ADDITIONAL GUIDANCE ON UTILIZATION QUESTIONS EFFECTIVE OCTOBER 1, 2023

Table of Contents

Introduction

Under 35 U.S.C. 202(c)(5), the Bayh-Dole Act provides agencies with the right to require "periodic reporting on utilization or efforts at obtaining utilization that are being made by the contractor or his licensees or assignees." This right is further explained in the implementing regulations at 37 CFR 401.14(h). The regulations state that the contractor agrees to submit these reports no more frequently than annually and that the reports "shall include information regarding the status of development, date of first commercial sale or use, gross royalties received by the contractor, and such other data and information as the agency may reasonably specify."

35 U.S.C. 202(c)(5) also discusses the confidentiality of information submitted in utilization reports. It states "That any such information as well any information on utilization or efforts at obtaining utilization obtained as part of a proceeding under section 203 of this chapter shall be treated by the Federal agency as commercial and financial information obtained from a person and privileged and confidential and not subject to disclosure under section 552 of title 5."

Effective October 1, 2023, all subject inventions reported in iEdison to which title has been elected will require annual utilization reporting. Reports will be due for each year starting two years after the date which the invention was reported to the agency (the date in which title election is due under the regulations at 37 CFR 401.14(c)(2)) or the year that title is elected, whichever is sooner. Contractors will receive notifications on October 1st of each year that utilization reports are due by December 31st of that year. Notifications will be sent each fiscal year until one year after the title election status of the invention is changed to Does Not Retain Title (though any outstanding utilization reports will still be due) or until one year after all nonprovisional patents / patent applications reported in iEdison have a Patent Status of "Expired" listed in iEdison. For example, if you elect title on May 1, 2023, you will start receiving notifications on October 1, 2023. If you change your title election decision to Does Not Retain Title on May 1, 2024, you will get one final utilization notification on October 1, 2024. You would not receive utilization notifications on October 1, 2025 and subsequent years.

The agencies have agreed to use a standard base set of utilization questions to be asked by all funding agencies with the possibility of additional, agency specific, supplemental questions. The iEdison system is designed to dynamically show only the applicable questions. Therefore, all questions asked within iEdison are required, and you will not be able to submit your utilization report without completing all questions shown. If there is an answer to a question that needs additional explanation or there is anything else you want the funding agency to know, each annual utilization report will have the option to include "Notes/Comments" to provide any additional context or information to the funding agency.

What follows is additional guidance on how to correctly answer the standard utilization questions. Some agencies have chosen to also ask limited "supplemental" questions in addition to these standard questions. If you have questions or concerns regarding an agency's supplemental questions, please reach out to that funding agency directly.

Definitions

Reporting Period

The term “reporting period” means the federal fiscal year, October 1st to September 30th. If a contractor submits a 2023 utilization report, the reporting period is October 1, 2022 through September 30, 2023.

Licensed

The term “licensed” means having one or more license agreements (exclusive, non-exclusive, or partially exclusive) or options agreement to license the subject invention(s) which were active at any time during the reporting period.

Commercialized

The term “commercialized” means that there has been an actual sale of a product by the owner or a licensee (including sublicensee) either outside or inside of the United States.

License

The term “license” or “license agreement” means a written agreement between the owner/licensor of a subject invention and another party (licensee) to use, manufacture, or sell the subject invention, including options to negotiate such license agreements. The term includes any type of license agreements, including but not limited to exclusive, non-exclusive, or partially exclusive, as well as options agreements. **For all agencies except NIH**, for purposes of utilization reporting, licenses **SHOULD NOT** include agreements executed solely for research purposes only and without even an option for commercial usage. **If your invention was funded by NIH**, licenses **SHOULD** include agreements executed solely for research purposes only (the exception to this is material transfer agreements, which **SHOULD NOT** be reported as licenses).

Option

The term “option” or “option agreement” means a written agreement that grants the licensee a certain amount of time to negotiate the terms of a license agreement.

