For Forty-Four Years, the Federal Government Has Declined to Exercise March-In Rights for Federally Funded Patents... It's Time to Revisit the Bayh-Dole Act

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Abstract

This Paper offers a critical examination of the public policy justification for "march-in" rights, why the federal government has not marched in on federally funded patents, and why it is unlikely the federal government ever will. The examination is grounded in the context of high drug pricing and the COVID-19 pandemic.

Table of Contents

I. Introduction

The 1980 Bayh-Dole Act is one of the most significant pieces of patent law in U.S. history. It backtracked thirty-five years of public policy and granted universities and small businesses the right to claim legal title of their inventions that were funded by government grants, but there are significant strings attached to this generous gift of legal title. Under the Bayh-Dole Act, the federal agency that provided the grant can exercise "march-in" rights to force the university or small business to grant a license of their patent to another entity to use, make, or sell the invention.

The circumstances in which the government can exercise march-in rights are significantly limited. However, the threat of Uncle Sam forcibly granting license of a

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hard-earned invention to a competitor looms over the heads of university researchers and tech start-ups each time they accept a grant from the government. But such a threat is essentially non-existent because the federal government has *never*—not once in forty-four years—exercised march-in rights for *any* invention. Since the passing of the Bayh-Dole Act, there have only been seven petitions for the government to exercise march-in rights. All have been denied.

Given that the federal government has declined to use march-in rights for nearly half a century, it's time to revisit the Bayh-Dole Act. What public policy is addressed by sanctioning the federal government to march in on federally funded patents? And have we, the taxpayers, suffered because federal agencies have declined to exercise this right?

II. A Consequential Bill Passed in a Lame Duck Session

The Bayh-Dole Act grants universities and small businesses the right to claim title to their own inventions that were funded, in part or in whole, with federal government grants.[1] Today, the concept does not seem particularly controversial. After all, "[s]ince 1790, patent law has operated on the premise that rights in an invention belong to the inventor."[2] However, at the time Bayh-Dole was passed, the ownership of a federally funded patent was a hotly debated and highly controversial topic.

At the end of the 1970s, the United States was economically suffering from a lack of new products and inventions compared to other countries.[3] At the time, the prevailing rule was that any inventions that resulted from federally funded research belonged to the government.[4] As articulated by Admiral Hyman B. Rickover, "[t]hese inventions are paid for by the public and therefore should be available for any citizen to use or not as he sees fit."[5] It is apparent why this was the established viewpoint; asking taxpayers to garnish their hard-earned wages to fund research for the benefit of for-profit entities like multi-billion-dollar corporations is a tough pill to sell. Thus, the default rule for decades was that the government owned federally funded inventions and only granted non-exclusive licenses for such inventions.[6] However noble the intention of this policy was, in execution it bottle-necked production and innovation. A significant reason for this was because the federal government did not license many of its patents. In 1978, records showed that the government owned 28,000 patents and licensed less than 4% of them.[7] Additionally, the government only granted *non-exclusive* licenses. These types of licenses are significantly less valuable

1 35 U.S.C. § 202.
2 Bd. of Trs. of the Leland Stanford Junior Univ. v. Roche Molecular Sys., 563 U.S. 776, 777 (2011).
3 *See* S. REP. NO. 96-480, at 1 (1979) (finding that industrial and technological innovation in the United States may be lagging when compared to historical patterns and other industrialized nations).
4 Ashley J. Stevens, *The Enactment of Bayh-Dole*, 29 BOS.UNIV. J. TECH. TRANSFER 93, 94 (2004).
5 *Id*. at 95.
6 *Id*. at 94.
7 Vicki Loise & Ashley J. Stevens, *The Bayh-Dole Act Turns 30*, 2 SCI. TRANSLATIONAL MED. 1, 1 (2010).

than exclusive licenses because the government is not restricted in granting the same license to a competitor.

