



## American Intellectual Property Law Association

February 4, 2019

Dr. Courtney Silverthorn  
Deputy Director  
Technology Partnerships Office  
National Institute of Standards and Technology (NIST)  
100 Bureau Drive MS 2201  
Gaithersburg, MD 20899

*Via email: roi@nist.gov*

Re: Additional Feedback on Draft Green Paper, Return on Investment Initiative for Unleashing American Innovation, December 2018

Dear Dr. Silverthorn:

The American Intellectual Property Law Association (“AIPLA”) is pleased to have the opportunity to present additional feedback on the U.S. Department of Commerce’s National Institute of Standards and Technology (“NIST”)’s draft green paper, *Return on Investment Initiative, Unleashing American Innovation*, NIST Special Publication 1234 released on December 6, 2018 (“the Draft Green Paper”). AIPLA appreciates NIST’s efforts to facilitate an open, honest discussion among technology stakeholders on how best maximize returns on taxpayer investment and make steps to pave the way for competition-driven technology advances that create value for our economy and society.

The American Intellectual Property Law Association is a national bar association of approximately 13,500 members 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. AIPLA’s mission includes helping governments establish and maintain effective policies and laws that will stimulate and reward invention while balancing the public’s interest in healthy competition, reasonable costs, and basic fairness.

### **Introduction**

On December 6, 2018, the Draft Green Paper was released based on wide ranging input from the public including: (1) responses to a Request for Information published in the Federal Register, (2) numerous public meetings; (3) multiple stakeholder engagement sessions and (4) input from federal stakeholders including the National Science and Technology Council’s (“NSTC”) Lab to Market Subcommittee. *See Draft Green Paper* at 20-23, fn. 15-23. While we understand that the Draft Green Paper is a discussion document and not a policy commitment or decision by the federal

government, we agree that implementation of certain actions that remove unnecessary obstacles and clarify ambiguity in our laws will advance science and technology in ways that enhance economic security and improve the quality of life.

Therefore, we encourage all efforts directed towards modernizing the U.S. system of technology transfer and innovation that has fueled the discoveries and inventions arising from federally funded R&D at our Nation's universities, research institutes and Federal Laboratories. As rightfully recognized in the Draft Green Paper, countless life changing technological advancements can be traced back to federal laboratories and federally funded R&D. Removal of barriers to promoting the innovations, however, should include clear guidelines, rules and procedures related to any government restrictions and/or interventions placed on intellectual property. Then, as a natural consequence and the product of the modernization efforts, America's competitiveness in the global market place will be strengthened and an increased investment of human and capital resources realized.

The Draft Green Paper sets out fifteen intended actions organized around the following five strategies: (1) identify regulatory impediments and administrative improvements in federal technology transfer policies and practices; (2) increase engagement with private sector technology development experts and investors; (3) build a more entrepreneurial R&D workforce; (4) support innovative tools and services for technology transfer; and (5) improve understanding of global science and technology trends and benchmarks. Each strategy chapter describes the challenges and the intended actions to streamline Federal technology transfer policies and practices, and to accelerate the transfer of technology to the private sector. These intended actions include policy guidance, statutory improvements, and clarification of regulatory changes.

As presented below, AIPLA has identified three of the fifteen intended actions having significant applicability to current market conditions as it relates to licensing intellectual property rights developed under Federally funded programs and efforts. For each of these intended actions, AIPLA addresses commercial aspects of obtaining clear license rights to use federally funded discoveries and the need to streamline allocating patent rights among the government, government employee, university, university employees, and government contractors and subcontractors. More specifically, with respect to the Regulatory and Administrative Improvements strategy, two of the three intended actions addressed below are (1) government use license and (2) march-in rights. These intentions can significantly impact whether a discovery can be further exploited through investment and subsequently brought to market. Also, with respect to the Regulatory and Administrative Improvements strategy, an overly broad mandate or preference to manufacturing domestically can increase barriers to innovation and economic growth. Therefore, a preference for US manufacturing must be considered in view of the global economy and the unique state of R&D across the many industries in the US.

***Intended Action 1. Define the scope of the “government use license” for use directly by the government - or a government contractor, in the performance of an agreement with the government - for a government purpose only such as continued use in research and development by the government. The scope of the government use license should be limited and not extend to goods and services made, sold, or otherwise distributed by third parties if the government - or a government contractor in the performance of an agreement with the government - does not directly use or consume those goods and services.***

#### A. UPDATE DEFINITION OF GOVERNMENT USE LICENSE FOR EXTRAMURAL R&D PROGRAMS

Implement regulatory change under Bayh-Doyle to (i) update the definition of government use license and its use directly by the government – or government contractor in the performance of an agreement with the government – for government purpose only and not for the use of a third party,<sup>1</sup> and (ii) clarify the appropriate processes and use of the government use right based on a consistent interpretation of the definition restricting scope of use.<sup>2</sup>

#### B. UPDATE DEFINITION OF GOVERNMENT USE LICENSE FOR INTRAMURAL AND PARTNERSHIP R&D PROGRAMS

As noted in the Draft Green Paper, the government use license permits the government to practice an invention stemming from funded research partnerships with Federal Laboratories and/or federally funded inventions produced by contractors and grantees, anywhere in the world, even if such use involves a different contractor. As a matter of policy, the primary benefit of the government use license is that the government can later utilize government funded research.

