

The New Bayh-Dole Rules:
What They Are, What They Mean



#	Topic	Question	Answer
1	Amendment	Paul mentioned that "amendments" signed after May 14 would be governed by the new rules. Would you please clarify what constitutes an amendment?	<p>The revised rule does not apply to a funding agreement (contract, grant or cooperative agreement) in effect on or before May 14, 2018.</p> <p>If a funding agreement in existence on or before May 14, 2018 is thereafter amended, the funding agency may, but is not required to, recite in the amended funding agreement that it will be subject to the revised rule.</p> <p>An amendment for this purpose is any formal communication from a funding agency informing the contractor that the revised rule will apply. A funding agency is not limited to any particular form or type of funding agreement amendment, and may amend a pre-existing funding agreement solely for the purpose of requiring compliance with the revised rule.</p> <p>The intent is to permit a pre-existing funding agreement to continue under the old rule even after the effective date of the revised rule, where, for example, a funding agency considers that requiring a change would be confusing.</p> <p>At the same time, a funding agency has discretion to amend a pre-existing funding agreement to require compliance with the revised rule prospectively (but not retroactively).</p>
2	Ownership	Under the new regulations, it is possible to abandon a provisional patent application without abandoning the underlying invention. Is that also true for abandonment of a nonprovisional or foreign patent application?	<p>NIST recognizes that a contractor may reasonably decide, as a matter of prosecution strategy, not to convert a provisional application under appropriate circumstances, without abandoning the subject invention itself or foreclosing the contractor's ability to file one or more additional applications directed to that invention. In this circumstance, the contractor would not need to convey title to the funding agency to protect the Government's interest in the subject invention. NIST expects that a contractor making such a strategic decision involving a provisional application will communicate to the funding agency contracting or grants officer its decision and its intent not to abandon the subject invention itself, so that the funding agency is assured that the contractor is protecting the Government's interest in the subject invention through appropriate patent application filings.</p> <p>In any country in which a contractor decides to abandon a non-provisional application or patent, 37 CFR 401.14(d) provides that the contractor will convey title to the subject invention to the funding agency upon written request.</p>

The New Bayh-Dole Rules:
What They Are, What They Mean



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3	SSP	Does "statutory deadline" mean SSP, or with all extensions?	The statutory deadline in 37 CFR 401.14(f)(3) refers to the six-month time provided under 35 USC 133 in the US, and to the corresponding statutory time in any foreign country.
4	Notification	What is the consequence of failing to provide sufficient advance of discontinuance (of patent prosecution)?sufficient advance notice*	The requirements under 37 CFR 401.14(f), including the requirement to notify the funding agency of a contractor's decision under 37 CFR 401.14(f)(3), are intended to protect the Government's interest in a subject invention. Failure to satisfy any of these requirements would violate the terms of the funding agency's award, and could subject a contractor to legal action. Depending upon the circumstances, the consequence could be as serious as contractor debarment or loss of rights in a subject invention (see, e.g., <i>Campbell Plastics Eng'g & Mfg. v. Brownlee</i> (Fed. Cir., 2004)).
5	Assignment	For SBIR/STTR (company-university collaboration), I saw several cases for a company filling a provisional patent application before the grant date (in order to avoid assignment/reporting altogether). Do you have a solution to control such attempts?	The Bayh-Dole Act applies to a "subject invention," defined as "any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement." 35 USC 201(e). An invention conceived <u>and</u> actually reduced to practice by a contractor prior to commencement of a funding agreement would not be a "subject invention" that would require reporting. However, an invention which had been conceived but not actually reduced to practice by a contractor prior to commencement of a funding agreement, and which was first actually reduced to practice under that agreement, would be a "subject invention," even if a provisional application had been filed prior to commencement. Failure to report a subject invention under this circumstance would violate the terms of the funding agency's award, and could subject the contractor to legal action, the consequence of which could include debarment or loss of rights in the subject invention (see, e.g., <i>Campbell Plastics Eng'g & Mfg. v. Brownlee</i> (Fed. Cir., 2004)).

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What They Are, What They Mean



