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RETHINKING BAYH-DOLE'S BAD-DEAL FOR THE AMERICAN TAXPAYER THROUGH THE LENS OF THE NIH-MODERNA DISPUTE

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Before 1980, the right to own the patent on any invention researched and developed under a federal funding agreement typically went to the federal agency that provided the funding. The Patent and Trademark Law Amendments Act of 1980, or Bayh-Dole Act, reorganized this framework by presumptively granting the ownership rights of any such patents to the entity that received the funding. To further promote the Act's stated purpose of increasing the commercialization rate of inventions derived under federally funded research agreements, Congress also ceded all financial interests in any resulting invention.

The Bayh-Dole Act successfully increased the number of federally funded research agreements and the rate that inventions created under these agreements are commercialized. But the Act has become an increasingly unfair economic bargain for the American taxpayer because the Act treats the public as a donor instead of an investor in research and development. The National Institutes of Health's ("NIH") current feud over inventorship concerning Moderna, Inc.'s ("Moderna") mRNA-1273 COVID-19 vaccine patent clearly illustrates this unfair bargain. The vaccine resulted from years of collaboration between the NIH and Moderna and was essentially funded in its entirety by the government. However, Moderna is seeking to exclude three NIH scientists from the patent on the vaccine's main genetic sequence

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that produces an immune response. The NIH claims these scientists should be listed on the patent as co-inventors.

Having the NIH scientists listed on the patent as co-inventors would give the NIH equal ownership of the patent which is likely to be quite valuable. On the other hand, excluding the NIH scientists would limit the public's rights in the vaccine to the provisions of the Bayh-Dole Act which, in practice, do little to vindicate any public interest in the vaccine, despite the significant investment made by the public to facilitate its development. Accordingly, the Bayh-Dole Act must be amended to adequately promote the public's financial interests in profitable inventions whose development is financed by the federal government.

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I. INTRODUCTION

The World Health Organization picked up the first reports of a cluster of "viral pneumonia" in Wuhan, China in a media statement by the Wuhan Municipal Health Commission on December 31, 2019.[1] By December 31, 2020, the official death toll from the COVID-19 pandemic stood at over 1.8 million people worldwide.[2] The race to develop vaccines and therapeutics to combat COVID-19 began immediately. Governments across the globe stepped in to provide unprecedented amounts of funding to hasten their development and to potentially save hundreds of thousands, if not millions, of lives.[3] The Food and Drug Administration ("FDA")[4] eventually issued Emergency Use Authorizations ("EUAs")[5] in the

[1] *Listings of WHO's Response to COVID-19*, WORLD HEALTH ORG., https://www.who.int/news/item/29-06-2020-covidtimeline [https://perma.cc/MYX9-2DLN] (last visited Feb. 20, 2022).

[2] *See The True Death Toll of COVID-19: Estimating Global Excess Mortality,* WORLD HEALTH ORG., https://www.who.int/data/stories/the-true-death-toll-of-covid-19-estimating-global-excess-mortality [https://perma.cc/TV5V-DSJ7] (last visited Feb. 20, 2022).

[3] *See, e.g.*, Riley Griffin & Drew Armstrong, *Pfizer Vaccine's Funding Came from Berlin, Not Washington*, BLOOMBERG (Nov. 9, 2020), https://www.bloomberg.com/news/articles/2020-11-09/pfizer-vaccine-s-funding-came-from-berlin-not-washington [https://perma.cc/X4HW-KYXP].

[4] The FDA is the government agency primarily responsible for "protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices." *What We Do*, FDA, https://www.fda.gov/about-fda/what-we-do [https://perma.cc/9D83-7M4G] (last visited Mar. 8, 2022).

