THE 2018 BAYH DOLE REVISIONS: COMPLIANCE GUIDANCE FOR TECHNOLOGY TRANSFER OFFICES
DISCLAIMER

The following content is presented solely for the purposes of discussion and illustration, and does not comprise, nor is not to be considered, as legal advice.
The Bayh-Dole action (1980)

The Bayh-Dole act permits a university, small business or non-profit institution to elect to pursue ownership of inventions supported by federally funded research (e.g., NIH, NSF, NASA, DOD).

Before the Bayh-Dole act, inventions that arose from federally funded research were assigned to the U.S. Government. The vast majority of these inventions were never commercially licensed.
Since passage of the Act, universities have benefited from ownership of these inventions. To gain ownership of such inventions, universities are required to follow certain procedures.
In the original Act the government agency was required to elect title by certain deadlines in the event that certain procedures were not followed.

As of May 14, 2018, these procedures have changed and the consequences of failure to comply can result in loss of title to an invention to the funding Govt. Agency at any time.

These regulations are set forth in

37 CFR §401 et seq.

(available at

https://www.law.cornell.edu/cfr/text/37/chapter-IV)
Changes in rules apply to all new funding agreements executed after May 14, 2018.

The new rules do not apply to funding agreements in effect on or before May 14, 2018.

BUT, if a previous funding agreement is amended after May 14, 2018, the relevant Federal agency can opt to apply the new rules.

Note:

No need to modify existing licenses for patents and applications supported by funding agreements executed before May 14, 2018.

However, existing licenses should be reviewed if funding agreement is amended after May 14, 2018.
Procedures

37 CFR 401.14(D)(1) – GOV’T TITLE

CONDITIONS WHEN GOVERNMENT MAY OBTAIN TITLE.

“IF THE CONTRACTOR FAILS TO DISCLOSE OR ELECT TITLE TO THE SUBJECT INVENTION WITHIN THE TIMES SPECIFIED IN PARAGRAPH (C) OF THIS CLAUSE, OR ELECTS NOT TO RETAIN TITLE.”
Procedures

37 CFR 401.14(D)(1) – GOV’T TITLE

CONDITIONS WHEN GOVERNMENT MAY OBTAIN TITLE

Change in rule eliminates previous 60-day limit on federal agency taking title.

Old 401.14 (d)(1)

(d) Conditions When the Government May Obtain Title

The contractor will convey to the Federal agency, upon written request, title to any subject invention—

(1) If the contractor fails to disclose or elect title to the subject invention within the times specified in (c), above, or elects not to retain title; provided that the agency may only request title within 60 days after learning of the failure of the contractor to disclose or elect within the specified times.

New 401.14 (d)(1)

(1) If the contractor fails to disclose or elect title to the subject invention within the times specified in paragraph (c) of this clause, or elects not to retain title.
Procedures

37 CFR 401.14(D)(1) – GOV’T TITLE

Contractor must be aware that if they fail to timely disclose invention, or timely elect title, federal agency can demand title at any time during life of the patent.

This effectively puts cloud on title unless timely disclosure of invention and electing title.

Contractors should keep time log for each invention to show compliance with rule for federal agency and/or potential licensee.
Procedures

Note:

Faculty at ODU are required to disclose potentially patentable subject matter to the Office of Research prior to initiation of any statutory bar. (i.e. public disclosure, offer for sale)

DO NOT disclose patentable subject matter in any manner that would result in public disclosure prior to the filing of applications.

DISCLOSE EARLY, DISCLOSE OFTEN!!!
Procedures

37 CFR 401.14(F)(2) – GOV’T TITLE

Contractors must obtain a written agreement requiring employees to assign inventions to the contractor.

No change from contractor standpoint if contractor has already adopted employment agreements reflecting U.S. Supreme court’s ruling in Stanford v. Roche (563 U.S. 776 (2011)).
Procedures

37 CFR 401.14(F)(2) – GOV’T TITLE

“The contractor agrees to require, by written agreement, its employees, other than clerical and nontechnical employees, to disclose promptly in writing to personnel identified as responsible for the administration of patent matters and in a format suggested by the contractor each subject invention made under contract in order that the contractor can comply with the disclosure provisions of paragraph (c) of this clause, to assign to the contractor the entire right, title, and interest in, and to each subject invention made under contract, and to execute all papers necessary to file patent applications on subject inventions and to establish the government’s rights in the subject inventions. 
TIME LINE

Learn of invention
0 2 Months

Inform Federal Agency
"The contractor will disclose each subject invention to the federal agency within two months after the inventor discloses it in writing to contractor personnel responsible for patent matters. The disclosure to the agency shall be in the form of a written report and shall identify the contract under which the invention was made and the inventor(s). It shall be sufficiently complete in technical detail to convey a clear understanding to the extent known at the time of the disclosure, of the nature, purpose, operation, and the physical, chemical, biological or electrical characteristics of the invention.