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6	Reporting	What are acceptable documents to submit to iEdison indicating assignment of rights? Further, what is the timeline, will it have to be submitted upon disclosure of the invention?	<p>You should always consult the General Terms & Conditions and any Special Award Conditions specific to your funding agency's award.</p> <p>NIH, which manages iEdison, notes that general information about documents and information required by NIH for an assignment or waiver can be found at: https://public.era.nih.gov/iedison/public/nihprocs.jsp.</p> <p>Depending on the circumstances of the assignment/waiver request, additional information may need to be submitted. Information about assignments/waivers can also be found at the Frequently Asked Questions link on the iEdison home page and at https://era.nih.gov/iedison/iedison_faqs.cfm. NIH has posted a webinar on inventor waivers at this link.</p> <p>For NIH awards, a decision typically takes 4-8 weeks from a complete waiver/assignment request submission.</p>
7	Disclosure	We have addressed required present assignment in 401.14(f)(2). Will we be addressing the implications of the requirement for the written agreement to disclose at the beginning of (f)(2)?	<p>The provision under 37 CFR 401.14(f)(2), that a contractor agree to require, by written agreement, that its employees disclose subject inventions, long pre-dates the revised rules that went into effect on May 14, 2018.</p> <p>Many contractors fulfill this and other elements of 37 CFR 401.14(f)(2) by incorporating these requirements into employment agreements or through separate written agreements with their employees.</p> <p>Such agreements are contracts generally governed by state law, and contractors may wish to seek counsel familiar with the laws of their state with questions regarding such agreements.</p>
8	Notification	How do we provide (sufficient) notification re: decision not to prosecute?	You should always consult the General Terms & Conditions and any Special Award Conditions specific to your funding agency's award, and contact your contracting or grants officer with questions about agency-specific notification requirements and processes.
9	Extension	Is the one-year extension of the filing date for a non-provisional application following the filing of a provisional application as the initial patent application, an extension of the 10 month deadline so that the new deadline for filing a non-provisional application would be 22 month from initial prov filing date?	<p>That is correct. In this scenario, the deadline for the contractor to file the corresponding non-provisional application will be one year from the 10-month deadline, or 22 months from the filing date of the provisional application.</p> <p>Under 37 CFR 401.14(c)(5), when a contractor has filed a provisional application as its initial patent application on a subject invention and timely requests an extension for filing a non-provisional application, an extension of one year from the 10-month deadline date will be granted unless the funding agency, within 60 days of receiving the contractor's extension request, notifies the contractor of its decision to deny the request or to grant an extension of other duration.</p>

The New Bayh-Dole Rules:
What They Are, What They Mean



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10	Extension	For the one-year extension, does that run from the date of request or from the 10-month deadline?	That is correct. In this scenario, the deadline for the contractor to file the corresponding non-provisional application will be one year from the 10-month deadline, or 22 months from the filing date of the provisional application. Under 37 CFR 401.14(c)(5), second sentence, when a contractor has filed a provisional application as its initial patent application on a subject invention and timely requests an extension for filing a non-provisional application, the an extension of one year from the 10-month deadline date will be granted unless the funding agency, within 60 days of receiving the contractor's extension request, notifies the contractor of its decision to deny the request or to grant an extension of other duration.
11	Extension	So, if we want to convert just at the 12 month deadline (more typical practice than converting 2 months early), do we just always ask for the extension?	If by "the extension" you mean the one-year extension for filing a non-provisional application after filing a provisional application as recited in 37 CFR 401.14(c)(5), second sentence, then the answer would be "No," because that "automatic" extension is calculated from the 10-month deadline date. A contractor seeking an extension of time for disclosure, election or filing under 37 CFR 401.14(c)(5), first sentence, must file a specific extension request, which the funding agency could grant in its discretion, and which would not be subject to the 60-day notification provision under 37 CFR 401.14(c)(5), second sentence.

The New Bayh-Dole Rules:
What They Are, What They Mean



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12	Notification	What is the reason/justification for this change? meaning the 10 mos to file a non-PRO	<p>Prior 37 CFR 401.2(n) limited the definition of "initial patent application" to "a nonprovisional U.S. national application for patent as defined in 37 CFR 1.9(a)(3)," and a provisional application was not included in this definition.</p> <p>The revised rule expands the definition of "initial patent application" to permit a contractor to file a provisional application as its initial patent application.</p> <p>If a contractor files a provisional application as its initial patent application, it is required to file a non-provisional patent application within 10 months under 37 CFR 401.14(c)(3) of the revised rule.</p> <p>Recognizing that a contractor may, as a matter of patent prosecution strategy, decide not to convert a given provisional application without necessarily abandoning the subject invention, this is not included among the conditions when the Government may obtain title under 37 CFR 401.4(d).</p> <p>However, if a contractor has filed a provisional application but thereafter does intend to abandon the subject invention and not file a corresponding non-provisional application, the 10-month requirement affords reasonable opportunity for the funding agency to take title and to protect the Government's interest in the subject invention.</p> <p>Provision to request extension of the 10-month requirement is made under 37 CFR 401.14(c)(5) of the revised rule. Such a request would evidence the contractor's intent to file a corresponding non-provisional application.</p>
13	Patent	Under the existing regulations, tech transfer offices have up to 30 months from the initial provisional application filing date to file a U.S. national application. Because of the change in the definition to "initial patent application", it looks like the new regulations only provide up to 22 months (10 months + 12 month extension) from the initial provisional application filing date to file a U.S. national application. Is that right?	<p>No. An international application filed under the Patent Cooperation Treaty as defined in 37 CFR 1.9(b) which designates the United States would itself satisfy the requirement under 37 CFR 401.14(c)(3) to file a corresponding non-provisional application, where the contractor had filed a provisional application as its initial patent application.</p> <p>In this scenario, a contractor's subsequent decision not to enter the US National Phase from the International Phase of prosecution would be a condition when the Government may obtain title under 37 CFR 401.4(d).</p>

