

March In



INTRODUCTION

Biden administration's plan to expand the application of march-in rights under the Bayh-Dole Act of 1980 raises grave concerns about the potential repercussions for consumer access to innovative products. While this move is intended to specifically lower pharmaceutical drug prices in the short term, broadening the scope of march-in rights threatens to undermine the very foundations of American innovation, considered a gold standard for the rest of the world. In addition, this expansion would likely also threaten other sectors of grand concern to consumers, including technology and science.



OVERVIEW

The law Biden seeks to invoke is the Bayh-Dole Act, a law that seeks to incentivize innovation and promote commercialization of federally funded research and development by granting patent ownership to contractors. This approach aims to foster a vibrant marketplace where consumers can access a diverse range of innovative products and services. However, the existence and invocation of march-in rights introduces complexities that warrant careful consideration, particularly regarding their potential impact on consumer access and affordability.

March-in rights, while rarely <u>exercised</u>, serve as a safeguard to ensure that the benefits of federally funded R&D are realized by the public, mostly through the public sector. Advocates argue that these rights provide a mechanism to address concerns about high drug prices and ensure equitable access to innovations. However, the potential, and likely, misuse or overly broad interpretation of march-in rights could have unintended consequences, such as stifling innovation or discouraging private investment in critical research areas across various industries. The Biden Administration's plan to use march-in rights deviates from the current norm, as they were originally intended to be used with high standards in mind such as safety or national security, not in setting arbitrarily low prices. It's worth noting that historically, of the <u>eight</u> cases where march-in rights were invoked in the United States, none of them were successful.

The invocation of march-in rights as a political norm will easily lead to the erosion of intellectual property rights, a cornerstone of the American innovation ecosystem. By compelling patent owners to license their IP rights on federally funded inventions, the administration's actions undermine the assurances provided by patent protection, ultimately discouraging private investment and stifling innovation. This erosion of intellectual property rights not only threatens the vitality of businesses and entrepreneurs but also jeopardizes the availability of inventions coming to market for consumers and patients to access.

What's more, the expansion of march-in rights presents a significant barrier to market competition, hindering the introduction of innovative products and solutions. By reducing competition, current supply chains will be disrupted and existing shortages will be exacerbated, resulting in inflated



prices for consumers. Compulsory licensing can distort pricing mechanisms within the market and when patents are forcibly licensed to third parties, it can also disrupt the ability of patent holders to set prices based on market demand and production costs. This disruption can discourage investment in R&D and disincentivize innovation in the long term, as eager entrepreneurs and innovators may limit their contributions if their intellectual property becomes expendable. While the US remains the global leader in R&D performance, contributing over 28%, China is catching up, having contributed 22% of global R&D in 2019. Its rate of growth in this area is almost double that of the US, which will put the United States' leadership in R&D in jeopardy.

While Biden's measure remains focused on medical innovations and drug prices specifically, there are many worries that march-in rights could also be applied to fields such as artificial intelligence, and data computing, as the administration has <u>hinted</u> at regulatory action to capture and direct future innovation. As Chinese firms continue to grow and compete, the incentive for the federal government to capture the advances in American technology will only grow.

CONCLUSION

The expansion of march-in rights poses a significant threat to consumer access to innovative products and services. By eroding intellectual property rights and stifling market competition, the government risks undermining the very principles that have long supported American innovation and economic growth.

Rather than resorting to measures that hinder and potentially freeze innovation, policymakers should focus on fostering an environment conducive to entrepreneurship and private investment. By prioritizing policies that support innovation and competition, we can ensure that consumers continue to benefit from access to high-quality products and services at competitive prices, while preserving the integrity of our nation's innovation ecosystem.



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