



February 6, 2024

Innovation Alliance Comment in Response to NIST Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights

The Innovation Alliance¹ (IA) appreciates the opportunity to submit these comments in response to the NIST request for information (RFI) on the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights under the University and Small Business Patent Procedures Act of 1980, Public Law No. 96–517 (as amended), codified at 35 U.S.C. § 200 *et seq.* (commonly known as the “Bayh-Dole Act.”). IA is a coalition of innovative U.S. companies that invest substantially in research and development (R&D), invent key technologies, create jobs, and support policies that further these goals. We are concerned that the draft guidance, if adopted, will erode the immeasurable success of the Bayh-Dole Act in driving U.S. private-sector innovation. Encouraging government agencies to exercise march-in rights based on an administration’s policy preferences, and adding consideration of pricing, which is not in the statute, would significantly disincentivize companies from applying for federal R&D grants and from licensing inventions created with federal R&D funds. The proposal broadly applies across all types of technologies, harming American innovation and competitiveness across industries. At a time when the Biden Administration and Congress are prioritizing public-private partnerships to develop critical and emerging technologies, this guidance would stunt innovation and further jeopardize U.S. global technological leadership.

Both Public Investments and Patent Rights Incentivize the Private Innovation Critical to U.S. Technology Competitiveness and National Security

By granting ownership rights to inventors “for limited times,”² U.S. patent rights—enshrined in the Constitution—have powered more than two centuries of U.S. technology leadership. Patent rights incentivize inventors to devote time and resources to risky R&D efforts by allowing them to earn returns on their investments³ They also create jobs: IP-intensive industries support 63 million jobs, accounting for 44 percent of the U.S. workforce, and startups that obtain patents increase their employment growth by an average of 55 percent.⁴ And intellectual property licensing is one of the few sectors where the

¹ <https://innovationalliance.net/>.

² See U.S. Const. art. I, § 8, cl. 8.

³ Cong. Rsch. Serv. R47267, *Patents and Innovation Policy 1* (June 25, 2022), <https://crsreports.congress.gov/product/pdf/R/R47267/2>.

⁴ See U.S. Patent and Trademark Off., *Intellectual Property and the U.S. Economy: Third Edition* at 5, 13, <https://www.uspto.gov/sites/default/files/documents/uspto-ip-us-economy-third-edition.pdf>; Joan Farre-Mensa, Deepak Hedge, and Alexander Ljungqvist, *What is a Patent Worth? Evidence from the U.S. Patent “Lottery,”* NBER (Dec. 2018), https://www.nber.org/system/files/working_papers/w23268/w23268.pdf.

United States maintains a trade surplus with China, with gross U.S. IP exports to China totaling \$8.3 billion in 2022.⁵

The Bayh-Dole Act reinforces U.S. technology leadership by allowing university researchers, independent inventors, small-business entrepreneurs, and other inventors from across industries to own and license inventions that emerge from federally funded R&D. The impact cannot be overstated: since its enactment the landmark legislation has directly contributed to more than \$1.3 trillion in U.S. economic growth, 4.2 million jobs, and 11,000 new start-up companies.⁶ Additionally, thanks in large part to Bayh-Dole, U.S. researchers have been the first to develop new technologies in areas critical to strategic leadership, including cloud computing, autonomous vehicles, and quantum computing.⁷

Today, however, as China invests heavily in developing its own innovation capacity, we are locked in a race to maintain our technological edge. The Chinese Communist Party's current Five-Year Plan calls for increasing public- and private-sector R&D spending by 7 percent each year.⁸ China already leads the world in 37 out of 44 key technologies in areas including artificial intelligence, advanced manufacturing, and defense, according to a study funded in part by the U.S. State Department.⁹ The economic and national security of the United States rely on maintaining a competitive pace of innovation in critical and emerging technologies.

The Administration has made laudable, impactful strides toward promoting continued U.S. global technology leadership, including by releasing the National Standards Strategy for Critical and Emerging Technology and the Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence.¹⁰ What's more, the CHIPS and Science Act invests billions of dollars in critical R&D. This includes \$11 billion for the CHIPS Research and Development Office to fund research and other initiatives, including through the Manufacturing USA Institutes, the National Semiconductor Technology Center, and other programs that direct research funding to private-sector innovators.¹¹ In signing the CHIPS and Science Act into law, President Biden stated that the Act's "increased research and development funding is going to ensure the United States leads the world in the industries of the future—from quantum computing, to artificial intelligence, to advanced biotechnology. . . ."¹² While

⁵ See Bureau of Economic Analysis, International Data tab. 1.4 (Dec. 2023), <https://apps.bea.gov/iTable/?ReqID=62&step=2#eyJhcHBpZCI6NjlsInNOZXBzljpbMiwxcw3XSwiZGF0YSI6W1siVGFibGVMaXN0IiwzMzAwNDEiXSB1IHRhYmxiTGZldFNIY29uZGFyeSIsIjMwMDYzIl1dfQ==>.

⁶ See Walter Copan, *Reflections on the Impacts of the Bayh-Dole Act for U.S. Innovation, on the Occasion of the 40th Anniversary of this Landmark Legislation*, IPWatchdog (Nov. 2, 2020), <https://ipwatchdog.com/2020/11/02/reflections-on-the-impacts-of-the-bayh-dole-act-for-u-s-innovation-on-the-occasion-of-the-40th-anniversary-of-this-landmark-legislation/id=126980/>.

⁷ See Bayh-Dole Coalition, *About*, <https://bayhdolecoalition.org/about/>.

