Insight

Biden Administration's Plan to Expand March-in Rights Could Harm All Sectors of the Economy

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Executive Summary

- The Biden Administration recently proposed to expand the use of march-in rights–the process of taking a patent derived in part from federal research funding and licensing it to competitors of the original rights holder–as a tool to lower the cost of pharmaceutical drugs.
- Limiting potential returns on investment will necessarily add risk for private companies engaging with federal funding opportunities, disincentivizing firms from investing in the research and development of new products and services.
- While the Biden Administration has focused on pharmaceuticals to justify the use of march-in rights, the expansion of this power could potentially impact public-private collaborations for a wide variety of technologies such as semiconductors and artificial intelligence.

Introduction

The Biden Administration recently requested comments on draft agency guidance regarding agency exertion of march-in rights. When a firm owns the rights to a patent derived in part from federal funding, federal law allows an agency to "march-in" and license that patent to a competitor under specific circumstances; to date, no federal agency has exercised these rights. Yet citing the rising cost of pharmaceutical drugs, the Biden Administration's proposed guidance would advise agencies to potentially exercise these rights when "the price or other terms at which the product is currently offered to the public are not *reasonable* [emphasis added]."

Every research and development investment necessarily involves a risk calculation regarding the potential return, and losing rights or artificially lowering the cost of an end-result product due to agency pressure adds more risk to that calculation. Considering that most federal research is foundational, and private firms must invest significantly to develop and commercialize practical applications of the products, adding risk could severely limit the development of new and innovative products and services.

While previous American Action Forum work regarding the draft guidelines focused on pharmaceuticals, the risk extends beyond any one sector. Currently, the Biden Administration has allocated significant funding for the research and development of technologies such as semiconductors and artificial intelligence. If its goal is to promote the research and development of these technologies, adding risk to the firms developing these tools will disincentive collaboration with federally funded research opportunities.

March-in Rights and the Bayh-Dole Act

Historically, when federal funds led to a patent, the federal government retained full ownership of that patent to

license as it saw fit. Under this model, commercialization of the product could only happen when the agency granted that license to a private firm, but license terms and lack of ownership of the patent led to a failure to fully develop and commercialize new products. In fact, under this regime, only 5 percent of patents were used in the private sector.

Congress passed the Bayh-Dole Act to address this problem. Primarily, the law granted firms and universities the rights of the patents on inventions they create with the help of federal funding. With ownership of these patent rights, private firms could take more of their own risks in research and development, and take the necessary steps to get products to market. And while no formal data show the commercialization of privately owned patents after Bayh-Dole was passed, survey data from agency officials indicate the legislation has largely been successful at making new products available to the public.

Congress didn't want to abandon control entirely to the private sector, and therefore created march-in rights. Specifically, when one of four statutory criteria is met, agencies can "march-in" and require the rights-holder to license the patent to a competitor. This provision would apply in cases such as when an assignee has not taken effective steps to achieve practical application of the patent or when action is necessary to alleviate health or safety needs, in which event the agency would be able to grant rights to another firm to ensure the public can benefit from the investment of taxpayer dollars. These rights, however, are reserved for extreme scenarios and in the 40 years since the bill's enactment, march-in rights have never been exercised.

The Biden Administration recently announced a draft framework that would consider the price of the patented good alone as a justification to establish that the rights holder is "not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention," as outlined in the Bayh-Dole Act. This is a radical departure from existing precedent, as agencies have specifically rejected petitions to march-in based solely on price.

Adding Risk Lowers Incentive to Invest

Expanding the exercise of march-in rights to cases solely based on the price of the commercialized product will add additional risk to R&D investments and disincentivize firms from working with the federal government at the outset.

When determining what investments to make, firms conduct opportunity cost calculations and factor in potential return on investment. In cases where risk is elevated, firms are less likely to make those investments and can prioritize funding elsewhere. For example, regulatory risk in the broadband industry due to Federal Communications Commission policy changes reduced broadband investment by 10 percent on average, meaning U.S. networks had less coverage, capacity, and reliability than they would have without that additional risk.

Likewise, when the private sector works with government partners to research and develop new products, it takes on the risk that the research will not return revenues large enough to offset costs. Often, commercialization of federally funded research requires additional investment from private firms or universities to develop practical applications for that technology. Federal investment can also supplement a firm's own research and development investment. If a firm must consider that it may lose patent rights after a product is commercialized, it may determine that the potential risk outweighs the potential reward, and thus forgo investing.

If federal agencies are directed to more flexibly use march-in rights to address competitive concerns, as

suggested in comments by the Federal Trade Commission, firms will necessarily have to consider the elevated risk of investment.

Expansion of March-in Rights Not Limited to Pharmaceuticals

While the draft guidance focuses on drug prices, expansion of march-in rights would impact all sectors of the economy. The federal government invested over $194 billion in R&D in FY 2021 and only $76 billion went to life sciences generally. Indeed, federal R&D covered areas such as computer sciences, atmospheric sciences, and engineering. Not all research will eventually lead to a patent or commercialization of the research, but research into all these fields can be significantly diminished if firms worry that their research could be taken and licensed to rivals.

For example, the CHIPS and Science Act of 2022 invested $53 billion in U.S. semiconductor manufacturing, including in its R&D and workforce. The Biden Administration argued this law would promote American competitiveness, make U.S. supply chains more resilient, and support our nation's security and access to key technologies. Firms such as Ericsson, IBM, Intel, and Samsung have all committed to working with the government and academic researchers to "spur innovation and technology transfer, to inform research needs, and to train future workforce."

Similarly, President Biden has made research and development of artificial intelligence (AI) models and technologies a key priority for his administration, and numerous bills currently before Congress propose to fund research into new models. Again, the policy goal of the administration is to lead in AI and "unlock the technology's potential to solve some of society's most difficult challenges." And indeed, the National Science Foundation just last month announced the launch of the National AI Research Resource pilot. While not a direct funding opportunity, the government collaboration between private firms such as AMD, Intel, Meta, Microsoft and Nvidia will only increase as these initiatives roll out.

While the march-in rights debate has focused on the patents for pharmaceuticals, broad changes to expand the use of march-in rights as a price control mechanism will limit private partnership and investment with R&D opportunities such as in AI or semiconductors, especially if they are a key priority for the administration. If firms that work with an agency and receive funds from, for example, the CHIPS and Science Act or one of the congressional AI research bills, they may begin to worry that their industry could be the next target of march-in rights and thus be less likely to partner with federal agencies. In the AI and semiconductor sectors, specifically, proprietary ownership of model weights and chip design processes, respectively, are critical to a firm's value and incentive to invest and iterate. If march-in rights are extended, it could act as an impediment to further collaboration between leading private-sector firms and the federal government. As a result, U.S. consumers will not benefit from these programs, ultimately resulting in wasted taxpayer dollars directed toward projects that never lead to commercialization.