**TWO (2) MONTH RULE**

* Requests for extension of time may be granted “at discretion of federal agency” (401.14(c)(5)), but the timing of such requests and conditions for granting them are not specified.
Procedures

37 CFR 401.14(C)(1) – TWO MONTH RULE

“Practice note:

No change in deadline rule per se, BUT consequences of noncompliance are possible loss of title at any time during life of patent.

Meaning, if procedure has not been followed, the Govt. Agency can allow the contractor to perform all remaining work to obtain patent and obtain license agreements and then elect title at a later time, like when it becomes lucrative.
Any communication of invention in writing (e.g., Invention Disclosure Form, e-mail, manuscript, meeting abstract, poster) by an inventor to contractor personnel responsible for patent matters (e.g., any Technology Transfer Office personnel) starts two (2) month period for informing Federal Agency of invention.

Contractors should keep time log for each invention to show compliance with rule for Federal Agency and/or potential licensee.
TIME LINE

Learn of invention
0

2 Months

2 years after Informing Agency*

Inform Federal Agency

Elect Title

* or no more than 60 days prior to end of statutory bar
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.

Deadline for electing title to invention is earlier of:

1. Two (2) years after disclosure of invention to federal agency, or

2. If statutory bar exists, no more than 60 days prior to end of statutory period

* Again requests for extension of time may be granted “at discretion of federal agency” (401.14(c)(5)), but the timing of such requests and conditions for granting them are not specified.

PRACTICE NOTE:
No change in deadline rule, BUT AGAIN consequences of noncompliance are possible loss of title at any time during life of patent.
Procedures

37 CFR 401.14(C)(2) – ELECTING TITLE

Contractor must elect title by writing to federal agency within earlier of

(i) 10 months of public disclosure of the invention (i.e., More than 60
days before the “statutory bar” in the US); or

(ii) 24 months from informing the federal agency of the invention if
no statutory bar exists.

Contractors should keep *time log* for each invention to show compliance
with rule for federal agency and/or potential licensee.
TIME LINE

Learn of invention

0

2 Months

2 years after Informing Agency*

1 year after Electing Title**

Inform Federal Agency

Elect Title

File Application

* or no more than 60 days prior to end of statutory bar

** or prior to end of statutory bar
“The contractor will file its initial patent application on a subject invention to which it elects to retain title within one year after election of title or, if earlier, prior to the end of any statutory period wherein valid patent protection can be obtained in the United States after a publication, on sale, or public use.”

Deadline to file initial patent application is earlier of:
(i) one year* after election of title, or
(ii) if statutory bar exists, prior to end of statutory period
* Requests for extension of time may be granted “at discretion of Federal Agency” (401.14(c)(5)) but the timing of such requests and conditions for granting them are not specified.
Procedures

37 CFR 401.14(C)(3) – PROVISIONAL FILINGS

“If the contractor files a provisional application as its initial patent application, it shall file a nonprovisional application within 10 months of the filing of the provisional application. The contractor will file patent applications in additional countries or international patent offices within either ten months of the first filed patent application or six months from the date permission is granted by the commissioner of patents to file foreign patent applications where such filing has been prohibited by a secrecy order.”

* Requests for extension of time will be granted “unless the Federal agency notifies contractor within 60 days of receiving the request” (401.14(c)(5))
Procedures

37 CFR 401.14(C)(3) – PROVISIONAL FILINGS

Contractor must file first patent application by the earlier of

(i) One (1) year after electing title or,

(ii) Prior to the end of statutory bar.

If first patent application is a provisional, contractor “shall” file ongoing patent application within 10 months of filing provisional application.