[5] An EUA allows for medical products that have not received full FDA approval to be used in a public health emergency under certain criteria, including when there are no adequate, approved, and available alternatives. *See Emergency Use Authorization*, FDA, https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-

United States for three COVID-19 vaccines found to be safe and effective, including Moderna, Inc.'s ("Moderna") revolutionary mRNA-1273 vaccine. The issuance of the EUA meant Americans could receive these vaccines before the completion of the FDA's potentially lengthy, full-approval process.[6]

Moderna's COVID-19 vaccine, however, did not simply result from a few months of intense research in response to the pandemic. Instead, it evolved out of a four-year collaboration before the outbreak of the pandemic with government research scientists at the National Institutes of Health's ("NIH") Vaccine Research Center.[7] The NIH, which is the primary federal agency responsible for biomedical and public health research, claims three of its scientists worked with Moderna scientists to design the genetic sequence that prompts the vaccine to produce an immune response, which is the most important piece of the vaccine.[8] Accordingly, the NIH believes these scientists should be named on the "principal patent application" as co-inventors.[9]

Moderna, however, disagrees and maintains that the NIH scientists should not be named on the principle patent application.[10] Underlying this assertion is the fact that Moderna collaborated with the NIH under an agreement to research coronavirus vaccines

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framework/emergency-use-authorization [https://perma.cc/M3L8-7MUG] (last visited Mar. 8, 2022).

[6] *See Statement from NIH and BARDA on the FDA Emergency Use Authorization of the Moderna COVID-19 Vaccine,* NIH (hereinafter "*Statement from NIH and BARDA*, NIH") (Dec. 18, 2020), https://www.nih.gov/news-events/news-releases/statement-nih-barda-fda-emergency-use-authorization-moderna-covid-19-vaccine [https://perma.cc/56E7-DEJ7].

[7] *See* Sheryl Gay Stolberg & Rebecca Robbins, *Moderna and U.S. at Odds Over Vaccine Patent Rights*, N.Y. TIMES (Nov. 9, 2021), https://www.nytimes.com/2021/11/09/us/moderna-vaccine-patent.html [https://perma.cc/S5ZR-JREQ].

[8] *Id.*

[9] *Id.*; *see also* Transcript of Virtual Signature Event with Dr. Francis Collins, Chris Nassetta, and Mary Brady, ECON. CLUB WASH., D.C. 3 (May 29, 2020), https://www.economicclub.org/sites/default/files/transcripts/Interview%20with%C20Collins%C20Nassetta%C20Brady%C20Edited%20Transcript.pdf [https://perma.cc/NU5P-4XVV] (quoting NIH Director Francis Collins as stating "we [NIH] do have some particular stake in the intellectual property" of Moderna's vaccine candidate).

[10] *See* Stolberg & Robbins, *supra* note 7.

for four years before the COVID-19 outbreak,[11] received over $900 million in grants from the federal government to speed the vaccine through clinical trials in 2020, and received nearly $3.2 billion from the federal government in advanced orders before the vaccine had received FDA approval to finance the manufacture of hundreds of millions of doses.[12] In an August 2021 filing with the U.S. Patent and Trademark Office ("USPTO"),[13] Moderna said it had "reached the good-faith determination" that the aforementioned NIH scientists did not co-invent the key vaccine component in question,[14] and maintained that several Moderna employees were the sole inventors of the most important piece of the vaccine—the genetic sequence that generates the immune response in the vaccine's recipient.[15]

The NIH does not intend on abandoning the fight with Moderna to have its scientists listed as co-inventors on the principal patent for the mRNA-1273 COVID-19 vaccine.[16] This dispute involves much more than mere accolades for the scientists involved. If the scientists are named on the patent as co-inventors, the government will have equal ownership of the patent with Moderna and can license the vaccine technology without Moderna's approval, which could bring substantial funds into the federal treasury and promote expanded access to the vaccine at

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[11] *See* NIH-Moderna Confidential Agreements, https://www.documentcloud.org/documents/6935295-NIH-Moderna-Confidential-Agreements.html [https://perma.cc/H4PA-FS6Y].

[12] *See COVID-19 Medical Countermeasure Portfolio: Vaccines*, BARDA, https://www.medicalcountermeasures.gov/app/barda/coronavirus/COVID19.aspx?filter=vaccine [https://perma.cc/RQF3-TKWQ] (last visited Mar. 8, 2022).

[13] The USPTO is the federal agency which grants U.S. patents and registers trademarks. *See About Us*, USPTO, https://www.uspto.gov/about-us [https://perma.cc/H8UE-YXXV] (last visited Mar. 8, 2022).

[14] *Statement Filed Pursuant to the Duty of Disclosure Under 37 C.F.R. §§ 1.56, 1.97, and 1.98*, Mihir Metkar (filed Aug. 21, 2020), https://int.nyt.com/data/documenttools/moderna-patent-filing/7b73f4609cf965c8/full.pdf [https://perma.cc/Z33B-PHQ3].

