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Re: National Institute of Standards and Technology, Rights to Federally Funded Inventions and Licensing of Government Owned Inventions Docket No.: 201207-0327 Document ID: NIST-2021-0001-0001 Federal Register 2020-27581

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We write in response to NIST’s request for comments, specifically on: “Clarify § 401.6 to include a provision that march-in rights shall not be exercised by an agency exclusively on the basis of business decisions of a contractor regarding the pricing of commercial goods and services arising from the practical application of the invention.”

The quoted section is inconsistent with the statute. As one of us (Arno) has argued with his co-author, the late law professor Michael H. Davis, price is the most important criteria in determining when a drug is made available to the public on reasonable terms.¹ If, as the proposed section states, “march-in rights shall not be exercised by an agency exclusively... regarding the pricing of commercial goods and services arising from the practical application of the invention,” what other criteria besides price, the essential criteria, should be considered? The proposed rule is silent on this, which only creates confusion.

This new rule would brazenly eviscerate the original bargain in the Bayh-Dole Act, namely that in exchange for substantial public investment in new inventions, the inventions must be made available to the public on reasonable terms.

¹ Arno PS, Davis MH. Why Don’t We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed upon Patents Deriving in Whole or in Part from Federally Funded Research. *Tulane Law Review*, 2001; 75(3): 631-693.
http://bit.ly/Arno_Davis2001

We argue that this is an effort to undermine the Bayh Dole Act through new proposed rulemaking and believe it was undoubtedly put into motion by the pharmaceutical industry (Big Pharma) during the Trump Administration. Is Big Pharma now afraid that the Biden Administration might encourage competition, protect the public, and scrutinize drug pricing by applying the Bayh Dole Act march-in provisions? It seems so, because we are now faced with a Big Pharma all-out assault to make them just about disappear, aided by NIST.

This vestige of compassionate capitalism and potential consumer protection contained within the Act—making drugs developed with federal taxpayer dollars “available to the public on reasonable terms”—is under attack. The proposed provision would invite Big Pharma to suppress competition, the hallmark of our capitalist democracy. Perhaps making drugs developed with federal taxpayer dollars has never been about making them affordable to everyone, but it was never intended to make taxpayer-funded inventions the object of uncontrolled excessive monopoly pricing. This is surely what would happen if the proposed version of 37 C.F.R. §401.6.e is implemented.

Under current law, march-in rights give the government the ability to grant a license to a responsible new applicant if, among other things, the current manufacturer has failed to make the product “available to the public on reasonable terms.” 35 U.S.C. § 201(f). The compulsory license is an important tool that allows other qualified companies to manufacture federally funded inventions, introducing competition that can help bring down their price.

The proposed change included in 37 C.F.R. §401.6.e would eliminate the crucial language, “on reasonable terms.” To pretend that the losers, should this come to pass, are not the American people, is nothing short of doubletalk. It would guarantee that Americans will be forced to pay multiple times for the drugs: first, through taxpayer funding for R&D; and then again, through higher taxpayer expenditures in Medicare, Medicaid, and other government programs, higher insurance premiums, and higher out-of-pocket expenses to consumers.

Although march-in rights have never been formally invoked, they provide the government with important leverage that it can use to moderate pharmaceutical companies’ behavior. For this reason, the pharmaceutical industry would like nothing better than to get rid of this legislative phrasing altogether. But practically, logically, and legally, making drugs available to the public

on reasonable terms surely must mean making them available **at a reasonable price**. How could it mean otherwise when the high price of drugs makes them unavailable to the public?

Individuals with ties to Big Pharma continuously recycle erroneous arguments for why “on reasonable terms” does not include unreasonable pricing. They argue, for example, that the 2002 letter to the editor at the *Washington Post* written by ex-Senators Bayh and Dole conclusively establishes that the Bayh-Dole Act did not intend for inventions to be available to the public on reasonable terms but only that they be commercialized. The letter was in response to an op-ed in which Mr. Davis and I argued that reasonable terms encompass price.²

Bayh and Dole were wrong to claim that the public should treat this letter to the editor as conclusively establishing the meaning and intent of the Bayh-Dole Act.

Real legislative history can be a useful tool when, for example, a statute is ambiguous. The Bayh-Dole Act, however, clearly requires not just that an invention is capable of being utilized, but also that its benefits are available to the public on reasonable terms. The statements of Bayh and Dole in their 2002 letter, made decades after enactment of the Bayh-Dole Act, are not a reliable indication of legislative intent and should be set aside for what they are: meaningless and untrustworthy, especially considering how the former senators acquired financial ties to the pharmaceutical industry in the intervening period. As the Supreme Court has held, this kind of post-enactment “legislative history,” a contradiction in terms, is not a legitimate method of statutory interpretation and has no value. Even if the letter to the editor were written in 1980 rather than 2002, it would still have little weight, because it is the language enacted by Congress that is controlling, language that represents the give and take of the legislative process.³ In the case of the Bayh-Dole Act, that give and take resulted in the government having the authority to march in if companies charge unreasonable prices for publicly funded inventions.⁴

² Peter Arno and Michael Davis. “Paying Twice for the Same Drugs,” *Washington Post*, March 27, 2002. http://bit.ly/Arno-Davis_WaPo_02

³ *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 242 (2011).

