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Via: www.regulations.gov, Docket No. 201207–0327
Attn: Dr. James Olthoff
Director, National Institute of Standards and Technology
United States Department of Commerce
101 Bureau Drive
Gaithersburg, MD 20899

Re: Comments on Rights to Federally Funded Inventions and Licensing of Government Owned Inventions, in Response to Notice of Proposed Rulemaking at 86 Fed. Reg. 1 (January 4, 2021)

Dear Director Olthoff:

The Boston Patent Law Association ("BPLA") thanks the National Institute of Standards and Technology ("NIST") for the opportunity to respond to the Notice of Proposed Rulemaking ("NPR") for revisions to regulations promulgated under the Bayh-Dole Act. The BPLA is an association of intellectual property professionals, providing educational programs and a forum for the exchange of ideas and information concerning patent, trademark, and copyright laws in the First Circuit, focusing on the greater Boston area. These comments were prepared with the assistance of the BPLA's Patent Office Practice Committee and Licensing Committee. The BPLA submits these comments solely as its consensus view. They are not necessarily the views of any individual member, any firm, or any client.

We appreciate NIST's efforts to further return on investment for subject inventions developed under Federal funding agreements by revising regulations promulgated under Bayh-Dole in an attempt to add clarity for both contractors and Federal agencies. We offer these comments to assist NIST in evaluating how best to reach this goal through its rulemaking efforts.

I. Response to NPR

The NPR indicates that NIST's proposed revisions make technical corrections, reorganize certain subsections, remove outdated and/or unnecessary sections, institute a reporting requirement on Federal agencies,

and provide clarifications on definitions, communications, scope of march-in rights, filing of provisional patent applications, electronic filing, the purpose of royalties on government licenses, and the processes for granting exclusive, co-exclusive, and partially exclusive licenses, as well as for appeals. The proposed revisions to which the BPLA offers its comments are listed below.

1. NIST Should Clarify the Rules to Reflect that Filing More Than One Provisional Patent Application is Permissible Under Certain Circumstances

The NPR proposes amending the regulations to state that "[e]ach provisional application filed following the initial patent application must contain additional written description of the subject invention not previously disclosed in a patent application." *See* new proposed 37 C.F.R. § 401.14(c)(3)(ii). While NIST has previously characterized this amendment as a "clarification," the BPLA believes that the proposed amended regulations would remain unclear. *See* NIST, Notice of Proposed Rulemaking: Regulatory Updates to 37 CFR 401 and 404 (Feb. 25, 2021), https://www.nist.gov/document/bayh-dole-public-webinar, slide 21.

For example, existing regulations state that "if the contractor files a provisional application as its initial patent application, it shall file a non-provisional application within 10 months of the filing of the provisional application." 37 C.F.R. § 401.14(c)(i) (emphasis added). While the proposed amendments would clarify that this requirement is "[s]ubject to the grant of an extension by an agency," such an extension is limited to one year. *Id.* § 401.14(c)(5). As a result, filing of a provisional application more than 22 months after the filing of an initial application as a provisional application would appear to be a violation of the proposed regulations. Although NIST has explicitly recognized 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)," this implicit embrace of the strategy of filing of more than one provisional application (also known as "serial" or "rolling" provisional applications) does little to alleviate the contradiction that would be present in the proposed amended rules. *See* NIST, Bayh-Dole Regulations FAQs, https://www.nist.gov/tpo/bayh-dole/2018-bayh-dole-regulations-faqs.

For these reasons, the BPLA encourages NIST to clarify this practice by promulgating regulations that explicitly endorse the practice of filing serial provisional applications under certain circumstances. For example, NIST should consider amending the mandate to file a non-provisional application within 10 months of filing a provisional application as an initial patent application in 37 C.F.R. § 401.14(c)(i) to expressly indicate that this requirement may not apply when a subsequent provisional application is filed under the appropriate circumstances.

