

January 30, 2024

The Honorable Laurie E. Locascio
Undersecretary of Commerce for Standards and Technology
Director, National Institute of Standards and Technology
Department of Commerce
Washington, DC 20230

Submitted electronically via www.regulations.gov

Re: Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights, Docket No. 230831-0207

Dear Undersecretary Locascio:

The Technology Councils of North America (TECNA) represents more than 60 technology business-serving councils and serves as the collective voice for regional technology organizations. Our members represent 22,000 small- to medium-sized technology companies across North America. Many of our members' companies are startups and are heavily dependent on a thriving ecosystem of investment capital and flexibility to innovate.

I write today in opposition to the National Institute of Standards and Technology's (NIST) proposed interagency guidance framework (the "Proposed Framework") for deciding and exercising march-in rights under the Bayh-Dole Act (the "Act"). We are deeply concerned that the Proposed Framework would significantly distort the criteria for compulsory licensing of patented technology and thereby upend the law that has served as the cornerstone for public-private R&D partnerships for over 40 years.

We thank the Department of Commerce and NIST for affording us an opportunity to comment and respectfully offer for your consideration the following comments:

The Current System is Working

The march-in rights system is essentially a policing mechanism to curb abuses of the Act. It is important to note that march-in rights have existed for more than forty years, but no federal agency has ever exercised its power to march-in and license patent rights to others. In fact, the only federal agency that has received petitions to march-in is the NIH, all of which petitions have been rejected on a bipartisan basis. This indicates that the innovation sector understands and is complying with the requirements of the Act, and that the intent of the Act is being effectuated. It is curious, then, that the Proposed Framework seeks to make significant changes to the successfully operating march-in provisions of such an effective program.

While this action appears to be part of a campaign to regulate drug pricing, TECNA is very concerned that the Proposed Framework calls into question *all* federally funded patents with *any* company in *every* industry. The unintended impact on other parts of the innovation community would be severe and immediate.

March-in Rights Should Not Include “Reasonable Pricing”

While the Act contains march-in provisions, it strictly limits the situations in which such rights can be exercised. And nowhere in the Act does it refer to reasonable pricing of resulting products as a march-in trigger.

Under the Proposed Framework, however, an agency may consider “[a]t what price and on what terms has the product utilizing the subject invention been sold or offered for sale in the U.S.” and whether “the contractor or licensee made the product available only to a narrow set of consumers or customers because of high pricing or other extenuating factors.” Importantly, the Proposed Framework explicitly considers pricing in determining whether the government can exercise its march-in authority.

The inappropriateness of inserting a pricing concept into the march-in provisions is best expressed by the Act’s sponsors, Senators Birch Bayh and Bob Dole:

[“Bayh-Dole did not intend that the government set prices on resulting products. The law makes no reference to a reasonable price that should be dictated by the government. 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.”](#)

Ironically, Senators Bayh and Dole made their comments in response to opponents of the Act who, twenty years after its passage, attempted to do what the Proposed Framework does – read a pricing component into the Act’s march-in provisions.

Although the Proposed Framework would establish reasonable pricing of resulting products as a new march-in trigger, nowhere does it define what would constitute reasonable pricing. Simply put, it introduces subjective and ambiguous language that could cause confusion and inconsistency in the adjudication process and will certainly create uncertainty and instability for the innovation community.

Impact on Small Business:

The Act, officially named the *University and Small Business Patent Procedures Act*, aptly describes one of its main objectives: to encourage *small businesses* to license federally funded inventions for the purposes of commercialization. The Act has been remarkably successful in doing so and has disproportionately benefitted American innovators, startups and small businesses. According to the Association of University Technology Managers (AUTM), [nearly 73% of university licenses are awarded to start ups and small companies and nearly 7,000 new companies were created from university-based discoveries.](#)

The Act also has served as the cornerstone for the Small Business Administration's (SBA) Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs. These programs serve as our nation's largest source of early stage/high risk funding for start-ups and small businesses.

The Proposed Framework puts all of these benefits in jeopardy and will have a potentially devastating effect on small businesses. By introducing a new and undefined concept (pricing of resulting products) as a march-in trigger, the Proposed Framework introduces uncertainty, second-guessing and increased risk into the process. For small technology companies and their investors, this is a disincentive for developing innovative products with any government funding.

