

AIPLA

American Intellectual Property Law Association

December 9, 2016

National Institute of Standards and Technology (NIST)
100 Bureau Drive
Gaithersburg, MD 20899
Attn.: Kent Rochford,
Associate Director for Laboratory Programs

via email: courtney.silverthorn@nist.gov

Re: Comments of AIPLA on NIST Proposed revisions to Bayh-Dole Regulations, 37 CFR Parts 401 and 404, [Docket No.: 160311229-6229-01] RIN 0693-AB63 -- Rights to Federally Funded Inventions and Licensing of Government Owned Inventions

Dear Sir or Madam:

INTRODUCTION

The American Intellectual Property Law Association (AIPLA) is pleased to have this opportunity to present its views on the proposed NIST revisions to the above-identified Regulations.

AIPLA is a national association of approximately 14,000 members who are primarily practitioners engaged in private or corporate practice, in government service, and in the academic community. AIPLA members represent a wide and diverse spectrum of individuals, companies, and institutions involved directly or indirectly in the practice of patent, trademark, copyright, trade secret, and unfair competition law, as well as other fields of law affecting intellectual property. Our members represent both owners and users of intellectual property. Many AIPLA members work under agency contracts in many fields and seek to commercialize (and accept the risk in commercializing) the innovations they develop, while some members seek to license and build upon the patents advanced by contractors.

Our mission includes helping to establish and maintain fair and effective laws, regulations, and policies that stimulate and reward invention while balancing the public's interest in healthy competition, reasonable costs, and basic fairness.

Below are comments on selected items of the NIST proposed revisions to the above-identified Regulations ("Comments"). Our Comments follow the questions and are highlighted with bold italics. The Comments consider the actual text in the existing and proposed Regulations in addressing the questions. AIPLA has not commented on every question covered by the Request for Comments. However, our decision not to do so for a

particular question or proposal should not be interpreted as agreement or acquiescence with the proposed change.

In general, AIPLA appreciates the changes to the Regulations to conform the Regulations to the Executive Order by providing that contractors of any size (not just nonprofit and small entities) may elect to hold title to patents on subject inventions made by the contractor with agency funds. The Comments are aimed at avoiding anomalies that may arise, to promote development and commercialization of funded inventions where election is made (as intended by the law and Regulations), and to address changes that may adversely affect contractors' interests in the subject inventions and their interest in participating in funded projects. In this regard, the Comments offer some suggestions as requested in the Notice instructions.

COMMENTS

The proposed revisions to [37 CFR § 401](#) will:

1. Clarify in § 401.1(b) that Federal agencies, under section 1, subparagraph (b)(4) of Executive Order 12591, as amended, may apply the presumption of the right to retain title to contractors which are large business firms as well as to those which are small business firms and nonprofit organizations;

The revision, which conform the Regulations to the Executive Order, is a beneficial change that AIPLA supports. Larger entities often have robust licensing and other IP management efforts that can promote elected invention dissemination and commercialization and those entities may enter reciprocal licensing arrangements that benefit the parties and the public.

2. Correct § 401.1(e) to refer to § 401.17, identifying the office to which copies of proposed and final agency regulations should be directed for approval by the Secretary of Commerce;

3. Clarify in § 401.2(b) that the term *contractor* includes any business firm regardless of size, under section 1., subparagraph (b)(4) of Executive Order 12591, as amended, which is a party to a funding agreement;

See our comments in Paragraph 1 above.

4. Clarify that the term *initial patent application* means the first provisional or nonprovisional U.S. national application for a patent as defined in [37 CFR §1.9\(a\)\(2\)](#) and (3), respectively, or the first international application as defined in [37 CFR §1.9\(b\)](#) which designates the United States, in accordance with accepted practice;

5. Clarify that the term *statutory period* refers to the one-year period in [35 U.S.C. §102\(b\)](#).

As with Paragraph 11 below, specify whether the term statutory period now refers to the one-year period in 35 USC § 102(b) "as amended by the America Invents Act,

Public Law 112-29,” and review and proposes updates/clarifications to the language used in various provisions of 37 C.F.R. §401.14 referring to the statutory period with respect to “a publication, on sale, or public use” to reflect the changes in the effective timing and availability of the triggered grace periods under the AIA as compared to the fixed one year grace period under pre-AIA 35 U.S.C. §102(b) and the addition of the language “or otherwise publicly available” to post-AIA 35 U.S.C. §102(a)(1).

