

April 17, 2024

Assistant General Counsel for Employment, Litigation and Information
U.S. Department of Commerce
Office of the General Counsel, Room 5896
1401 Constitution Ave., NW
Washington, D.C. 20230

RE: Freedom of Information Appeal in No. DOC-NIST-2024-000072

Dear Sir/Madam:

Pursuant to 15 C.F.R. §4.10, the Chamber of Commerce of the United States of America appeals the determination of the Freedom of Information Act Officer (dated January 18, 2024) regarding the Freedom of Information Act (“FOIA”) request identified above (dated January 9, 2024).

The Chamber submitted the following request for records relating to the Interagency Working Group for Bayh-Dole (“Working Group”) referenced in the Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights, 88 Fed. Reg. 85593 (Dec. 8, 2023):

1. The name, title, and organizational affiliation of each person who served as a member of the Working Group at any time between January 20, 2021, and the date of processing this request;
2. The resume or CV for each person who served as a member of the Working Group at any time between January 20, 2021, and the date of processing this request;
3. Minutes of every Working Group meeting that took place between January 20, 2021, and the date of processing this request;
4. The agenda of every Working Group meeting that took place between January 20, 2021, and the date of processing this request, and any other documents or records attached to that agenda or distributed with that agenda;
5. All communications since January 20, 2021, between (a) any person who served as a member of the Working Group at any time between January 20, 2021, and the date of processing this request, and (b) any staff member, employee, or representative of the Office of Senator Elizabeth Warren or the Office of Senator Bernie Sanders;
6. All communications since January 20, 2021, between (a) any person who served as a member of the Working Group at any time between January 20, 2021, and the date of processing this request, and (b) any staff member, employee, or representative of Knowledge Economy International (KEI), the Initiative for Medicines, Access, and Knowledge (I-MAK), the Center for American Progress, Patients for Affordable Drugs, or Public Citizen.

Ex. A, at 1 (FOIA Request). The Chamber requested expedited processing of that request pursuant to 15 C.F.R. § 4.6(f)(1)(iv) because “there is an urgency to inform the public about the federal

government’s activities—namely, the composition, activities, and influences on the Working Group.” *Id.*

On January 18, 2024, the Freedom of Information Act Officer asserted that the Chamber’s request did not qualify for expedited processing under 15 C.F.R. § 4.6(f)(1)(iv) because “there is no ‘urgency’ to inform the public of the information you requested.” Ex. B, at 2 (Denial Letter). The denial of § 4.6(f)(1)(iv)’s applicability did not rely on any other basis, such as a finding that the request did not relate to “actual or alleged Federal Government activity” or that the request was not “made by a person primarily engaged in disseminating information.” 15 C.F.R. § 4.6(f)(1)(iv).

The Denial Letter should be reversed due to the demonstrated and admitted urgent need to inform the public about the Executive Branch’s plans to assert march-in rights and confiscate the intellectual property of American businesses under the Bayh-Dole Act.

The records sought pertain to the Biden administration’s announced plan to exercise march-in rights under the Bayh-Dole Act. That never-before-used provision would permit the government to override property rights and confiscate business patents to impose price controls on any product which the government believes to be overpriced. That is a matter of extraordinary significance, as it would be the first such use of this law and would override private property rights on valuable patents responsible for thousands of innovative products. Not only would that devastate the settled expectations of the innovators who engineered these products, it would also fundamentally alter the economic framework for investment in future innovation. And the proposed price-based exercise of march-in would also violate the plain text and legislative history of the Bayh-Dole Act. For these reasons, the development and implementation of the administration’s march-in proposal—including information relating to the composition of the Working Group and its communications—are a matter of high importance to the business community and the public.¹

The importance of the prospective exercise of march-in is matched only by the immediacy of the concern. NIST has already closed comments on its December 8, 2023, Request for Information regarding the Working Group. Those comments will “inform NIST and the [Working Group] in developing a final framework.” 88 Fed. Reg. at 85593. That means the Working Group is already presumably finalizing the framework for the exercise of march-in, even as the public has no access to information about the continued operations or considerations of the Working Group. The relevance of information about the Working Group is at its height right now, while the public still has a chance to influence those operations and considerations. If, for example, the requested records reveal communications that undermine the legitimacy of the Working Group’s operations, it will become only harder to cure such problems once the Working Group has finished the final march-in framework. The Department should want this information made public as soon as possible, and the private sector and general public need this information made public as soon as possible.

It would be difficult to accept the conclusion that there is no urgent need for public information regarding the prospective exercise of march-in, given the Department’s own assertions that march-in is a subject of high public significance that needs public engagement. Secretary Raimondo described the Bayh-Dole Act as “a cornerstone of our innovation system in the U.S.” that requires “a successful balance” of “the interests of the taxpayer, government, and the private

¹ These matters are discussed in further depth in the Chamber’s comment letter, <https://www.regulations.gov/comment/NIST-2023-0008-0769>.

sector”²—the taxpayers and the private sector being two overlapping groups that have no access to information about the Working Group. Secretary Raimondo later said that any exercise of march-in needs “continued stakeholder input,” including on how to continue “incentivizing companies to innovate.”³ The composition of the Working Group and its activities are crucial information for effective stakeholder input. Having highlighted the importance of any exercise of march-in for the general public and for the private sector, Secretary Raimondo and the Biden Administration cannot now assert there is no urgent public need for information about that process.