The New Bayh-Dole Rules:
What They Are, What They Mean



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14	Patent	Why is the time for filing a non-provisional 10 months instead of 12 months?	<p>Prior 37 CFR 401.2(n) limited the definition of "initial patent application" to "a nonprovisional U.S. national application for patent as defined in 37 CFR 1.9(a)(3)," and a provisional application was not included in this definition.</p> <p>The revised rule expands the definition of "initial patent application" to permit a contractor to file a provisional application as its initial patent application.</p> <p>If a contractor files a provisional application as its initial patent application, it is required to file a non-provisional patent application within 10 months under 37 CFR 401.14(c)(3) of the revised rule.</p> <p>Recognizing that a contractor may, as a matter of patent prosecution strategy, decide not to convert a given provisional application without necessarily abandoning the subject invention, this is not included among the conditions when the Government may obtain title under 37 CFR 401.4(d).</p> <p>However, if a contractor has filed a provisional application but thereafter does intend to abandon the subject invention and not file a corresponding non-provisional application, the 10-month requirement affords reasonable opportunity for the funding agency to take title and to protect the Government's interest in the subject invention.</p> <p>Provision to request extension of the 10-month requirement is made under 37 CFR 401.14(c)(5) of the revised rule. Such a request would evidence the contractor's intent to file a corresponding non-provisional application.</p>
15	Reporting	Does anyone know if the iEdison website will be changed to provide an easy way to request the extension for filing a non-provisional to avoid the 10-month requirement?	<p>While it is expected that iEdison will be updated to reflect this and other changes under the revised rules for participating federal agencies, a contractor should always consult the General Terms & Conditions and any Special Award Conditions specific to the funding agency's award, and contact its contracting or grants officer with questions about agency-specific notification requirements and processes.</p>
16	Invention	Is software a subject invention? We've received different answers. We report disclosures of software but don't always file a patent but still license copyrights. With removal of 60 day period there would appear to be new uncertainty w/r/t title - university or gov't.	<p>The definitions of "invention" and "subject invention" under prior 37 CFR 401.2(c) and (d) have not been changed under the revised rule.</p> <p>Subject matter eligibility under 35 USC 101 is outside the scope of this rulemaking.</p>

The New Bayh-Dole Rules:
What They Are, What They Mean



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17	Invention	Regarding the definition of "subject invention" - does the government consider software to be a subject invention?	The definitions of "invention" and "subject invention" under prior 37 CFR 401.2(c) and (d) have not been changed under the revised rule. Subject matter eligibility under 35 USC 101 is outside the scope of this rulemaking.
18	Funding	Cloud on title is huge. University could have paid 10's of 000 \$'s in IP costs. Govt should reimburse these. Also, to meet all these deadlines, USG must fund at least 1 FTE for even small offices to adhere.	Cost principles applicable to funding agreements are outside the scope of this rulemaking.
19	Effective Date	Based on my reading, tech transfer offices will have to monitor compliance under two different regulatory frameworks. Existing techs would be governed by the current regulations and its timeline and technologies from grants issued after 5-14-18 and potentially amendments will have to comply with the revised regulations. Is this right?	Yes. The revised rule does not apply to a funding agreement (contract, grant or cooperative agreement) in effect on or before May 14, 2018. If a funding agreement in existence on or before May 14, 2018 is thereafter amended, the funding agency may, but is not required to, recite in the amended funding agreement that it will be subject to the revised rule. An amendment for this purpose is any formal communication from a funding agency informing the contractor that the revised rule will apply. A funding agency is not limited to any particular form or type of funding agreement amendment, and may amend a pre-existing funding agreement solely for the purpose of requiring compliance with the revised rule. The intent is to permit a pre-existing funding agreement to continue under the old rule even after the effective date of the revised rule, where, for example, a funding agency considers that requiring a change would be confusing. At the same time, a funding agency has discretion to amend a pre-existing funding agreement to require compliance with the revised rule prospectively (but not retroactively).

