Comments for the Record



Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights

JEFFREY WESTLING | FEBRUARY 6, 2024

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The federal government has a duty to use taxpayer dollars efficiently and to promote the welfare of its citizens. If taxpayer dollars fund the development of new and innovative technologies, taxpayers should benefit from their development and deployment. At the same time, limiting the rights of private companies to commercialize products that rely on these partnerships as they see fit could jeopardize future developments.[2]

Previous American Action Forum research highlighted the general concern with the Biden Administration's application of march-in rights for the patents of pharmaceuticals, primarily based on the cost or speed of deployment of the drugs.[3] These comments seek to expand this research to a broader application of march-in rights beyond pharmaceuticals, specifically technology firms. As the United States races to lead the way on a wide range of new technologies, an expansive reading of march-in rights could cause American firms to hesitate with government partnerships, ultimately harming the innovation and development that regulators seek to promote. This isn't to say march-in rights should never be used, but NIST should clearly outline the situations and types of patents for which agencies would exercise these rights.

Increasing Regulatory Risk Decreases Investment

Congress passed the Bayh-Dole Act to promote innovation and commercialization of new products.[4] By granting firms and universities the ownership of the patents on inventions they create with the help of federal funding, companies can obtain a return on their research and development investments, which normally outweigh federal funding.[5] At the time of the law's passage, only 5 percent of patents were used in the private sector, largely because the government-maintained ownership of the patent.[6] After Bayh-Dole was passed, granting firms and universities the ownership of those patents, commercialization of research largely increased.

Any action taken by NIST should promote the goal of commercialization of new technologies. Congress created march-in rights for the rare situation in which a critical invention was not made commercially available, but after over 40 years no agency has exercised these rights.[8] Understandably, agencies instead largely defer to the market and private companies to determine the best path for commercialization.

The draft framework abandons this approach and instead cites high prices as a justification for the exercise of march-in rights. This could have significant negative consequences that agencies should consider when

determining whether to exercise march-in rights.

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. 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. [9] For example, regulatory risk in the broadband industry due to Federal Communications Commission policy changes reduced broadband investment by 10 percent on average, meaning American networks had less coverage, capacity, and reliability than they would have without that additional risk. [10]

Likewise, when firms work with government partners to research and develop new products, they take on risk that the research will not return revenues large enough to offset costs. This is especially true in fields that require more theoretical applications of the research, as additional uncertainty adds risks, hence the need for government support at the outset.

Congress designed the Bayn-Dole Act primarily to promote the development and deployment of new inventions. NIST should be careful not to impede this process here by adding additional risk to the decision to invest in research and development.

Additional Risk Impacts All Sectors of the Economy

While NIST focuses on drug prices, it should also carefully consider how the expansion of march-in rights affects other industries and inventions. The federal government invested over \$194 billion in FY 2021 in R&D, and only \$76 billion went to life sciences generally.[11] Indeed, federal R&D covered areas such as computer sciences, atmospheric sciences, and engineering. Not all research is eventually going to lead to a patent or commercialization of the research, but research into all these fields can be significantly affected if firms worry that their research will be taken and licensed to rivals.

For example, Congress passed the CHIPS and Science Act in 2022, which invested \$53 billion in U.S. semiconductor manufacturing, including in its research and development and workforce.[12] 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."[13]

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."[14] 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 collaboration between private firms such as AMD, Intel, Meta, Microsoft and Nvidia will only increase as these initiatives roll out.[15]

While the march-in rights debate has focused on the patents for pharmaceuticals, NIST also should carefully consider how any changes to agency policy may affect these types of R&D opportunities, 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 these firms will be less likely to partner with federal agencies in the future. 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, this 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 commercial success.

- [1] Jeffrey Westling is the Director for Technology & Innovation Policy at the American Action Forum. These comments represent the views of Jeffrey Westling and not the views of the American Action Forum, which takes no formal positions as an organization.
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- [3] Laura Hobbs, "March-In Rights: A Hostile Regulatory Environment," Insight (Dec. 20, 2023), https://www.americanactionforum.org/insight/march-in-rights-a-hostile-regulatory-environment/.
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