The White House, too, has emphasized its belief that the potential exercise of march-in is an urgent issue for the general public. The White House in December cited the proposed march-in framework as its signature action to “support lowering prescription drug costs and increase Americans’ access to life-saving medications.”⁴ The President took to the social media platform X in a video declaring that this was “a very important step toward ending price-gouging,” stating in the accompanying text that this proposal was “good for competition,” “good for the economy,” and “good for ... millions of Americans.”⁵ In selling the proposal to the press, the director of the National Economic Council told reporters that the administration’s work on march-in was meant to “make clear” that the government will “allow other companies to provide those drugs for less.”⁶ President Biden dedicated a significant portion of his 2024 State of the Union address to declaring that he “finally beat Big Pharma” by passing a law allowing the government to set drug prices,⁷ and he has since declared that with the exercise of march-in he “can do it again.”⁸ Given the White House’s express statements that they consider the potential for march-in an issue of paramount importance for the public, it would be inconsistent for the executive branch to conclude now that the public has no urgent need for information regarding those anticipated actions. If President Biden claims to be using march-in to “beat Big Pharma,” the administration cannot now disclaim that pronouncement.

The significant media coverage of the administration’s march-in proposal further highlights the urgency to inform the public. *See* 15 C.F.R. § 4.6(f)(3) (“The existence of numerous articles published on a given subject can be helpful to establishing the requirement that there be an ‘urgency to inform’ the public on a topic.”). The media reaction to the prospect of march-in has been intense and negative. It has prompted news stories and opinion pieces in outlets like the Wall Street Journal,⁹

² <https://www.commerce.gov/news/press-releases/2023/03/hhs-and-doc-announce-plan-review-march-authority>

³ <https://www.nist.gov/news-events/news/2023/12/nist-releases-public-comment-draft-guidance-march-rights>

⁴ <https://www.whitehouse.gov/briefing-room/statements-releases/2023/12/07/fact-sheet-biden-harris-administration-announces-new-actions-to-lower-health-care-and-prescription-drug-costs-by-promoting-competition/>

⁵ <https://twitter.com/POTUS/status/1732759511629173221>.

⁶ <https://thehill.com/homenews/administration/4346435-white-house-announces-ready-to-deploy-march-in-rights-high-drug-prices/>

⁷ <https://www.whitehouse.gov/briefing-room/speeches-remarks/2024/03/07/remarks-of-president-joe-biden-state-of-the-union-address-as-prepared-for-delivery-2/>

⁸ <https://twitter.com/POTUS/status/1733884071808287126>

⁹ <https://www.wsj.com/articles/biden-decides-to-march-in-on-drug-patents-price-control-biotech-research-3e327f6b>; <https://www.wsj.com/articles/biden-ambushes-pharma-patents-30a71b62>.

Politico,¹⁰ NPR,¹¹ the Hill,¹² Forbes,¹³ Reuters,¹⁴ RealClear Health,¹⁵ and others.¹⁶ And the Chamber's own FOIA request has prompted news coverage as well.¹⁷ This media coverage makes more than clear that the prospective exercise of march-in is a matter of grave importance, and one on which the public has an urgent need for more information.

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For the foregoing reasons, the Chamber requests that you reverse the Denial Letter and order the expedited processing of the Request.

Sincerely,



Senior Vice President
Global Innovation Policy Center
U.S. Chamber of Commerce

¹⁰ Adam Cancryn, *Targeting costly meds, Biden admin asserts authority to seize certain drug patents*, Politico, <https://www.politico.com/news/2023/12/06/biden-admin-authority-seize-certain-drug-patents-00130452>.

¹¹ Sydney Lupkin, *White House proposes to 'march in' on patents for costly drugs*, NPR, <https://www.npr.org/sections/health-shots/2023/12/07/1217882958/white-house-proposes-to-march-in-on-patents-for-costly-drugs>.

¹² Joseph Choi, *Biden administration threatens seizure of US-funded drug patents if prices too high*, The Hill, <https://thehill.com/homenews/administration/4346435-white-house-announces-ready-to-deploy-march-in-rights-high-drug-prices/>.

¹³ Joshua Cohen, *Biden Administration says it plans to use march-in rights for drugs to lower prices*, Forbes, <https://www.forbes.com/sites/joshuacohen/2023/12/07/biden-administration-says-it-plans-to-use-march-in-rights-for-drugs-to-lower-prices/?sh=a80941f389aa>.

¹⁴ Patrick Wingrove, *US sets policy to seize patents of government-funded drugs if prices deemed too high*, Reuters, <https://www.reuters.com/business/healthcare-pharmaceuticals/us-sets-policy-seize-government-funded-drug-patents-if-price-deemed-too-high-2023-12-07/>.

¹⁵ Robert Taylor, *Our nation must reject Biden Administration overreach on march-in rights*, RealClear Health, https://www.realclearhealth.com/blog/2024/03/13/our_nation_must_reject_biden_administration_overreach_on_march-in_rights_1017906.html.

¹⁶ See, e.g., Kathryn Palmer, *Lawmakers side with universities against proposals that could 'chill' research partnerships*, Inside High Ed, <https://www.insidehighered.com/news/government/science-research-policy/2024/02/28/lawmakers-oppose-allowing-seizure-federally>.

¹⁷ Caitlin Oprysko, *Chamber launching a coalition to oppose march-in proposal*, Politico, <https://www.politico.com/newsletters/politico-influence/2024/03/19/chamber-launching-a-coalition-to-oppose-march-in-proposal-00147859>; Eileen McDermott, *Chamber's GIPC wants details on Bayh-Dole Working Group*, IPWatchdog, <https://ipwatchdog.com/2024/01/10/chambers-gipc-wants-details-bayh-dole-working-group/id=171833/>.