Please refer to Attachment 1 of this letter, which provides further background information and citation to a relevant reference that may be helpful on this topic.

6. Clarify that the use of the standard clause at § 401.14 is applicable to nonprofits and to all businesses regardless of size, consistent with section 1., subparagraph (b)(4) of Executive Order 12591, as amended.

See our comments in Paragraph 1 above.

7. Create additional conditions under § 401.3(a) for the use of alternate provisions other than § 401.14(a) through a formatting revision;

8. Create additional conditions under § 401.3(a) for the use of alternate provisions other than § 401.14(a) when work is completed under a Cooperative Research and Development Agreement (CRADA) and removes outdated language related to Department of Energy naval nuclear propulsion and weapons related programs;

9. Create additional conditions under § 401.3(a) for the use of alternate provisions other than § 401.14(a) when the contractor is not a non-profit organization and is not in the business of commercializing subject inventions that would arise under a funding agreement, consistent with the commercialization intent of [35 U.S.C. §200](#);

10. Remove language from § 401.3(h) related to size protests that, per subparagraph (b)(4) of Executive Order 12591, as amended, no longer applies to a distinction between large and small businesses, and clarify language related to furnishing evidence of non-profit status;

See our comments in Paragraph 1 above.

11. Update the provision for distribution of royalty payments in § 401.5(g)(3) to be consistent with [35 U.S.C. §202\(c\)\(7\)\(E\)\(i\)](#) as amended by the America Invents Act, [Public Law 112-29](#);

12. Revise § 401.7(b) to include participation of the funding Agency in the review of an organization's nonprofit status;

13. Revise § 401.10 to clarify the management of subject inventions when there is a Federal employee who is a co-inventor of the subject invention, including clarifying that an agency may file an initial patent application provided that it does not negate a contractor's ability to elect rights, that a funding agency will provide administrative assistance to an agency who employs a Federal co-inventor in the management of co-

invented subject inventions when a contractor has waived rights, that funding agencies and Federal agencies employing co-inventors shall consult on the management of co-invented subject inventions that Federal agencies may enter into agreements with contractors for the management of co-invented subject inventions, and that Federal agencies employing co-inventors retain their ownership rights when a contractor elects title to a co-invented subject invention;

14. Redesignate § 401.14(a)(c)(4) as 401.14(a)(c)(5);

15. Revise § 401.14(a)(c)(2) to clarify that a Federal agency may shorten the two year period of election of title by a contractor if necessary to protect the Government's interest.

Are there any guidelines on when shortening the election time is “necessary”? Along this line, it is proposed that “‘Necessary’ means that national safety or health or security or defense are involved, or where there is a documented risk of lost patents rights or loss of market opportunity.”

16. Clarify in § 401.14(c) that a Federal agency may file an initial patent application at its own expense on a jointly-owned subject invention, if necessary to protect the Government's interest in the subject invention.

Please also clarify whether the “team exception” of post-AIA §102(b)(2)(C) is intended to/may be invoked with respect to any such filings for joint inventions, and for that matter with respect to which, if any, filings that might arise under these provisions (e.g., can contractor rely on the team exception to exempt other potentially related government patent filings that have not yet published

17. Remove the 60-day agency time limitation after learning that a contractor has failed to disclose an invention or elect rights, in § 401.14(a)(d)(1), in order to improve due diligence and enhance the ability of agencies to work with contractors;

18. Clarify the requirement in § 401.14(a)(f)(2) for a contractor to require its employees to assign rights in subject inventions to the contractor and in order for the contractor to file patent applications on subject inventions developed under the contract;

19. Revise § 401.14(a)(f)(3) to extend the required notification period for decisions not to continue patent prosecution from 30 days before the expiration of the response period to 120 days, in order to allow the Federal agency adequate time to determine whether to assume responsibility for patent prosecution of the subject invention;

