

# What They Are Saying About the Biden Administration's Draft Framework for March-In Rights

In December 2023, the White House released new guidance clarifying when federal agencies can exercise march-in authorities under the 1980 Bayh-Dole Act. In a stunning break from decades of precedent, the guidance encourages federal officials to revoke patent licenses as a means to regulate the prices. The guidance would apply to any invention that benefited from federal research funding.

Such heavy-handed government intervention would not only violate the Bayh-Dole Act, but it would also discourage the commercialization of groundbreaking discoveries and relegate taxpayer-funded inventions to laboratory shelves.

A number of current and former government officials and intellectual property experts have come out against this dangerous misuse of march-in rights. Below are key excerpts from their opposing comments:



# Former U.S. Department of Commerce Officials

"We emphasize in the strongest possible terms: the proposed framework poses a major threat to America's prosperity. And it undermines numerous other initiatives by the Biden administration to improve America's economy."

### **Gary Locke**

Secretary of Commerce (2009-2011)

#### **Carlos Gutierrez**

Secretary of Commerce (2005-2009)

#### Andrei lancu

Under Secretary of Commerce for Intellectual Property and Director of the USPTO (2018-2021)

#### David J. Kappos

Under Secretary of Commerce for Intellectual Property and Director of the USPTO (2009-2013)

#### Jon W. Dudas

Under Secretary of Commerce for Intellectual Property and Director of the USPTO (2004-2009)

### Walter G. Copan

Under Secretary of Commerce for Standards and Technology and Director of NIST (2017-2021)

#### Willie E. May

Under Secretary of Commerce for Standards and Technology and Director of NIST (2015-2017)

#### Patrick D. Gallagher

Under Secretary of Commerce for Standards and Technology and Director of NIST (2009-2013); Acting Deputy Secretary of Commerce (2013-2014)

### William A. Jeffrey

Director of NIST (2005-2007)



## **Council for Innovation Promotion**

"The draft guidelines are not limited to a single agency, a single area of technology, or a single point in time in the development lifecycle. They will cause a sea change in how private industry views engagement with the federal government or any entity conducting research with the federal government. Federally-funded research will again be viewed as 'contaminated' and untouchable by the private sector, the very problem the Bayh-Dole Act set out to solve."



## National Association of Manufacturers

"[The Bayh-Dole] Act has sparked tremendous innovation and economic growth, including throughout the manufacturing sector...But the Proposal would undermine the manufacturing industry in the U.S. by disincentivizing the use of federally funded patents and public-private collaboration, to the detriment of American manufacturing and workers."



# Small Business & Entrepreneurship Council

"Small entrepreneurial companies are crucial to research and development...[But] they may not be willing to invest in the kind of research taking place in dynamic university laboratories if they do not have the assurance that they can maintain exclusive rights to the patents on any new products they invent."



# **Small Business Technology Council (SBTC)**

"Small businesses licensing federally funded research have helped jumpstart U.S. leadership in a variety of high-tech, globally competitive sectors...If the administration's new interpretation of the Bayh-Dole Act is finalized, breakthrough innovations in fields like semiconductors, agriculture, aviation, and more will all be in jeopardy."



# Ohio Manufacturers' Association

"Our members operating in this industry face billions in investment requirements and years of effort to successfully bring a single drug to market. Government "march-in" to commandeer the intellectual property critical to this process would be nothing short of theft."



## Texas Association of Manufacturers

"Bayh-Dole has enabled states like Texas to develop some of the most competitive manufacturing sectors in the world. Yet the proposed framework on march-in rights now threatens this success."



# Alliance of U.S. Startups and Inventors for Jobs

"If the U.S. is going to compete and lead in areas like clean energy, advanced manufacturing, robotics, AI, semiconductors, materials science and yes, even life sciences, we will need our best ideas and research driving another generation of great companies with the support of private capital. In other words, the exact promise of Bayh Dole over 40 years ago."

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## **ALL**vanza

"The Bayh-Dole Act has served as a cornerstone of the United States' IP infrastructure for over four decades. ALLvanza believes the proposed framework to reinterpret the law's march-in provisions poses a threat to underserved innovators in particular and to many technology-driven industries across our economy."



# American Bar Association Intellectual Property Law Section

"[T]he "Guidance Framework" allows anyone to file a "march-in" petition, in conflict with traditional principles of standing to challenge a property right...No rational investor nor venture capital firm would fund any entity developing a business where the essential patent underlying the technology could be seized at will."



# American Intellectual Property Law Association

"The proposed framework represents a policy shift that will disproportionately diminish the positive benefits of the BDA to startups, universities, and small companies, because private sector collaborators will become more reluctant to license early-stage federally funded technologies."



# **Association of American Medical Colleges**

"The past four decades have demonstrated that Bayh-Dole has been remarkably successful in catalyzing academic-industry collaborations... The AAMC is concerned that the framework, with its open-ended considerations for march-in on a successfully developed and marketed product, would make these investments unattractive for private investors."



# Association of American Universities (AAU)

"Without the intellectual property rights and protections created by the Bayh-Dole Act, private sector partners will be less likely to devote scarce resources to the risky work needed to advance research from federally funded university laboratories to market."



## Association of Public & Land-Grant Universities

"[M]atching research to marketplace needs takes time and dedicated resources, and negotiations around intellectual property agreements are complex. Adding regulations to the technology transfer process, such as the currently proposed framework, that increases complexity will result in fewer new products and innovations in the marketplace."