Income

The term “income” means any monies received from a license or option agreement.

Product

The term “product” includes any device, machine, composition of matter, system, material, or other physical object that embodies or is produced through the use of the subject invention. In the case of a variety of plant, a product includes the sale of seeds, plants, and/or tissues thereof.

Initial Question: Stage of Development

Please indicate the latest stage of development of any product arising from this invention, according to the following categories: Not Licensed or Commercialized; Licensed; or Commercialized

The response to this question will determine the subsequent questions that you will be required to answer. If you answer "Not Licensed or Commercialized," you will be asked one follow-up question regarding commercialization plans. If you answer "Licensed," you will be asking certain licensing questions. If you answer "Commercialized," you will be asked questions about licenses and commercialization activity.

For purposes of this question, "Latest Stage of Development" means the furthest stage in development and/or commercialization that the subject invention(s) achieved during the reporting period. For example, if a subject invention was licensed at any point of the reporting period, but that license was terminated before the end of the reporting period, then you should select "Licensed."

Please see the Definitions section of this guidance document for definitions of "Licensed" or "Commercialized." If a subject invention(s) does not fall within either of these categories, then you should select "Not Licensed or Commercialized."

Not Licensed or Commercialized Questions

What are your current commercialization plans for this invention?

If the subject invention(s) is neither licensed nor commercialized during the selected reporting period, the agency wants to know what efforts were made to achieve utilization during the reporting period. The system will display a list of choices for selection; you should select the closest or most accurate selection displayed that demonstrates the closest step toward licensing or commercialization. For example, if you were seeking funding while at the same time marketing the invention for licensing, you should select "Marketing and/or furthering development of this invention to attract commercial partners."

If you think that you need to provide additional information or context to the agency to better explain your selection, you may use the "Notes" section at the end of the utilization report. Please note that for certain choices, additional explanation is required; if you select one of those choices, the "Notes" section will become a mandatory field.

The available choices are listed below as well as additional information to help you select which option is closest or most accurate for the subject invention(s).

Seeking additional funding to further develop this invention

This choice should be selected if the subject invention is too early stage to market or license, but you did not have sufficient funding during the reporting period to further develop the subject invention. Therefore, during the reporting period, you were seeking additional funding to further develop the invention in preparation for future development, license, and/or commercialization.

Marketing and/or furthering development of this invention to attract commercial partners

This choice should be selected if you are currently marketing the subject invention to seek potential licensee and/or you are actively furthering the development of the subject invention. Marketing the subject invention could include active or passive marketing, and the marketing could either be broad or targeted. For example, listing the subject invention as available for licensing on your website is a form of broad, passive marketing. Contacting identified technology scouts at companies with similar products or related products to tell them about the invention and to ask about potential collaboration or licensing is a form of targeted, direct marketing. However, solely having a published patent application or issued patent that is only searchable through the United States Patent and Trademark Office (USPTO) or other general website would not be considered a form of marketing.

Developing and/or preparing this invention with intent to commercialize ourselves

This choice would generally only be selected by for-profit companies. Making this choice indicates that during the reporting period, you were taking steps toward development of the subject invention with the goal that eventually your organization would directly sell or distribute the product for commercial purposes. Selecting "developing and/or preparing this invention with intent to commercialize ourselves"

does not mean that you cannot change commercialization strategies in the future; it is simply an indicator of what the organization's intent was during the reporting period.

Making available for distribution and/or licensing for research purposes only
This choice should be selected if the subject invention is available for research licenses only and is not being made available for any commercial licenses (e.g., commercial license or an option for commercial licenses). Such licenses may include research tools, reagents, animal models, etc. that are only to be transferred via MTA. This option should NOT be selected if you have funding from NIH (see definition of "license").

