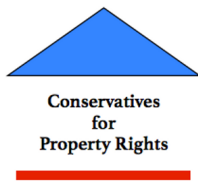


The Biden administration recently released draft interagency guidance on the 1980 Bayh-Dole Act, which would allow federal agencies to forcibly relicense patents on federally-funded inventions if the agency disagrees with the price of that product.

Not only does this new interpretation fly in the face of more than four decades of legislative history and intent, but it undermines intellectual property rights that are vital to American inventorship and global competitiveness.

The following are excerpts from the public comments of hundreds of individuals and organizations that oppose the draft guidance:



Conservatives for Property Rights

“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.”



Advancing American Freedom (AAF)

“The proposal presents itself as advocacy for “the little guy.” In reality, that could not be further from the truth...This guidance mainly hurts federally funded inventions and can easily be weaponized by big businesses that can hit small businesses that can’t afford to charge lower prices and do not have the networks or economies of scale to keep up.”



Americans for Prosperity

“Imposing backdoor price controls through march-in rights would put U.S.-based pharma companies — the world’s innovation leaders — at a disadvantage compared to their international counterparts, needlessly hobbling our economy and destroying jobs.”



Americans for Tax Reform

“This Draft Framework, by opening the door to such an arbitrary standard such as pricing, and therefore ensuring more patents will be seized by federal agencies, sets the U.S. on track to return to a time when Americans were barred access to important innovations.”



Center for American Principles (CAP)

“This proposed new authority for government intervention would not only deter pharmaceutical investors and cause partnerships with the National Institute of Health (NIH) to crumble, but also would undercut the entire American system of market-based public-private partnership for innovation.”



Center for Individual Freedom (CFIF)

“Strong patent protections, which Bayh-Dole codifies, help ensure that those costs and risks [of innovation] will be fairly and sufficiently rewarded...Rather than undermine the patent regime brought forth by Bayh-Dole, the NIST should instead provide greater clarity and certainty to universities and other private innovators that Bayh-Dole will continue to protect patent rights and expectations.”



Center for Innovation and Free Enterprise (CIFE)

“The policy’s unprecedented attempt to broaden the government’s ability to “march-in” and seize patent rights is a cause for concern. The potential infringement on the property rights of innovators poses a threat to the core principles of the innovation economy.”



Center for Medicine in the Public Interest

“In a risky industry where the research and development of a drug can cost more than \$2 billion -- and only 12% of those that enter clinical trials end up receiving FDA approval -- anything that deters the licensing of university research will have a massive chilling effect on pharmaceutical innovation. Unfortunately, expanding march-in rights would do just that.”



Citizens Against Government Waste

“The United States leads the world in drug research and development due in large part to the protection of IP in the Constitution, which is the only property right given such protection...If the unprecedented use of march-in rights is allowed, it will cause irreparable damage to medical innovation and dissuade biopharmaceutical companies from spending their valuable research dollars on future treatments [and] cures.”



Consumer Action for a Strong Economy (CASE)

“[C]ountless products that have improved consumers’ lives and bolstered America’s status as the world’s leading economy — from Google and touch screen technology, to scanners at airports that keep travelers safe from threats — have all been made possible by the Bayh-Dole Act. Abusing the law would spell trouble for many industries and restrict consumers’ access to products ranging from lifesaving drugs to new technologies that make daily life better and safer.”



Eagle Forum Education and Legal Defense Fund

“[T]he draft guidance enables rival companies, foreign adversaries, and bad actors to harass innovators and devalue their IP...[B]ased on the broad scope, wide applicability, and unbounded discretion given government agencies, the proposed guidance will almost certainly cause a dramatic reversal of Bayh-Dole’s great success.”



FreedomWorks

“Put simply, the Draft Interagency March-In Guidance Framework is bad policy that history has proven will fail...[I]t will undermine the United States, exacerbate the existing sense of uncertainty, and make us less internationally competitive at a time when we need to unleash the forces of innovation.”



Market Institute

“If the Administration follows through on their proposal to basically negate all intellectual property licenses it would add in yet another hurdle to drug innovation, and as written all other markets as well. Additionally, it would mean that less research from Universities and research organizations would ever be used.”



National Taxpayers Union

“National Taxpayers Union firmly believes that this entire framework should not proceed in light of continuing the decades-long success of Bayh-Dole at unlocking public-private partnerships to generate new and innovative cures, thousands of startups, and hundreds of billions in economic growth.”



Pacific Research Institute

“By proposing a new guidance framework that would drastically expand these federal government march-in and re-licensing authority, however, the Biden administration would diminish incentives for private institutions, such as universities and nonprofit labs, to seek public funding...The American public would cease to reap the benefit of public funding.”



Taxpayers Protection Alliance

“[T]hreatening rights-holders with a march-in should they raise prices past what regulators deem “reasonable” would dampen innovation and harm taxpayers. As U.S. economic history from Franklin Roosevelt to Richard Nixon and beyond demonstrates clearly, price controls regularly cause shortages, slow investment in the price-controlled industry, and, particularly in the long term, reduce the choices to which Americans have access.”



Trade Alliance to Promote Prosperity

“Misapplication of the Bayh-Dole Act’s provisions would have a serious chilling effect on public-private partnerships and could create a disincentive for scientists and drug companies to make the large and long-term investments required to explore new cures and therapies for diseases like cancer or to respond quickly to global health emergencies.”



Alden F. Abbott

Senior Research Fellow, Mercatus Center at George Mason University

“[T]he proposed Framework would twist Bayh-Dole and weaken the U.S. intellectual property system. It is misguided and will harm market competition, consumer access to new technologies, and our strategic global interests in technology leadership.”



Kristen Osenga

Austin E. Owen Research Scholar and Professor of Law and Associate Dean for Academic Affairs, University of Richmond School of Law

“For more than four decades, venture capital has freely flowed to companies licensing federally supported university research because of the Bayh-Dole Act and effective and reliable patent rights. The new Framework introduces enormous unpredictability to this system. It could empower large corporations to harass smaller innovators – and will certainly deter companies from licensing federally funded research more broadly.”



Tomas Philipson

Daniel Levin Professor of Public Policy Studies, University of Chicago

“These scenarios – and the overall uncertainty created by the framework – will undoubtedly deter private companies and investors from licensing university research... Before Bayh-Dole, patented academic discoveries languished in obscurity. This framework will return us there.”