[15] *See* Stolberg & Robbins, *supra* note 7.

[16] *See* Sheryl Gay Stolberg & Rebecca Robbins, *The N.I.H. Says it Isn't Giving Up in Its Patent Fight With Moderna*, N.Y. TIMES (Nov. 10, 2021), https://www.nytimes.com/2021/11/10/us/politics/moderna-vaccine-patent-nih.html [https://perma.cc/QN4C-LZVD].

home and abroad.[17] Consequently, unless Moderna and the NIH resolve the dispute amicably, the possibility of a protracted legal battle looms large, with broad implications for the vaccine's long-term distribution and billions of dollars in future profits.[18] Notably, in December 2021, Moderna paused its efforts in securing the patent to "avoid any distraction to the important public-private efforts ongoing to address emerging SARS-CoV-2 variants, including Omicron," and to allow for continued discussions with the NIH to resolve the patent dispute.[19] However, Moderna can still move forward and seek the patent at a later date, regardless of the state of its dispute with the NIH. As of this writing, the parties have not reached an agreement.

Importantly, Moderna's claim that the NIH scientists did not directly "co-invent" the mRNA genetic sequence and therefore have no rights to be listed as co-inventors on the vaccine's patent is squarely in the realm of possibility. However, this possibility should not discredit the years of collaboration with the NIH that laid the foundation for the vaccine's creation and also should not discount the more than $4 billion provided by the government to hasten its procession through clinical trials and subsequent manufacturing within a short few months in 2020.

Regardless of the eventual resolution of the NIH's dispute with Moderna, the dispute's existence alone illustrates the need to reevaluate what rights, particularly economic rights, the public should have to inventions derived from federally funded research and development ("R&D"). The public's rights should not rise or fall based on legal disputes involving factual inquiries into who

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[17] *See* Stolberg & Robbins, *supra* note 7.

[18] *Id.* If co-inventorship is confirmed, federal patent law will enable the NIH to perform several actions—including the manufacture, use, or sale of the vaccine—without the consent of Moderna. *See* 35 U.S.C. § 262 ("In the absence of any agreement to the contrary, each of the joint owners of a patent may make, use, offer to sell, or sell the patented invention within the United States . . . without the consent of and without accounting to the other owners.").

[19] *See* Dan Diamond, *Moderna Halts Patent Fight Over Coronavirus Vaccine With Federal Government*, WASH. POST (Dec. 17, 2022), https://www.washingtonpost.com/health/2021/12/17/moderna-vaccine-patent-dispute-nih/ [https://perma.cc/E7W7-FSBQ].

discovered what and when under a public-private research funding and collaboration agreement.

The Patent and Trademark Law Amendments Act of 1980,[20] commonly referred to as "the Bayh-Dole Act,"[21] primarily governs who retains the ownership rights to any patents for inventions developed from federally funded R&D.[22] Bayh-Dole was intended to promote the commercialization of federally funded inventions.[23] However, what was meant to incentivize universities and entrepreneurs to enter into federally funded R&D agreements has ballooned into a mechanism for large businesses to monopolize the economic benefits of R&D financed by the public.[24] Under the Bayh-Dole Act, the public holds limited rights to the inventions arising from R&D funding agreements—despite financing those inventions' development in whole or in part. However, in practice,

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[20] 35 U.S.C. §§ 200–12.

[21] Referring to its two Senate sponsors, Senators Birch Bayh of Indiana, and Bob Dole of Kansas.

[22] *See* 35 U.S.C. § 201(b) (defining "funding agreement" as "any contract, grant, or cooperative agreement entered into between any Federal agency . . . and any contractor for the performance of experimental, developmental, or research work funded in whole or in part by the Federal Government); § 201(e) (defining "subject invention" as "any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement").

[23] *See* 35 U.S.C. § 200 (stating the policy and objective of the Bayh-Dole Act).