The New Bayh-Dole Rules:
What They Are, What They Mean



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20	Effective Date	What happens when a disclosure is funded by grants awarded before and after May 14th? Which Bayh Dole regs would apply?	<p>The revised rule does not apply to a funding agreement (contract, grant or cooperative agreement) in effect on or before May 14, 2018.</p> <p>If a funding agreement in existence on or before May 14, 2018 is thereafter amended, the funding agency may, but is not required to, recite in the amended funding agreement that it will be subject to the revised rule.</p> <p>An amendment for this purpose is any formal communication from a funding agency informing the contractor that the revised rule will apply. A funding agency is not limited to any particular form or type of funding agreement amendment, and may amend a pre-existing funding agreement solely for the purpose of requiring compliance with the revised rule.</p> <p>The intent is to permit a pre-existing funding agreement to continue under the old rule even after the effective date of the revised rule, where, for example, a funding agency considers that requiring a change would be confusing.</p> <p>At the same time, a funding agency has discretion to amend a pre-existing funding agreement to require compliance with the revised rule prospectively (but not retroactively).</p>
21	Effective Date	Could you clarify what inventions will be subject to these revised rules? Only those developed under grants or amendment awarded after the date the new rules go into effect or is it any invention disclosed after the rules go into effect?	<p>The revised rule does not apply to a funding agreement (contract, grant or cooperative agreement) in effect on or before May 14, 2018.</p> <p>If a funding agreement in existence on or before May 14, 2018 is thereafter amended, the funding agency may, but is not required to, recite in the amended funding agreement that it will be subject to the revised rule.</p> <p>An amendment for this purpose is any formal communication from a funding agency informing the contractor that the revised rule will apply. A funding agency is not limited to any particular form or type of funding agreement amendment, and may amend a pre-existing funding agreement solely for the purpose of requiring compliance with the revised rule.</p> <p>The intent is to permit a pre-existing funding agreement to continue under the old rule even after the effective date of the revised rule, where, for example, a funding agency considers that requiring a change would be confusing.</p> <p>At the same time, a funding agency has discretion to amend a pre-existing funding agreement to require compliance with the revised rule prospectively (but not retroactively).</p>

The New Bayh-Dole Rules:
What They Are, What They Mean



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22	Notification	No time limit on election? does this mean contractor can not publish until agency makes decision?	<p>If a contractor fails to timely disclose or elect title to a subject invention as required under 37 CFR 401.14(c), 37 CFR 401.14(d) provides that the contractor will convey title to the subject invention to the funding agency upon written request.</p> <p>A contractor's publication of a subject invention under such circumstances could work to deny the Federal government any rights in the funded invention, through no fault of the funding agency.</p> <p>A contractor should consult the General Terms & Conditions and any Special Award Conditions specific to the funding agency's award, and contact the contracting or grants officer with questions or concerns.</p>
23	ROI	Is there any public agreement on the preferred metric for ROI?	Information about the ROI Initiative may be found at https://www.nist.gov/tpo/return-investment-roi-initiative .
24	Patent	For the 60 day time period change, can you repeat the recommendation to file the application with missing parts and not pay the fee?	Contractor prosecution strategy is outside the scope of this rulemaking.
25	Extension	Is there a way to extend the 60 day time change?	The provision under 37 CFR 401.14(f)(3) for 60-day notification balances the needs of contractors to have sufficient time to respond to actions, and the needs of Federal agencies to receive information in sufficient time to evaluate whether to request conveyance and assume prosecution of an application. The revised rule does not provide for alteration of this 60-day notification requirement.
26	MES	Micro-entity application should be retained when joint IP with USG sponsor. Can this be done?	Entity Status for US patent application fee purposes, governed generally under 37 CFR 1.27 - 1.29, is outside the scope of this rulemaking.

The New Bayh-Dole Rules:
What They Are, What They Mean



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27	Assignment	Can the present assignment agreement collected at the time of invention disclosure serve as the "written agreement...to assign" in the revised rule? Does the assignment agreement have to be in place at the time of award funding?	<p>The purpose of the requirement under 37 CFR 401.14(f)(2), that a contractor agree "to require, by written agreement, its employees . . . to assign to the contractor the entire right, title and interest in and to each subject invention made under contract . . ." is to ensure that an employee's written obligation to assign to the contractor is clearly established for the entirety of the funding agreement, and so to protect the Government's interest against competing claims. This issue was addressed by the Supreme Court in <i>Stanford University v. Roche Molecular Systems, Inc.</i>, 563 U.S. 776 . Waiting until the time of invention disclosure to require an employee to execute an agreement to assign to the contractor would satisfy neither the rule nor the purpose of the rule. Many contractors fulfill this and other elements of 37 CFR 401.14(f)(2) by incorporating these requirements into employment agreements or through separate written agreements with their employees. Such agreements are contracts generally governed by state law, and contractors may wish to seek counsel familiar with the laws of their state with questions regarding such agreements.</p> <p>Another of the elements under 37 CFR 401.14(f)(2) is the contractor's agreement to require its employees to "execute all papers necessary to file patent applications on subject inventions and to establish the government's rights in the subject inventions." These papers may include, <i>inter alia</i>, an assignment identifying a patent application by number as required by the USPTO under 37 CFR 3.21, separate and apart from the employee's written obligation to assign, discussed above.</p>
28	Invention	Please expand on what the 401.10 regulation language is.	37 CFR 401.10, Government assignment to contractor of rights in invention of government employee, addresses the management of subject inventions when there is a Federal employee who is a co-inventor of a subject invention made under a funding agreement with a contractor.