⁴ *Oncala v. Sundowner Offshore Services, Inc.*, 523 U.S. 75, 79 (1998) (“[I]t is ultimately the provisions of our laws rather than the principal concerns of our legislators by which we are governed.”).

It is also worth mentioning that when Bayh submitted an amicus brief in a Supreme Court case regarding the meaning of a provision of the Bayh-Dole Act, the Court took the opposite position and did not even cite his brief.⁵

The members of Congress that enacted the Bayh-Dole Act understood, and most people understand, that when an individual investor invests in a private company that generates a profit, the individual is entitled to a return on his or her investment. Thus, if a public entity such as the federal government invests in a pharmaceutical firm by funding its research and innovation, it too deserves a return on its investment. This is how our modern competitive capitalist system is supposed to work.

U.S. drug prices are the highest in the world. A recent study by the Rand Corporation found that we pay on average 3.44 times what 32 other developed countries in the OECD pay for the same brand-name drugs⁶ even though we don't consume more drugs than Europeans and others in developed countries. To be clear, it is not higher consumption but the excessive drug prices that we as consumers and taxpayers pay that generate the outsized profits for pharmaceutical manufacturers, and it is these high prices that prevent reasonable access to vital medications. According to the Kaiser Family Foundation, "polling data has shown that almost eight in ten people in the U.S. say the cost of prescription drugs is unreasonable, and three in ten report they have not taken a prescription medicine as directed because of the cost."⁷ In another national survey conducted by Gallup in September 2019, researchers found that **58 million Americans** were "unable to pay for medicine or drugs that a doctor had prescribed."⁸ This is not what Congress intended when enacting the Bayh-Dole Act. A stated policy and objective of the statute is to ensure that the government retains sufficient rights in federally funded inventions to protect against their nonuse and unreasonable use. 35 U.S.C. § 200.

⁵ The case is *Board of Trustees of the Leland Stanford Junior University v. Roche Molecular Systems*, 563 U.S. 776 (2011).

⁶ Mulcahy AW, Whaley CM, Mahlet GT, et al. "International Prescription Drug Price Comparisons: Current Empirical Estimates and Comparisons with Previous Studies." Santa Monica, CA: RAND Corporation, 2021. <https://bit.ly/3a5f9eJ>

⁷ Twitter MR, Kamal R, Cox C. "Who is most likely to have high prescription drug costs?" Peterson-Kaiser Family Foundation Health Tracker, September 29, 2020. <https://bit.ly/38HujWh>

⁸ Witters D. "Millions in U.S. Lost Someone Who Couldn't Afford Treatment," (2019). Gallop Poll conducted Sept. 16-30, 2019. <https://bit.ly/389rWMw>

We also know that when patients cutback on their medications or forgo them entirely because of costs, there are serious adverse outcomes including higher rates of hospitalization, morbidity and mortality.⁷⁻¹² These are the potential clinical consequences, aside from the adverse financial impact on taxpayers and consumers, when drugs are not made available to the public on reasonable terms.

Rather than the proposed rulemaking undermining the Bayh-Dole Act, it would be in the public interest to enforce or strengthen the law already on the books. The proposed rule 37 C.F.R. §401.6.e would eliminate the requirement to make drugs reasonably available to the public, which is enshrined in current law. This would increase the financial burdens on all Americans, increase health disparities, and it would also harm the public's health and enhance the power of unchecked monopolies.

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⁹ Chandra A, Flack E, Obermeyer Z. "The Health Costs of Cost-Sharing." National Bureau of Economic Research Working Paper No. 28439; 2021 Feb 8.

¹⁰ Navar AM, Taylor B, Mulder H, et al. Association of prior authorization and out-of-pocket costs with patient access to PCSK9 inhibitor therapy. *JAMA cardiology*. 2017;2(11):1217-25.

¹¹ Jung K, Feldman R, McBean AM. Nonlinear pricing in drug benefits and medication use: the case of statin compliance in Medicare Part D. *Health Serv Res*. 2014;49(3):910-928.

¹² Fung V, Reed M, Price M, et al. Responses to Medicare drug costs among near-poor versus subsidized beneficiaries. *Health Serv Res*. 2013;48 (5):1653-68.

¹³ Goldman DP, Joyce GF, Zheng Y. Prescription drug cost sharing: associations with medication and medical utilization and spending and health. *JAMA*. 2007;298(1):61-69.

¹⁴ Hsu J, Price M, Huang J, et al. Unintended consequences of caps on Medicare drug benefits. *N Engl J Med*. 2006;354(22):2349-2359.