Developing and/or using this invention for internal purposes only
This choice should be selected if you are not planning on licensing or commercializing the invention, but only intend to use this invention internally. It should be noted that funding agencies may view selection of this option as evidence that the contractor is not taking effective steps to achieve practical application of the subject invention as required by Bayh-Dole. If this option is selected, the "Notes" section will be required for the contractor to explain how they are fulfilling Bayh-Dole requirements regarding achieving practical application.

No current commercialization plan
This choice should be selected if there is no plan to make the invention available or otherwise commercialize the invention. If this option is selected, the "Notes" section will be required for the contractor to explain how they are fulfilling Bayh-Dole requirements regarding achieving practical application.

Licensed Questions

General guidance for answering licensing questions:

Agreements that include multiple subject inventions should be credited toward each subject invention included in the agreement. For example, if there is a single license agreement that covers three subject inventions, that license would be credited as one license under each of the three subject inventions' utilization reports. Income received in connection with those agreements should be split amongst the licensed inventions as accurately as possible. If you can identify the amount of income attributable to each invention, you should split the income accordingly. However, if you cannot identify the exact amount or percentage attributable to each invention, it is acceptable to split the income amongst the licensed inventions equally–but do not report the total income in the utilization report for each subject invention.

The reporting of a license as exclusive or non-exclusive should be based on the specific terms of the license agreement. If a license is designated as exclusive in the license agreement, including exclusivity as it relates to field of use, territory, etc., it should be reported as an exclusive license. An agreement which includes both exclusive and non-exclusive aspects (e.g., exclusive in one country, but non-exclusive in another) should be counted once in both the exclusive and non-exclusive categories. However, co-exclusive licenses should be reported as non-exclusive licenses.

Parent-Child Inventions: All licenses and royalties of a subject invention that is linked as a child invention in iEdison should be credited in the parent invention's utilization report.

In the designated reporting period, how many exclusive licenses and/or options are or were active? If a number other than 0 is answered, list the name of each licensee

To answer the questions about licenses and licensees, click the "Worksheet" button. A table will pop up for you to complete and populate the answers to the associated questions. You must complete each field to submit the utilization report.

How to calculate total number of exclusive licenses:

- Total the number of exclusive licenses and/or option agreements that are or were active during the reporting period for each subject invention. Even if a license/option was active for one day during the reporting period, it should be included.
- Generally, MTAs for internal research purposes only should not be counted as a license for purposes of this question.
- Licenses to software or biological material (not MTAs) end-users may be counted per license, as 1 license, or 1 for each major software or biological material, whichever is determined (at contractor's discretion) to be the best representation of the institution's data. Licenses for technology protected under US plant patents or plant variety protection certificates (PVPs) may be counted in a manner similar to software or biological material products described above, at the contractor's discretion.
- If an agreement with a licensee was terminated and then a new agreement executed both within the reporting period, count this as 2 separate agreement(s).
- If an option is exercised and a license agreement is executed both within the same reporting period, count this as 2 separate agreement(s).
- Sublicenses should be included if the contractor permits sublicensing.

How to report licensees:

- Please use the full, legal name of the licensee.
- For FY2024 and subsequent years, please complete the worksheet for license, licensee, and small business information. If you have multiple licenses to the same licensee, you will list the licensee once and enter the total number of exclusive and non-exclusive licenses in the worksheet.

In the designated reporting period, how many non-exclusive licenses and/or options are or were active? If a number other than 0 is answered, list the name of each licensee

To answer the questions about licenses and licensees, click the "Worksheet" button. A table will pop up for you to complete and populate the answers to the associated questions. You must complete each field to submit the utilization report.

