

Protecting Your Federally-Funded Inventions

Understanding the Department of Energy
Reporting Requirements under
the Bayh-Dole Act.

COURTESY OF:
Han Santos
Intellectual Property Team



Protecting Your Federally-Funded Inventions

Understanding the Department of Energy Reporting Requirements under the Bayh-Dole Act.

You worked hard on your invention. Perhaps it has commercial application or warrants further research. Now you must consider how you will protect your invention.

If you're working under a federally funded research grant, there are specific requirements you'll want to follow to ensure that you don't lose the rights of ownership to the Department of Energy (DoE). This guide will discuss the details of the Bayh-Dole Act, breaking it down into its terms, timelines, and requirements.

We'll teach you how to disclose inventions to the DoE, the basics and timing of when, where, and how to report inventions, and how you can protect the grantee's interest in the DoE-funded inventions.

Most importantly, note that new compliance requirements were implemented in 2018. **Ignorance of the law is not an excuse for non-compliance**, so read carefully.

Contents

The Bayh-Dole Act.....	2
Federal Agency.....	2
Funding Agreement.....	2
Contractor	3
Invention.....	3
Subject Invention.....	3
Disclosure.....	3
Receiving Funding from the Department of Energy.....	4
Importance of Reporting Subject Inventions	4
Timeline of Events — Summary	5
Maintaining Your Disclosure	6
The Invention Disclosure (EIR or Extramural Invention Report).....	7
What Must Be Reported to the DoE Using iEdison?.....	7
Recommended Cover Sheet for Invention Disclosure.....	8
How to Report a Subject Invention in iEdison	8
Common Pitfalls – Reasons for EIR Rejection	9
Requesting Extensions of Time	9
Report An Invention Disclosure.....	10
Elect Title to a Subject Invention Disclosure	10
File an Initial Patent Application	11
What is a Government Support Clause (GSC)?	11
GSC Pitfalls	12
What is a Confirmatory License (CL).....	12
Confirmatory License Pitfalls	13
Summary.....	13
References.....	13

The Bayh-Dole Act

The Bayh-Dole Act, or the Patent and Trademark Law Amendments Act,¹ is U.S. legislation regulating the use and reporting of inventions that arise from federally funded research.

The Act was adopted in 1980. It is codified in 94 Stat. 3015 and 35 U.S.C. § 200-212, and is implemented by 37 C.F.R. § 401 for federal-funding agreements and 37 C.F.R. § 404 for licensing of inventions owned by the federal government.

All new funding agreements executed after May 14, 2018, are subject to the revised Bayh-Dole Act changes.

It's important that you understand the following terms when evaluating compliance.

Federal Agency

Any executive agency, such as an Executive department or government corporation, or a military department, such as the Department of the Army

"Any executive agency as defined in section 105 of title 5, and the military departments as defined by section 102 of title 5."²

Funding Agreement

Any agreement between a federal agency and a contractor for work funded partially or completely by the Federal Government

"...any contract, grant, or cooperative agreement entered into between any federal agency, other than the Tennessee Valley Authority, and any contractor for the performance of experimental, developmental, or research work funded in whole or in part by the Federal Government."³

¹ Bayh-Dole Act of 1980, Pub. L. No. 96-517, 94 Stat. 3015 (1980).

² Patents, 35 U.S.C. § 201(a) (2011).

³ Patents, 35 U.S.C § 201(b) (2011).

Contractor

The entity that enters into the funding agreement with a federal agency

"...any person, small business firm, or nonprofit organization that is a party to a funding agreement."⁴

Invention

A product, idea, or discovery that can be protected under 35 U.S.C.

"Any invention or discovery which is or may be patentable or otherwise protectable under this title..."⁵

Subject Invention

An invention subject to the Bayh-Dole Act due to being fully or partially funded by the government

"Any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement."⁶

Disclosure

A written report to the DoE that includes information on what the invention is and how it works

"The disclosure to DOE shall be in the form of a written report and... be sufficiently complete in technical detail to convey a clear understanding to the extent known at the time of disclosure, of the nature, purpose, operation, and the physical, chemical, biological or electrical characteristics of the invention."⁷

⁴ Patents, 35 U.S.C § 201(c) (2011).

