not be manufactured in the United States, including I) the direct or indirect investment in U.S. plants or equipment, such as for marketing or packaging; ii) the creation of new or higher quality U.S.-based jobs, iii) the enhancement of the domestic skills base, iv) the further domestic development of the technology, v) a positive impact on the U.S. trade balance considering product and service exports as well as foreign licensing royalties and receipts, or vi) cross-licensing, sublicensing, and reassignment provisions in the license which seek to maximize benefits to the U.S.	- Used by agencies to ascertain benefits to the United States other than those that might be received if the product(s) were manufactured substantially in the United States, benefits that might not be received if a waiver were not granted.
37	To the extent known to the Contractor/Petitioner at the time of the submission of this request, are any potential economic or national security impacts related to the subject invention or manufacturing the subject invention abroad? If so, identify those impacts and explain any mitigating factors.	- Used by agencies to understand the economic and national security implications of the invention and the potential granting of a waiver
38	Please propose revised U.S. manufacturing requirements. Contractors/Petitioners are encouraged to maintain the applicable U.S. manufacturing requirements with only such modifications as are necessary to address the circumstances or concerns which led to this waiver request. Contractors/Petitioners are also encouraged to include contractual obligations to promote approval by the funding agencies.	- Allows the Contractor to propose manufacturing requirements to the agency for consideration as these terms are usually negotiated through the waiver process
39	Please add any additional information or considerations you would like to include with this request. You may also add any relevant attachments for support.	- Allows the Contractor the opportunity to provide any additional information they think might be helpful to the agency in weighing whether or not the criteria are met or otherwise whether or not to grant a waiver

The information detailed above will be collected from recipients of federal funding with resulting inventions, including universities, research institutions, hospitals, non-profit organizations, for-profit businesses, etc., who wish to seek a waiver of domestic manufacturing requirements. These organizations may need to collect some of this information from companies and manufacturers who are seeking to license and/or manufacture the invention(s)/product(s). federal funding. This information will generally be submitted electronically as an attachment through the iEdison reporting system for an easily centralized location for reporting information to all of the agencies who have registered with iEdison. If an agency is not a registered user of iEdison, the individual agency will be responsible for the collection of the information outside of the iEdison system as well as the retention and security of the data. Executive Order 14104 requires that all agencies begin planning for their agency use of the iEdison system by the end of

calendar year 2025. Therefore, the expectation is that by the end of 2025, all Domestic Manufacturing Waivers will be submitted via the iEdison System.

Because of the volume of information, the implication of publication on the availability of patent protection, and the legislative and regulatory timeline requirements, the information related to inventors' gender will be reported and used constantly and on an on-going basis. However, the utilization questions are only asked up to annually in accordance with the Bayh-Dole regulations at 37 CFR 401.14(h).

Overall, the information collected is either required by the Bayh-Dole Act and its regulations or they help advance, track compliance and/or measure impact related to the Act's purpose and objectives. Agreement to provide the information is essentially a requirement to receive the benefit of federal research dollars. The information is used by federal agencies in the following ways:

a. To track participation by gender in the innovation process, including inventing, patenting, and licensing.
b. To tie inventions and patents and resulting products to their associated federal funding programs;
c. To track compliance with the Bayh-Dole Act and its implementing regulations, specifically as it relates to taking steps to achieve practical application and compliance with domestic manufacturing requirements;
d. To track ROI from federal research funding in a number of ways, including revenue, licenses, products, domestic manufacturing, jobs, etc.

In general, we only anticipate that limited data derived from the information received under this collection would be made public. Some information provided may be required to be reported by funding agencies to the Department of Commerce and/or the Made in America Director pursuant to 37 CFR 401.16 and Executive Order 14104 respectively. However, any business confidential information provided would not be released publicly.

3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses, and the basis for the decision for adopting this means of collection. Also describe any consideration of using information technology to reduce burden.

Information will be primarily entered electronically via NIST's iEdison website so that Contractors have a consistent means to which to deliver these forms without having to track down the appropriate party at each agency. This also provides a way to Contractors to track when requests were submitted and confirm when an agency is reviewing the request (the agencies can change the status from "Submitted" to "Pending"). Additionally, this allows for one form to be submitted instead of multiple forms to different agencies in the event that more than one funding agency funded an invention. These features reduce burden on the Contractors. Additionally, pursuant to EO 14104, steps are being made to transition all funding agencies to iEdison by 2025 to further eliminate duplicative reporting where a Contractor might have to report in iEdison and then again to an agency that does not participate in iEdison.

4. Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purposes described in Item 2 above.

Utilizing iEdison, if multiple funding agreements supported one invention, each agency and funding agreement are entered into the single Invention Report in iEdison and a single domestic manufacturing waiver request would be submitted under that Invention Report, notifying all associated funding agencies. Therefore, the users only have to report this information in iEdison once to submit their request to every funding agency that contributed to the invention instead of having to submit to each funding agency individually. There are certain fields regarding the invention (e.g., the Invention Report Number, Title, Docket Numbers, and Funding Information) which could be pulled out of iEdison and into the form automatically. However, we opted to require these fields in the form for a number of reasons. First, these fields do not represent a significant burden to populate. Secondly, it allows Contractors to begin filling out the form with or without first logging into iEdison. Thirdly (and perhaps most importantly), this allows the same form to be used if a single waiver were to cover multiple subject inventions instead of having to create unique forms for each, significantly reducing burden. Finally, it allows a user to more easily keep track of what invention a waiver is related to while is it being completed. If a Contractor has more than one form in progress, they will be able to identify which form is which from the identifying information they have completed on the form.

5. If the collection of information impacts small businesses or other small entities, describe any methods used to minimize burden.

We have implemented time-saving features by building in the capabilities discussed in Question 3 above.