How to calculate total number of non-exclusive licenses:

- Total the number of non-exclusive licenses and/or option agreements that are or were active during the reporting period for each subject invention. Even if a license/option was active for one day during the reporting period, it should be included.
- Generally, MTAs for internal research purposes only should not be counted as a license for purposes of this question.
- Licenses to software or biological material (not MTAs) end-users may be counted per license, as 1 license, or 1 for each major software or biological material, whichever is determined (at contractor's discretion) to be the best representation of the institution's data. Licenses for technology protected under US plant patents or plant variety protection certificates (PVPs) may be counted in a manner similar to software or biological material products described above, at the contractor's discretion.
- If an agreement with a licensee was terminated and then a new agreement executed both within the reporting period, count this as 2 separate agreement(s).
- If an option is exercised and a license agreement is executed both within the same reporting period, count this as 2 separate agreement(s).
- Sublicenses should be included if the contractor permits sublicensing.

How to report licensees:

- Please use the full, legal name of the licensee.
- For FY2024 and subsequent years, please complete the worksheet for license, licensee, and small business information. If you have multiple licenses to the same licensee, you will list the licensee once and enter the total number of exclusive and non-exclusive licenses in the worksheet.

In the designated reporting period, how many licenses and/or options of any type to small businesses (as defined by relevant SBA regulations) are or were active?

When to report a licensee as a small business:

- The SBA requirements for categorization as a "small business" can be found at https://www.sba.gov/federal-contracting/contracting-guide/size-standards.
- If your licensee qualifies as a "small business" at any point during the reporting period, you should count that license as one to a small business.

In ***the designated reporting period, what was the total gross income received as a result of license or option agreements? Do not include specific patent cost reimbursements.***

How to calculate total gross income:

- Gross, not net, income should be reported. Income may include but is not limited to upfront fees, annual minimums, milestone payments, royalties, cashed-in equity, payments under options, etc. It should not include specific payments made explicitly for the reimbursement of legal expenses but should include general income used for recoupment of expenses (e.g., income from non-exclusive licenses which was used to recover unpaid patent expenses prior to internal distribution of net income).
    - Examples of specific patent cost reimbursements that are <u>not</u> counted as income:
        1. You have incurred $17,540.79 in past patent expenses. You execute an exclusive license wherein the licensee explicitly agrees to pay you for past patent expenses and sends you a check for $17,540.79.
        2. You specifically bill and receive payments from a licensee for ongoing patent expenses.
        3. Your licensee is directly billed by your law firm for patent expenses.
        4. If they sent you one payment covering additional fees (such as upfront fees or royalty payments) plus the patent expenses, you would subtract the patent reimbursements from the total and only count the other fees as income. For example, if the licensee sends $20,000 upfront fee plus $17,540.79 to reimburse for past patent expenses, in one combined payment of $37,540.79, you would subtract the $17,540.79 from the total and report the remaining $20,000 as income.
    - Examples of recoupment of expenses that <u>would</u> be counted as income:
        1. A licensee sends you an upfront fee of $20,000. The license agreement is silent on the reimbursement of patent expenses, but you have patent expenses of $17,540.79 and you use that upfront fee to recover those patent costs before you distribute income to inventors and others. In this case the full $20,000 would be counted as income.
- Income should be calculated using cash basis accounting methods, not accrual accounting methods (i.e., you should only include royalties actually received during the reporting period, not income that is due but not paid).
- If an ownership interest or equity in a company is received in lieu of or in addition to cash payments, the value of the equity should not be counted as income for utilization report unless or until that ownership or equity is cashed in, resulting in a transfer of cash to the organization. When a cash transfer is made to the organization, that amount should be counted as income for the reporting year in which it was received.
- If, due to complex licensing of related invention families, it is not possible to get an exact accounting for invention for utilization purposes, please use your best judgement to be as accurate as possible. You may consider using similar methodology as those you may have used to determine the calculation and split of inventorship royalties.