The New Bayh-Dole Rules:
What They Are, What They Mean



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29	Effective Date	What is the effective date of this new rule with respect to existing (pending) provisional applications. Must they be converted within 10 months of the provisional filing date? Or are they grandfathered in and can be filed within 12 months of the provisional filing date?	<p>The effective date of the revised rule is May 14, 2018. The revised rule does not apply to a funding agreement (contract, grant or cooperative agreement) in effect on or before May 14, 2018, and a provisional application that was pending on May 14, 2018 would not fall under the revised rule.</p> <p>If a funding agreement in existence on or before May 14, 2018 is thereafter amended, the funding agency may, but is not required to, recite in the amended funding agreement that it will be subject to the revised rule.</p> <p>An amendment for this purpose is any formal communication from a funding agency informing the contractor that the revised rule will apply. A funding agency is not limited to any particular form or type of funding agreement amendment, and may amend a pre-existing funding agreement solely for the purpose of requiring compliance with the revised rule.</p> <p>The intent is to permit a pre-existing funding agreement to continue under the old rule even after the effective date of the revised rule, where, for example, a funding agency considers that requiring a change would be confusing.</p> <p>At the same time, a funding agency has discretion to amend a pre-existing funding agreement to require compliance with the revised rule prospectively (but not retroactively).</p>
30	Reporting	To summarize ? Is it a requirement under BD to report provisional and PCT appls. What about reporting foreign appls?	A "patent application" as to which reporting requirements apply under the rule continues to include a provisional or nonprovisional U.S. national application for patent as defined in 37 CFR 1.9 (a)(2) and (a)(3), respectively, or an application for patent in a foreign country or in an international patent office. 37 CFR 401.2(m).
31	Patent	Does non-provisional under 401.14(c)(3) include a PCT filing?	An international application filed under the Patent Cooperation Treaty as defined in 37 CFR 1.9(b) which designates the United States would satisfy the requirement under 37 CFR 401.14(c)(3) to file a corresponding non-provisional application, where the contractor had filed a provisional application as its initial patent application.
32	Contractor	Will the definition of "contractor" in the new rules allow for separate entity TTOs (i.e. direct assignment to the TTO)?	<p>Under 37 CFR 401.2(b) of the revised rule, "contractor" means "any person, small business firm or nonprofit organization, or, as set forth in section 1, paragraph (b)(4) of Executive Order 12591, as amended, any business firm regardless of size, which is a party to a funding agreement."</p> <p>The revised rule does not change the definition of a contractor as "a party to a funding agreement."</p>

The New Bayh-Dole Rules:
What They Are, What They Mean



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33	Patent	Our provisionals are converted within a year to file a PCT WIPO or Utility Application. If the GSC is incorrect, can we use EPAS to revise it?	Under 37 CFR 401.14(f)(4), the contractor is required to include a Government Support Clause (GSC) within the specification of any United States patent applications and any patent issuing thereon covering a subject invention. EPAS, the USPTO's Electronic Patent Assignment System, would not achieve inclusion of a GSC within the specification of the patent application or patent as required under the rule. Inclusion of a GSC in the specification notifies those reading the patent application or patent that the Government has certain rights in the subject invention. Where a GSC is included in the specification, but is incorrect, a contractor should contact the funding agency contracting or grants officer about correction.
34	Patent	Is there a definition of non-provisional patent only initial patent application?	As referenced in 37 CFR 401.2(m) and (n), the definition of a provisional patent application is set forth under 37 CFR 1.9(a)(2), and the definition of a non-provisional patent application is set forth under 37 CFR 1.9(a)(3). And, under 37 CFR 401.2(n), an international application filed under the Patent Cooperation Treaty as defined in 37 CFR 1.9(b) which designates the United States may, depending on the circumstances under which it is filed, be a non-provisional application for the purposes of the revised rule.
35	Assignment	Is there a template available for a present assignment in employment agreements? And perhaps a supplemental template for employees who are already employed?	No. Contractors in fulfilling the requirements of 37 CFR 401.14(f)(2) may wish to seek counsel familiar with present assignment of future rights, addressed by the Court of Appeals for the Federal Circuit in <i>FilmTec Corp. v. Allied-Signal, Inc.</i> , 939 F.2d 1568, 1572-73 (Fed. Cir. 1991), and with the laws of their state, when crafting employment agreements or separate written agreements with their employees.
36	Extension	Can we request a one year extension for records that have a sponsor that is not NIH, ie DOD?	The revised rule applies to any funding agreement as defined in 37 CFR 401.2(a). You should always consult the General Terms & Conditions and any Special Award Conditions specific to your funding agency's award, and contact your contracting or grants officer with questions about agency-specific notification requirements and processes.

