

Guidelines for Bayh-Dole Compliance

Function:	Industry and External Affairs
Procedure	N/A
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Basis for Guidelines

The University and Small Business Patent Procedures Act of 1980, Public Law 96-517 (as amended), codified at title 35 of the United States Code (USC) 200 et seq., commonly known as the "Bayh-Dole Act" or simply "Bayh-Dole," governs rights in inventions made with Federal assistance. Bayh-Dole regulations (37 CFR 401 (<https://grants.nih.gov/grants/bayh-dole.htm>)) were revised on April 13, 2018, effective as of May 14, 2018. Purpose of the revision was to reduce burdens by clarifying electronic reporting, updating certain sections to conform with patent law changes; to streamline licensing processes; to clarify the role of provisional patent application filing; explain the role of funding agencies in the Bayh-Dole process; and address Subject Inventions as to which a Federal laboratory employee is a co-inventor.

The May 14, 2018 revisions to the Bayh-Dole Act only apply to inventions arising from federal grants or contracts that are issued after May 14, 2018. Please note that this may include new task orders or amendments to agreements executed after May 14, 2018.¹ The table that accompanies these RF Guidelines for Bayh-Dole Compliance is meant to be used as a tool to further illustrate the impacts the revisions have to SUNY technology transfer office operations and practice, and provides suggestions for how to use InTeum to support compliance. Please note that any reference to "contractor" throughout these Guidelines shall mean The Research Foundation for SUNY (RF).

¹ To determine if the May 14, 2018 revisions to the Bayh-Dole regulation apply to a Subject Invention, please review the provisions of the Funding Agreement related to the sponsor award number cited on the new technology disclosure form submitted. If there are any ambiguities please always contact the appropriate point of contact at the Funding Agency for clarification.

General Guidance for Existing (not new) Standard Requirements

Generally, complying with the Bayh-Dole regulation is facilitated through the use of iEdison. RF uses iEdison to comply with the disclosure, election of title, other requirements of § 401.14(c), and other requirement of 37 CFR 401 including, but not limited to, requests for extensions, waivers, and releases.

- In cases where the Federal Agency does not utilize iEdison for Bayh-Dole compliance or if the matter is not resolvable via iEdison please refer to the funding agreement for guidance or contact the iEdison helpdesk for additional information.
- In cases where the Federal Agency uses iEdison for Bayh-Dole compliance and you are experiencing difficulty please refer to the iEdison Agency Contact List and contact the appropriate individual at the Federal Agency.

Bayh-Dole and its implementing regulations require Federal funding agencies to employ certain "standard clauses" in funding agreements awarded to contractors (e.g., RF) except under certain specified conditions, 37 CFR 401.3. Through these standard clauses, set forth at 37 CFR 401.14, contractors (e.g., RF) are obligated to take certain actions to properly manage Subject Inventions, including but are not limited to:

§ 401.14(c)(1) – Period to disclose Subject Inventions

RF must disclose each subject invention to the Federal Agency within two months after the inventor(s) disclose it in writing to the appropriate technology transfer office.

§ 401.14(c)(2) – Period to elect title to Subject Inventions

RF must elect whether to retain title to any subject invention by notifying the Federal Agency within two years of disclosure to the funding agency unless an extension is sought. The funding agency may shorten period of election to a date that is not more than 60 days prior to expiration of a publication, on sale, public use or other statutory bar.

§ 401.14(c)(3) – Must file Initial Patent Application within 1 year of title election

RF must file "initial patent application" on Subject Inventions within one year after election of title or prior to a US publication, on sale, or public use

bar.

§ 401.14(f)(1) – Contractor must execute and deliver documents substantiating Government rights

RF must execute and promptly deliver to Federal Agency all instruments necessary to establish or confirm Government's rights in Subject Inventions for which RF elects to retain title.

§ 401.14(f)(2) – Contractor must require disclosure by written agreement

RF must require, by written agreement, employees to disclose promptly in writing each subject invention.

SUNY appointment letters or employment contracts would either need to include this obligation or require compliance with, SUNY Patents and Inventions Policy (link). This requires prompt disclosure. RF shall instruct employees through employee agreements or suitable educational programs on the importance of reporting inventions in time to enable filing of patent applications prior to statutory bars.

§ 401.14(f)(3) – Contractor must notify of any decision to stop non-provisional prosecution

RF must notify the Federal Agency of any decision to stop prosecution of a non-provisional patent application or discontinue patent maintenance. If Contractor is also no longer intending to commercialize the subject invention, should return title.

§ 401.14(f)(4) – Contractor must include the Government Support Clause in US patent applications

RF must include the Government Support Clause in the specification of any US patent applications, and any patent issuing thereon, covering a subject invention.