AIPLA agrees that a consistent and narrow construction of the government use license is aligned with the original intent of the Bayh-Dole Act to allow rights to be elected and retained by the contractor. AIPLA further agrees that an overly broad interpretation of this right is contrary to the original intent.

On the other hand, from the perspective of later advancing technology derived from government funded research and development, investors are often concerned about the various types of contracts entered into by the government. Such contracts can include research grant agreement,

---

<sup>1</sup> Insert new definition in 37 CFR § 401.2: “The term government use is defined as use directly by the government for a government purpose and the direct benefit of an agency, not to the benefit of a third party even if related to the government mission. Continued use in research and development by the government is included.”

<sup>2</sup> Insert new language into existing standard patent rights clause in 37 CFR § 401.14(b) “Allocation of Principal Rights” clause: “The government use license is restricted by the following conditions: (A) for use directly by the government or on behalf of the government for its own consumption or practice for its own direct benefit. (B) to continue to perform research. (C) This right does not extend authority to third parties to make, sell, or otherwise distribute goods and services as a commercial product where the government is not procuring the goods or services for its own direct use or consumption through a contract.”

procurement contracts and cooperative agreements. Therefore, AIPLA is supportive of the update presented to the definition of a government use license and agency rules related to the same.

Updating the definition and the rules to reduce and/or eliminate uncertainties by third parties who are willing to invest in further research and development activities is necessary to fully advance discoveries originally funded by the government. The scope of a government use license is often unclear as the process of allocating government funds for R&D is regulated by federal acquisition regulations, federal laws and executive orders, along with the policies and regulations of more than 25 different governmental agencies. Later determining who has the rights in and to a patent resulting from federal funded discoveries can be a complex problem. In investor negotiations, the government use license often generates uncertainty in the ownership rights to be transferred and can pose freedom to operate concerns, putting at risk investment and the advancement of the technology. In short, both the government use license and march-in rights can present a significant risk to the investment that investors cannot afford, and stifles technological advancements and commercialization of these discoveries.

Therefore, AIPLA supports defining the scope of the “government use license” with specificity so that the definition establishes certainty as to the rights held by the government. A third party contracting with the government to make or use a patented product developed with federal funds is not “government use” nor is it a “direct use” or “consumption” by the government. Therefore, AIPLA supports clarification of what is a direct use, or consumption, by the government of goods and services “made, sold, or otherwise distributed by third parties.” Knowing the boundaries of what the government can and cannot do with technology funded by the government provides certainty within the R&D community, streamlines the due diligence process for investors when examining new technology, speeds up the development of new technologies and will lead to more efficient commercialization of these technologies with affordable risks of investment.

Under the Bayh-Dole Act, each funding agreement with the Federal Government must contain a provision that grants the Federal Government a “nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world.”<sup>3</sup> Presently, neither the statutory language or the regulations implementing the Bayh-Dole Act provide any further definition or limitation on the Government’s retained right in an invention. The terms “government use” or “government use license” or “government use right” do not appear in the statute or regulations.

---

<sup>3</sup> 35 U.S.C. § 202(c)(4), relating to inventions made by contractors funded by the Federal Government *See also* 15 U.S.C. § 3710a(b)(1)(A), which implements the Stevenson-Wydler Act relating to inventions made during research partnerships with Federal Laboratories (“nonexclusive, nontransferable, irrevocable, paid-up license to practice the invention or have the invention practiced throughout the world by or on behalf of the government.”) and 15 U.S.C. § 3710d(a), relating to inventions made by government employees (“nonexclusive, nontransferable, irrevocable, paid-up license to practice the invention or have the invention practiced throughout the world by or on behalf of the Government”).

The Draft Green Paper proposes:

- a) implementing regulatory changes under the Bayh-Dole Act to:
  - i. provide a definition of government use; and
  - ii. clarify processes and use of the government use right; and
- b) implementing regulations under the Stevenson-Wydler Act<sup>4</sup> consistent with the changes proposed under the Bayh-Dole Act, immediately above.<sup>5</sup>

As mentioned, the Bayh-Dole regulations do not presently define “government use.” The lack of definition has created ambiguity and uncertainty about what the government could and could not do under the broad license language quoted above. Thus, AIPLA supports the Draft Green Paper’s proposal to expressly define and limit this term in the Bayh-Dole regulations.