# Association of University Research Parks (AURP)

"[The framework] will create uncertainty in utilizing federally supported patents and create substantial barriers in building tech hubs across the U.S. that have been contemplated under bipartisan CHIPS + Science Act. Having federal funding agencies micromanage patent licensing from federally supported research will create substantial harm to the nation's technology competitiveness."

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## **AUTM**

"By making it less likely that industry will license and devote time, effort, and resources to developing federally funded innovation, the Draft Guidelines will result in fewer products and less market competition—which equates to higher (not lower) prices...[T]he adverse effects on innovation and access to drugs and other technologies will be devastating."



## **Bayh-Dole Coalition**

"The proposed framework violates both the letter and spirit of the Bayh-Dole Act and would cause untold harm to American companies, workers, and consumers if implemented...The issuance of the guidelines is already casting a cloud over public/private sector partnerships at a time when we need them to promote public welfare by solving pressing problems, growing our economy, and meeting the threat posed by rivals such as China to eclipse our lead in the technologies that will determine who leads the 21st century."



## Council on Governmental Relations (COGR)

"[T]he Framework applies to all types of technologies...[It] will undermine the utilization of Bayh-Dole subject inventions, since companies will be reluctant to invest in licensing and development when faced with the increased uncertainty associated with the potential of march-in on pricing grounds."



# Information Technology and Innovation Foundation (ITIF)

"[N]ot only will "price as a basis for march-in" have an impact on public availability of innovations—because the private sector will be commercializing far fewer technologies arising from federally funded R&D—there will also be fewer innovations because federal agencies will be forced to spend far more of their resources on adjudicating march-in petitions."



## **Innovation Alliance**

"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... not raise the prospect of routine march-in on government-funded projects."

International Center for Law & Economics

# International Center for Law & Economics (ICLE)

"The proposed changes to the Bayh-Dole Act's march-in rights pose serious threats to the successful innovation regime that has propelled the United States to the forefront of global innovation...[R]egulators are fundamentally incapable of matching, on average, the market's efficiency in setting prices."

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# Licensing Executives Society (USA & Canada)

"Bayh Dole created a virtuous cycle of innovation by decentralizing and incentivizing the commercialization of federally-funded basic research...The Framework will kill that virtuous cycle."



# **National Venture Capital Association**

"Because patent ownership is such a critical factor motivating VC funding, reductions in the predictability and dependability of the patent system directly and immediately disrupt VC-driven innovation... If agencies begin exercising march-in rights in the way the guidance advises—or even if agencies threaten to do so—it will upend the predictability of patent rights, undermining the very incentive structure the [Bayh-Dole] Act created to drive innovation."



# Pharmaceutical Industry Labor-Management Association (PILMA)

"[I]mplementing this policy would directly impact union construction jobs in the biopharmaceutical sector and potentially beyond. In addition to the economic impact, patients counting on continued collaboration between private and public sectors to discover and produce medicines to treat challenging diseases would be at a loss."



# The Coalition for 21st Century Patent Reform

"[T]he Proposal would subject startups and small- and medium-sized businesses, in addition to all companies, to the uncertainty of potential "march in" based upon the price of their product only after they have invested significant sums to develop the product...

[This] would chill innovation, especially when it comes to the attempt by startups and small and medium-sized businesses to create the technologies of the future."



# **United Inventors Association**

"[T]he "Guidance Framework" would allow ANYONE—a larger competitor or one financed by China or other countries with which we are in a race to achieve dominance in key technologies...to file a "march-in" petition. The simple filing of a petition will dry up funding, disrupt markets, and likely cause irreparable damage to an entrepreneurial company—whether the federal agency decides to "march-in" or not."



# **U.S. Chamber of Commerce**

"The actions contemplated by the proposed guidance are unlawful and directly contradict both the plain text and the spirit of the Bayh-Dole Act...[and they] would radically alter and undermine America's innovation ecosystem, thwarting American technological leadership and the ability of Americans to access the next generation of innovative technologies."

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## **Senator Thom Tillis**

Ranking Member of the U.S. Senate Judiciary Subcommittee on Intellectual Property (R-NC)

"The threat that government agencies will "march-in" and seize patents if prices exceed a vague and undefined threshold undermines the certainty that innovators need to make investments and bring complicated new technologies to market. The recent guidance will stop progress in its tracks with little discernible benefit to the public."



#### **Howard Dean**

Governor of Vermont (1991-2003); Chair, Democratic National Committee (2005-2009)

"Innovation depends on intellectual property protections. The United States is still the global leader in the development of new medicines and new technology – and weakening patent rights will destroy that advantage, along with the many jobs that IP-intensive industries support."



## Ron Klink

U.S. Congressman, D-PA (1993-2001)

"The absence of intellectual property protection will dissuade companies from licensing and commercializing federally-funded research, deeming it excessively risky. The consequence is a trifecta of drawbacks: no new treatments, a decline in jobs, and persistently high prices — a lose-lose-lose scenario."



## **James Pooley**

Deputy Director General, United Nations World Intellectual Property Organization (2009-2014)

"No matter the good intentions behind this proposal, the fact remains that exercising this new form of march-in rights - which would allow the federal government to forcibly relicense patents at any time based on unpredictable "price" determinations - will drastically diminish the available incentive-based funding that has led to the creation of so many innovative products."



## Lamar Smith

U.S. Congressman, R-TX (1987-2019)

"All patent-intensive industries, from renewable energy and sustainable agriculture to artificial intelligence and biotechnology, will suffer the consequences of reduced investment and breakthroughs left undeveloped. This reality is especially disheartening, as some of those sectors are ones I worked to protect and promote as chairman of the House Science Committee."

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