Guidance for Revisions to Bayh-Dole Regulations

1. Revisions to § 401.2(n) – Definitions

"Initial patent application" is defined to include a provisional or non-provisional US national application for patent (respectively 37 CFR 1.9(a)(2) and (3)), or the first international application filed under the Patent Cooperation Treaty (37 CFR 1.9(b)) which designates the United States, or the first application for a Plant Variety Protection certificate.

Impact: This definition now includes provisional patent applications, with cascading repercussions with respect to other obligations to file non-provisional or PCT applications

Suggested Changes to Inteum: N/A

2. Revisions to § 401.14(c)(3) - Contractor obligations under standard patents rights clauses

If the "initial patent application" is a US provisional, must file a US non-provisional (and any foreign or PCT patent applications) within 10 months of the provisional unless extension is requested under §401.14(c)(5) and not rejected. RF must file patent applications in additional countries or international patent offices, either within 10 months of the first filed patent application or within 6 months from grant of permission to file foreign patent applications following a Secrecy Order.

Impact: RF longer has 12 months to file a non-provisional following a provisional unless extension is requested and request is not rejected. If PCT is desired, RF may need to file US non-provisional in parallel to comply with new regulatory framework.

Suggested Changes to Inteum:

1. Set Inteum activity reminders for US provisional conversion dates to account for:

- a. the new 10 ten month filing deadline, and
- b. the submission of a extension request as described in revision number 3 below. Note that the deadline to file the initial patent application will depend on whether an extension to this deadline is sought.

3. Revision to § 401.14(c)(5) – Automatic extensions of time to file non-provisional applications

This revision provides RF with the ability to requests extensions of time to disclose, elect title or file an initial patent application (using iEdison), may be granted automatically, at Federal Agency's discretion.

Impact: To comply with the revision to §401.14(c)(3) the RF has two choices: 1)RF must file non-provisional applications within 10-months of the date of filing the related provisional application, or 2)Take the appropriate steps to obtain a one-year extension of time from new requirement of 10-month deadline for filing a non-provisional application (including PCT).

According to revised section §401.14(c)(5), one year extensions are automatic if requested by the RF and not rejected by the Federal sponsor within 60 days of receiving the extension request.

Suggested Changes to Inteum:

1. Set activity reminder for need to request a time extension at six months to allow for cases where the Federal Agency may reject the extension within 60 days of receiving the request.²

Other Considerations:

1. Requests to extend the 10-month deadline to file a non-provisional following a provisional filing will automatically be granted for one year, unless the Federal Agency notifies the Contractor within 60 days after receiving the request.

2. If the Federal Agency rejects RF extension request, at least 60 days will remain to prepare and file a non-provisional and meet the 10-month filing deadline. This applies only if the RF's extension is requested immediately eight months after filing the provisional and the Federal Agency takes the full 60 days to respond negatively to RF's request.

3. If the Federal Agency will not accept automatic requests through iEdison, the RF can notify the agency as provided in 401.14(f)(3) within 60 days of 10 months with a statement of intent to not file a non-provisional but to retain title and to continue commercialization efforts.

4. Alternatively, just let a provisional lapse, and decide whether or not to retain or waive title pursuant to regulatory requirement.

² Requesting extensions earlier than later is the best practice and to be safe all extension request should be submitted no later than eight months after the filing date of the related provisional application.

4. Revisions to § 401.14(d)(1) – Conditions when the government may obtain title

Upon written request, Contractor will convey to Federal Agency title to a subject invention if the contractor fails to disclose or elect title to the subject invention within the times specified in § 401.14(c), or elects not to retain title. According to § 401.14(c) RF must:

1. Disclose each subject invention to the Federal Agency within two months after receiving an invention disclosure;
2. Elect whether or not to retain title to any subject invention by notifying the Federal Agency within two years after disclosure; and
3. File an initial patent application on a subject invention that RF elected title to within one year after election.
Impact: This removes requirement for Federal Agency to request title within 60 days of learning of the Contractor failure to disclose or elect within the required times. Failure to disclose or elect title within the required timeframes (disclosure to Federal Agency within two months following receipt of an invention disclosure and elect title within two years of receiving a disclosure) results in being out of compliance. Following a compliance violation under this provision Federal Agency may at any future time request return of title to the invention and any associated patent rights.

Suggested Changes to Inteum:

1. Set activity reminders to ensure compliance with disclosure, election of title and filing of patent applications (401.14(d)(2)). The best way to avoid this problem is to ensure compliance.

Other Considerations:

1. This could scare off potential licensees because issues regarding title to the patent rights related to the invention not timely disclosed may be permanently present if the government makes a request. Attempt to get back into compliance by communicating with Federal Agency and establishing a written record indicating clearance to proceed and commitment by the Federal Agency to not request return of title following licensing. This written record may be relied on to give reassurance to prospective licensees.
2. Please note that all historic iEdison errors need to be corrected before iEdison system permits the return title
5. Revision to § 401.14(d)(3) – Title to Subject Inventions claimed in abandoned patent applications

Upon written request, RF will convey to Federal Agency title to a subject invention in any country in which the RF abandons a patent or a non-provisional patent application.

