



Andrei Iancu, Co-Chair  
David Kappos, Co-Chair  
Judge Paul Michel (Ret.), Board Member  
Judge Kathleen O'Malley (Ret.), Board Member  
Frank Cullen, Executive Director

October 25, 2023

The Honorable Xavier Becerra  
U.S. Department of Health  
and Human Services  
200 Independence Avenue SW  
Washington, D.C. 20201

The Honorable Gina Raimondo  
U.S. Department of Commerce  
1401 Constitution Avenue NW  
Washington, D.C. 20230

Dear Secretary Becerra and Secretary Raimondo,

We write to express our concern regarding the interagency working group reviewing the march-in provision of the Bayh-Dole Act for the Department of Health and Human Services and Department of Commerce.

Our organization, the Council for Innovation Promotion, is a bipartisan coalition dedicated to fostering strong and effective intellectual property rights. We stand united against any effort to weaken the Bayh-Dole Act, a cornerstone of American economic competitiveness.

This 1980 law, spearheaded by Senators Birch Bayh (D-IN) and Bob Dole (R-KS), revolutionized U.S. innovation by decentralizing the licensing process for federally funded research. By giving universities and other nonprofits the ability to license their researchers' discoveries to the private sector, the Bayh-Dole Act incentivized them to commercialize their breakthroughs. In so doing, the law [contributed](#) nearly \$2 trillion to America's GDP and supported 6.5 million jobs between 1996 and 2020.

Unfortunately, anti-patent activists and some members of Congress are pushing to misinterpret Bayh-Dole's march-in provision in a way that would dismantle this success.

The march-in provision allows the government to forcibly relicense federally funded intellectual property under [narrow circumstances](#), such as when the patent owner

has failed to commercialize a product or relicensing is the only way to meet public health and safety needs.

The law makes clear that the government is only authorized to reclaim its rights to an invention if there is inadequate development or commercialization. Nowhere does the plain text specify price as a trigger for march-in -- and the authors of the law, Senators Bayh and Dole, [stated](#) that "Bayh-Dole did not intend that government set prices on resulting products." Yet the [activists](#) seek to make that happen. They would have the federal government lower drug prices by relicensing patents on already-commercialized, publicly available medicines, handing them over to generic manufacturers to make cheaper copycat products.

Because Bayh-Dole clearly does not say what the activists think it does, both Republican and Democratic administrations have repeatedly rejected calls to unilaterally relicense patents where price is the justification for doing so. Most recently, in March 2023, the Department of Health and Human Services rejected a march-in petition on the prostate cancer drug Xtandi.

We urge the interagency working group to follow the letter of the law and reject any specious interpretations that would turn Bayh-Dole into a price control mechanism.

We are also gravely concerned about the working group's process, beginning with its troubling lack of transparency. The agencies have not said who makes up the working group, nor shared any details on its deliberation process. The working group is effectively a black box, and we fear that it will blindside the public with its recommendation.

We are furthermore concerned that the agencies have not invited either members of the public or outside experts like ourselves to share their views with the working group. Its recommendation will likely become a proposed government rule, which means an official public comment period is warranted. Allowing any group to issue proposed rules without public input undermines the basic process of creating regulation.

The working group's recommendation, which will profoundly impact whether America remains a nation on the cutting edge, surely deserves a public hearing.

As the working group moves forward, we ask that you ensure a transparent process that seriously considers the economic impact of dismantling Bayh-Dole as we know it. Please do not hesitate to contact us with any questions or comments.

Sincerely,

A handwritten signature in black ink, appearing to read 'Frank Cullen', is positioned below the text 'Sincerely,'. The signature is fluid and cursive, with a long horizontal stroke at the end.

Frank Cullen  
Executive Director  
Council for Innovation Promotion

cc:

Director Kathi Vidal, United States Patent and Trademark Office

Director Laurie E. Locascio, National Institute of Standards and Technology