A bipartisan team of Senator Birch Bayh and Senator Bob Dole introduced the Bayh-Dole Bill to the Senate in 1978 as S. 414 to amend the current policy of federally-funded patents.[8] The Committee Report of S. 414 stated that the purpose of the bill was to "promote the utilization and commercialization of inventions made with Government support" and promote collaboration between the private sector, universities, and small businesses.[9] The Bayh-Dole Bill allowed universities and small businesses to claim title to their inventions made with federal funds, thereby allowing such patents to be sold or licensed more readily.[10] The Committee Report claimed that the bill would allow universities and small businesses to optimize the commercialization of their inventions by selling their patents or granting the much more lucrative exclusive license.[11]

To address the concern of taxpayer money being used to benefit the commercial sector, march-in rights were added to the bill. The Committee Report alleged that "[t]he presence of march-in-rights" would "be a sufficient safeguard to protect public welfare requirements and prevent any undesirable economic concentration."[12] The Committee Report further claimed march-in rights to be "a remedy to be invoked by the Government" if reasonable efforts were not made to achieve practical application of the invention or for alleviation of public health and safety needs.[13]

Despite being passed in the Senate on a 91–4 vote, the Bayh-Dole Bill was nearly snuffed out.[14] The bill was not introduced into the House before Congress adjourned for the 1980 elections, and it began to look like it was doomed to fail. But a glimmer of hope presented itself: because Congress had adjourned without passing a budget, it had to return for a lame duck session. Working quickly, the Bayh-Dole Bill, S. 414, was inserted into an Omnibus Patent Bill, H.R. 6933, and signed into law by President Carter. While it was ultimately saved, a peculiar legislative history was created for the Bayh-Dole Act. Because the Bayh-Dole Bill was inserted into H.R. 6933, the official record for the legislative history of the Bayh-Dole Act is H.R. 6933, *not* the legislative history S. 414. More on the impact of that congressional record later.

III. Zero for Seven: The Failed Petitions

Since the passing of the Bayh-Dole Act, no federal agency has marched-in on a federally funded patent. The National Institutes of Health (NIH)—the only federal agency to receive petitions—has received seven march-in petitions and has denied all of them.[15] All of the petitions were concerned with drug pricing, with two of the

8 Stevens, *supra* note 4, at 94–95.
9 *Id.* at 96 (citing S. REP. NO. 96-480, at 3 (1979)).
10 35 U.S.C. § 202.
11 S. REP. NO. 96-480, at 28 (1979).
12 *Id*.
13 *Id*. at 34.
14 Stevens, *supra* note 4, at 97–98.
15 *See* JOHN R. THOMAS, CONG. RSCH. SERV., R44597, MARCH-IN RIGHTS UNDER THE BAYH-DOLE ACT

petitions concerning the prostate cancer drug Xtandi and another two concerning the HIV/AIDS drug Norvir.[16] In its 2004 proceedings regarding Norvir, the NIH declared that "the extraordinary remedy of march-in is not an appropriate means of controlling prices."[17] In 2023, the NIH reiterated this stance in the proceedings regarding Xtandi, emphasizing that the purpose of the Bayh-Dole Act was to promote the commercialization and public availability of government inventions, not to control drug prices.[18]

It is true the text of the Bayh-Dole Act provides four circumstances in which the relevant federal agency can march-in, and none of the four are on the basis of drug pricing.[19] However, as discussed *supra*, the legislative intent, as outlined in the Committee Report of S. 414, was that the march-in rights would function as a safeguard to "protect public welfare requirements." It is not a terrible stretch of the imagination to argue that making drugs affordable to the average American is a public welfare requirement, especially drugs that treat grim and lethal diseases like prostate cancer and HIV/AIDS.