The New Bayh-Dole Rules:
What They Are, What They Mean



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37	Assignment	What exactly is the "Magic Language" that needs to be added?	Contractors in fulfilling the requirements of 37 CFR 401.14(f)(2) may wish to seek counsel familiar with present assignment of future rights, addressed by the Court of Appeals for the Federal Circuit in <i>FilmTec Corp. v. Allied-Signal, Inc.</i> , 939 F.2d 1568, 1572-73 (Fed. Cir. 1991), and with the laws of their state, when crafting employment agreements or separate written agreements with their employees.
38	Title	Is the right the agency has to elect title when the contractor fails to notify greater than March-in rights?	These are different rights and obligations. The provision that a contractor will convey title to the subject invention to the funding agency upon written request under 37 CFR 401.14(d)(1) applies only if a contractor fails to disclose or elect title to a subject invention, or elects not to retain title, as set forth under 37 CFR 401.14(c). Under 37 CFR 401.14(c)(5), first sentence, a contractor may request an extension of time to make that disclosure or election. Under these provisions, the march-in right does not apply. The provision for march-in rights, 37 CFR 401.14(j), which addresses licensing of a subject invention, recites the determinations which must be made by the funding agency, and governing procedures are set forth in 37 CFR 401.6. Under these provisions, conveyance of title does not apply.
39	Effective Date	When does this take effect?	The effective date of the revised rule is May 14, 2018. The revised rule does not apply to a funding agreement (contract, grant or cooperative agreement) in effect on or before May 14, 2018, and a provisional application that was pending on May 14, 2018 would not fall under the revised rule. If a funding agreement in existence on or before May 14, 2018 is thereafter amended, the funding agency may, but is not required to, recite in the amended funding agreement that it will be subject to the revised rule. An amendment for this purpose is any formal communication from a funding agency informing the contractor that the revised rule will apply. A funding agency is not limited to any particular form or type of funding agreement amendment, and may amend a pre-existing funding agreement solely for the purpose of requiring compliance with the revised rule. The intent is to permit a pre-existing funding agreement to continue under the old rule even after the effective date of the revised rule, where, for example, a funding agency considers that requiring a change would be confusing. At the same time, a funding agency has discretion to amend a pre-existing funding agreement to require compliance with the revised rule prospectively (but not retroactively).

The New Bayh-Dole Rules:
What They Are, What They Mean



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40	Assignment	Regarding the matter of assignment by written agreement, is the "I hereby assign" the only magic language that you're referencing or is there other magic language? Could you please give an example of what proper language would be?	Contractors in fulfilling the requirements of 37 CFR 401.14(f)(2) may wish to seek counsel familiar with present assignment of future rights, addressed by the Court of Appeals for the Federal Circuit in <i>FilmTec Corp. v. Allied-Signal, Inc.</i> , 939 F.2d 1568, 1572-73 (Fed. Cir. 1991), and with the laws of their state, when crafting employment agreements or separate written agreements with their employees.
41	Effective Date	Please clarify that the new rules apply to grants awarded on or after May 14, 2018.	<p>The effective date of the revised rule is May 14, 2018. The revised rule does not apply to a funding agreement (contract, grant or cooperative agreement) in effect on or before May 14, 2018, and a provisional application that was pending on May 14, 2018 would not fall under the revised rule.</p> <p>If a funding agreement in existence on or before May 14, 2018 is thereafter amended, the funding agency may, but is not required to, recite in the amended funding agreement that it will be subject to the revised rule.</p> <p>An amendment for this purpose is any formal communication from a funding agency informing the contractor that the revised rule will apply. A funding agency is not limited to any particular form or type of funding agreement amendment, and may amend a pre-existing funding agreement solely for the purpose of requiring compliance with the revised rule.</p> <p>The intent is to permit a pre-existing funding agreement to continue under the old rule even after the effective date of the revised rule, where, for example, a funding agency considers that requiring a change would be confusing.</p> <p>At the same time, a funding agency has discretion to amend a pre-existing funding agreement to require compliance with the revised rule prospectively (but not retroactively).</p>
42	Patent	If we decide not to pursue a non-provisional patent application after marketing the technology during the pendency of the provisional, are we required to still file a nonprovisional if we refer rights back to the funding agency?	<p>If a contractor files a provisional application as its initial patent application, it is required to file a non-provisional patent application within 10 months under 37 CFR 401.14(c)(3) of the revised rule.</p> <p>However, if a contractor has filed a provisional application but thereafter does intend to abandon the subject invention and not file a corresponding non-provisional application, conveying title to the funding agency within 10 months would relieve the contractor of the obligation to file a non-provisional application.</p> <p>A contractor in this situation should contact its contracting or grants officer.</p>