Examples of how to calculate income:

1. Basic – one invention, one license
    a. Example: "New Widget" has been non-exclusively licensed to SmallBiz, LLC. SmallBiz, LLC pays an annual licensing fee of $2,000 every year on January 1st.
    b. Report: $2,000 in income.
2. Parent-Child invention, each are licensed to the same licensee
    a. Example: "Widget" is a parent invention with 1 child invention, "Improved Widget." Both inventions are exclusively licensed to SmallBiz, LLC. During the reporting period, SmallBiz, LLC paid $2,000 in royalties for sales of "Widget" and $3,000 in royalties for sales of "Improved Widget."
    b. Report: Combined royalties for sales of both "Widget" and "Improved Widget" ($5,000) would be reported as income in the utilization report under the Parent Invention.
3. Multiple inventions (all subject inventions) when you know specific income amounts for each invention
    a. Example: "New Widget" and "Improved Gadget" are two subject inventions, reported separately in iEdison. Both inventions are exclusively licensed to SmallBiz, LLC. During the reporting period, SmallBiz, LLC paid $2,000 in royalties for sales of "New Widget" and $3,000 in royalties for sales of "Improved Gadget."
    b. Report: $2,000 in income in the utilization report for "New Widget" and $3,000 in income in the utilization report for "Improved Gadget."
4. Multiple inventions (all subject inventions) where you do not know specific income amounts for each invention, but you do know percentage of how much each invention contributed to the commercial product
    a. Example: "Invention A" and "Invention B" are two subject inventions, reported separately in iEdison. These inventions are combined into one commercial product. "Invention A" comprises about 75% of the commercial product and "Invention B" comprises about 25% of the commercial product. Both inventions are exclusively licensed to SmallBiz, LLC, who sells the commercial product. During the reporting period, SmallBiz, LLC paid $10,000 in royalties.
    b. Report: 75% of the royalties received ($7,500) in income in the utilization report for "Invention A" and 25% of the royalties received ($2,500) as income in the utilization report for "Invention B."
5. Multiple inventions (all subject invention) where you do not know *either* the specific income amounts for each invention *or* how much each invention contributed to the commercial product
    a. Example: "Invention A" and "Invention B" are two subject inventions, reported separately in iEdison. These inventions are combined into one commercial product, but their relative contributions to the commercial product are completely unknown. Both inventions are exclusively licensed to SmallBiz, LLC, who sells the commercial product. During the reporting period, SmallBiz, LLC paid $10,000 in royalties.
    b. Report: Unless there is reason to calculate otherwise, split the royalties as seems reasonable amongst the inventions. For example, you may report 50% of the royalty received ($5,000) as income in the utilization report for "Invention A" and 50% of the royalty received ($5,000) as income in the utilization report for "Invention B."

6. Multiple inventions (NOT all inventions are subject inventions) where you don't know what income is attributed to each invention, but you know a breakdown of how much each invention contributed to the commercial product
    a. Example: "Invention A" and "Invention B" are two subject inventions, reported separately in iEdison. "Not Funded Invention C" is an invention that was not federally funded. These inventions are combined into one commercial product. "Invention A" comprises about 25% of the commercial product, "Invention B" comprises about 25% of the commercial product, and "Not Funded Invention C" comprises about 50% of the commercial product. All inventions are exclusively licensed to SmallBiz, LLC, who sells the commercial product. During the reporting period, SmallBiz, LLC paid $10,000 in royalties.
    b. Report: 25% of the royalties received ($2,500) would be reported as income in the utilization report for "Invention A" and 25% of the royalties received ($2,500) would be reported as income in the utilization report for "Invention B." The remaining 50% (revenue attributed to "Not Funded Invention C") would not need to be included in any utilization report because "Not Funded Invention C" was not federally funded.
7. Multiple inventions that are NOT all subject inventions where you do not know *either* the specific income amounts for each invention *or* how much each invention contributed to commercial product
    a. Example: "Invention A" and "Invention B" are two subject inventions, reported separately in iEdison. "Not Federally Funded Invention C" is an invention that was not federally funded. These inventions are all licensed and combined into one commercial product, but their relative contributions to the commercial product are completely unknown. All inventions are exclusively licensed to SmallBiz, LLC, who sells the commercial product. During the reporting period, SmallBiz, LLC paid $10,000 in royalties.
    b. Report: Unless there is reason to calculate otherwise, split the royalties as seems reasonable amongst the inventions. For example, you may report one third of the royalties ($3,333) as income in the utilization report for "Invention A" and one third of the royalties ($3,333) as income in the utilization report for "Invention B." The remaining ($3,334) attributed to "Not Funded Invention C" would not need to be included in any utilization report because it was not federally funded.