Unfortunately, the language of the provisions proposed in the Draft Green Paper does not resolve that ambiguity. For example, the second sentence of the definition implies that the government use right is broader than “continued use in research and development by the government.” It is not immediately clear what uses other than use in R&D might be included within the right. Furthermore, despite the word “directly” in the first sentence, it is uncertain whether the right is limited solely to uses conducted by federal employees, or whether the use can be extended to third parties contracted by the government “for a government purpose and the direct benefit of an agency” in a circumstance in which such use does not benefit the contractor or other entity. The additional language proposed to be added to § 401.14(b) does not remedy these deficiencies. AIPLA suggests that NIST clarify these ambiguities before proceeding with regulatory changes.

For example, presently an antecedent is missing in the existing § 401.14(b) for “[t]he government use license.” Further, as to the proposed provisions, there are certain inconsistencies in language and meaning between the provisions, 37 CFR § 401.2 and 37 CFR § 401.14(b). However, each provision must be clear on its own and make sense when read together and within the existing Bayh-Dole Act regulations.

Therefore, consistency, meaning, and clarity could be improved if the proposed provisions as revised below were adopted:

---

<sup>4</sup> The 1980 Stevenson-Wydler Act was the first federal legislation relating to technology transfer from government laboratories to non-government entities.

<sup>5</sup> It is noted that authority to implement regulations under the Stevenson-Wydler Act would require legislative changes and that the Draft Green Paper discusses a legislative plan under Strategy 1, Section G (“Strengthen Technology Transfer at Federal Laboratories”).

37 C.F.R. § 401.2:

The term *government use license* is defined as a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States a subject invention throughout the world, subject to the following limitations: the use is directly by the government for a government purpose and for the direct benefit of an agency, not to the benefit of a third party even if related to a government mission; the use is to continue to perform research or development; and the license does not extend authority to third parties to make, sell, or otherwise distribute goods and services as a commercial product.

37 C.F.R. § 401.14(b)

The Contractor may retain the entire right, title, and interest throughout the world to each subject invention subject to ~~the provisions of this clause~~ a government use license and 35 U.S.C. 203. ~~With respect to any subject invention in which the Contractor retains title, the Federal government shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States the subject invention throughout the world.~~

AIPLA strongly supports the right of the Government to continue to use inventions created with Federal funding in its own continuing research and development, provided such use is solely for the benefit of a Federal agency and not for the benefit of a third party, or a person or entity that is not an agency of the Federal Government. New laws and rules to this effect must be written clearly and promulgated without ambiguity.

***Intended Action 2. Define the circumstances under which the government may exercise march-in rights consistent with the uses of march-in specified in statute and not as a regulatory mechanism for the Federal Government to control the market price of goods and services.***

The AIPLA supports NIST's efforts to define and clarify the circumstances under which the government may exercise its march-in rights, and the march-in rights processes and terminology. Under current statutory language (35 USC § 203), the government may compel action, or march in, to "require the contractor, an assignee or exclusive licensee of a subject invention to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants," and, if the contractor, assignee or exclusive licensee refuses, then the Federal Government can grant such license itself. However, initiating regulatory change is appropriate under the Bayh-Dole Act to make explicit that the use of march-in rights specified by statute are reserved for a compelling national issue or declared national emergency when other remedies have failed and not to affect pricing of goods and services or competition in the market.

Ambiguities and uncertainty over circumstances which trigger the exercise of march-in rights has contributed to the reluctance by investors to license and develop federally funded technologies, and can cause misuse of these rights. For example, as noted in the Draft Green Paper (*See* p. 30-32), the National Institutes of Health (NIH) has made determinations on six petitions asking the

government to exercise its march-in rights as a means to control pricing of pharmaceutical products. The federal agency involved denied each petition.<sup>6</sup> With respect to the life sciences industry, the use of march-in rights as a mechanism to control prices is inappropriate. Congress has created separate mechanisms for price control, namely, the Drug Price Competition and Patent Term Restoration Act (Public Law 98-417) of 1984, informally known as the Hatch-Waxman Act, and the Biologics Price Control and Innovation Act of 2009 (Public Law 111-148). Therefore, AIPLA advocates that any change to the Bayh-Dole regulations make explicit the use of march-in rights and that such rights be reserved for a compelling national issue or a legitimately declared national emergency and only after all other remedies have failed. More specifically, the regulations should be explicit: march-in rights are not to be used as a mechanism to control or regulate the market price of goods or services in the US or to control or regulate competition in the US.