The New Bayh-Dole Rules:
What They Are, What They Mean



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43	Notification	What is the deadline for notifying the federal government if you are not going to convert a provisional application and neither have you asked for an extension?	<p>If a contractor files a provisional application as its initial patent application, it is required to file a non-provisional patent application within 10 months under 37 CFR 401.14(c)(3) of the revised rule.</p> <p>However, if a contractor has filed a provisional application but thereafter does intend to abandon the subject invention and not file a corresponding non-provisional application, conveying title to the funding agency within 10 months would relieve the contractor of the obligation to file a non-provisional application.</p> <p>A contractor in this situation should contact its contracting or grants officer.</p>
44	Patent	But do we actually have to FILE within 10 months, or just give our decision?	<p>If a contractor files a provisional application as its initial patent application, it is required to file a non-provisional patent application within 10 months under 37 CFR 401.14(c)(3) of the revised rule.</p> <p>However, if a contractor has filed a provisional application but thereafter does intend to abandon the subject invention and not file a corresponding non-provisional application, conveying title to the funding agency within 10 months would relieve the contractor of the obligation to file a non-provisional application.</p> <p>A contractor in this situation should contact its contracting or grants officer.</p>
45	Reference	Are these changes available to see now on NIH?	The revised rule is available at https://www.ecfr.gov/cgi-bin/text-idx?SID=b8963a82ebc28a4d20a06b733592b396&mc=true&node=pt37.1.401&rgn=div5 .
46	Fee	Is there any fee?	No fee is established, authorized, or charged under the Bayh-Dole Act or its implementing regulations.

The New Bayh-Dole Rules:
What They Are, What They Mean



#	Topic	Question	Answer
47	Extension	Is the 12 month NPA filing extension requested via iEdison or is that a request submitted directly to the sponsor agency?	<p>Under 37 CFR 401.14(c)(5), second sentence, when a contractor has filed a provisional application as its initial patent application on a subject invention and timely requests an extension for filing a non-provisional application, the an extension of one year from the 10-month deadline date will be granted unless the funding agency, within 60 days of receiving the contractor's extension request, notifies the contractor of its decision to deny the request or to grant an extension of other duration.</p> <p>While it is expected that iEdison will be updated to reflect this and other changes under the revised rules for participating federal agencies, a contractor should always consult the General Terms & Conditions and any Special Award Conditions specific to the funding agency's award, and contact its contracting or grants officer with questions about agency-specific notification requirements and processes.</p>
48	Notification	If you have elected title and then decide not to pursue further prosecution due to an office action, can we retain title and just report the office action?	<p>Under 37 CFR 401.14(f)(3), a contractor is required to notify the funding agency of any decision not to continue prosecution of a non-provisional patent application no less than 60 days prior to the expiration of the statutory deadline.</p> <p>In any country in which a contractor decides not to continue the prosecution of a non-provisional application for a patent, 37 CFR 401.14(d) provides that the contractor will convey title to the subject invention to the funding agency upon written request.</p>
49	Extension	Could you clarify the mechanism by which we request the extension - is this agency by agency, or is this an anticipated feature of iEdison?	<p>A contractor seeking an extension of time for disclosure, election or filing under 37 CFR 401.14(c)(5) must file a specific extension request, which the funding agency may grant in its discretion.</p> <p>While it is expected that iEdison will be updated to reflect this and other changes under the revised rules for participating federal agencies, a contractor should always consult the General Terms & Conditions and any Special Award Conditions specific to the funding agency's award, and contact its contracting or grants officer with questions about agency-specific notification requirements and processes.</p>

The New Bayh-Dole Rules:
What They Are, What They Mean



#	Topic	Question	Answer
50	Title	Can you wait to elect title until a non-provisional is filed, even if a provisional is filed prior to the 2 years?	Under 37 CFR 401.14(c)(2) "the contractor will elect in writing whether or not to retain title to any such invention by notifying the Federal agency within two years of disclosure to the Federal agency. However, in any case where a patent, a printed publication, public use, sale, or other availability to the public has initiated the one year statutory period wherein valid patent protection can still be obtained in the United States, the period for election of title may be shortened by the agency to a date that is no more than 60 days prior to the end of the statutory period."
51	Notification	Just to make sure my previous question wasn't missed: with respect to the 60 day notification, is that prior to shortened statutory period deadline, or deadline with all extensions available?	The statutory deadline in 37 CFR 401.14(f)(3) refers to the six-month time provided under 35 USC 133 in the US, and to the corresponding statutory time in any foreign country.
52	Assignment	Could you please repeat the preferred "magic language" for assignment by the inventors?	Contractors in fulfilling the requirements of 37 CFR 401.14(f)(2) may wish to seek counsel familiar with present assignment of future rights, addressed by the Court of Appeals for the Federal Circuit in <i>FilmTec Corp. v. Allied-Signal, Inc.</i> , 939 F.2d 1568, 1572-73 (Fed. Cir. 1991), and with the laws of their state, when crafting employment agreements or separate written agreements with their employees.
53	Notification	How through iEdison does a contractor notify the government (i.e., funding agency) that it does not plan to convert a provisional application?	If a contractor files a provisional application as its initial patent application, it is required to file a non-provisional patent application within 10 months under 37 CFR 401.14(c)(3) of the revised rule. However, if a contractor has filed a provisional application but thereafter does intend to abandon the subject invention and not file a corresponding non-provisional application, conveying title to the funding agency within 10 months would relieve the contractor of the obligation to file a non-provisional application. A contractor in this situation should contact its contracting or grants officer. While it is expected that iEdison will be updated to reflect this and other changes under the revised rules for participating federal agencies, a contractor should always consult the General Terms & Conditions and any Special Award Conditions specific to the funding agency's award, and contact its contracting or grants officer with questions about agency-specific notification requirements and processes.

