February 5, 2024

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

Dear Director Locascio:

As a scholar and professor of patent law and innovation policy, I respectfully submit this comment in response to the National Institute of Standards & Technology (NIST) Request for Information on the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights (Framework). I am writing to express concerns with both the legality and prudence of the Framework. Specifically, I'd like to draw your attention to how the Framework would violate long-standing legal precedent and jeopardize the role of American research universities in propelling innovation.

It is impossible to overstate the importance of strong and predictable intellectual property rights. Reliable patent law catalyzes innovation, incentivizing our brightest minds to break new technological ground with the assurance that they will have reliable and effective property rights in their inventions. These property rights then allow for further investment in research, as well as development of new products and services that are then available on the market.

By allowing universities to retain the intellectual property rights to their federally-funded research and license those patents to the private sector, the Bayh-Dole Act has enabled research institutions to produce nearly 500,000 unique inventions and secure over 125,000 U.S. patents. Public-private partnerships have also been responsible for over 200 drugs and vaccines.[1]

Bayh-Dole has also grown our economy. All told, academic discoveries licensed through tech transfer systems enabled by Bayh-Dole have contributed nearly $2 trillion to U.S. gross industrial output and $1 trillion to U.S. GDP. Over 17,000 startups have formed as a result of the licensing of publicly-funded research.[2]

Despite the positive outcomes associated with Bayh-Dole, this basic model has angered activists who believe that when the government helps pay for the development of a drug or other product, "taxpayers shouldn't pay twice" – once to help develop the product and again to purchase the drug when it comes to market. These critics mislead the public regarding government support of scientific research.

While it's true that government agencies like the National Institutes of Health (NIH) provide valuable support to biopharmaceutical research by backing a lot of basic science, the private sector alone invents, develops, and commercializes novel compounds.

[1] https://autm.net/AUTM/media/Surveys-Tools/Documents/AUTM-Infographic-22-for-uploading.pdf
[2] https://autm.net/AUTM/media/Surveys-Tools/Documents/AUTM-Infographic-22-for-uploading.pdf

Consider a recent analysis from Vital Transformation. In a review of novel patented medicines approved by the Food and Drug Administration between 2011 and 2020, it found that industry funding for the medicines was $44.3 billion, compared to just $276 million from U.S. government. Tellingly, 99% of the medicines analyzed "cannot be marched-in upon [under Bayh-Dole], as the key patents studied do not cover the entire asset's intellectual property."[3]

Arguing that *any* amount of public funding for a drug justifies the government stepping in – either to set an "equitable" price or take ownership outright – is akin to arguing a novel should belong to the government and be free to the public because a public school teacher taught the author how to write.

To use another example, taxpayers fund all sorts of activities for the public good. Every day, Americans drive to work and ship their products on roads built with public funds. Our government built those roads for our collective benefit – but not so that it can lay claim to the specific fruits of our labor. Instead, it takes its "share" by taxing our income and our profits.

Similarly, the federal government supports basic research at universities and nonprofit labs across the country. When this work yields a critical new insight, the scientists involved typically seek a patent to protect their discovery; however, they also will seek private capital to fund serious, applied research and development to create a marketable product.

Far from "paying twice," we are getting a great bargain from government spending on basic research. The Milken Institute estimates that the long-term boost to total economic output could be as high as $3.20 for every dollar the NIH invests in biopharmaceutical research.[4]

For more than four decades, venture capital has freely flowed to companies licensing federally supported university research because of the Bayh-Dole Act and effective and reliable patent rights.

The new Framework introduces enormous unpredictability to this system. It could empower large corporations to harass smaller innovators – and will certainly deter companies from licensing federally funded research more broadly.

Because the Framework places no strictures on who may file a march-in petition, a multi-billion dollar company could petition the National Institutes of Health to march in on patents licensed by a small biotech. The corporate giant, with its robust global infrastructure, could justify this by simply arguing that it can manufacture and distribute the drug at a lower cost than the small biotech.

Such potential for abuse would drive investors to avoid collaborating with smaller companies that license federally backed research for fear that their patents can be effectively nullified at any time. As a result, university research will struggle to find a path to commercialization. Countless

[3] https://vitaltransformation.com/wp-content/uploads/2023/11/march-in_v11_BIO-approved-30Nov2023.pdf

[4] https://milkeninstitute.org/sites/default/files/2023-02/Ross%20and%20Anu%20NIH%20Report.pdf

promising discoveries will instead languish in obscurity, as was the case with 95% of federally owned patents prior to the Bayh-Dole Act.

The text of the law is clear. There is no mention of price. It is not one of four delineated triggers for march in.

Moreover, both Senators Bayh and Dole publicly confirmed that the omission of price was intentional. "The law makes no reference to a reasonable price," they wrote in 2002. "The ability of the government to revoke a license granted under the act is not contingent on the pricing of a resulting product."

In its public announcement about this Framework, the White House claimed it would "Lower Health Care and Prescription Drug Costs by Promoting Competition." There is no evidence to support this claim. But there is ample reason to believe this radical re-interpretation of Bayh-Dole would stifle the development of life-saving medicines in the first place.

Virtually every high-tech sector would incur similar consequences. The proposed march-in Framework applies to all inventions and discoveries backed in whole or part with federal funds – not just pharmaceuticals.

Universities would also lose out, as they'd be unable to reinvest revenue from licensing deals back into their research departments. This funding also helps universities attract and retain innovative faculty and renovate and construct facilities.

Without money from commercialized products, universities across the country will be left scrambling to find new ways to fund their research programs – delaying or even sacrificing future work and projects currently underway.

Ultimately, the public would lose the most. Ordinary Americans would be deprived of life-saving treatments and other transformative technologies after generations of progress.

The new march-in framework has catastrophic implications. I urge you to withdraw it in its entirety.

Sincerely,

Kristen Jakobsen Osenga
Associate Dean for Academic Affairs,
Austin E. Owen Research Scholar & Professor of Law
University of Richmond School of Law
203 Richmond Way
University of Richmond, VA 23173
Phone 804-289-8112
kosenga@richmond.edu