Other than U.S. Preference (35 U.S.C. 204), is the invention subject to any U.S. manufacturing requirements (e.g., U.S. Competitiveness provision, a U.S. Manufacturing DEC, etc.)? (Y/N)

35 USC 204 details the Preference for United States Industry imposed by the Bayh-Dole Act. This section provides the following (emphasis added):

> Notwithstanding any other provision of this chapter, no small business firm or nonprofit organization which receives title to any subject invention and **no assignee of any such small business firm or nonprofit organization shall grant to any person 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, in individual cases, the requirement for such an agreement may be waived by the Federal agency under whose funding agreement the invention was made upon a showing by the small business firm, nonprofit organization, or assignee 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 manufacture is not commercially feasible.

This provision is generally included in funding agreements' terms and conditions via the Standard Patent Rights Clause at 37 CFR 401.14(i). However, there are some circumstances where a different domestic manufacturing requirement may be imposed. For example, DOE has imposed different domestic manufacturing requirements in many of their funding agreements since 2021 via a Determination of Exceptional Circumstances (DEC) as described at U.S. Manufacturing | Department of Energy, which includes the following (emphasis added):

> 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.

This question is asking whether the standard requirements under 35 USC 204 apply to your funding agreement or if your funding agreement includes different domestic manufacturing requirements.

The answer to this question will determine which follow-up question below you are asked.

If the answer is NO: In the designated reporting period do all grants to any person of the exclusive right to use or sell the subject invention in the United States require that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States as required by 35 U.S.C. 204?

This question would only appear and require a response if you answered "No" to the previous question, indicating that your funding agreements include only the domestic manufacturing requirements under 35 U.S.C. 204. This question aims to determine if exclusive license agreements granting the right to use

or sell in the United States include the preference for United States industry required under 35 U.S.C. 204 (i.e., that those exclusive licenses include a clause requiring that any products embodying the subject invention or produced through the use of the subject invention being manufactured substantially in the United States?).

It should be noted that a negative response to this question does not necessarily indicate non-compliance if you have been granted a waiver by your funding agency(ies).

If the answer is YES: In the designated reporting period, do all licenses include a requirement that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States (including manufacturing requirements other than 35 U.S.C. 204)?

This question would only appear and require a response if you answered "YES" to the previous question, indicating that your funding agreements include domestic manufacturing requirements ***OTHER THAN*** under 35 U.S.C. 204. This question aims to determine if ***ALL*** license agreements include the requirement that ***ALL*** products embodying the subject invention or produced through the use of the subject invention be manufactured substantially in the United States.

It should be noted that a negative response to this question does not necessarily indicate non-compliance if you have been granted a waiver by your funding agency(ies).

Commercialized Questions

General guidance for answering commercialization questions:

If you select “commercialized” as the stage of development for your subject invention(s), you will be required to answer both the licensing and commercialization questions.

Products may be composed of or incorporate a single subject invention, several subject inventions, or a mix of subject invention and other inventions and/or components that are not federally funded. In cases where a product is composed of or incorporates more than one subject invention, you should report the products, licensees, and manufacturing locations under each subject inventions’ utilization report(s). The exception to this is when subject inventions are linked as parent-child inventions in iEdison. Where subject inventions have been linked as parent and child inventions in iEdison, all of the combined information is entered under the parent invention’s utilization report. Utilization reports are not entered under child inventions. If you complete a utilization report(s) under a separate invention and then decide to link it as a child, you should amend the parent’s utilization report(s) (if any) for each year to include the child’s utilization information. If the parent invention did not already have a utilization report, you should create utilization reports under parent as necessary to include both the parent and child inventions’ utilization data.