Indeed, a similar argument has been made for drugs that treat COVID-19. At the height of the pandemic in 2020, a letter signed by the attorneys general of thirty-four states implored Dr. Francis Collins, then-Director of the NIH, to exercise march-in rights to increase supply and lower the cost of Remdesivir.[20] The letter came at the heels of a June announcement by Gilead that the cost of Remdesivir would be $3,120 for private insurance and $2,340 for Medicaid and Medicare patients, despite academic scholars calculating that the manufacturing cost of the drug is only $12.50 per patient.[21] The letter claimed that a 2020 $30 million grant for clinical trials to Gilead, the patent owner for Remdesivir, by the NIH was a satisfactory basis for march-in rights.[22] However, while the Remdesivir patents and relevant publications mention the assistance of federal scientists and laboratories, the patents themselves did not identify the federal scientists as inventors and did not identify specific federal funding that supported the research that led to the Remdesivir patents.[23]

The fly in the ointment, however, is not whether drug pricing broadly falls within the scope of protecting public welfare requirements. The crux of the issue is that, even if it did and even if the NIH or whatever federal agency attempted to march-in on a federally funded patent, the odds of it being successful are close to nil.

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9 (2016) (describing the six march-in petitions the NIH had previously denied at the time of the report); Michael Brodowski, *NIH Again Refuses to Exercise March-In Rights to Control Drug Price*, JD SUPRA (Mar. 27, 2023), https://www.jdsupra.com/legalnews/nih-again-refuses-to-exercise-march-in-5137775/ (describing the NIH's seventh and most recent denial of a march-in petition).

16 THOMAS, *supra* note 15, at 9; Brodowski, *supra* note 15.

17 THOMAS, *supra* note 15, at 10.

18 Brodowski, *supra* note 15.

19 *See* 35 U.S.C. § 203.

20 Jordan Paradise, *COVID-IP: Staring Down the Bayh–Dole Act with 2020 Vision*, 7 J.L. & BIOSCIENCES 1, 11 (2020).

21 *Id*.

22 *Id*.

23 *Id*. at 12.

IV. The Lack of Case Law and Legislative Intent

A major consequence of the federal government snoozing on its march-in rights is that there is absolutely no statutory interpretation of this provision of the Bayh-Dole Act. And because the Bayh-Dole Act was passed in a lame duck session, courts would have a difficult time interpreting this law.

As discussed *supra*, the Bayh-Dole Bill, S. 414, was not signed into law before Congress adjourned, so it was inserted as an amendment into another patent bill, H.R. 6933. Thus, the official legislative record for the Bayh-Dole Act does not contain any of the records from S. 414, including the Committee Report that clearly delineated the purpose and intent of the Bayh-Dole Act. While courts are certainly not barred from using the legislative history of S. 414 if they were called on to interpret the Bayh-Dole Act, introducing legislative history from a failed senate bill to interpret a provision of a bill passed in a lame duck session (that already has its own distinct legislative record) is not a winning strategy. Even if a court were to read the S. 414 Committee Report into the Bayh-Dole Act and find that "protect[ing] public welfare requirements" is a legitimate purpose for exercising march-in rights, and then further find that controlling drug pricing is a public welfare requirement, courts would still run into another significant problem. What does it mean for a patent to be "funded in whole or in part" by a federal agency under the Bayh-Dole Act?

The key concern is what it means for a patent to be "funded." As discussed *supra*, in their letter to the Director of the NIH, the attorneys general claimed that Gilead "received substantial federal funding" for manufacturing Remdesivir.[24] Citing a *Washington Post* article, the letter claimed that Gilead received, at minimum, a $30 million NIH-funded clinical trial.[25] That *Washington Post* article itself provided an in-depth look at how much money taxpayers relinquished to Gilead to develop and bring Remdesivir to market.[26] According to the article, no fewer than three federal agencies were "deeply involved" in the development of the drug; nonprofit watchdog group Public Citizen estimated Gilead received $70 million in public investments; and public health advocacy group PrEP4All Collaboration alleged that, because of the extent of the government's contributions, government scientists should be listed as co-inventors on Remdesivir patents.[27] And yet, a court would probably find that this would not meet the statutory requirement of being "funded in whole or in part" because Gilead created Remdesivir a decade before the COVID-19 pandemic even started and was issued a patent for using Remdesivir to treat various viral infections.[28]

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[24] Letter from Xavier Becerra, Off. of the Att'y Gen. of the State of Cal., & Jeff Landry, Off. of the Att'y Gen. of the State of La., to Alex M. Azar, Sec'y of U.S. Dep't of Health & Hum. Serv., Dr. Francis Collins, Dir. of Nat'l Inst. of Health, & Stephen Hahn, Comm'r of U.S. Food and Drug Admin. 1 (Aug. 4, 2020) (on file with author).