⁸ See Paul Mozur and Steven Lee Myers, *Xi's Gambit: China Plans for a World Without American Technology*, New York Times (Mar. 10, 2021), <https://www.nytimes.com/2021/03/10/business/china-us-tech-rivalry.html>.

⁹ Jamie Gaida et al., *ASPI's Critical Technology Tracker: The Global Race for Future Power*, Australian Strategic Policy Institute (2023) at 1, available at <https://www.aspi.org.au/report/critical-technology-tracker>.

¹⁰ The White House, *United States Government National Standards Strategy for Critical and Emerging Technology* (May 2023), <https://www.whitehouse.gov/wp-content/uploads/2023/05/US-Gov-National-Standards-Strategy-2023.pdf>; Exec. Order No. 14110, 88 Fed. Reg. 75191 (Oct. 30, 2023).

¹¹ Pub. L. 117–167 (2022).

¹² Remarks by President Biden at Signing of H.R. 4346, "The CHIPS and Science Act of 2022" (Aug. 9, 2022).

these programs are massive in scale and scope, the innovators who accept these funds still assume risk in undertaking new research, which is why the promise of the CHIPS and Science Act can only be fully realized if innovators can rely on the Bayh-Dole Act's grant of patent protections to federally funded R&D.

The Draft Guidance Would Undermine Proven Drivers of Innovation and Threaten U.S. Strategic Leadership by Encouraging Agencies to March-In on the Bases of Price and Broad Policy Objectives

Unfortunately, if the draft guidance goes into effect, it will discourage innovators from accepting federal R&D funds, including those authorized in the CHIPS and Science Act. This is because, for the first time since the Bayh-Dole Act came into effect, it would create uncertainty around funding recipients' rights in their intellectual property. By issuing the draft guidance, the Administration threatens to both undermine its own progress in strengthening U.S. competitiveness and damage the enormous success of the Bayh-Dole Act, which has driven U.S. technology leadership for more than four decades. Encouraging government agencies to assert their march-in rights, as the draft guidance does, undercuts the Bayh-Dole Act's central purpose of extending the incentives of patent rights to federally funded researchers and inventors. The draft guidance is detrimental to innovation for several critical reasons.

First, the draft guidance would undermine the innovation economy by broadly subjecting all federally funded R&D to the constant threat that a funding agency will assert its march-in rights based on the "reasonableness of the [invention's] price." This would both contravene the legislative intent of the Bayh-Dole Act and create unprecedented uncertainty for innovators seeking to finance and plan their investments in risky R&D.¹³

Second, the guidance would hinder U.S. innovation by allowing agencies to march-in based on the policy preferences of the administration in office. For example, the draft guidance specifically directs agencies to "weigh how an individual march-in decision could impact the broader policy objectives for U.S. competitiveness and innovation."¹⁴ This vague standard would degrade the value of patents on inventions supported with government funding, in turn reducing innovators' willingness to accept such funding.

Third, the hypothetical scenarios proposed in the guidance itself also envision a broad reach, suggesting that march-in would be appropriate for inventions ranging from emerging technologies, such as connected vehicles and 3-D printing, to everyday applications like water purification and road signs. This broad scope raises the specter of government march-in across the innovation economy, especially in areas of strategic importance like AI, quantum, and semiconductors. If adopted, the guidance would have the disastrous consequence of discouraging U.S. universities and businesses from accepting federal R&D funding, chilling innovation precisely at a moment when the United States' strategic leadership is under pressure. To maintain technological competitiveness in critical and emerging technologies, we

¹³ See Birch Bayh, *Statement of Senator Birch Bayh to the National Institutes of Health*, (May 25, 2004), <https://www.techtransfer.nih.gov/sites/default/files/documents/2004NorvirMtg/2004NorvirMtg.pdf>/ ("NIH wisely realized that the greater good is to allow American taxpayers to have access to important new products and processes, along with the new jobs and taxes they create than to try and regulate prices. Bob Dole and I made the same choice in 1980. I still believe that we were correct.")

¹⁴ In 2022, nearly half of all patent applications in the world were filed by entities in China—triple the number of patent applications sought by U.S.-based entities. See World Intellectual Property Organization, *World Intellectual Property Indicators Report: Record Number of Patent Applications Filed Worldwide in 2022* (Nov. 6, 2023), https://www.wipo.int/pressroom/en/articles/2023/article_0013.html.

must preserve the incentive to innovate in the United States and leverage crucial federal programs like Bayh-Dole to do so.

Now is not the time to sever this major artery in our innovation economy. In the face of growing competition from China for global technology leadership, the Administration should incentivize innovative researchers and businesses to seek federal R&D funding—a primary objective of the CHIPS and Science Act—not raise the prospect of routine march-in on government-funded projects. Although march-in rights have been a feature of the Bayh-Dole Act since its inception, the Act has been so successful in accelerating innovation that, according to the U.S. Patent and Trademark Office, “no agency has ever exercised their march-in rights.”¹⁵ The draft guidance clearly aims to change that.

The Administration must not take for granted the enormous success of Bayh-Dole and the era of prolific public-private research collaboration it has ushered in. Especially amid heightened geopolitical competition, continued U.S. technological leadership depends on it. We urge NIST to withdraw or modify the draft guidance to preserve this essential engine of U.S. innovation, technology leadership, and economic growth.

¹⁵ U.S. Patent and Trademark Office, *NIST calls for public comments on draft March-In Rights Guidance*, Press Release (Dec. 8, 2023), <https://www.uspto.gov/about-us/news-updates/nist-calls-public-comments-draft-march-rights-guidance>.