Impact: This revision clarifies an ambiguity from the prior version of the Bayh-Dole Act to to make clear that this provision only applies to non-provisional applications and patents, and is not applicable to provisional applications.

Rationale: *Under appropriate circumstances, NIST acknowledges that it is a reasonable prosecution and commercialization strategy to not convert a provisional to a non-provisional without abandoning the subject invention or foreclosing the opportunity to file additional applications directed to the invention. NIST expects that a contractor making such a strategic decision will communicate this decision and the intent to retain title to the subject invention to the funding agency.*

Suggested Changes to Inteum: N/A, see Suggested Changes to Inteum for §?401.14(f)(3). Please note that all historic iEdison errors need to be corrected before iEdison system permits the return title

6. Revision to § 401.14(f)(2) – Present assignment of Subject Inventions

RF will require by written agreement its employees to assign to the contractor the entire right, title and interest in and to each subject invention, and to execute all papers necessary to file patent applications on Subject Inventions and to establish the government's rights in the Subject Inventions.

Impact: In addition to disclosure, RF must require present assignment of future IP.

Rationale: This revision is intended to address potential Stanford v. Roche scenarios.

Suggested Changes to Inteum: N/A

Other Considerations:

1. SUNY's Patent and Inventions Policy does require that all Creators of Intellectual Property to disclose and assign Intellectual Property.
2. New Technology Disclosure Forms must have the following language on signature page:
3. "All inventors with an obligation to assign to The Research Foundation for The State University of New York do hereby assign their right, title and interest in any intellectual property resulting herefrom to The Research Foundation for The State University of New York."
4. RF's Employee Appointment Form has been updated to include the appropriate disclosure and assignment language.

7. Revision to § 401.14(f)(3) – Notification of decisions not to continue prosecution

RF must notify the Federal Agency of its decision to abandon a patent or a non-provisional patent application in any country at least 60 days prior to expiration of the patent office response period.

Impact: This section has been revised to make clear that this provision only applies to non-provisional applications and patents, which alleviates an ambiguity in the prior version of the regulation.

Suggested Changes to Inteum:

1. Set activity reminder to decide whether to abandon 90 days prior to expiration of the patent office response period to ensure ability to notify Federal Agency at least 60 days prior to expiration.

i. Alternatively, notify the agency as provided in 401.14(f)(3) at least 60 days prior to expiration of a statutory deadline for non-provisional applications with a statement of intent to not continue prosecution, but to retain title and to continue commercialization efforts.

Other Considerations: Regulation is unclear whether it is feasible to retain title when abandoning a non-provisional, may only be able to retain title to abandoned provisionals.

8. Revision to § 401.10(a) – Co-inventors employed by federal agencies

For Subject Invention(s) with Federal Agency employed co-inventors, at its discretion Federal Agency may determine that it is in the interest of the Government (under 35 USC 207(a)(3)), and file at its own expense an initial patent application on the subject invention, in consultation with the RF, provided that the RF retains the ability to elect title (under 35 USC 202(a)).

Impact:

This revisions includes new detailed provisions regarding situations when a co-inventor is also Federal Agency employee (e.g., national laboratory employees, VA employee):

- If the agency employing the co-inventor reassigns to RF its acquired rights in the invention, the assignment will be made pursuant to the patent rights clause of the funding agreement.
- The agency employing the co-inventor may submit (in consultation with RF) an initial patent application, provided that RF retains the right to elect to retain title to the patent.
- None of the revisions to §401.10 supersede any existing IIAs between RF and a Federal Agency for the management of jointly-owned inventions.

Suggested Changes to Inteum:

1. Elect title or request extension to elect title within required two year time frame from disclosure or at least more than 60 days prior to a statutory bar.

Other Potential Changes to Practices:

Update New Technology Disclosure to include a field for indicating Federal Agency employee status.