In the event that your subject invention is commercialized but that the resulting product or service is not manufactured in any way, you should enter “None” as a manufacturer and then select “None” for both the manufacturing country and state *and* provide an explanation in the “Notes” section provided at the end of the utilization report. An example of this might be software. However, it should be noted that if your software is incorporated into a device or machine, you should enter where that device/machine is manufactured.

Note: For purposes of completing utilization reporting, manufacturing also includes “grown” in the case of a variety of plant.

Other than U.S. Preference (35 U.S.C. 204), is the invention subject to any U.S. manufacturing requirements (e.g. U.S. Competitiveness provision, a U.S. Manufacturing DEC, etc.)? (Y/N)

See explanation and guidance under the Licensing questions.

IF the answer is NO: In the designated reporting period are all products embodying the subject invention or produced through the use of the subject invention manufactured substantially in the United States for all grants to any person of the exclusive right to use or sell the subject invention in the United States as required by 35 U.S.C. 204?

This question would only appear and require a response if you answered "No" to the preceding question, indicating that your funding agreements include ***ONLY*** the domestic manufacturing requirements under 35 U.S.C. 204. This question aims to determine if your exclusive licensees are actually compliant with the terms of the license and the preference for United States industry required under 35 U.S.C. 204 (i.e., are any products embodying the subject invention or produced through the use of the subject invention being manufactured substantially in the United States?).

It should be noted that a negative response to this question does not necessarily indicate non-compliance if you have been granted a waiver by your funding agency(ies).

If the answer is YES: In the designated reporting period, are all products embodying the subject invention or produced through the use of the subject invention manufactured substantially in the United States (including manufacturing requirements other than 35 U.S.C. 204)?

This question would only appear and require a response if you answered "YES" to the preceding question, indicating that your funding agreements include domestic manufacturing requirements ***OTHER THAN*** under 35 U.S.C. 204. This question aims to determine if ***ALL*** products embodying the subject invention or produced through the use of the subject invention are being manufactured substantially in the United States.

It should be noted that a negative response to this question does not necessarily indicate non-compliance if you have been granted a waiver by your funding agency(ies).

What was the calendar year of the first commercial sale? (YYYY)

This is the calendar year that the first actual commercial sale occurred, not when it was first offered for sale. Once this year has been entered into iEdison, it cannot be deleted or edited, even if the stage of development reverts to “Licensed” or “Not Licensed or Commercialized.” If you enter this year by mistake or enter it incorrectly, you should contact your funding agency to correct this year.

List any products made through the use of or embodying the subject invention(s) (PRODUCT NAME)

For each product listed, enter the Name of Manufacturer(s) and Manufacturing Country(ies). If United States, enter manufacturing state

How to report products, manufacturers, and manufacturing locations:

- Please enter the full, official product name when entering products into iEdison. You can enter multiple products into the system.
- For each product, you will first need to indicate the associated licensee. The licensees that you listed in the previous licensing questions will appear in a drop-down box for you to select the applicable licensee(s) for that product. If your licensee is not appearing in the drop-down box, please ensure that you have properly reported them as either an exclusive or a non-exclusive licensee in the previous licensing questions. If there is not a licensee because you are directly commercializing the subject invention, select "None/Self."
- Then you will list each manufacturer being used by that licensee (or your organization). You can enter multiple manufacturers for each licensee. If you are manufacturing the product directly, insert your own company name. If you are manufacturing using a contract manufacturer(s), enter the contract manufacturer(s)'s name.
- For each manufacturer, you will then list each country in which manufacturing is occurring. You can enter multiple countries for each manufacturer.
- If the United States is selected as the manufacturing country, you will then enter each state(s) in which U.S. manufacturing is occurring. You can enter multiple states.