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The Biden Administration's Unprecedented Proposal for Government Intervention in Technology Companies under the Bayh-Dole Act

On December 7, 2023, the Biden administration released a request for information (RFI) regarding an unprecedented proposal for the government to take over the patents of start-ups and other companies where those patents are the byproduct of a federal grant. The proposal is based on a never-used provision of the Bayh-Dole Act -- exercising the government's so-called "march in" rights. The administration's proposal would apply to all technologies and all sectors of the economy and likely halt private sector investment in many early-stage, developing technologies.

- The proposal would affect any entity owning patents in any technology that arises from federally-supported research, ranging from semiconductors and quantum computing to agricultural and green technology.
- Although Bayh-Dole has always allowed the government to march-in and reclaim title to federally-funded inventions, administrations under both parties have never exercised this right -- understanding that the Act's intent was to allow seizure only for egregious failure to engage in developing federally-funded patents.
- Bayh-Dole transformed the practical utilization of inventions arising from federally-funded research. Before the Act, less than 4% of patents resulting from federal funding were licensed and put to work. After the Act, it is estimated that the tech transfer it enabled has added nearly \$2 trillion to the U.S. GDP, along with countless life-changing innovations.
- The administration's proposal would empower federal bureaucrats to second-guess the business strategy and adequacy of a licensee's marketplace progress rather than the research institute that actually developed the technology and understands it better.
- Under the administration's proposal, some large market incumbents (including foreign entities with U.S. operations) will be permitted to regularly petition the government to march-in and transfer patents to these incumbents. This will hurt the small companies and start-ups that are the biggest licensees of federally-funded patents and that take the risk of developing federally-funded inventions.
- Under the administration's proposal, VCs will again refrain from investing in companies with federally-funded patents -- because the more successful such a company is, or the more promising the invention, the more likely it is to be a target for government march-in. Investors cannot afford to take that chance.
- The administration's proposal -- if not affirmatively rejected and withdrawn -- will chill private investment in federally-funded patents just as the U.S. is fighting to maintain its global technological leadership. Moreover, undeveloped federally-funded patents will provide a blueprint for state-driven economies like China, which can direct funds to commercialize the inventions sitting unused on the shelves of America's research institutions for their own benefit.

The administration's misguided initiative would decimate America's innovation economy and must be stopped before it goes any further.

Detailed Explanation of How the Biden Administration's Proposal Will Harm American Innovation

Bayh-Dole has brought tremendous value and innovation to the U.S. economy:

- The Act has enabled tech transfer from universities and non-profits to the private sector, mobilizing the private capital necessary for bringing inventions to the market and the American public. It is credited with adding nearly \$2 trillion to U.S. GDP.
- The Act accomplished this by allowing federally-funded researchers (or their institutions) to claim title to a patent covering their invention, absent exceptional circumstances. This allows those who understand the invention the best to develop it or to exclusively license the patent to others who can do so.
- Universities, for example, have created tech transfer offices with expertise in crafting exclusive licensing deals with private businesses -- often startups -- that have clearly defined milestones and deadlines for development and commercialization. Universities have an incentive to ensure that these milestones are met since they stand to benefit financially, and they usually retain the right to terminate the license or license to others if the first company fails to deliver. This decentralized system that vests responsibility in the entity in the best position to monitor progress has led to the unprecedented commercialization of university research.
- In addition, by giving clear title to a patent based on federally-funded research to the researchers, their institutions, or startups receiving a license, venture capitalists and investors have felt confident investing in the development and commercialization of these early-stage innovations, leading to new products and services to the benefit of the American public.
- In 2002, [the *Economist* praised this law](#), writing, "[p]ossibly the most inspired piece of legislation to be enacted in America over the past half-century was the Bayh-Dole act of 1980... [T]his unlocked all the inventions and discoveries that had been made in laboratories throughout the United States with the help of taxpayers' money. More than anything, this single policy measure helped to reverse America's precipitous slide into industrial irrelevance."

The Biden Administration proposal would undo this progress and repeat mistakes of the past that wasted federal research funding:

- For the three decades before the Bayh-Dole Act, the federal government claimed ownership of any patents that resulted from federal funding and would only grant companies non-exclusive licenses to practice them.
- With no guarantee of exclusivity, private capital could not be assured of any return on their investment in bringing an innovation to market -- any successful product easily could be copied by a competitor who obtained its own non-exclusive license from the government.
- By 1978, the government had obtained [approximately 28,000 patents](#) but had licensed fewer than 4% since few private entities would risk such an investment. Federally-funded patents were so toxic that they were described as "contaminated."

