Client Alert: Product Pricing May Be Relevant When Federal Agencies Consider Exercising March-in Rights

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On December 7, 2023, the Biden-Harris Administration announced new actions intended to promote competition in health care and support lowering prescription drug costs for American families. Included in the announcement is the release of a draft framework for Federal agencies to facilitate their determination of whether they may exercise march-in rights with respect to taxpayer-funded drugs and other inventions. Under the draft framework, price may be a factor in considering whether a drug is accessible to the public.

Background

The University and Small Business Patent Procedures Act of 1980, commonly known as the "Bayh-Dole Act," reformed the way that intellectual property resulting from federally funded research is treated by allowing small businesses, non-profit organizations, and academic institutions to retain ownership of "subject inventions" arising from the performance of federally funded work, and also allowing the licensing of the rights to such subject inventions for commercial use. The Bayh-Dole Act also provides certain rights for the Federal government with respect to such subject inventions, including the Federal funding agency's right to require the contractor, an assignee, or an exclusive licensee of a subject invention to grant a license to responsible applicant(s) upon terms that are reasonable under the circumstances, and if the contractor, assignee, or exclusive licensee refuses such request, for the Federal funding agency to grant such a license itself — the so called "march-in right."

What Steps Need to be Met?

The Bayh-Dole Act provides the Federal government the right to exercise its march-in right if the Federal funding agency determines that one or more of the statutory criteria set forth below have been met and action is necessary:

1. because the contractor has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in the requested field of use;
2. to alleviate health and safety needs which are not reasonably satisfied by the contractor;
3. to meet requirements for public use specified in Federal regulations and such requirements are not reasonably satisfied by the contractor; or
4. because the agreement required has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of its agreement.

To date, no Federal government agency has ever exercised its march-in rights.

As part of the Administration's announcement, the United States Department of Commerce's National Institute of Standards and Technology (NIST) released for public comment its *Draft*

Interagency Guidance Framework for Considering the Exercise of March-In Rights, to provide guidance to Federal funding agencies in their evaluation of factors to consider in their determination of whether any of the statutory criteria set forth above have been met. The draft framework provides that product pricing may be a relevant factor to be considered in determining whether certain statutory criteria have been met, and directs Federal funding agencies to consider the price and terms under which the product utilizing the subject invention has been sold or offered for sale in the United States.

What's Next?

Adoption of the draft framework and the consideration of price as a factor in determining whether the statutory criteria have been met would represent the most significant expansion of Federal march-in rights since the enactment of the Bayh-Dole Act and will continue to be monitored by Morse for further developments. The public comment period will close at **5:00 PM EST on February 6, 2024**.

If you have questions regarding this topic, please reach out to Stan Chalvire or a member of Morse's Life Sciences Industry team.

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