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#	Topic	Question	Answer
54	Reference	The regulatory requirement of an assignment is a step in the right direction. However, it will not capture inventions covered by a previous assignment, only those inventions outside of the scope of that previous assignment. For example, the Stanford scientist can move from Stanford to another institution and sign that new institution's assignment. However, his assignment to Roche still exists and subject matter that he invents that falls within that assignment will be still be claimed by Roche. Institutions (and research sponsors) will need to conduct due diligence regarding the previous assignments executed by researchers.	Contractors in fulfilling the requirements of 37 CFR 401.14(f)(2) may wish to seek counsel familiar with present assignment of future rights, addressed by the Court of Appeals for the Federal Circuit in <i>FilmTec Corp. v. Allied-Signal, Inc.</i> , 939 F.2d 1568, 1572-73 (Fed. Cir. 1991), and with the laws of their state, when crafting employment agreements or separate written agreements with their employees.
55	Notification	The question of how to provide sufficient notification when not pursuing prosecution was not really addressed.	A contractor seeking an extension of time for disclosure, election or filing under 37 CFR 401.14(c)(5) must file a specific extension request, which the funding agency may grant in its discretion. While it is expected that iEdison will be updated to reflect this and other changes under the revised rules for participating federal agencies, a contractor should always consult the General Terms & Conditions and any Special Award Conditions specific to the funding agency's award, and contact its contracting or grants officer with questions about agency-specific notification requirements and processes.
56	ROI	Can people provide public comments without attending the public meeting?	Information about the ROI Initiative may be found at https://www.nist.gov/tpo/return-investment-roi-initiative .
57	Invention	what happens if the invention is not something that we want to file a patent application on, but we do want to elect title and license such as a transgenic animal?	A contractor must file an initial patent application on a subject invention to which it elects to retain title. 37 CFR 401.14 (c)(3).

The New Bayh-Dole Rules:
What They Are, What They Mean



#	Topic	Question	Answer
58	Effective Date	How will iEdison know when the agreements were effective after 5-14-18?	While it is expected that iEdison will be updated to reflect the effective date of the revised rules for participating federal agencies, a contractor should always consult the General Terms & Conditions and any Special Award Conditions specific to the funding agency's award, and contact its contracting or grants officer with questions about agency-specific notification requirements and processes.
59	Assignment	Would it make sense to have a present assignment in an employer agreement, but also a future assignment "agree to assign" once a specific app number and title are known for submission to the patent office? How would you recommend a best practice for a university?	Contractors in fulfilling the requirements of 37 CFR 401.14(f)(2) may wish to seek counsel familiar with present assignment of future rights, addressed by the Court of Appeals for the Federal Circuit in <i>FilmTec Corp. v. Allied-Signal, Inc.</i> , 939 F.2d 1568, 1572-73 (Fed. Cir. 1991), and with the laws of their state, when crafting employment agreements or separate written agreements with their employees.
60	Patent	When a contractor decides to convert a provisional to a non provisional but not a PCT, how does the contractor let the funding agency know this? How specifically does a contractor do this in iEdison?	As referenced in 37 CFR 401.2(m) and (n), the definition of a non-provisional patent application is set forth under 37 CFR 1.9(a)(3). And, under 37 CFR 401.2(n), an international application filed under the Patent Cooperation Treaty as defined in 37 CFR 1.9(b) which designates the United States may, depending on the circumstances under which it is filed, be a non-provisional application for the purposes of the revised rule. iEdison allows Users to upload all aspects of patent reports needed to fully comply with reporting statutes and regulations. While it is expected that iEdison will be updated to reflect the effective date of the revised rules for participating federal agencies, a contractor should always consult the General Terms & Conditions and any Special Award Conditions specific to the funding agency's award, and contact its contracting or grants officer with questions about agency-specific notification requirements and processes.

About the Webinar

Date

May 8, 2018

Presenters

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Summary

Learn more about the new regulations recently issued (effective May 14) by the National Institutes of Standards and Technology, which governs the implementation of the Bayh-Dole Act. This webinar gets you up-to-speed on key issues and how your office may need to adapt to new rules for handling technologies created in your labs.

This is a "must" for tech transfer personnel focused on compliance.

Recording

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