



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

December 15, 2022

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

Dear Secretary Becerra,

We write to urge you to reject calls for the Department of Health and Human Services to misuse the Bayh-Dole Act's march-in provision to depress the price of the patent-protected prostate cancer medicine, Xtandi.

Seizing a company's intellectual property at the whim of lawmakers, who arbitrarily decide the price of the patented product is too high, sets a dangerous precedent and will cripple the fruitful research ecosystem spurred by Bayh-Dole in the first place.

That's due to one simple, but important, reason: Government march-in casts a pall of uncertainty over investment incentives. Investors will be less inclined to risk billions of dollars to research, develop, and commercialize cutting-edge medicines or technologies if patent rights can be stripped at any moment. Without these intellectual property protections, it would become difficult, if not impossible, to recoup investors' steep upfront costs and yield returns that can then be invested in future research.

As a result, the next generation of lifesaving and life-changing innovations -- from every IP-intensive industry -- will be less likely to be created and reach Americans.

And in any event, there is simply no basis in the march-in provision embedded in the Bayh-Dole Act for the patent seizure some members of Congress are asking you to undertake.

Specifically, cost is not one of the criteria that warrants the relicensing of patents via Bayh-Dole's march-in provision. The law does not allow the government to revoke a developer's patent rights and license them to generic manufacturers except for exceptional circumstances -- such as national emergencies, when a patent-holder cannot adequately alleviate the nation's "health or safety needs."

The federal government has always abided by these criteria. We, as a bipartisan coalition, led by former directors of the U.S. Patent and Trademark Office from both Republican and Democratic administrations, remind you that no prior administration -- of any party -- has approved a march-in petition filed on the basis of price.

The intent of the Bayh-Dole Act is not -- and has never been -- to use march-in rights as a price control mechanism. Those contending otherwise are acting directly against the letter of the law. And if their calls to invoke march-in under these perverse conditions are answered, it will have dire consequences for American innovation. A reliable intellectual property system is a necessary predicate for a strong innovation economy. Destabilize the carefully balanced IP system and you will destroy innovation.



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We at the Council for Innovation Promotion trust you will stand against misconceived efforts to undermine America's patent system -- and the decades of discoveries it has engendered. And we invite you to consider us a resource as you do.

Sincerely,

A handwritten signature in black ink, appearing to read 'Frank Cullen'.

Frank Cullen
Executive Director
Council for Innovation Promotion (C4IP)

cc:

Sen. Chuck Schumer, Senate Majority Leader
Sen. Mitch McConnell, Senate Minority Leader
Rep. Nancy Pelosi, Speaker of the House
Rep. Kevin McCarthy, House Minority Leader
Sen. Dick Durbin, Chair, Senate Judiciary Committee
Sen. Chuck Grassley, Ranking Member, Senate Judiciary Committee
Sen. Patrick Leahy, Chair, Senate Judiciary Subcommittee on Intellectual Property
Sen. Thom Tillis, Ranking Member, Senate Judiciary Subcommittee on Intellectual Property
Rep. Frank Pallone, Chair, House Energy & Commerce Committee
Rep. Cathy McMorris Rodgers, Ranking Member, House Energy & Commerce Committee
Rep. Jerrold Nadler, Chair, House Judiciary Committee
Rep. Jim Jordan, Ranking Member, House Judiciary Committee
Rep. Hank Johnson, Chair, House Judiciary Subcommittee on Courts, Intellectual Property, and the Internet
Rep. Darrell Issa, Ranking Member, House Judiciary Subcommittee on Courts, Intellectual Property, and the Internet
Rep. Anna Eshoo, Chair, House Energy & Commerce Health Subcommittee
Rep. Brett Guthrie, Ranking Member, House Energy & Commerce Health Subcommittee
Sen. Patty Murray, Chair, Senate Health, Education, Labor & Pensions Committee
Sen. Richard Burr, Ranking Member, Senate Health, Education, Labor & Pensions Committee