



February 2, 2024

Robert Schmidt
Kevin Burns
Co-Chairmen

SBTC Comment to NIST–2023–0008, 88 Fed. Reg. 85593

Jere Glover
Executive Director

Dear Director Locascio:

Larry Nannis
Treasurer

The Small Business Technology Council (SBTC) disagrees strongly with the “Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights” proposed by the National Institute of Standards and Technology. We believe that this guidance is based on a flawed and false understanding of the Bayh-Dole Act that is contrary to its intended purpose allow businesses and universities to own and commercialize their inventions derived from government-funded research. We request that NIST withdraws this guidance.

Matt Oristano
Mid-Atlantic
Regional Chair

Ash Thakker
Southeast
Regional Chair

Mary Delahunty
Southwest
Regional Chair

Russ Farmer
Mountain
Regional Chair

Michael Browne
Pacific
Regional Chair

While march-in rights were included in the Bayh-Dole Act, “reasonable pricing” was not a standard every considered by the authors of the bill. Senators Bayh and Dole have both said that the purpose of the march-in rights provision was never to allow the government to set prices for products derived from government funding. Doing so would severely disincentivize companies from accepting government funding, and drive innovative high-tech companies to avoid government contracting. Ironically, this was exactly the problem that the Bayh-Dole Act sought to fix when it was first introduced.

The Bayh-Dole Revolution

Roy Keller
State Liaison

Paul Donovan
Michael Squillante
NIH Committee
Co-Chairs

To understand the threat that this new interpretation of march-in rights poses, it's important to understand the landscape prior to Bayh-Dole. For years, virtually all discoveries funded by federal government dollars gathered dust in Washington. Senators Birch Bayh (D-IN) and Bob Dole (R-KS) recognized this waste and passed the Bayh-Dole Act in 1980, allowing more government-funded inventions to make it to market as useful products.¹

Ash Thakker
Phase III Committee
Chair

Russ Farmer
DCAA Committee
Chair

The Act (introduced as The University and Small Business Patent Procedures Act) allowed universities and small companies to retain ownership of patents that came about thanks to federal grant or contract dollars. Universities can then license these inventions to private companies with the expertise for further development. In this way, the Bayh-Dole Act has set up a public-private synergy that has paid rich dividends for the United States: Federally supported universities generate promising leads for new technologies, while private businesses assume the cost and risk of developing and incorporating such untested technology into practical, real-life products. The law also assured innovative small companies that their patents made with federal support would no longer be taken away from them, opening the door for greater participation by these companies in federal R&D programs and the creation of the highly successful Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs.

¹ <https://bayhdolecoalition.org/wp-content/uploads/2023/05/HR-6933-Signed-Law.pdf>



Innovative Small Businesses are Bayh-Dole's Biggest Beneficiary

While this proposed guidance is ostensibly aimed at curbing drug prices by large pharmaceutical companies, it is more likely that small businesses will be the ones principally targeted by march-in petitions under this new guidance. Over 70% of university patent licenses go to small businesses, not Big Pharma firms. Many of these firms are small, start-up companies whose primary assets are their patents and IP. The government deciding to "march in" and force such a company to license its invention to a competitor would in many cases result in the death of that company.

Despite accounting for less than 2% of overall Federal R&D funding, SBIR/STTR's outsized results are a primary driver of American economic strength. SBIR/STTR firms have created over 20% of the world's major innovations², and as many patents as all universities combined. There have been nearly 150,000 patents issued to SBIR firms since the program began³. In most years SBIR firms receive more patents than all colleges and universities combined.

High quality R&D tackles federal challenges and creates new innovation while seeding new startups and driving the growth of small businesses with their new technology products and services. Global giants such as Qualcomm, Symantic, Biogen, iRobot, Genzyme, Illumina, and Genentech emerged from SBIR funding. Follow-on new product investment and sales have totaled many hundreds of billions of dollars.

NIST's Proposed March-In Guidance is Inconsistent with the Law

The Bayh-Dole Act created "March-In Rights" as a failsafe mechanism for the government to use in very specific situations. For example, if a company simply sits on government-funded intellectual property (IP) and makes no effort to commercialize it; or if there is a legitimate health or safety crisis when production of a product needs to ramp up quickly, then the government can lawfully exercise march-in rights⁴.

Nowhere in the law is a product's price mentioned or even implied as a possible trigger for march-in rights. Senators Bayh and Dole recognized that if the government could re-license patents based on the price of a product alone, few companies would be willing to license government-funded research in the first place. It can take tens of millions of dollars of private capital -- or more -- to commercialize a discovery, and firms wouldn't be able to put such large amounts of equity capital at risk if the government could revoke their exclusive licenses because someone in the government didn't like the price they set.

² Fred Block and Matthew Keller, *Where Do Innovations Come From? Transformations in the U.S. National Innovation System 1970-2006*, Information Technology and Innovation Foundation, July 2008.

³ www.innovation.com

⁴ <https://www.law.cornell.edu/uscode/text/35/203>



NIST's proposed framework has worrying national security implications as well. Under the proposal, anyone can file a march-in petition.⁵ It's easy to imagine China or another foreign adversary taking advantage of the march-in process to slow the gears of American innovation. Such misuse of the system should not be allowed and would be detrimental to U.S. small businesses that lack the resources to bankroll prolonged litigation.

As a non-partisan, member-driven organization dedicated to promoting America's high-tech, innovative small companies, SBTC is deeply concerned that the proposed changes to the exercise of "march-in" rights under the Bayh-Dole Act will severely affect the American technology transfer system as we know it. SBTC asks that NIST withdraw this guidance to remove the "reasonable price" standard for march-in rights. This proposed guidance could have severe unintended consequences for small businesses, all while failing to accomplish its primary purpose of lowering drug prices.

The Small Business Technology Council (www.SBTC.org) is the nation's largest association of small, technology-based companies in diverse fields. SBTC is a council of the National Small Business Association (www.NSBA.biz), the nation's first small-business advocacy organization. NSBA is a staunchly nonpartisan organization with 65,000 members in every state and every industry in the US. SBTC advocates on behalf of the 6000 firms who participate in the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs.

⁵ <https://www.federalregister.gov/documents/2023/12/08/2023-26930/request-for-information-regarding-the-draft-interagency-guidance-framework-for-considering-the>