In particular, we are concerned that the Proposed Framework creates a predatory environment by creating a new and ill-defined basis for large corporations to file march-in petitions against smaller companies who have already assumed all of the risk and development costs for innovative products. The Proposed Framework enables large corporations, copycat companies, or foreign adversaries to file march-in petitions – at significant cost and delay to startups – to unfairly piggy-back off of their progress or, in some cases, to kill future competition. This type of predatory petitioning is completely counter to the spirit of the Act and discourages small businesses and their investors from doing business with the government.

Small companies are likely to have risked everything on the successful invention of one or two commercially viable products. Consequently, they are uniquely vulnerable to the costs and delay of regulatory processes and to their larger competitors' ability to use those regulatory processes to damage smaller competitors. The Proposed Framework is an example of an ill-defined regulatory process that, however well-intentioned, will be used as a weapon against smaller competitors.

Impact on Innovation

Innovation is one of America's greatest strengths and a significant contributor to job creation, economic growth, competitiveness and national security. Indeed, much of the success of the U.S. innovation system is attributable to the Act. [Google search engine, firefighter drones, airport scanners for detecting explosives, advanced ultrasound imaging, autonomous vehicles, cloud computing and even the Honeycrisp apple](#) are innovative byproducts of the Act.

Unfortunately, the changes in the Proposed Framework call into question the patent system's reliability and stability. Simply put, misusing the Act to control after-market pricing will result in a severe distrust in federally funded partnerships and a massive decline in innovation. It sends a clear signal to private investors, often key in bringing early-stage technologies to the marketplace, that future U.S. patent management cannot be trusted and will steer industry away from leveraging federal funding.

From 1996 to 2020, the Act, in its current form, has contributed [\\$1.9 trillion to the U.S. gross industrial output, created more than 495,000 inventions and 17,000 startups, and supported 6.5 million jobs](#). The proposed changes would put all of that in jeopardy going forward.

This is especially counterproductive given NIST's recent efforts to boost the U.S. innovation ecosystem through the CHIPS and Science Act (the "CHIPS Act".) The historic funding and incentives in the CHIPS Act is a public-private partnership designed to strengthen R&D leadership and give the country a competitive edge on the world stage. The Proposed Framework undermines confidence in government partnerships, a key component of the CHIPS Act. TECNA expects the Proposed Framework to drive private industry away from these initiatives.

The Proposed Framework is also counterproductive to the Biden administration's recent landmark Executive Order (EO) on Safe, Secure, and Trustworthy Artificial Intelligence (AI). As global leaders seek to develop and deploy AI, many countries are developing plans to accelerate development of advanced technologies. In 2021, China [released](#) its 14th Five-Year Plan, which increases R&D spending, bolsters its network of national laboratories and revises regulation to facilitate the flow of private investment in Chinese startups. To meet this global competitiveness and capture our full economic and strategic potential in AI and quantum computing, the U.S. must ensure that no barriers exist for innovation and knowledge sharing. We are concerned that the Proposed Framework will undermine efforts to bolster America's longstanding and successful public-private partnerships.

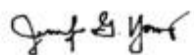
Conclusion

The Bayh-Dole system has served as the cornerstone for public-private R&D partnerships that long fueled America's innovation engine. Without the Act's long-standing and consistent framework to enforce and exclusively license patent rights, industry is discouraged from investing in the risky process of creating new products that utilize federally backed research.

The Proposed Framework's insertion of government approval of pricing into the march-in concept is a major change to the Act's structure – and an adverse one. It will hurt small businesses, stymie U.S. innovation and help our global competitors and foreign adversaries. Moreover, this reinterpretation of the Act includes subjective language that has the potential to impact every industry, from medicine to clean energy to advanced computing and agriculture. We urge NIST to abandon the Proposed Framework. It runs counter to both long-standing agency procedures and the Biden administration's major initiatives on innovation.

We thank NIST for affording us and other stakeholders the opportunity to comment. Should you have any questions about these comments or any of the information contained herein, please contact me at 412-545-3493 or at jyoung@tecna.org.

Respectfully Submitted,



Jennifer G. Young, CEO
TECNA