	Section Impacted and Subject Area	Bayh-Dole Prior to May 14, 2018	May 14, 2018 Revisions to Bayh-Dole	Suggested changes to Inteum	TT Operational Changes	Ambiguities
1	§ 401.2(n) Definition	Provisional patent applications was excluded from the definition of "initial patent application."	The definition of "initial patent application" now includes provisional patent applications or the first international application filed under the PCT, or the first application for Plan Variety Protection.			
2	§ 401.14(c)(3) and File a Non-Provisional/PCT Within 10 months	Filing non-provisional applications and PCT by within 10-months of filing the related provisional application was not required.	Requires RF to file a US non-provisional (and any foreign applications or PCT within 10-months after filing a provisional application, unless an extension is requested. See § 401.14(c)(5) guidance to request extensions.	Set Inteum activity reminder to convert provisional applications to no later than six months after provisional filing date and have reminders reoccur. Extensions	No longer have 12 months to file a non-provisional following a provisional unless an extension is requested and not rejected. It's important to submit the extension request early in case the Federal agency rejects RF's request.	
3	§ 401.14(c)(5) Requests for Extension		If requested, the extension is considered accepted so long as the Federal agency does not notify the RF otherwise within 60 of receiving the extension request §401.14(c)(5). ³		Same as above.	
4	§ 401.14(d)(1)	The Federal agency had a 60-day	Requires RF to be extremely	Set Inteum activity reminders to		

	Government Requests for Title At Any Time	time limit to make a request to RF to request title after RF failed to timely disclose a subject invention or elect title.	diligent in disclosing a subject invention and electing title to the subject invention to the Federal agency within the times specified in 401.14(c). Failure to disclose or elect title within the required times enables the Federal agency to request return of title to the invention and any associated patent rights at any time.	ensure compliance with disclosure and election of title requirements of §401.14(d)(2)		
5	§ 401.14(d)(3) Title to Invention of Abandoned Non-provisional Applications	It was not clear if this section applied to provisional applications that lapsed.	Makes it clear that upon written request from the Federal agency, RF will convey title to a subject invention in any country in which RF abandons a related patent or non-provisional application.			
6	§ 401.14(f)(2) Assignment	No regulatory enablement for contractors to require employees to assign by written agreement invention rights.	RF (as the federal contractor) will require its employees (e.g., faculty, principal investigator, project staff) to promptly disclose in writing each subject invention made with support from the Federal agency.		This requirement has already been implemented with the "hereby assign" language to the signature of the new technology disclosure form.	
7	§ 401.14(f)(3) Decisions to End Prosecution	It was not clear that this section applied only to non-provisional and issued patents.	RF must notify the Federal agency of its decision to abandon a patent or a non-provisional patent application in any country at least 60 prior to the expiration of the patent office response period.			Regulation is unclear whether it is feasible to retain title when abandoning a non-provisional, may only be able to retain title to abandoned provisional applications.
8	§ 401.10(a) Co-inventors Employed by Federal Agencies	There was ambiguity in how to address Subject Inventions with federal inventor co-inventors	This provision provides detailed information regarding situations when a co-inventor of a subject invention is employed by a federal agencies			

³ Generally, extensions can be requested via iEdison. If the Federal agency does not accept requests through iEdison then the RF can notify the agency as provided in §401.14(f)(3) within 60 days of the 10 month deadline with as provided in 401.14(f)(3) [add hyperlink] within 60 days of the 10-month date with a statement of intent to not file a non-provisional but to retain title and to continue commercialization efforts.

Definitions

Intellectual Property – Patentable Inventions, tangible research materials, computer software, and any unique or novel innovation in the technical arts or any new and useful improvements thereof, including methods or processes for creating an object or result (a way of doing or making things), machines, devices, products of manufacture, product designs, or composition, mask works or layout designs for printed circuit boards or integrated circuits, compositions of matter, materials, any variety of plant, and any know-how essential to the practice or enablement of such innovations and improvements, whether or not patentable.

Creator – One who has Created Intellectual Property, in whole or in part.

Federal Agency – The party or parties other than the RF to a Funding Agreement

Funding Agreement – Any contract, grant, or cooperative agreement entered into between any Federal Agency, other than the Tennessee Valley Authority, and any contractor (RF) for the performance of experimental, developmental, or research work funded in whole or in part by the Federal government. This term also includes any assignment, substitution of parties, or subcontract of any type entered into for the performance of experimental, developmental, or research work under a funding agreement as defined in the first sentence of this paragraph.

Subject Invention – Any invention of a contractor (RF) conceived or first actually reduced to practice in the performance of work under a funding agreement; provided that in the case of a variety of plant, the date of determination (as defined in section 41(d) of the Plant Variety Protection Act, 7 U.S.C. 2401(d)) must also occur during the period of contract performance.

Related Information

[SUNY Patents and Inventions Policy](#)

[SUNY Procedures for the Disclosure and Management of Patents and Inventions](#)

[SUNY Guidelines for the Management of Intellectual Property](#)

Bayh-Dole Regulations (37 CFR 401) (<https://grants.nih.gov/grants/bayh-dole.htm>)

Change History

Date	Summary of Change
July 6, 2020	Retitled (previously "Ensuring Compliance with the Bayh-Dole Act Revisions of May 2018"); and updated Function to Industry and External Affairs (previously "Enterprise Technology Transfer").
July 3, 2019	New document.

Feedback

Was this document clear and easy to follow? Please send your feedback to webfeedback@rfsuny.org.

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