- The Biden proposal resurrects this kind of aggressive government intervention with its open-ended set of scenarios where the government could "march-in" and transfer the right to practice a patented invention to another entity. The framework provided in the RFI does little more than restate the statutory text, meaning that the decision for the government to intervene is likely to be highly subjective.
- From the RFI's examples, as well as the framework itself, it is clear the proposed "march-in" framework will dramatically favor large companies with major resources over small companies and individuals. Big companies will nearly always be able to argue that they meet the requirements of the framework and should be allowed to take over the commercialization of the patented invention.
- The factors under the framework are extremely fact-bound, making government decisions difficult to predict. The RFI contemplates extensive agency fact-finding before a decision and potential litigation in the Court of Federal Claims afterward. With no check on entities making a request to the government to exercise march-in rights, this process could devolve into a free-for-all where big companies -- including foreign companies -- frequently petition the government to take over the operations of their smaller competitors in lengthy, expensive proceedings. In the case of foreign companies, this would make it particularly easy for our adversaries, such as China, to mount state-backed campaigns against innovative U.S. companies.
- While much of the press around the Biden administration's proposal has focused on pharmaceutical patents and using "march-in" to lower drug prices, [a recent study](#) reviewing drugs approved between 2011 and 2020 found that 99% of approved drugs would not be subject to "march-in" -- only 5 out of 361 would. In all, 92% of approved drugs received no federal funding at all, and for the remainder, the government did not fund research into all the applicable patents.
- Instead, this proposal will have a chilling effect on start-ups, who license [about 70%](#) of patents with a connection to university research, which are often federally-funded. The symbiotic relationship between American research universities, innovative startups, and venture capital investors is one of America's most profound competitive advantages. There are world-renowned examples of this, including Silicon Valley and Research Triangle Park in North Carolina, but there are technology incubators and research parks in nearly every city and state in America. The Biden administration itself recently named 31 "[Tech Hubs](#)" across 32 states that will share \$500 million in grant funding from the CHIPS Act.
- The Biden administration proposal would undercut these engines of innovation, advancement, and job creation. Any companies that collaborate with or spin out of these Tech Hubs would have their entire business subject to future "march-in" by the government. Companies and start-ups that are lucky enough to be successful in commercializing federally-funded inventions will have a target on their back, especially from larger competitors, who will often be able to argue that they could bring a product to market more quickly and with less expense -- particularly given that they did not bear any of the research and development costs.

- Government bureaucrats will be petitioned to second-guess the progress of these companies and start-ups, rather than the universities or institutions who executed license agreements with them with defined milestones and who are in a better position to understand the technology and gauge the adequacy of progress. Neither companies nor investors are going to be willing to take this risk.
- Investors, for example, will have no way to anticipate when they are making investments whether a federally-funded invention may become a march-in target. No matter how low a company sets a price, or how much effort it puts into developing a product, or how fast it develops a product, there will always be the possibility of some other company petitioning the government to march-in. Without the ability to meaningfully plan for this risk, federally-funded inventions will become lower-priority investment targets, often at the critical early stage when companies are making the go/no-go decisions about investments.

Bayh-Dole never intended to allow aggressive government intervention:

- Although the Biden administration claims to be operating under the Bayh-Dole Act's "march-in" provisions, the Act was never intended to invite regular government intervention. [As Senators Bayh and Dole wrote](#) in the *Washington Post*, "The law instructs the government to revoke such licenses only when the private industry collaborator has not successfully commercialized the invention as a product."
- That such intervention was not intended is reinforced by the fact that the government has never "marched-in" during the 43 years of the Act's existence under the administrations of both parties.
- In particular, the literal text of the Bayh-Dole Act does not allow the price of a good or service to be a factor that justifies marching-in. [As Senators Bayh and Dole wrote](#), "Bayh-Dole did not intend that government set prices on resulting products. The law makes no reference to a reasonable price that should be dictated by the government. This omission was intentional[.]" The Biden administration's proposal allowing consideration of price would set a dangerous precedent of government interference in price regulation -- in addition to simply being illegal under the text of the Act.
- As the Senators further explained, "Government alone has never developed the new advances in medicines and technology that become commercial products. For that, our country relies on the private sector... the primary purpose of the [A]ct was to entice the private sector to seek public-private research collaboration rather than focusing on its own proprietary research."

Chilling successful public-private partnerships under Bayh-Dole will be a gift to the U.S.'s competitors, especially China:

- The market-based economy of the U.S. relies on private capital to drive research and development of early-stage innovations that result from federal funding.

- Without this partnership, federally-funded research will not lead to broader innovation the way that it does now. Initiatives like the CHIPS Act will not work because private industry will not want to take government money.
- The strength of the U.S. system historically relies on the market picking winners and losers -- not the government, as the Biden administration proposal would promote. This change would undermine one of the U.S.'s greatest advantages over China, with its centrally-directed economy and technological development.
- Federally-funded U.S. patents will languish as they did before the Bayh-Dole Act. But with the public disclosures provided in these patents, our competitors will have a blueprint for developing the

technologies developed using U.S. taxpayer dollars. China, for example, can direct its enormous state-run apparatus to mine unused U.S. federally-funded patents and develop them into commercial products, enabling it to become the first-mover in new areas of technology. This is the opposite of smart competition with other would-be world technological leaders.

- At bottom, undermining the Bayh-Dole Act threatens American technological leadership, just as we face mounting competition from abroad, especially China.