2. NIST Should Reconsider the Requirement that Subsequent Provisional Applications Include "Additional Written Description"

As discussed above, the NPR proposes amending the regulations to state that "[e]ach provisional application filed following the initial patent application must contain additional written description of the subject invention not previously disclosed in a patent application" at new proposed 37 C.F.R. § 401.14(c)(3)(ii). The BPLA believes that requiring the inclusion of undefined "additional written description" in subsequent provisional applications may run counter to the purposes of the Bayh-Dole Act by artificially accelerating the patent prosecution and disclosure process in a way that could prejudice further development and commercialization of the subject invention. In particular, this requirement fails to recognize that the contractor is often in the best position to determine when to begin the patent prosecution process to secure protection of the subject invention, and when additional time (e.g., to conduct further research or experiments, or to seek licensees) would ultimately be more likely to maximize return on investment.

For example, a contractor's initial efforts may trigger the requirement for disclosure of a subject invention to the Federal agency and subsequent filing of a provisional application as the initial patent application, but development of that invention may stall during the ensuing 10 months, causing the contractor to request an extension of the deadline to file a non-provisional application. In such a situation, where no intervening public disclosures exist to prejudice obtaining patent rights, the contractor may continue developing the invention, but have a need to re-file the same provisional application (i.e., without additional written description) in anticipation of a public disclosure that could prejudice patentability. The new rules as written would prevent such a filing, thereby jeopardizing the ability of the contractor to obtain patent protection.

The BPLA respectfully submits that this proposed change would have the effect of hampering commercialization and utilization of inventions arising from federally supported research or development in certain circumstances, which runs counter to the stated purpose of the Bayh-Dole Act. *See* 35 U.S.C. § 200.

3. Allowing Agencies to Waive the Requirement to Convey Title is a Welcome Change that NIST Should Consider Expanding

The BPLA welcomes NIST's proposal to explicitly allow Federal agencies, at their discretion, to waive the requirement for the contractor to convey title to any subject invention. *See* 37 C.F.R. § 401.14(d)(2). Waiver provides a mechanism for contractors to cure the potential cloud on title to subject inventions that was made possible by the previous amendments to the Bayh-Dole regulations. *See* NIST Final Rule at 83 Fed. Reg. 15954, 15962 (April 13, 2018)

(amending 37 C.F.R. § 401.14(d)(1) to remove the 60-day time limit within which a Federal agency must make written request to a contractor to convey title, after learning of the failure of the contractor to disclose an invention or elect title within the specified times). By permitting the waiver of so-called the "take title" provisions of Bayh-Dole, the proposed rules provide a path for a contractor that missed the deadline to disclose or elect title to a subject invention to clarify ownership, which can be a critical aspect of development and commercialization of a subject invention.

However, the BPLA suggests that NIST consider expanding this rulemaking by establishing additional scenarios in which a Federal agency can or must waive this requirement. Doing so would provide additional mechanisms to eliminate the possibility of a permanent cloud on title that is likely to hinder efforts to commercialize the subject invention and ultimately provide a return on investment, both to the contractor and the Federal agency. These concerns are particularly relevant for efforts to license or develop subject inventions in the life sciences area, as the value of those patent rights can be heavily dependent on the ability to provide certainty on not only the ability of the contractor to enter agreements, but also freedom to operate with respect to the subject invention.

The BPLA proposes the promulgation of additional rules to provide a path towards clearing that uncertainty in certain situations. For example, NIST could consider a rule that the Federal agency must respond to a contractor's request for waiver of the requirement for the contractor to convey title to the subject invention within a certain timeframe. As another example, NIST could engage in rulemaking setting forth certain circumstances where the agency is required to grant a request for waiver of the requirement for the contractor to convey title to the subject invention, such as where the contractor is able to demonstrate that its ability to commercialize, license, or further develop the subject invention has been or is reasonably expected to be hampered by the potential for the agency to later request title.

The BPLA believes that such additional regulation would further serve the purpose of the Bayh-Dole Act in promoting the commercialization and utilization of inventions arising from federally supported research or development, as well as the promotion of collaboration between commercial concerns and nonprofit organizations such as universities. *See* 35 U.S.C. § 200.

II. Conclusion

The BPLA appreciates the opportunity to respond to the NPR. Thank you in advance for your consideration of these comments.

Sincerely,

Boston Patent Law Association

By:

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