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Comments of Public Citizen on the National Institute of Standards and Technology (NIST) Proposed Rule: "Rights to Federally Funded Inventions and Licensing of Government Owned Inventions"

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Public Citizen is a consumer advocacy organization with more than 500,000 members and supporters. Public Citizen's Access to Medicines Program works with partners across the United States and around the world to make medicines affordable and available for all through tools in policy and law. We are writing today to express serious concerns with elements of NIST's proposed rule that would undermine public interest protections in the Bayh-Dole Act and to call on the Biden Administration to withdraw the proposal.

Introduction

Even before the pandemic, people across the United States were struggling to access the medicines they need. Three-in-ten Americans reported not taking their medicine as prescribed due to costs.[1] High prices of medicines and hormones like insulin that millions of people throughout the country need to stay alive have led to rationing, and ultimately death.[2] Drug corporation price gouging disproportionately impacts people of color, who face higher rates of diabetes and other conditions requiring expensive medicines. Pandemic-related economic strains have only made our drug pricing and access to medicines crisis more acute.

Predictably, the need for relief has not abated during the pandemic, with more than eight in 10 Americans saying it is "extremely important" that the federal government take action to lower prescription drug prices.[3] But rather than providing relief to people whose health and wellbeing is negatively impacted by excessive drug prices and treatment rationing, the proposed rule would erode the ability of the federal government to respond.

These comments will underscore Public Citizen's concerns with the proposal to explicitly prohibit exercise of march-in rights on the basis of price alone (through modifying 37 CFR § 401.6) and briefly highlight other elements of the proposal we oppose, including narrowing the scope of inventions to which government interests attach by changing the definition of "subject invention" (through modifying 37 CFR § 401.14), restricting who has standing to challenge exclusive licenses granted by Federal agencies (through modifying 37 CFR § 404.11) and reducing transparency by removing the requirement that agencies inform the public of prospective exclusive licenses through modifying 37 CFR § 404.7(a)(1)(I).

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[1] https://www.kff.org/slideshow/public-opinion-on-prescription-drugs-and-their-prices/
[2] https://www.npr.org/sections/health-shots/2018/09/01/641615877/insulins-high-cost-leads-to-lethal-rationing
[3] https://cdn1.sph.harvard.edu/wp-content/uploads/sites/94/2021/01/Politico-HSPH-Jan-2021-PollReport.pdf

Prohibiting exercise of march-in rights on the basis of price alone (modifying 37 CFR § 401.6)

"Practical application" is defined under statute as follows:

> "The term "practical application" means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized *and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms*."[4] (emphasis added)

The plain language of the statute makes clear the need for inventions to be available on *reasonable terms*. Price is central in determining what is reasonable. Exorbitant prices constrain access and contribute to treatment rationing. Many federally-funded inventions remain out of reach for American taxpayers.

Despite the inclusion of the word "reasonable", some have interpreted the statute only to require that inventions are made available on *any* terms, including at prices multiples higher than those charged in other wealthy countries. They are wrong. Public Citizen is not alone in understanding the definition practical application (and thus the scope of march-in rights under 35 USC 203(a)(1)) to include reasonable pricing. NIST has already received comments from dozens of members of Congress and senators expressing concern with its narrow interpretation of practical application in the proposed regulation. Vice President Harris, as a U.S. Senator and presidential candidate, as well as Secretary Becerra, as a member of the U.S. Congress and again as California Attorney General, have advocated for use of march-in rights as a remedy to high prices charged by drug corporations for prescription drugs. Sen. Murphy recently highlighted his disagreement with the interpretations excluding price in a public Senate Appropriations Committee hearing last year.[5]

In 2018, under the leadership of Sen. Angus King (I-Maine), the Senate Armed Services committee went so far as to include language in a committee report regarding the National Defense Authorization Act that directs the Department of Defense to exercise its Bayh-Dole rights 1) to practice or have practiced on its behalf the subject invention throughout the world without the payment of royalty, or 2) to force a rights holder to license an invention that is not being made available on reasonable terms when it passes a certain pricing threshold. The following language was approved unanimously by the committee:

> ***Licensing of federally owned medical inventions***
> *The committee directs the Department of Defense (DOD) to exercise its rights under sections 209(d)(1) or 203 of title 35, United States Code, to authorize third parties to use inventions that benefited from DOD funding whenever the price of a drug, vaccine, or other medical technology is higher in the United States than the median price charged in the seven largest economies that have a per capita income at least half the per capita income of the United States.*

[4] 35 U.S. Code § 201(f)

[5] https://www.appropriations.senate.gov/hearings/review-of-operation-warp-speed-researching-manufacturing-and-distributing-a-safe_effective-coronavirus-vaccine

NIST should not advance through regulation a narrow interpretation that prohibits exercising march-in rights due to price. Doing so would run contrary to the plain language of the statute and would take away an important tool to protect patients and remedy to corporations price gouging consumers for medicines developed with their taxpayer dollars.

Other harmful provisions

Additionally, Public Citizen adds its voice in support of comments made by Knowledge Ecology International, Drs. Reshma Ramachandran, Ravi Gupta, Joseph Ross and others who have expressed opposition to excluding certain inventions from the definition of "subject invention" through modifying 37 CFR § 401.14, restricting who has standing to challenge exclusive licenses through modifying 37 CFR § 404.11, and reducing transparency by removing the requirement that agencies inform the public of prospective exclusive licenses through modifying 37 CFR § 404.7(a)(1)(I).

Conclusion

The Bayh-Dole act was introduced, under intense lobbying pressure, because valuable inventions were supposedly languishing in laboratories, and incentives were needed for commercialization. But this assumption was always questionable, and much evidence has emerged disputing the need to provide additional incentives.[6] The government has further sweetened the deal for corporations—and against the interests of taxpayers—by repeatedly failing to enforce its authority to demand reasonable pricing on federally-funded inventions.[7] As government giveaways have increased, so too have drug prices. If NIST proceeds with finalizing the proposed regulations, the practice of allowing corporations to reap the rewards of publicly funded research without condition will likely continue, and, indeed, this imbalance will be further entrenched.

Instead, the Biden Administration should strengthen the government's hand by delineating clear, actionable standards on when an invention is not "available to the public on reasonable terms" due to its price. The Administration should also require public disclosure of all information necessary to determine whether licensees are serving the public interest[8], and take further action to respond to the drug pricing crisis our country faces with the urgency it demands.[9]

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[6] 6 See A So et al., Is Bayh-Dole Good for Developing Countries? Lessons from the US Experience, 6 PLoS Biology 10 (2008). ("Although universities can and do patent much more in the post-BD era than they did previously, neither overall trends in post-BD patenting and licensing nor individual case studies of commercialized technologies show that BD facilitated technology transfer and commercialization. Empirical research suggests that among the few academic patents and licenses that resulted in commercial products, a significant share (including some of the most prominent revenue generators) could have been effectively transferred by being placed in the public domain or licensed nonexclusively.")

[7] Robert Weissman, The Role of Federally-Funded University Research in the Patent System, Testimony Before the Committee on the Judiciary US Senate (2007), available at https://tinyurl.com/ya5x3nh7

[8] Reporting requirements should include information about the number of patents and licenses obtained, the funds expended on patenting and licensing activities, licensing revenues, pricing policies and key terms (e.g., exclusive or nonexclusive, humanitarian access, research exemption, definition of market segmentation or field of use, performance milestones, and march-in rights).

[9] https://www.citizen.org/article/letter-to-president-elect-biden-calling-for-executive-action-to-lower-drug-prices-january-2021/