6. Describe the consequence to Federal program or policy activities if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.

If this information is not put into a standardize form, the Contractors will have to go to each funding agency to determine their unique set of questions asked in order to seek a waiver. Additional if the information is not collected by Federal funding agencies in a timely manner, then the agencies would not have all of the information needed to analyze whether a domestic manufacturing waiver was warranted. They may have to go back to Contractors multiple times for more and additional information, thus delaying the process and causing additional burden on all parties. Furthermore, NIST would be in violation of EO 14104, which requires the development of common questions to be utilized by all agencies.

7. Explain any special circumstances that would cause an information collection to be conducted in a manner: requiring respondents to report information to the agency more often than quarterly; requiring respondents to prepare a written response to a collection of

information in fewer than 30 days after receipt of it; requiring respondents to submit more than an original and two copies of any document; requiring respondents to retain records, other than health, medical, government contract; grant-in-aid, or tax records, for more than three years; in connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study; requiring the use of a statistical data classification that has not been reviewed and approved by OMB; that includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or requiring respondents to submit proprietary trade secrets, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

a. Respondents required to report information to the agency more often than quarterly: Respondents would only need to submit these waiver forms in instances where they are required to manufacture substantially in the United States and they wish to seek permission to waive that requirement. Once a waiver is granted, it is often valid for a number of years. Therefore, the only time a respondent would need to submit this form more often than quarterly would be if they had a completely different invention/product for which they were also seeking a waiver within a short time frame of one another, however, it is unlikely that the information submitted would be the same as in this form if it were for a different invention/product.
b. Respondents required to submit proprietary information: There may be circumstances under which business confidential information may be needed in order to support an argument that domestic manufacturing is not commercially feasible. However, any proprietary business information submitted would be held confidential and not made public.

The remaining scenarios described do not apply.

8. If applicable, provide a copy and identify the date and page number of publication in the Federal Register of the agency's notice, required by 5 CFR 1320.8(d), soliciting comments on the information collection prior to submission to OMB. Summarize public comments received in response to that notice and describe actions taken by the agency in response to these comments. Consultation with representatives of those from whom information is to be obtained or those who must compile records should occur at least once every 3 years - even if the collection of information activity is the same as in prior periods. There may be circumstances that may preclude consultation in a specific situation. These circumstances should be explained.

A 60-day Federal Register Notice soliciting public comment was published on Thursday, December 7, 2023 (Vol. 88, pg. 85243-85244). No comments were received.

A 30-day Federal Register Notice soliciting public comment was published on Friday, May 24, 2024 (Vol. 89, pg. 45847-45848).

Due to the nature of the Executive Order outlining the requirements of this information collection, consultation was not engaged in for this information collection request. E.O/ 14104, Sec.7(e).

9. Explain any decision to provide any payment or gift to respondents, other than remuneration of contractors or grantees.

There are no plans to provide payments or gifts to respondents.

10. Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy. If the collection requires a systems of records notice (SORN) or privacy impact assessment (PIA), those should be cited and described here.

Because information submitted by the respondents may contain business confidential information, we have included the following statement to make respondent's aware that the agencies are on notice that the responses may contain such information: "CONTROLLED UNCLASSIFIED INFORMATION NOTICE: This document may contain Controlled Unclassified Information, trade secrets, commercial, or financial information obtained from a non-governmental source. Such information may be protected by law or regulation from unauthorized disclosure."

A Privacy Impact Assessment is not currently needed for this system. The information is deemed a Privacy Act System and is covered under the System of Records Notice COMMERCE/DEPT-23: Information Collected Electronically in Connection with Department of Commerce Activities, Events, and Programs.

11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private. This justification should include the reasons why the agency considers the questions necessary, the specific uses to be made of the information, the explanation to be given to persons from whom the information is requested, and any steps to be taken to obtain their consent.

Other than business information, no other sensitive information is anticipated.

12. Provide estimates of the hour burden of the collection of information.

Annual Burden

Number of waiver requests expected by NIST annually	Time to complete	Annual Burden Hours
10	13 hours	130 hours

13. Provide an estimate for the total annual cost burden to respondents or record keepers resulting from the collection of information. (Do not include the cost of any hour burden already reflected on the burden worksheet).

There are no capital/start-up or ongoing operation/maintenance costs associated with this information collection.

14. Provide estimates of annualized costs to the Federal government. Also, provide a description of the method used to estimate cost, which should include quantification of hours, operational expenses (such as equipment, overhead, printing, and support staff), and any other expense that would not have been incurred without this collection of information. Agencies may also aggregate cost estimates from Items 12, 13, and 14 in a single table.

Cost to the government should be minimal as shown in the below chart:

Staff	Grade/Step	Salary	Fringe (if applicable	% of Effort	Total Annualized Cost to Gov't
Federal Oversight					
NIST Project Oversight -	GS15-10	166,500	1.5%		$2,498

15. Explain the reasons for any program changes or adjustments reported on the burden worksheet.

This is a new information collection.

16. For collections of information whose results will be published, outline plans for tabulation and publication. Address any complex analytical techniques that will be used. Provide the time schedule for the entire project, including beginning and ending dates of the collection of information, completion of report, publication dates, and other actions.

There are no in-depth statistical analyses being conducted at this time and only information required under EO 14104 is expected to published (specifically, "a summary of each waiver application received, approved, and rejected" including "terms of any approved waiver and the processing time needed to reach a decision."

17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons that display would be inappropriate.

The expiration date will be clearly displayed with the OMB Control Number.

18. Explain each exception to the topics of the certification statement identified in "Certification or Paperwork Reduction Act Submissions."

There will be no exceptions to the certification statement and NIST certifies compliance with 5 CFR 1320.9 and the related provisions of 5 CFR 1320.8(b)(3).