⁵ Patents, 35 U.S.C § 201(d) (2011).

⁶ Patents, 35 U.S.C § 201(e) (2011).

⁷ Appendix A, Patent Rights (Small Business Firms and Nonprofit Organizations), 10 CFR 600.325 (2003).

Receiving Funding from the Department of Energy

The DoE is a great source of funding for your company, but there are strings attached.

Just like any employer, an invention you conceive of as a result of working on a DoE contract belongs to the DoE unless

- you disclose your subject invention to the DoE in a timely manner;
- you maintain your disclosure/election with the DoE;
- you elect to retain title worldwide to the subject invention in a timely manner.

WARNING: If you fail to follow these rules, you run the risk that the DoE will take ownership of all or some of your rights to the invention.

Importance of Reporting Subject Inventions

The term “subject invention” identifies DoE inventions that were conceived of or first reduced to practice in the performance of DoE-funded work. Inventions are just one result of DoE-funded research. The DoE Program Officer and the public are informed of inventions through annual and final reports and the U.S. Patent and Trademark Office (USPTO). Technical descriptions and information about subject inventions are provided to the public via research publications citing DoE funding.

The only sure way to retain ownership of your invention is to comply with Bayh-Dole requirements. What happens if you do not report according to Bayh-Dole requirements?

Failure to Report — Consequences

Failure to comply with the reporting requirements of the Patent Rights Clause can result in the *loss of the recipient's rights* to an invention⁸ or the use of the Government's right to march-in. You may, however, be able to retain a non-exclusive right to use the invention if this happens.

Failure to report inventions appropriately is usually caused by ignorance of the law or misunderstanding the legislation and its implementing regulations. An additional concern that may contribute to a failure to report is based on the incorrect premise that the government will inappropriately interfere with the commercialization of subject inventions.

In fact, the Bayh-Dole Act provides very few restrictions on commercial development. As long as government-funded inventions are reported and commercially viable inventions are being reasonably developed by the organization (which is in everyone's interest), government involvement is limited to retaining its confirmatory license.

Timeline of Events — Summary

1. Disclosure of invention

- a. Disclose within two months after an inventor completes a written submission and submits that to the company's patent administrator. Remember the requirements of disclosure outlined in 10 CFR 600.325.

2. Election to retain title of the invention

- a. Within two years after disclosing the invention to the agency or within sixty days prior to the end of any one-year statutory period (e.g., publication, on sale bar, public use, etc.), whichever occurs first.

3. Filing of an initial patent application

- a. Due within one year of election of title or prior to the end of any

⁸ Patents, Trademarks, and Copyrights, 37 CFR 401.14(d) (2018).

statutory period, and filing in additional countries or international patent offices within ten months of filing the initial application.

- b. Under the updated regulations, if the initial patent application is a provisional application, a non-provisional application must be filed within ten months of filing the provisional application. The regulations also state that a request to extend the ten months for filing a non-provisional application will automatically be granted for one year unless the agency notifies the contractor to the contrary within sixty days of the request. In addition, the contractor must file patent applications in additional countries or international patent offices within either ten months of filing the initial patent application or within six months if the invention is subject to a secrecy order.
- c. However, the contractor will still retain title in a non-U.S. country even if an application was filed after the specified time as long as a written request (to take title) from the federal agency was not received prior to filing in that country.⁹

Extensions of time for disclosure, election, and filing may be granted at the discretion of the agency.

Maintaining Your Disclosure

Contractors must notify the federal agency of any decisions not to continue the prosecution of a patent application, pay maintenance fees, or defend in a reexamination or opposition proceeding on a patent, in any country, no less than sixty days before the expiration of the response period required by the relevant patent office.⁹

Patent prosecution is the process of filing with the USPTO to establish patent protection over your rights to the invention. The updated regulation increased the notification time from thirty to sixty days, reducing the decision-making time for the contractor to decide whether to proceed with prosecution or maintain a patent.

Contractors must notify the federal agency of any publications of the subject

⁹ Patents, Trademarks, and Copyrights, 37 CFR 401.14 (2018).

invention. If a contractor elects not to continue the prosecution of any application, the government can obtain title upon request.⁹ Contractors must submit periodic reports as requested (no more than annually) on the utilization of the invention or on efforts at obtaining such utilization.

