UNIVERSITY OF CALIFORNIA, BERKELEY
Office of Intellectual Property & Industry Research Alliances

BERKELEY • DAVIS • IRVINE • LOS ANGELES • MERCED • RIVERSIDE • SAN DIEGO • SAN FRANCISCO • SANTA BARBARA • SANTA CRUZ

2150 Shattuck Avenue, Suite 408
Berkeley, CA 94704-1362
Web: http://ipira.berkeley.edu

Tel: (510) 642-4548
carolm@berkeley.edu

January 23, 2024

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

Comments to the National Institutes of Standards and Technology
Re: RFI Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-in Rights
(Doc #230831-0207)

Dear Director Locascio,

As a former Executive Director of the Office of Technology Licensing at UC Berkeley and the current Assistant Vice Chancellor for Intellectual Property & Industry Research Alliances, much of my 30+-year career has been concentrated on technology transfer and intellectual property -- particularly regarding the careful balance required between innovation and regulation. It's from this perspective that I am compelled to comment on the administration's proposed expansion of "march-in" rights under the Bayh-Dole Act.

Passed in 1980, the Bayh-Dole Act was nothing short of revolutionary when it was signed into law -- with the legislation allowing universities and other research institutions to retain ownership of patents that resulted from federally-funded research. The act has fundamentally altered the landscape of technology transfer and the commercialization of inventions. It spurred unprecedented collaboration between universities and the private sector that propelled countless groundbreaking discoveries into the market.

However, recent political developments threaten to undermine the principles that have made the Bayh-Dole Act a cornerstone of American ingenuity. At the heart of this debate lies the proposed framework for expanding the use of "march-in" rights, a pivotal aspect of the Act that was originally intended to be exercised only in rare cases of failure to commercialize federally-funded patents.

The central issue with the proposed framework is the assertion that federal agencies should exercise march-in rights based on the "reasonableness" of the price at which a product is offered to the public. This interpretation, however, deviates significantly from the plain text and original intent of the Bayh-Dole Act, which does not grant federal agencies the authority to set prices.

Multiple presidential administrations, including the Biden administration as recently as 2023, have consistently rejected using march-in to regulate prices. In fact, in a 2002 opinion piece in the Washington Post, the architects of the law explicitly stated that it was not intended for such purposes. If Congress ever decided to make price a trigger for march-in, the law would have to be amended. To date, no such amendment has been made.

One of the glaring issues with the proposed framework is the lack of a clear and objective definition of what constitutes a "reasonable price." This lack of clarity opens the door to arbitrary march-in petitions and creates uncertainty that may discourage potential licensees in the private sector from engaging in federally-funded research projects.

Small companies, which receive over 70% of university patent licenses and rely heavily on venture capital investments, stand to suffer the most. Investors will be hesitant to put up the capital required to develop a wide range of inventions originally created with federal research dollars. The consequences of the proposed march-in framework would impact a multitude of high-tech fields that depend on federally-funded IP. These include life sciences, agriculture, renewable energy, telecommunications, and many others.

Furthermore, it is essential to recognize that misusing march-in rights in this manner is unlikely to significantly lower drug prices, as many proponents claim. Most drugs are protected by multiple patents. As such, only a small fraction of these patents would potentially be subject to march-in. Oft-used rhetoric about "lowering drug prices" simply does not align with the practical implications of the framework.

Yet perhaps the most alarming element of the proposed framework is the potential for virtually anyone to file a march-in petition -- opening the door for rival companies, opportunistic actors, and even foreign adversaries to serially harass innovators.

More broadly, Bayh-Dole has been a driving force behind the U.S. economy. Academic technology transfer generated $1.9 trillion in gross industrial output from 1996 to 2020. It's also supported 6.5 million jobs and enabled the formation of over 17,000 startups. The proposed march-in framework would jeopardize these enormous economic gains. It would also jeopardize the enormous number of products that are current in corporate R&D pipelines, and even those that are now on the market.

In order to safeguard the future of our innovation economy, it's imperative that the administration re-evaluate its draft proposal on march-in rights. As written, the new framework threatens the very essence of Bayh-Dole and the vital public-private partnerships it has nurtured -- which are foundational to America's success.

Sincerely,

Carol Mimura, Ph.D., RTTP
Former Executive Director of the Office of Technology Licensing at UC Berkeley
Assistant Vice Chancellor for Intellectual Property & Industry Research Alliances