Published on *The National Law Review* https://natlawreview.com

Mintz IRA Update — Biden Administration Proposes Allowing Agencies to 'March-In' to Control Rising Drug Prices

Article By:

Madison M. Castle

Abdie Santiago

Stephnie A. John

The Biden administration appears steadfast in its efforts to lower prescription drug costs and continues to explore multiple avenues — even as the Medicare Drug Price Negotiation Program continues to move forward — to tackle high drug prices. In fact, the administration's latest attempt to lower drug prices received criticism from industry stakeholders raising similar arguments to those criticizing the Medicare Drug Negotiation Program, namely that such changes would only serve to stifle innovation, research, and development.

One example of the administration's multi-pronged approach is the Request for Information (RFI) on *Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights* ("Draft Guidance"), which was issued by the US Department of Commerce's National Institute of Standards and Technology (NIST) on December 8, 2023. The Draft Guidance provides government agencies with policy considerations when deciding to enforce government march-in rights, which give federal agencies, under certain circumstances, the ability to require patent licenses be given to third parties if a product was developed or conceived with the assistance of federal funding. To date, the government has never exercised its march-in rights.

History of "March-in Rights"

The Bayh-Dole Act of 1980 ("the Act") broadly grants entities, such as drug manufacturers and academic institutions, the ability to patent inventions developed with NIH or federal grant funding. However, the Act also allows the government to exercise "march-in" rights under certain circumstances, if needed, in connection with licensing or commercialization efforts of those patented inventions. In order to meet the threshold for exercising march-in rights under the Act, the government must prove one of the following four criteria:

1. that the action is necessary because the contractor or assignee has not taken, or is not expected to take, effective steps to achieve practical application of the invention,
2. that the action is necessary to alleviate health or safety needs that are reasonably satisfied by

the contractor, assignee, or their licensees,
3. that the action is necessary to meet requirements for public use, specified by federal regulations, or
4. that the action is necessary because the inventor-contractor did not use or sell the invention in the US, in breach of agreement with the US

Proposals and Reception to Draft Guidance

The Draft Guidance sets forth specific factors and hypothetical scenarios to assist agencies in determining whether (i) any of the four statutory criteria is met and (ii) the agency should exercise its march-in rights under the Act. Factors that an agency may consider include the reasonableness of pricing, and whether the march-in would be necessary to alleviate health or safety, meet public use and access requirements, achieve practical application, and/or meet manufacturing requirements. The Draft Guidance's proposed framework also calls upon agencies to determine both the practical and potential impact of march-in on the broader research and development ecosystem.

The Biden administration, on one hand, notes in its announcement that this is the first time a presidential administration has asserted that price be a consideration in analyzing whether a drug or any other commercial product derived from a taxpayer-funded invention warrants march-in rights under the Act. Laurie E. Locascio, Director of NIST, stated that the Draft Guidance resulted from a "consensus-based, interagency collaboration to bring consistency and transparency to the march-in decision making process." Director Locascio further stated that the goal is to "set up agencies for success in these decisions and effectively support the policy and objectives of Bayh-Dole."

On the other hand, the Pharmaceutical Research and Manufacturers of America (PhRMA) trade group released a statement that the Draft Guidance is "a road map for seizing patents" and "another loss for American patients and inventors."

The 60-day comment period for the Draft Guidance closed on February 6, 2023 and we will provide updates on the Draft Guidance in our future editions.

National Law Review, Volume XIV, Number 197