The threat of march-in rights introduces uncertainty into the innovation systems and deters parties from investing in developments that the Bayh-Dole Act seeks to encourage. Before the Bayh-Dole Act, federal funds went into research and developments in order to advance the Nation's understanding and produce discoveries, but the government kept the practical application of the new knowledge contained. Government agencies, with limited capacity to do so, did not have the incentive to pursue further development and commercialization.

After Bayh-Dole and subsequent amendments, federally funded basic research discoveries could be put to practical use. Yet, march-in rights if used outside a very narrow statutory exception could remove the foundation of technology commercialization of federally funded inventions away from that which the Bayh-Dole's guarantees fostered. A march-in on any industry could cause a crisis in confidence for use of an intellectual property connected to federal funds, the effect being potentially far reaching and resulting in dangerous precedent. Abuse of patent rights could serve as a government control in any one of a variety of industries (i.e., government-rationed health care or government-regulated cellphone industry). The "march-in approach" of commercialized technologies would quickly dampen any private sector motivation to develop and advance federally funded discoveries.

Therefore, AIPLA supports the NIST recommendation to initiate regulatory change under the Bayh-Dole Act by specifying that march-in rights should not be used as a mechanism to control or regulate the market price of goods and services. Transparent definitions for "reasonable terms" and "practical terms" must provide certainty for investors and corporations involved in the technology transfer business.

***Intended Action 3. Protect and strengthen the statutory requirement that products embodying or using federally funded inventions be manufactured substantially in the United States. Streamline and implement a uniform waiver process government-wide in accordance with statutory requirements.***

---

<sup>6</sup> Four petitions specifically dealt with pricing of drugs, one dealt a first-to-market competitor seeking a license to avoid patent infringement, and one dealt with the inability of a manufacturer to supply the US market with a drug while it was experiencing complex, serious manufacturing issues that affected the safety of the drug.

The current statutory language relating to this issue is set forth in 35 USC § 204, as set forth below:

*35 USC 204 - Notwithstanding any other provision of this chapter, no small business firm or nonprofit organization which receives title to any subject invention and no assignee of any such small business firm or nonprofit organization shall grant to any person the exclusive right to use or sell any subject invention in the United States unless such person agrees that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States. However, in individual cases, the requirement for such an agreement may be waived by the Federal agency under whose funding agreement the invention was made upon a showing by the small business firm, nonprofit organization, or assignee that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible.*

AIPLA supports simplifying and clarifying the process of obtaining a waiver for the U.S. substantial manufacturing requirement. However, in seeking “uniformity,” care must be taken to avoid the new standard being applied in a more rigid and restrictive manner. The current system provides a certain level of flexibility to account for the varied circumstances specific to different technologies, manufacturing capabilities, etc., which is particularly relevant given the global nature of not only many companies, but our economy. This flexibility must be preserved in any system moving forward, otherwise the goal of “uniformity” may manifest itself as too restrictive, causing manufacturing requirements to act as a hurdle to bringing new technologies to market.

Similarly, the preference for U.S. manufacturing across all industries engaged in R&D is overbroad and fails to consider the unique state of R&D for many industries. Particularly, many companies utilize a global R&D approach to innovation to solve the world’s most complicated issues. This global and diverse R&D strategy provides an incredibly robust innovation ecosystem. Restricting manufacturing to U.S. manufacturers will increase the barriers to innovation. Many companies already must adhere to strict manufacturing requirements that are globally imposed by the Food and Drug Administration. Instead of this broad-brush approach that may stifle innovation, NIST should maintain the current statutory preference for US manufacturing to exclusive licenses that are not already subject to federal regulatory requirements regarding manufacturing processes.

Therefore, AIPLA supports Proposals A and B (Streamline the Waiver Processes) provided such streamlining is not intended to restrict obtaining waivers. On the other hand, AIPLA does not support Proposal C (Identifying the Pathway to Extended Preference for U.S. Manufacturing to Non-Exclusive Licenses) or Proposal D (Identifying the Pathway to Extended Preference for U.S. Manufacturing to All Contractors) as currently presented because companies often choose to invest in manufacturing plants outside the US or to contract for manufacturing outside the US for commercially reasonable reasons, such as cost, expertise, and tax benefits.



February 8, 2019

Page 9

AIPLA appreciates the opportunity to provide feedback on the Draft Green Paper and looks forward to continued dialogue with the NIST. If there are any questions regarding the above comments or the NIST would like to further discuss any of the topics in the Draft Green Paper, please let us know.

Sincerely,

A handwritten signature in blue ink, appearing to read "Sheldon H. Klein", with a stylized flourish at the end.

Sheldon H. Klein

President

American Intellectual Property Law Association