

May 14, 2024

U.S. Patent and Trademark Office 600 Dulany Street P.O. Box 1450 Alexandria, VA 22313

RE: Unlocking the Full Potential of Intellectual Property by Translating More Innovation to the Marketplace (Docket No. PTO-C-2024-0004)

To whom it may concern:

I write in my capacity as Executive Director of Conservatives for Property Rights (CPR) to comment on Unlocking the Full Potential of Intellectual Property by Translating More Innovation to the Marketplace (Docket No. PTO-C-2024-0004). CPR is a coalition of public policy organizations concerned with preserving and protecting private property rights, and we have long advocated for policies that bolster U.S. technological innovation and leadership. We believe it is imperative that public policies provide clear, secure, reliable, enforceable property rights, including intellectual property (IP) rights.

The U.S. Patent and Trademark Office (PTO) writes,

"Intellectual property rights create a critical engine that powers our economy and supports our nation as a global leader in innovation and entrepreneurship. For example, patents drive our nation's technological progress and achievement by incentivizing and protecting new ideas, encouraging investment in creative problem solving, and promoting knowledge sharing to inspire others to engage in follow on innovation. When brought to the market through commercialization, patented products save lives, improve our standard of living, and address some of the pressing issues to solve global challenges."

CPR agrees. Indeed, our historically strong patent system has contributed substantially to the United States' decades of economic and technological leadership. Since enactment of the Bayh-Dole Act in 1980, technology transfer has facilitated democratized decisionmaking by IP owners (e.g., universities, small businesses) over how best to commercialize patented inventions. This model has resulted in saved lives, a higher standard of living, and solutions to pressing problems.

It is ironic that PTO does not want comments regarding "Bayh-Dole rights, pandemic preparedness, and Trade-Related aspects of Intellectual Property Rights waivers"—the live threats to U.S. IP tech transfer, private investment, and commercialization. It would be derelict were CPR not to raise concerns over dangerous public policies that threaten to close key facets of the IP commercialization model.

Thus, we reply generally to certain PTO questions:

- 4. Please identify any changes to IP policies and practices that may help streamline or accelerate commercialization of IP in general.
- 6. Please identify any changes to IP policies and practices that may help streamline or accelerate commercialization of critical and emerging technologies.
- 14. Please identify any role that the USPTO can play in incentivizing innovations in commercially viable technologies.

Response: The Bayh-Dole Act of 1980 is clear: The government may only exercise march-in in four specific circumstances—none of which includes the price of a product. The safeguards laid out in Bayh-Dole protect innovation and allow it to flourish, without the possibility of government expropriation of IP. Plainly, Bayh-Dole march-in is not intended as a government price control mechanism.

CPR warned the National Institute of Standards and Technology (NIST): "The single most destructive policy conceivable—subjecting successful commercializers to the tremendous risk that their success will be punished by march-in based on the price the market sets for their products years after beginning commercialization—is exactly what NIST, along with the Departments of Commerce and Health and Human Services, is proposing." Further, "Failure to proceed with prudence will reduce practical benefits from basic research funded by billions of taxpayer dollars. The proposal to assault related intellectual property (IP) rights will weaken our economy, hurt innovative U.S. startup and early-stage small businesses, and hand adversarial competitors such as China the advantage in technological leadership."

PTO should be the chief guardian of patents and IP rights within the U.S. government. For PTO to fail to act now would be dereliction. **Thus, PTO should stand up and vigorously oppose NIST's extrastatutory "reasonable pricing" framework.**<sup>1</sup>

Until now, IP rights have made possible technology transfer between universities and those able to bring these innovations to market. Critical to this successful transfer is exclusive, reliable IP rights. These are the core principles of Bayh-Dole. NIST march-in threatens innovation by suffocating progress. Prior to Bayh-Dole, less than 5 percent of 28,000 government-owned patents was licensed or attempted to be

<sup>&</sup>lt;sup>1</sup> NIST, Request for Information Regarding Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights (Docket No. NIST-2023-0008).

commercialized. Taxpayers got little to no return on federal "investment" of their tax dollars that funded those inventions.

The writing on the wall today prophesies a return to the pre-Bayh-Dole waste of taxpayers' money and the squandering of potential technological breakthroughs because NIST's price-based march-in framework would scare off U.S. innovators, entrepreneurs, and investors from commercialization attempts. This is also the lesson of the National Institutes of Health's (NIH) failed experiment of the 1990s when NIH added a "reasonable pricing" clause to its licensing contracts.<sup>2</sup>

PTO asks what "policies and practices . . . may help streamline or accelerate commercialization of IP in general." Preserve the Bayh-Dole Act's core principles by rejecting the unlawful addition of price-based march-in and defend the TRIPS Agreement from allowing expropriation of IP rights.<sup>3</sup>

PTO asks what measures it can take to help commercializing critical and emerging technologies. Protect Bayh-Dole to ensure government-funded basic research that promises potential innovations actually makes it to market, items like medicines and other critical innovations including green and climate technologies, and urge the U.S. Trade Representative (USTR) to defend TRIPS against any more waivers and advocate for repeal of the COVID vaccine waiver.

In closing, it is imperative that PTO engages on the side of maintaining the Bayh-Dole framework, which limits march-in to legitimate, specified circumstances, and advocating that USTR uphold the integrity of the TRIPS Agreement's IP protections.

Thank you for considering these comments.

James Edwards, Ph.D. Founder and Executive Director Conservatives for Property Rights

<sup>&</sup>lt;sup>2</sup> See CPR's January 26, 2024, comments regarding the NIST Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights (Docket No. NIST-2023-0008).

<sup>&</sup>lt;sup>3</sup> See CPR's May 2, 2023, comments regarding International Trade Commission (ITC) COVID-19 Diagnostics and Therapeutics: Supply, Demand, and TRIPS Agreement Flexibilities (Investigation No. 332-596).