[25] *Id*. at 3.

[26] Christopher Rowland, *Taxpayers Paid to Develop Remdesivir but Will Have No Say When Gilead Sets the Price*, WASH. POST (May 26, 2020), https://www.washingtonpost.com/business/2020/05/26/remdesivir-coronavirus-taxpayers/.

[27] *Id*.

[28] *Id.*; *see also* U.S. Patent No. 10,251,904 (filed Sep. 16, 2016).

Despite the fact that tens of millions of taxpayer dollars were used to bring Remdesivir to the public, those funds were not used to finance the patent for Remdesivir. As discussed next, the crux of the issue is that, while federal dollars may fund patents, they do not *fund* patents.

V. Funded By, But Not *Funded* By, Federal Grants

Since the passage of the Bayh-Dole Act, methodological studies have attempted to quantify the efficacy of government-funded research. After all, the purpose of the Bayh-Dole Act was to boost the economy by increasing innovation and commercialization, so evaluating the potency of federal research grants is a legitimate interest to investigate.

Generally speaking, the majority of studies agree that government-funded research increases innovation.[29] One way to measure the impact of federally funded research on innovation is through citations. Specifically, one can measure how many scientific articles, patents, and patent applications cite a particular source of federally funded research. The more citations the research has, the more influential and impactful the research is. A 2018 study indicated that patents that were funded by federal grants were more influential (i.e., had larger and more interconnected citations) than patents that were not.[30] Additionally, the number of patents that cite federal research generally can also indicate the value of such research. In 2019, Science Magazine identified that 34.6% of patents assigned to venture-backed companies cited federally supported research.[31] This indicates that, in recent years, a non-insignificant number of start-ups are patenting technology that is built off of federally supported research. Similarly, a 2023 study from PLOS One identified that a staggering 99% of all drug approvals from 2010–2019 were associated with NIH-funded research.[32] Thus, it is not controversial to say that federal research grants propel innovation.

However, despite the fact that the U.S. government spent over $100 billion in research grants and R&D procurement contracts from 2010–2019, the number of patents that are *funded* by the federal government, and thus subject to the Bayh-Dole Act, is shockingly small.[33] A 2023 study investigated how much of the $187 billion worth in federal funding (from 2010–2019) from the NIH resulted in pharmaceutical patents, which would be subject to the provisions of the Bayh-Dole Act.[34] The study concluded that only 1.5% of NIH-funded applied research and 0.38% of NIH-funded basic research produced pharmaceutical patents.[35] The study suggested that the

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29 *See* L. Fleming et al., *Government-Funded Research Increasingly Fuels Innovation*, 364 SCI. 1139, 1139–41 (2019); *see also* Rafael A. Corredoira et al., *Federal Funding and the Rate and Direction of Inventive Activity*, 47 RSCH. POL'Y 1777, 1777–1800 (2018).

30 Corredoira, *supra* note 29, at 1796.

31 Fleming, *supra* note 29, at 1140.

32 Fred D. Ledley & Ekaterina Galkina Cleary, *NIH Funding for Patents That Contribute to Market Exclusivity of Drugs Approved 2010–2019 and the Public Interest Protections of Bayh-Dole*, 18 PLOS ONE 1, 8 (2023).

33 *See id.* at 1.

34 *Id*. at 1.

