COUNCIL FOR AFFORDABLE
HEALTH COVERAGE

Background on March-in Rights

Before Bayh Dole was enacted in 1980, the United States lagged behind other first-world nations in developing innovative technologies. The government held the patents and licensing rights to all discoveries resulting from federally funded research. Funding agencies, however, had little incentive to encourage the commercialization of these discoveries.

- The incentive problem was abstract, but the consequences were concrete. During the pre-Bayh-Dole era, the U.S. government held around 28,000 patents resulting from government-sponsored research. But it had licensed barely 5 percent of them for development.[1]

- The Bayh-Dole Act transferred to universities, federal labs, and businesses that received federal research funds the patent and licensing rights on their discoveries and inventions, empowering them to license them to commercial partners in exchange for royalty payments and other compensation. With the incentive structure corrected, tech transfer flourished. Between 1996 and 2020, the introduction of the new system led to the issuance of 126,000 new patents to research institutions and the creation of almost 17,000 startups.[2] The new system added $1 trillion to U.S. gross domestic product and contributed more than 200 life-saving drugs and vaccines to the healthcare system.[3]

- Bayh-Dole's "march-in" provision allows the government to relicense patents in certain, limited circumstances, such as when licensees fail to make a good-faith effort to develop them. These rights were included as a fail-safe in the legislation to ensure federally backed inventions were reaching the marketplace. The government has never invoked this authority and has consistently rejected activist petitions that urge agencies to march in based on a successfully developed product's price.

- The proposed framework reverses course, allowing federal officials to consider price as a trigger for march-in.

- Because of the complexity of most pharmaceuticals, intellectual property underlying each product typically consists of multiple patents, many of them developed without the use of public funding. According to a 2023 study by Vital Transformation, which examined a cohort of 361 pharmaceutical products launched in recent years, only five depend solely on government-funded patents.[4] In other words, even the most aggressive efforts to reinterpret march-in rights would not affect 99 percent of drugs.[5]

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[1] https://www.gao.gov/assets/rced-98-126.pdf

[2] https://autm.net/AUTM/media/Surveys-Tools/Documents/AUTM-Infographic-22-for-uploading.pdf, p. 1

[3] https://autm.net/AUTM/media/Surveys-Tools/Documents/AUTM-Infographic-22-for-uploading.pdf, p. 1

[4] https://vitaltransformation.com/wp-content/uploads/2023/11/march-in_v11_BIO-approved-30Nov2023.pdf, p. 19

[5] https://vitaltransformation.com/wp-content/uploads/2023/11/march-in_v11_BIO-approved-30Nov2023.pdf, p. 19

- Nevertheless, the mere threat of having to contend with march-in petitions would introduce a new element of uncertainty into biotech companies' investment decisions.