This revision requires the contractor to review the office action for a Subject Invention, determine whether it will discontinue pursuing patent protection, and send the agency notice of the discontinuance, all within 120 days before the response period ends. While the patent statute discusses a 6-month response period, the USPTO typically provides a (shortened) 90-day or, in some cases, 30-day period to respond to an office action. It is unclear how an electing contractor can reasonably comply. Suppose the contractor receives an office action providing 90 days to respond. If the contractor decides to discontinue on the day the office action is received, it is already 30-days

delinquent on sending the discontinuation notice. If the revision is intended to address only 6-month response periods, it is unclear how the revised provision would operate in practice. If the provision is intended to cover all responses, including 30- and 90-day response periods, the deadline would be anomalous and uncertain. Accordingly, AIPLA suggests that the 120-day revision be withdrawn and that either the original 30-day period be restored or that a different algorithm be used that provides the contractor reasonable time to take action

The 120-day period, at best, shortens or eliminates the response period during which a contractor may consider the commercial prospects and value of the invention against the cost of continuing prosecution. It is recognized that patent applicants may request extensions to the shortened periods, but there is no requirement and there may be no interest in paying to do so. The proposed revision becomes particularly unreasonable when the invention relates to defense or armaments where the agency's response period can be extended up to 3 years, under 35 USC § 267. In that case, the contractor may have little or no time to act, while the Government can enjoy a 3- year review period. The challenge is in providing the contractor as well as the Government sufficient time to consider their interests to move forward.

If the current 30-day notification period to the Federal agency is increased, consideration should be given not only to the benefit such additional time may provide to the Government, but also to the burden such additional time places on the contractor. If the 30-day time period is increased, justification for the increase in time should be provided. As an alternative proposal, AIPLA suggests that the USPTO, in consultation with other government agencies, adopt Rules that enable a funding agency to extend its response time at the USPTO (beyond the customary response date) if the contractor certifies that it is discontinuing action with respect to the subject patent application, regardless of invention subject matter. Synchronizing USPTO practices and agency regulations relating to Bayh-Dole inventions would be most beneficial, better enabling invention commercialization.

The proposed revisions in this section further require the contractor to notify the agency when it files a PTAB proceeding. AIPLA believes that the reference to PTAB proceedings should only apply to instances in which the contractor is the patent holder and not the challenger. Section (f) (3) states that:

[T]he contractor ... will ... notify the federal agency of any decision: ... to request, be a party to, or take action in a trial proceeding before the Patent Trial and Appeals Board...

Clarification is recommended. . In addition, the revision should not extend to actions like pre-issuance submissions. The provision needs to be tied in one way or another to the contractor's subject patent.

20. Revise § 401.14(a)(k)(4) to provide for the funding agency's participation in the small business preference review process for the licensing of subject inventions by nonprofit contractors, and providing that the funding agency or the contractor may request review by the Secretary of Commerce as well;

21. Revise § 401.16 to make electronic filing the default format for reporting and elections unless otherwise directed by an agency; and

22. Add contact information for Interagency Edison, which is used by many Federal agencies, to § 401.17.

The proposed revisions to [37 CFR part 404](#) will:

23. Redesignate the existing text in § 404.8 as paragraph (a) and create a new paragraph (b) to provide that a CRADA partner is not required to submit a separate license application to an agency in order to access, under the CRADA, background technology owned by the Government.

This proposed rulemaking does not address contractor appeals of exceptions (§ 401.4), exercise of march-in rights (§ 401.6), small business preference (§ 401.7), subject invention utilization reporting (§ 401.8), contractor employee inventor rights retention (§ 401.9), appeals (§ 401.11), background patent rights licensing (§ 401.12), patent rights clauses administration (§ 401.13), or deferred determinations (§ 401.15) of part 401, and addresses only the license application provision (§ 404.8) of part 404.

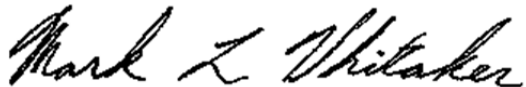
Proposals

- 1. It would be helpful if revised sections were provided in context with strikethrough deletions and underlined inserts reflecting the changes. Where a section is lengthy and detailed, comparing the revised and current text is formidable. Similarly, where edits are requested from the public, an editable copy would be helpful as well. It is appreciated that there may be a reason for the current format (e.g. paper reduction), however, it would be helpful to reassess redlining.*
- 2. A number of measures would increase the burden on contractors and possibly limit rights. Are the changes the result of actual experiences or anticipated problems? Have rights been lost due to the 2 year election period, for example? Have there been difficulties getting contractor employees to sign documents, thereby warranting the revisions addressing that? Has the 30 day period for the Government to consider how to proceed if the contractor discontinues prosecution been a problem, triggering the 120 day proposal? Have there been parties who have taken title and “not” commercialized (per added §401.3(a)(6)), where march-in rights were not adequate? Because the revisions will have substantial impact on contractors, it would be helpful to know the reason(s) prompting the proposed revisions.*
- 3. While the Regulations include a definition of the key term “Contractor,” the provision that states what text must be included in the contractor agreement with the agency has no such definition. It is recommended that the “Definitions” section in §401.14, which includes the text to be imported into the contractor agreement, include a definition for “CONTRACTOR” (as including entities of any size, copying §401.2(b)).*

