MILKEN INSTITUTE
CENTER FOR PUBLIC HEALTH

FUTURE OF HEALTH SUMMIT PRIVATE SESSION SUMMARY

Solving the Affordability/Innovation Conundrum

A private session at the Milken Institute Future of Health Summit in October 2019 assembled representatives from the patient advocacy community, universities, the legal profession, and the pharmaceutical and biotech industry to discuss public concerns about drug prices. The session focused on the potential use of so-called march-in provisions of the Bayh-Dole Act of 1980 as a lever to lower prices and increase accessibility of therapies. This topic is particularly relevant eight months later, as the scientific community searches for a vaccine or treatment for COVID-19. The urgency to develop vaccines and anti-viral therapeutics for this deadly virus will likely raise questions about incentives (including those related to intellectual property), pricing, and equal access. Policymakers already grappling with how to bolster essential public health and health-care infrastructure and to protect citizens in a cost-effective way will be looking to encourage innovation while providing easy, widespread access to life-saving preventive and therapeutic options.

Background

Congress enacted the Bayh-Dole Act in 1980. The law allows for universities and other nonprofit organizations to patent and retain title to their inventions and to license it to commercial entities to research and potentially develop new therapeutics. It also allows a government funding agency to retain and potentially exercise so-called march-in rights for a patented invention if a company doesn't develop the technology, exercise diligence in development, or does not/cannot supply the product for the purposes for which it was intended.

There have been only six instances in which the National Institutes of Health (NIH) has been petitioned to exercise march-in rights. The NIH rejected each request. Had any of the petitions succeeded, such march-in actions would have resulted in the government taking control of patented technology and licensing the patent to other commercial entities to develop and bring a product to market. To date, the NIH march-in petitions have been based principally on the argument that the high price of a product limits its availability to patients. In denying the petitions, the NIH stated that Congress did not identify high prices as a trigger for march-in and did not comment specifically on the cost of the products.

Amidst public concerns, some members of Congress and other political leaders over the past 18 months have urged revisiting the Bayh-Dole Act march-in provisions to control drug pricing. In theory, march-in would result in the government funder regaining control and licensing the technology to a company that offers a lower price for the product and would give patients easier access to the lower-cost drugs.

A private session at the Milken Institute's Future of Health Summit 2019 assembled a broad spectrum of public- and private-sector stakeholders to consider issues surrounding march-in rights. Their overall message: not so fast.

Key Discussion Points

Policymakers and legislators have been unable to agree on how to reign in high drug prices. That's because of the complexities of pricing and drug distribution and sales, and because the issue is controversial politically and socially. Reaching a more positive path forward requires involving all stakeholders, particularly patients and caregivers, from the onset of discussions, and ensuring they have access to complete, accurate information about such areas as:

1. the costs of research and development, production, and acquisition of new drugs;

2. a comprehensive understanding of the value proposition both from the perspective of patient outcomes and in consideration of the market and data protection necessary to incentivize the development of novel therapeutics; and

3. the benefits of federally supported research.

The session's principal purpose was to consider legislators' recent discussion of possible changes that would allow federal funding agencies to take control (march-in) of intellectual property associated with an approved drug or drug in development whenever the high cost would prevent the product from reaching patients. Large and small pharmaceutical and biotechnology companies shared their perspectives with patient representatives and university scientists, who are the main recipients of government support and a critical source of research and innovation.

Regardless of their background, the participants agreed that intervening with patents or intellectual property is perilous. By creating a singular patent policy among federal agencies, the Bayh-Dole Act allowed small companies, universities, and other nonprofit groups to retain their ownership of inventions enabled by federal funding. The Bayh-Dole Act was enacted explicitly to increase the extent of technology transfer from universities to the private sector and to incentivize commercial application of innovative technology discovered in non-commercial research funded by the federal government.

But those opposing said the changes would amount to a mandate based on arbitrary judgments about drug pricing. This would destroy the value of intellectual property that serves as a key incentive for private-sector investment in new therapies. The act's purpose was not to control pricing of products developed from government-supported research. Modification or re-interpretation of the act to permit retracting patents and dissolving licenses more easily would lead commercial enterprises simply not to license university-based inventions. The unintended consequence would be a lessening of competition and development of fewer products.

Participants noted earlier unsuccessful attempts in the 1990s via the Federal Technology Transfer Act to impose "reasonable pricing" standards for licenses of technology developed in the NIH Intramural Research program. The effect of these efforts was to reduce the number of licenses, resulting in potentially important new technology being shelved. In light of this impact and the likelihood that modifying Bayh-Dole's march-in provisions would lead to a similar outcome, session participants strongly suggested that any actions to reduce or control drug prices should occur after the product reaches the market, not while it is in development.

The participants also discussed the negative impact that modifying patent policy would have on the development of startups. These companies frequently spin out of research institutions that have created promising therapies and medical devices and often license patents arising from federally supported research. For example, the America Invents Act created uncertainty about the validity of patents and appears to have impacted early-stage development.

The real problem, according to the participants, is not that Bayh-Dole must be amended but that the public, policymakers, and legislators do not trust the pharmaceutical industry and blame companies' focus on profitability for the high cost of drugs. While they do not want to eliminate intellectual property protection, the lack of trust has spurred suggestions that the majority of session participants said are not in the industry's best interest. Participants said that the industry, patient groups, insurers, academia, investors, and others must form a strong partnership to address drug pricing concerns and patient access to new therapies.

Conclusion

The consensus from this discussion was clear on three key points:

1. The intellectual property system is a significant driver of investment that supports innovation.

2. Without innovation, there will be fewer new therapies, which would likely lead to fewer generic drugs and biosimilars, both of which may lower drug prices.

3. Manipulating the intellectual property system will discourage innovation, and by extension, harm patients in need of new therapies and cures.

Participant Insights

Intellectual property incentivizes innovation, without which, there will be fewer new therapies for patients.

Participants in the session agreed that modifying the march-in provisions of the Bayh-Dole Act will interfere with the development and marketing of innovative therapies and medical devices and not improve patient access to medications. To form the basis of future policy deliberations, these perspectives will also need to account for the perspectives of additional, relevant stakeholders.

The pharmaceutical and biotech industry must work with other stakeholders to address the public's concern about drug prices, to rebuild public trust by showing the public, policymakers, and legislators that it is, has been, and will continue to be dedicated to improving patient lives.