The Invention Disclosure (EIR or Extramural Invention Report)

iEdison (Interagency Edison) is a data system that government grantees and contractors use to remain compliant with federal laws and regulations. Each subject invention must be reported in iEdison. It must be sufficiently complete in technical detail to convey a clear understanding of the invention to the extent known at the time of the disclosure.

Your disclosure should include “the nature, purpose, operation, and the physical, chemical, biological or electrical characteristics of the invention.”¹⁰ If it is created in iEdison and doesn’t meet the “sufficient detail” requirement above, then the DoE will reject the disclosure. You must periodically monitor your disclosure in iEdison!

What Must Be Reported to the DoE Using iEdison?

Subject Inventions must be reported to the DoE using iEdison within sixty days of written disclosure to the company or within sixty days of transmitting the first draft application to the inventors, whichever occurs first.

You must disclose all inventions, including those the patent administrator rejects (you need to disclose to keep trade secrets). Disclose any invention “conceived or first actually reduced to practice in the performance of work under a funding agreement.”¹¹ These are subject inventions, meaning they are subject to the Bayh-Dole act.

¹⁰ Appendix A, Patent Rights (Small Business Firms and Nonprofit Organizations), 10 CFR 600.325 (2003).

¹¹ Patents, 35 U.S.C § 201(e) (2011).

Recommended Cover Sheet for Invention Disclosure

You can create your own cover sheet for your invention disclosure. We recommend the format below to ensure you include all the necessary information in an easy-to-read format.

Today's Date:

HS Docket No.:

EIR#: [generated by iEdison]

DoE "S" No.: [generated by iEdison]

Date Invention Reported to Institution: [Date of IDF or first draft to inventors]

Invention Title:

Grant Used: DE-EE0008360

Award Date:

Inventor(s):

Date/Location of First Publication (bar date): UNPUBLISHED (unless date exists)

How to Report a Subject Invention in iEdison

1. From the iEdison main menu, select the link to "Create Invention Report."
2. After creating the Invention Report, select "Submit."
3. Create the report, select "Submit," then the "Create New Invention Report" confirmation screen will be displayed. A permanent invention report number (i.e., EIR number) and DoE "S" will be assigned.
4. You may upload the disclosure document as part of the "Create New Invention Report" process.
 - a. Whether you upload the document before or after creating the invention report, ensure the EIR number is noted clearly on the document.

- b. After creating the new invention report, note the EIR from the confirmation screen.

Common Pitfalls – Reasons for EIR Rejection

If your EIR is rejected, there could be a number of reasons behind the decision. Review the EIR carefully and check for some of the following issues.

- The invention disclosure describes what the inventors hope to prove and not “the nature, purpose, operation, and the physical, chemical, biological or electrical characteristics of the invention.”
 - The invention disclosure should describe what the invention is, not what the invention will be if funded.
- Not all awards were included in the disclosure.
- Award numbers are incorrect, e.g., it’s missing numbers, numbers are transposed, or numbers are entered incorrectly.
- The title in the invention report does not match the title in the document.
- Not all inventors are included.
- The inventors’ names do not match.
- The disclosure references a publication date and the date of first publication, sale, or public-use field is not populated.
- The publication includes authors who are not inventors, but they are not noted as such on the publication.

Note that iEdison will not notify you if there are problems with the submission. You must log in periodically to check.

Requesting Extensions of Time

If you’re unable to meet the sixty-day reporting deadline, you can request an extension of time. This can be requested for disclosure, electing title, and filing the



initial patent application.

Report An Invention Disclosure

1. Specify the request in an email to the contract program manager before the sixty-day reporting deadline.
2. Include in the request the reasons why an extension of time is needed to file an invention disclosure.
3. Include the name of the organization requesting an extension and indicate in the subject line "Invention Disclosure Extension Request."

The DoE will review the request and reply by email to the requestor. Typically, they'll approve it, and you can proceed as planned.

Elect Title to a Subject Invention Disclosure

Election of title must be made before submission/reporting filed patent applications.

