

IP HOT TOPIC

Biden Administration Proposes Framework for Exercising Bayh-Dole March-in Rights to Control Drug Pricing

- The National Institute of Standards and Technology (NIST) released a draft framework allowing the U.S. government to consider product pricing as a factor in whether to exercise “march-in” rights under the Bayh-Dole Act.
- NIST is currently accepting public comments until **February 6, 2024**.
- Stakeholders should monitor the comments and further action by NIST.
- Federal grant and CRADA recipients should exercise diligence in timely complying with Bayh-Dole requirements to avoid giving the federal government an easy opportunity to take title to patents.

The Biden-Harris Administration recently announced various actions to lower healthcare and prescription drug costs. In one action, the National Institute of Standards and Technology (NIST) released in December 2023 a draft framework on the U.S. government’s exercise of “march-in” rights. [Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights](#), 88 F.R. 85593 (Dec 08, 2023). “March-in” rights are provided in the Bayh-Dole Act at 35 USC § 203, and provide for the government’s ability to unilaterally sublicense privately-owned patents if such patents were created using government funding and the patent owner or its assignee has not taken steps to put the invention into practical application, to use the invention to alleviate health or safety needs, to meet requirements for public use specified by Federal regulations, or because the preference for U.S. industry has been breached or not met. NIST’s draft framework potentially expands the government’s discretion to “march-in,” a power that has previously never been employed. Most notably, this framework gives explicit permission for agencies to include product pricing in this discretion. *See id.*

at 85599.

The proposed framework requires that a federal agency consider three overarching questions before instituting march-in. First, the invention in question must be subject to Bayh-Dole, i.e., the presence of a federal funding agreement in the conception or reduction to practice of an invention. Second, and most extensively, statutory criterion must be met. Third, march-in must support the policy and objective of Bayh-Dole.

For inventions subject to Bayh-Dole, the Draft Framework provides numerous factors to consider for the second criteria, which relate to three areas of concern and seek to demonstrate how high pricing can lead to a finding that the government should march-in:

1. Practical Application. Here, the agency must consider if action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, “effective steps to achieve practical application of the subject invention in such field of use.” at 85598. “Practical application” is defined as utilizing the invention allowing the benefits to be available to the public on “reasonable terms,” The Draft Framework explicitly authorizes the agency to assess at what price and on what terms the product utilizing the subject invention has been sold or offered for sale in the U.S., and whether such a price is “unreasonably limiting availability of the subject invention to consumers or customers.” However, price is not the only factor to be considered. Other inquires include the “degree of investment, time, and regulatory requirements” needed to bring the product to market. *Id.*
2. Health and Safety Needs. The agency must seek a “clear picture of the health or safety need that is not being reasonably satisfied,” as well as how the product at issue addresses that need. at 85599. Is the Contractor or Licensee is “exploiting a health or safety need in order to set a price that is extreme and unjustified given the totality of the circumstances”? The Draft Framework mentions a “sudden, steep price increase” in response to a disaster as an area of concern. *Id.*
3. Public Use Requirements. The agency must evaluate whether any Federal regulations relate to the use of products commercialized from the subject invention, and whether the contractor or licensee has taken reasonable steps

to address any needs related to these Federal regulations, including “making the subject invention available to all that need it.” at 85599. Is there evidence that the contractor or licensee is “restricting access or imposing barriers to access”?

Furthermore, under the third criterion, a decision to march-in must support the policy and objective of Bayh-Dole—promoting “the development of new products” and their availability to U.S. consumers—and must be valued against potential negative effects such as chilling innovation and discouraging businesses from licensing technologies from institutions who frequently employ such funding agreements (e.g., universities). Alternative solutions to marching in must also be considered, such as allowing the contractor or licensee to take action to remedy the matter without the agency exercising march-in, or if the matter is a problem such as antitrust activity, fraud, or bankruptcy that would be best addressed by another governmental authority. *Id.* at 85600.

Finally, the Draft Framework contains seven hypothetical scenarios where march-in could occur. *Id.* at 85601. Several of these scenarios include pharmaceutical products.

NIST held a public webinar on December 13, 2023, to walk through the Draft Framework, the slides of which have been posted [here](#). NIST is currently accepting public comments until **February 6, 2024**, which can be posted [here](#). Particular areas of interest include: the clarity of the guidance and factors, the helpfulness of the provided definitions, areas of improvement for comprehension, the balance between public utilization of subject inventions against the central objection of encouraging development and commercialization, and applicability across all technology sectors and states of development. Currently, the posted comments express a wide range of viewpoints. Careful review of the Draft Framework and the submission of thoughtful comments is encouraged. Sterne Kessler will be following the issue and providing updates on this topic.

Patent owners and licensees should carefully review their practices and consider whether they are currently in compliance with Bayh-Dole obligations for government-funded inventions, including disclosure of the invention and prompt filing of an initial patent application. Notably, failure to comply with Bayh-Dole obligations places a patented invention at risk for the government to take title independent of the march-in considerations, as federal regulations treat failure to

comply with obligations similarly to a breach of contract. A discussion of such obligations can be found in a previous Sterne Kessler publication, "[Federally Funded Inventions and Compliance with the Bayh-Dole Act.](#)"

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