

May 20, 2024

The Honorable Dick Durbin
Chairman
Senate Committee on the Judiciary
224 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Lindsey Graham
Ranking Member
Senate Committee on the Judiciary
224 Dirksen Senate Office Building
Washington, DC 20510

Dear Chairman Durbin and Ranking Member Graham:

On behalf of the Bayh-Dole Coalition, I'd like to comment in advance of your upcoming hearing on drug pricing. The Bayh-Dole Coalition is a diverse group of innovation-oriented organizations and individuals committed to celebrating and protecting the Bayh-Dole Act, as well as informing policymakers and the public of its many benefits.

It is largely due to the leadership of the Senate Judiciary Committee that the United States became the innovation leader of the world, including in the life sciences. In the 1970's, we were rapidly losing markets to foreign competitors, and many predicted that trend would only accelerate and we should resign ourselves to second or third place.

However, that didn't happen because this Committee helped unleash American innovation by strengthening our patent laws and using its incentives to commercialize the results of billions of dollars of federally-funded R&D. That was done by passage of the Bayh-Dole Act in 1980 and creation of the Court of Appeals for the Federal Circuit in 1982. These actions helped ignite the greatest innovation boom in history. The Economist Technology Quarterly said: "Possibly the most inspired piece of legislation to be enacted in America over the past half-century was the Bayh-Dole Act of 1980... More than anything, this simple policy measure helped reverse America's precipitous slide into industrial irrelevance."

The Bayh-Dole Act and our patent system are intended to provide confidence that the rules of the game are understood and consistently enforced, regardless of who's in power. That is particularly important to us because, unlike our competitors, our system, even in the life sciences, is driven by small companies which must raise high-risk venture capital while knowing that the odds against success are formidable.

Thus, suggestions that the Bayh-Dole Act should be misused for Washington-imposed price controls or that the government can arbitrarily seize privately funded inventions as a price control mechanism pose fundamental threats to our innovation engine. And, once unleashed, such misuse cannot be confined to

drugs, but would inevitably spread to any technology. The Bayh-Dole Act is one of the most transformative policy reforms in U.S. history. By empowering academic institutions and small companies to own the patents on inventions they make with federal funding, it sparked an innovation boom that brought thousands of new products to American consumers.

Bayh-Dole had a particularly significant impact in the life sciences. To date, over 200 new drugs and vaccines — including revolutionary treatments for cancer, HIV/AIDS, Covid-19, Ebola, pneumonia, psoriasis, rotavirus, and multiple sclerosis — have been developed thanks to the academic tech transfer system created by the law. Before Bayh-Dole was enacted, fewer than 10% of new drugs were first introduced in the United States. Today, more than six in 10 are.

Countless patients around the world now have hope because of Bayh-Dole. But one much-discussed proposal to lower drug prices would destroy this important law and the pipeline of treatments it has opened. The proposal, put forth by the National Institute of Standards and Technology (NIST) in December, would allow government agencies to misuse Bayh-Dole's "march-in" rights, allowing copiers to make any product that someone feels is not "reasonably priced," a completely undefined term.

In reality, this strategy would be ineffective at reducing drug prices, as even its advocates now admit. The vast majority of drugs — including more than 97% of those approved since 1985 — rely on at least one private-sector patent — that is, one or more patents that did not involve government funding. Such drugs could not be copied through march-in rights, which only applies to patents made with federal funding.

The misuse of march-in would actually *reduce* access to affordable drugs, because it would undermine crucial incentives for generic drug manufacturing. Thus, the generic drug industry, which would be the prime beneficiary of this policy, wrote to NIST opposing the proposed change, because of the danger it poses to the availability of less expensive generics as drugs go off-patent — a process that reduced overall expenditures on prescription drugs by \$402 billion in 2022 alone.

But beyond its inability to achieve its stated objective, NIST's proposal would do extensive damage to the intellectual property incentives that have made America the world leader in life science innovation, and every other field. Senators Bayh and Dole, as members of this Committee, carefully crafted the march-in provision and stated many times that it does not allow for imposing price controls on a successfully commercialized invention. I was privileged to serve as a Senate Judiciary Committee staffer to Senator Bayh and organized its hearings, and wrote the Committee's report on the law. Nowhere did it sanction the use of march-in rights for price controls. And that is not just our opinion. Every administration over the past 25 years has uniformly rejected every attempt to misuse the march-in rights provision for lowering the costs of drugs based on federally funded inventions. That includes the Biden administration, which rejected the most recent petition to misuse march-in rights for price control and the appeal of the denial.

If this misuse is allowed now, private companies and investors will no longer have reason to take risks on commercializing early-stage drugs whose discovery involved federal funding. We should remember that unlike any other country in the world, over 50% of our new drugs originate in small companies. New drug breakthroughs would collect dust on laboratory shelves, as they did before 1980. Policymakers seeking to serve the needs of patients must recognize this concern, which has been echoed by leading patient advocacy groups like the World Patients Alliance.

I also want to briefly address another pernicious drug pricing proposal. Some have implored the government to attempt to apply Section 1498 of Title 28 of the U.S. Code to ignore patents on drugs and make them cheaply available to federal healthcare programs like Medicare and Medicaid.

Like the proposed misuse of Bayh-Dole, this is a misreading of the law that would have a devastating impact on innovation. Section 1498 has roots more than a century old. The clear purpose of the statute is to allow the government to manufacture, or contract for, urgently needed products for its own use during times of crisis, such as a world war. It applies only under narrow circumstances and requires the government to provide “reasonable and entire compensation” to the patent holder.

Twisting Section 1498 to become a price control mechanism plainly contravenes the purpose and history of the law. Not only that, it would introduce a dangerous precedent that would further weaken the reliability of patent rights and corrupt the incentives responsible for bringing new medicines to patients.

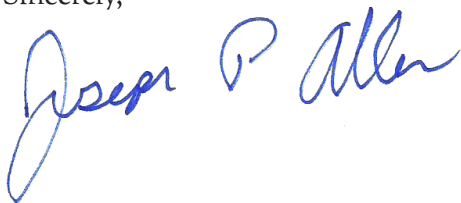
Because of the subject matter of today’s hearing, I have largely confined my comments to the effects of misuse of march-in and Section 1498 on life sciences innovation.

But the danger here is much broader.

The NIST proposal openly states that it is technology-agnostic, meaning that patents stemming from government funding in any area could be subject to march-in if officials decide the resulting commercial products are too expensive. If the law is allowed to be misused for drug price control, that weapon will also be used against products in any field against entrepreneurs who took the risk and expense to commercialize a product. Most times that will be a small business. And misapplying Sec. 1498 means that not even privately funded inventions are safe from federal expropriation attempts on the whims of the moment. Such actions not only destroy investment and innovation in the life sciences but across the board.

I respectfully urge members of this committee to sound a warning about this catastrophic threat to our economy. The executive branch should immediately withdraw the NIST march-in proposal and forswear the use of Section 1498 as a mechanism for government price controls.

Sincerely,



Joseph P. Allen
Executive Director
Bayh-Dole Coalition