In order to obtain the maximum 12-month period from filing provisional to perfect the ongoing application, contractor should request an extension within 8 months of filing the provisional (because the federal agency has 60 days to deny such a request).
Procedures

37 CFR 401.14(C)(4) – AGENCY FILINGS (NEW RULE)

“For any subject invention with federal agency and contractor coinventors, where the federal agency employing such co-inventor determines that it would be in the interest of the government, pursuant to 35 U.S.C. 207(a)(3), to file an initial patent application on the subject invention, the federal agency employing such co-inventor, at its discretion and in consultation with the contractor, may file such application at its own expense, provided that the contractor retains the ability to elect title pursuant to 35 U.S.C. 202(a).”
Procedures

37 CFR 401.14(F)(3) – GOV’T TITLE

“For each subject invention, the contractor will, no less than 60 days prior to the expiration of the statutory deadline, notify the federal agency of any decision: not to continue the prosecution of a non-provisional patent application; not to pay a maintenance, annuity or renewal fee; not to defend in a reexamination or opposition proceeding on a patent, in any country; to request, be a party to, or take action in a trial proceeding before the patent trial and appeals board of the U.S. Patent and trademark office, including but not limited to post-grant review, review of a business method patent, inter partes review, and derivation proceeding; or to request, be a party to, or take action in a non-trial submission of art or information at the U.S. Patent and trademark office, including but not limited to a pre-issuance submission, a post-issuance submission, and supplemental examination.”
(K) SPECIAL PROVISIONS FOR CONTRACTS WITH NONPROFIT ORGANIZATIONS

(4) It will make efforts that are reasonable under the circumstances to attract licensees of subject inventions that are small business firms and that it will give a preference to a small business firm when licensing a subject invention if the contractor determines that the small business firm has a plan or proposal for marketing the invention which, if executed, is equally as likely to bring the invention to practical application as any plans or proposals from applicants that are not small business firms; provided, that the contractor is also satisfied that the small business firm has the capability and resources to carry out its plan or proposal. The decision whether to give a preference in any specific case will be at the discretion of the contractor. However, the contractor agrees that the Federal agency may review the contractor’s licensing program and decisions regarding small business applicants, and the contractor will negotiate changes to its licensing policies, procedures, or practices with the Federal agency when the Federal agency’s review discloses that the contractor could take reasonable steps to implement more effectively the requirements of this paragraph (K)(4). In accordance with 37 CFR 401.7, the Federal agency or the contractor may request that the Secretary review the contractor’s licensing program and decisions regarding small business applicants.
TIME LINE

Learn of invention  
0  2 Months  2 years after Informing Agency*  1 year after Electing Title**  10 months after Filing Provisional ***

Inform Federal Agency  Elect Title  File Application  File Ongoing Application

* or no more than 60 days prior to end of statutory bar  
** or prior to end of statutory bar  
*** or in case of Secrecy Order, 6 months from date permission granted to file foreign application, or request extension of time
Summary

No need to modify existing licenses for IP supported by funding agreements executed before May 14, 2018. Existing licenses should be reviewed if funding agreement is amended after May 14, 2018.

Contractors should keep time log for each invention to show compliance with disclosure and election of title rules for federal agency and/or potential licensee. Licensees expected to look for proof of timely disclosure & election.

Communication of invention in writing by inventor to contractor personnel responsible for patent matters starts two month period for informing federal agency of invention.
Summary

Contractor must elect title in writing to federal agency within earlier of

(i) 10 months of public disclosure of invention (i.e., More than 60 days before “statutory bar” in the US) or

(ii) 24 months from informing the federal agency of the invention if no statutory bar.

Contractor must file a first patent application by the earlier of

(I) one year after electing title or

(ii) prior to the end of any statutory bar.

If first patent application is a provisional, contractor “shall” file ongoing patent application within 10 months of filing provisional application.
In order to obtain maximum 12-month period from filing provisional to perfecting ongoing application, contractor should request extension within 8 months of filing provisional (because the federal agency has 60 days to deny such a request).

Contractor must obtain a written agreement requiring employees to assign inventions to contractor.

Contractor must inform federal agency within 60 days prior to deadline to respond to office action/pay maintenance fee etc. Of contractor’s intent not to pursue non-provisional application/patent. Where contractor has licensed the invention, the license should require licensee give contractor at least 90 days notice of intent not to proceed, so that contractor can timely inform federal agency.