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FTC Promotes Next Front in Administration's Efforts to Lower Pharmaceutical Prices: Bayh-Dole Act's "March-In" Rights

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The U.S. Federal Trade Commission (FTC) took the next step in its long-standing effort to encourage lower prices and increase competition in the pharmaceutical industry. As part of the Biden administration's whole government approach to antitrust, the FTC announced its support for the National Institute of Standards and Technology (NIST) and the Interagency Working Group for Bayh-Dole on their *Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights* (Draft). The FTC described the Draft as an "effort[] to reactivate an important check on companies charging Americans high prices for drugs that taxpayers funded."

According to U.S. Secretary of Commerce Gina Raimondo, "The Bayh-Dole Act is an important tool for fostering U.S. innovation and the commercialization of inventions that come from federally funded research and development" and the Draft seeks to "maintain a balance between incentivizing companies to innovate and making sure those innovations serve the American people." This newfound enthusiasm for march-in rights is a departure from the federal government's track record, considering that march-in rights have never been exercised in their 40 years of existence.

The Bayh-Dole Act

Under the Act, in exchange for private entities receiving federal funding and retaining ownership of resulting inventions, the federal agency funders reserve the right to march in on patents arising from taxpayer funds. These march-in rights allow government agencies to require patent holders to license certain federally funded patents to responsible applicants — including licensing a competitor to produce the taxpayer-funded invention. Under the Act, a funding agency may exercise march-in rights where: (1) "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"; (2) "health or safety needs … are not reasonably satisfied by the contractor, assignee, or their licensees"; (3) "requirements for public use specified by Federal regulations … are not reasonably satisfied by the contractor, assignee, or licensees"; or (4) the subject invention will not be manufactured in the United States.

The Draft provides that agencies should consider three overarching questions: (1) whether Bayh-Dole applies to the invention(s) at issue; (2) whether any of the four statutory criteria for exercising march-in rights (set forth above) apply; and (3) whether the exercise of march-in rights would support the policy and objectives of Bayh-Dole. Although neither the four statutory criteria for exercise of march-in rights nor the Draft focus directly on price, the Draft discusses several scenarios where price could be relevant to an agency's march-in decision. For

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example, the Draft suggests that an unreasonably high price — or other unreasonably arduous terms of access to the product — may amount to "nonuse or unreasonable use" of the subject patent.

The agency praises the Draft for its more concrete guidance on when the government should exercise its march-in rights and argues that, under the Draft, price alone is an appropriate basis for marching in. The agency explains that, in prescription drug markets where pricing is buoyed by a sponsor with patent rights over a government-funded invention, exercising march-in rights and enabling additional licensees to access the inventions can foster competition and provide a check on high drug prices that can limit access. Specifically, the FTC asserts that march-in rights are "an essential check to ensure that taxpayer-funded inventions are affordable and accessible to the public."

FTC Urges Agencies to Collaborate on Governmentwide Strategies

The FTC's comments go beyond promotion of the Draft and march-in rights. In addition to encouraging the exercise of march-in rights based on high prices, the agency argues that governmentwide solutions are required to address pharmaceutical companies' use of large patent portfolios — often described as a "patent thicket" — to protect a single treatment. The agency expressed concern that the effectiveness of march-in rights could be limited where publicly funded patents are included in unnecessary patent thickets.

According to the FTC, patent thickets do not necessarily reflect true innovation and pharmacological advancement and can impede competition and delay generic or biosimilar entry even where some component patents are invalid. The comments urge agencies to work collaboratively to also address such patent thickets.

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