35 *Id*.

march-in provision of the Bayh-Dole Act would be limited in its ability to curb drug prices because very few patented drugs would meet the "funded in whole or in part by" requirement.[36] A similar 2019 study investigated how many patents resulted from $50 billion of R&D procurement contracts from the federal government between 2005 and 2015; that study found that 1.5% of all R&D procurement contracts produced at least one patent.[37]

A conundrum presents itself when considering all these studies as a whole. Federally funded research provides necessary and influential research, and such research is the basis for new technology and patents. However, while federal grants may serve as the launch pad for new technology, a very small portion of federal grants are actually funding patents that would be subject to the Bayh-Dole Act because the majority of federal grants are for basic research. This point, somewhat ironically, was noted by Senator Birch Bayh way back in 1978 when he introduced S. 414 to the Senate, acknowledging that:

> Government sponsored research is often basic rather than applied research. Therefore, many of the resulting inventions are at a very embryonic stage of development and require substantial expenditures before they actually become a product or applied system of benefit to the public.[38]

Despite that statement being made forty-six years ago, it remains true today. Government research is necessary for developing inventions, but it does not fund them.

VI. Conclusion

In December 2023, the Biden Administration announced new plans to lower the cost of prescription drugs, which included a new proposed framework for federal agencies on the exercise of march-in rights.[39] The framework, if implemented, would explicitly allow federal agencies to consider price as a factor when evaluating a petition to exercise march-in rights.[40] The National Institute of Standards and Technology recently closed public comments on the new framework on February 6, 2024.[41] While the introduction of the framework can be seen as a positive sign of change to come, the actual implementation will fall short of the Biden Administration's goals to reduce drug pricing. Unfortunately, scholars, academics, and even the federal government (i.e., the NIH) appear to agree that an extraordinarily small number of patents are subject to the Bayh-Dole Act. Not only that, but they all

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36 *Id*. at 10.

37 Gaetan de Rassenfosse et al., *The Procurement of Innovation by the U.S. Government*, 14 PLOS ONE 1, 1 (2019).

38 Stevens, *supra* note 4, at 95.

39 Press Release, The White House, FACT SHEET: Biden-Harris Administration Announces New Actions to Lower Health Care and Prescription Drug Costs by Promoting Competition (Dec. 7, 2023), https://www.whitehouse.gov/briefing-room/statements-releases/2023/12/07/fact-sheet-biden-harris-administration-announces-new-actions-to-lower-health-care-and-prescription-drug-costs- by-promoting-competition/.

40 *Id*.

41 Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights, 88 Fed. Reg. 85593 (Dec. 8, 2023).

also seem to agree that a court would find marching-in on patent holders is an inappropriate remedy to solve exorbitantly high drug pricing. The gravity of this conundrum is especially problematic during a global pandemic. As of the date of this article, over one million people have died in the U.S. due to COVID-19.[42] Because the "public health and safety needs" of the Bayh-Dole Act only applies to patents funded by the government, the government has no mechanism of marching-in on non-federally funded patents like Remdesivir.

In the forty-four years since the Bayh-Dole Act was passed, not once has a federal agency exercised march-in rights, and it is unlikely that a federal agency ever will. Because no federal agency has endeavored to use the rights, there is no case law on the books on interpreting its provisions. No court has yet to take a stab at the complicated legislative history of the Bayh-Dole Act, nor has a court had to reckon with what it means for a patent to be "funded" by the federal agency or what "public health and safety needs" includes.

In conclusion, new legislation is essential to take on the most pressing public health patent-related crises of the day because it is evident that the march-in provision of the Bayh-Dohl Act will not solve them. The American people, through their tax dollars, have been funding pharmaceuticals that some cannot even afford when they eventually hit the market, as evidenced by the prohibitive pricing of Remdesivir by Gilead. The words of Admiral Hyman B. Rickover ring true now more than ever; the public is paying to bring these drugs to market, and therefore these drugs should be priced so any citizen can afford to purchase them.

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[42] *COVID-19 Update for the United States*, CTR. FOR DISEASE CONTROL & PREVENTION (Sept. 27, 2023), https://covid.cdc.gov/COVID-data-tracker/#datatracker-home.