1. In iEdison, choose one or two additional years from the dropdown box in the "Request Title Extension Years."
2. Attach your request for an extension of time to the iEdison invention record in the "other document" section.
3. Provide details as to why an extension is needed.
4. Identify the document being uploaded as "Extension of Time to Elect Title Request."
 - a. Only this document title can be used for submission.
5. Click "Submit" at the bottom of the invention page.

If the title of the submitted document is "Extension of Time to Elect Title Request," then submission will trigger a notice to the DoE. The DoE will review the extension request. Following the review, the invention record will reflect that the request for extension was approved or denied. If denied, an explanation will be provided. We haven't encountered this yet personally.

File an Initial Patent Application

To request an extension of time to file the initial patent application:

1. Choose “Yes” in the “Request One Year Extension to File Initial Patent Application.”
2. Attach your “Request For an Extension of Time” document to the iEdison invention record in the “Other Document” section.
3. Provide details as to why an extension is needed.
 - a. Identify the document being uploaded as “Extension of Time to File an Initial Patent Application.”
 - i. Only this document title can be used.
4. Click Submit at the bottom of the invention page.

If the title of the document that is submitted is “Extension of Time to File an Initial Patent Application,” then submission will trigger a notice to the DoE. They will review the extension request. Following their review, the invention record will reflect whether the request was approved or denied. If denied, an explanation will be provided.

What is a Government Support Clause (GSC)?

A **Government Support Clause (GSC)** is a statement acknowledging federal support of a subject invention. One must be included in the specification of a U.S. patent application or a U.S. issued patent.¹² You can see an example of a GSC below.

“This invention was made with government support under contract DE-EE0008360 awarded by the Department of Energy. The government has certain rights in the invention.”

¹² Patents, 35 U.S.C § 201(c)(6) (2011).

GSC Pitfalls

There are several common mistakes in the GSC that could cause your application to be rejected.

- Uses extensive language
 - Rather than make this a creative exercise, fill in the blank — keep it clear and to the point.
- Does not meet the requirements of 37 C.F.R. § 401.14(f)(4)
- Uses conditional language (i.e. “may or may not”, “in whole or in part”, etc.)
- Omits leading zeros
- Transposes grant numbers

To satisfy the requirements, upload the full patent application and the USPTO Filing Receipt. The GSC is required in all patent applications, including provisional applications.

What is a Confirmatory License (CL)

The **Confirmatory License (CL)** notifies the public of the granting to the government a “nonexclusive, nontransferable, irrevocable, paid-up license” for the U.S. Government to practice, or have the invention practiced, on its behalf worldwide.¹³

If the CL is accepted in iEdison, it will be automatically recorded via EPAS. A standard CL can be auto-populated in iEdison and printed to PDF for a representative of the client to sign. Electronic signatures are acceptable (include the DocuSign certificate). An accepted CL in the earliest filed application will apply to all child applications appropriately linked in iEdison (CIPs require a new CL).

¹³ Patents, Trademarks, and Copyrights, 37 CFR 401.14(b) (2018).

Confirmatory License Pitfalls

There are a few reasons that will cause your CL to be rejected.

- The title does not match the invention record or patent record.
- Inventors listed in the CL do not match the invention record.
- The grantee lists the PCT Application number on the line for intended foreign countries instead of the names of those countries.
- The grantee lists an incorrect grant number.

Carefully review your CL to avoid delays related to rejections.

Summary

Protecting your invention under the Bayh-Dole Act requires a detail-oriented eye and careful adherence to the regulations. It doesn't have to be overwhelming. By carefully reviewing this guide, you'll be able to disclose, elect title, and file the patent application for your invention.

Should you need additional assistance, you can rely on the experienced team of IP attorneys at Han Santos. [Contact us](#) and we will help you ensure that your intellectual property is protected.

References

Appendix A, Patent Rights (Small Business Firms and Nonprofit Organizations), 10 CFR 600.325 (2003)

Bayh-Dole Act of 1980, Pub. L. No. 96-517, 94 Stat. 3015 (1980)

Cooper, Scott. "Invention Reporting Under Bayh-Dole." October 2020

Patents, 35 U.S.C. § 201 (2011)

Patents, Trademarks, and Copyrights, 37 CFR 401.14(d) (2018)