HEALTHCARE LEADERSHIP COUNCIL

February 1, 2024

National Institute of Standards and Technology
ATTN: Laurie E. Locascio
100 Bureau Drive
Gaithersburg, MD 20899

RE: NIST Docket ID No. 230831-0207

Dear Under Secretary Locascio:

The Healthcare Leadership Council (HLC) writes to express profound concern regarding the Biden administration's proposed march-in framework. It is our view that "reasonable" drug pricing does not constitute an appropriate criterion on which the government may exercise march-in rights. Further, this change in policy would hinder innovation and would not accomplish its goal of reducing pharmaceutical prices.

HLC is a coalition of chief executives from all disciplines within American healthcare. It is the exclusive forum for the nation's healthcare leaders to jointly develop policies, plans, and programs to achieve their vision of a 21st century health system that makes affordable, high-quality care accessible to all Americans. Members of HLC – hospitals, academic health centers, health plans, pharmaceutical companies, medical device manufacturers, laboratories, biotech firms, health product distributors, post-acute care providers, home care providers, and information technology companies – advocate for policies that increase the quality and efficiency of healthcare by ensuring the development of new and improved lifesaving, life-enhancing medical innovations.

The Bayh-Dole Act's march-in provision (35 U.S.C. § 203) names four specific reasons for the government's use of march-in rights. None states or implies product price. Senators Birch Bayh and Robert Dole deliberately excluded product price as a criterion for march-in. "Bayh-Dole did not intend that government set prices on resulting products. The law makes no reference to a reasonable price that should be dictated by the government," Senators Bayh and Dole wrote in the Washington Post. "This omission was intentional; the primary purpose of the act was to entice the private sector to seek public-private research collaboration rather than focusing on its own proprietary research."[1] Notably, the proposed march-in framework does not specify what constitutes a "reasonable price," instead giving different agencies the broad discretion to define it as they see fit.

[1] https://www.washingtonpost.com/archive/opinions/2002/04/11/our-law-helps-patients-get-new-drugs-sooner/d814d22a-6e63-4f06-8da3-d9698552fa24/

Heightened risk that the government will exercise march-in rights on extra statutory grounds will reduce medical (and other) innovation. Diminished investment in this research and development translates into a much smaller pipeline of new therapies vying to enter the market, reducing both medical progress and product competition. This will ultimately result in fewer options for patients and providers, over time putting brakes on improvements in clinical outcomes and causing increased health costs in other medical services necessitated to compensate for the absence of novel therapies and curative treatments.

Fewer new medicines being commercially developed and marketed will reduce the candidates for generic drugs, which represent 90 percent of U.S. prescriptions and contribute to health cost savings without endangering incentives to innovate. That virtuous circle will suffer once Bayh-Dole's intellectual property-centered innovation model is tainted with march-in based on end-product price. Injecting price into march-in decision-making will undoubtedly curb the practical benefits the public enjoys from taxpayer-funded research. The proposal will effectively return to how things stood in 1980, when the federal government owned 28,000 patents and less than 5 percent of them were licensed to attempt their commercialization.

Moreover, the proposal will likely fall short of its stated goals. A new study from Vital Transformation found that 90 percent of pharmaceuticals would not be eligible for march-in rights and thus be unaffected by the proposed framework.[2] This is because "there are only 5 out of 361 pharmaceutical products in which all available MoA (mechanism of action) and CoM (composition of matter) patents include a government interest statement and could be subject to march-in rights."[3] Those few drugs eligible under the Bayh-Dole framework are largely from startups, indicating this will disproportionately draw new investments away from that segment of the industry, while failing to lower current consumer prescription costs.

Further, the framework, which disrupts the settled Bayh-Dole equilibrium, would not only affect pharmaceutical patents; it would have broad impacts on all patents, including innovations in other technologies. The framework would give the government free range to march in on any invention proceeding from government-funded research. If put into practice, the framework will widely hamper innovation and create uncertainty for IP of all kinds, including vital medical technologies apart from and in addition to pharmaceutical patents. Not only biomedical, but other areas of invention and patents in emerging fields of technology (e.g., quantum computing, artificial intelligence, semiconductors) would become less attractive to private investment. With weakened IP, high-risk, high-reward innovative efforts that take many years to develop into products and commercialize would suffer and shrink as a result of undermining Bayh-Dole.

Were march-in to become allowed because of an eventual product's price, billions of private dollars of risk capital and cutting-edge innovation would be redirected to projects with less tenuously held IP. Price-based march-in will essentially defund the applied research and development that is crucial for future breakthroughs and critical for U.S. competitiveness with competitors such as China.

---

[2] https://vitaltransformation.com/2023/11/march-in-rights-under-the-bayh-dole-act-nih-contributions-to-pharmaceutical-patents/

[3] https://ipwatchdog.com/2023/12/10/new-march-guidelines-threaten-u-s-innovation/id=170491/#

Thus, the proposed dramatic shift in the grounds for march-in holds serious consequences for U.S. innovation leadership, economic and national security, and lost U.S. jobs in leading sectors of our innovation economy, beginning with the biopharmaceuticals sector. It puts patients around the globe in danger. And it reduces the amount of innovation that IP-based industries and commerce produce, which serves the interests of humanity and raises standards of living.

The present request for information on draft guidance cites a 2021 proposed rule (NPRM) request for comments, "including [on] a provision related to march-in rights which stated that march-in 'shall not be exercised exclusively based on the business decisions of the contractor regarding the pricing of commuercial goods and services arising from the practical application of the invention." That withdrawn rule broke with the Bayh-Dole statute. The current proposal goes even further in the wrong direction.

In a Dec. 20, 2023, letter, Sen. Thom Tillis (R-NC), Ranking Member of the Senate Intellectual Property Subcommittee, writes," [M]arch-in' was never intended to serve as a mechanism for regulating the pricing of any products. The law makes no reference to a 'reasonable price' that should be dictated by the government, and this omission was intentional." Sen. Tillis points out that in Bayh-Dole's entire existence, the National Institutes of Health under the leadership of administrations of both political parties has denied every pricing-related march-in petition.[4] The proposal would upend more than 40 years of precedent that has led to extensive practical public benefit from eventual commercialization of basic research discoveries arising from a modicum of federal funding. This record of positive results now stands at risk of disappearing.

It is for these reasons that HLC strongly urges NIST to reconsider the proposed march-in framework. Enacting such a framework would do great harm that would far outweigh any marginal good envisioned.

Sincerely,

Maria Ghazal
President and CEO

[4] https://ipwatchdog.com/wp-content/uploads/2023/12/Letter-to-the-WH-on-the-Bayh-Dole-Act-Final.pdf