CONCLUSION

AIPLA appreciates the opportunity to provide Comments on the revisions proposed by NIST in this vital area. If further information or explanation would be helpful, AIPLA welcomes the opportunity to discuss these Comments with appropriate individuals at NIST.

Sincerely,

A handwritten signature in black ink that reads "Mark L. Whitaker". The signature is written in a cursive style with a large, prominent initial "M".

Mark Whitaker
President
American Intellectual Property Law Association

ATTACHMENT 1

Further to AIPLA's Comments in Paragraph 5, the impact of the AIA on the Patent Rights clauses that implement the Bayh Dole Act is discussed in a recently published treatise on the AIA. The relevant passages are as follows:

Through September 2015, the Patent Rights clauses that implement the Bayh-Dole Act have not been revised to reflect changes in the law made by the AIA. The Patent Rights clauses specify the specific periods for both reporting a Subject Invention to the U.S. government and filing a patent application directed toward the Subject Invention. For example, the Patent Rights clauses at 37 C.F.R. §401.14(c)(1) and Federal Acquisition Regulation (FAR) 52.227-11(c)(1) both require that a Subject Invention be disclosed to the U.S. government within two months after the inventor discloses it in writing to the contractor personnel responsible for patent matters. In addition, both 37 C.F.R. §401.14(c)(3) and FAR 52.227-11(c)(3) require that a U.S. patent application directed toward the Subject Invention be filed within one year from election of title. These times are extendable upon request to, and approval of, the Contracting Officer for the U.S. government R&D agreement.

A primary concern in the timely reporting of a Subject Invention and filing of a patent application directed toward the Subject Invention is to preserve the U.S. government's rights in the Subject Invention. Before the AIA, even if there was a sale, offer for sale, or disclosure of the subject matter related to the invention by the contractor, or a third party not more than one year from the effective filing date of a patent application directed toward the Subject Invention, the contractor could swear behind the sale, offer for sale, or disclosure. In the case of the third party the contractor's invention must predate the third party's sale, offer for sale, or disclosure. If a third party independently made the same invention, and filed his or her patent application before the contractor filed his or her patent application, an interference could be declared to determine who was the first to have made the subject matter, regardless of who was the first to file a patent application. These options available under pre-AIA law to preserve the U.S. government's rights in the Subject Invention may have made it more likely that the Contracting Officer of a U.S. government R&D agreement would have granted extensions of time for disclosing a Subject Invention to the U.S. government or for filing a U.S. patent application directed toward the Subject Invention.

After the AIA, the ability to swear behind certain prior art, or to have an interference declared has been eliminated. Although the post-AIA First-Inventor-to-File system provides some limited post-AIA Section 102(b)(1)(A) and (b)(1)(B) grace periods, to prudently pursue U.S. patent protection a patent application that describes and claims the Subject Invention should be filed as soon as practical to preserve the contractor's and the U.S. government's rights in the Subject Invention.

The Leahy-Smith Act made two changes to the Bayh-Dole Act, which is codified in 35 U.S.C. §§202 through 212. Sec. 3 of the Leahy-Smith Act amended Section 202(c) to conform to post-AIA 35 U.S.C. §102. First, Section 3(g)(7)(A) of the Leahy-Smith Act provided that the federal agency for the U.S. government R&D agreement may shorten the deadline for a written election for title to a subject invention to 60 days before the end of the one-year period in post-AIA Section 102(b). Further, the federal agency may

require that the contractor electing title agree to file a U.S. patent application prior to the end of the one-year period in post-AIA Section 102(b).

Patents After the AIA: Evolving Law and Practice (Alan J. Kasper *et al.*, AIPLA/Bloomberg-BNA 2016) Chapter 12, pp. 12-33:36 (footnotes omitted).