[24] *See e.g.*, Jorge Contreras, *Will NIH Learn from Myriad when Settling Its mRNA Inventorship Dispute with Moderna?*, BILL OF HEALTH (Jan. 6, 2022), https://blog.petrieflom.law.harvard.edu/2022/01/06/nih-moderna-mrna-covid-vaccine-patent/ [https://perma.cc/P752-LS3M] (outlining how Myriad was able to secure unfettered rights to price its *BRCA* testing for breast and ovarian cancer, developed in concert with NIH scientists, in the 1990s); Rachel Barenie et al., *Discovery and Development of Pregabalin (Lyrica): The Role of Public Funding*, AM. ACAD. OF NEUROLOGY (Oct. 2021), https://n.neurology.org/content/97/17/e1653.long [https://perma.cc/D46L-AGAN] (concluding that development of pregabalin relied both public sector and industry contributions, including NIH funding). Lyrica earned Pfizer around $3.6 billion in sales in the United States as recently as 2018. *See* Kyle Blankenship, *Lyrica Looking Grim: Pfizer Blockbuster's Market Share Crumbles Under Generic Attack*, FIERCE PHARMA (Aug. 19, 2019), https://www.fiercepharma.com/pharma/lyrica-looking-grim-pfizer-s-blockbuster-faces-crumbling-market-share-after-generic [https://perma.cc/9595-VUUU].

these rights offer little recourse to the public and are particularly ill-suited to address concerns that could arise regarding Moderna's vaccine.[25] The Bayh-Dole Act's fatal flaw is that it treats the American taxpayer as a donor instead of an investor when it comes to funding R&D. Accordingly, the Bayh-Dole Act must be amended to provide the public with rights that better reflect its position as an *investor* in R&D, while still promoting and preserving economic gains for entities willing to enter into public-private partnerships for R&D.

This Article comments on the larger debate surrounding what rights the public should have to the inventions derived from federally funded research—specifically contextualizing this debate through the lens of the current dispute between the NIH and Moderna—and recommends needed changes to the existing Bayh-Dole Act framework to promote the economic interests of the public in the inventions derived from the tax dollars it dedicates to public-private R&D collaborations. Part II supplies background information on Operation Warp Speed, the federal government's program to rapidly develop and manufacture a COVID-19 vaccine, the development of Moderna's mRNA-1273 vaccine, and the current dispute between the NIH and Moderna over the NIH's scientists' claimed right to co-inventor status on the principal patent for the vaccine. Part III introduces the Bayh-Dole Act and general patent law concepts and then analyzes how the Bayh-Dole Act's provisions, in practice, do little to promote the public's interest in resulting inventions and, particularly, in Moderna's vaccine if the NIH scientists are excluded as co-inventors from the patent. Part IV recommends needed changes to the Act to ensure that the public receives a better bargain for funding R&D with the private sector.

II. OPERATION WARP SPEED AND THE VACCINE PATENT DISPUTE BETWEEN MODERNA AND THE NIH

Moderna's relationship with the NIH concerning coronavirus vaccines predates the pandemic by several years. This collaboration set the groundwork which allowed for mRNA-1273's

[25] *See infra* pp. 899–900.

creation and procession through clinical trials in the matter of a short few months after the federal government supplied an unprecedented infusion of funding through Operation Warp Speed ("OWS"). This Part supplies background on OWS, Moderna and the NIH's collaboration before the pandemic, and the current dispute regarding co-inventorship of mRNA-1273.

A. Operation Warp Speed

OWS, the Trump Administration's "crash development program for a coronavirus vaccine that could be widely distributed by the beginning of [2021]" was officially announced on May 15, 2020.[26] It was met with "widespread skepticism that such an effort could succeed and considerable concern about the implications for safety."[27] OWS was described as a "public-private partnership to facilitate, at an unprecedented pace, the development, manufactur[e], and distribution of COVID-19 countermeasures" between various federal agencies and the private sector.[28] The primary goal of OWS was to have "substantial quantities of a safe and effective vaccine available for Americans by January 2021."[29]

OWS effectively consolidated a series of vaccine development efforts already underway and was backed by considerable amounts of federal funding.[30] The Coronavirus Preparedness and Response Supplemental Appropriations Act of 2020, signed into law by President Trump on March 6, 2020, initially appropriated more than $3 billion in discretionary funds "to prevent, prepare for, and respond to coronavirus . . . including the development of necessary

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[26] David E. Sanger, *Trump Seeks Push to Speed Vaccine, Despite Safety Concerns*, N.Y. TIMES (Apr. 29, 2020), https://www.nytimes.com/2020/04/29/us/politics/trump-coronavirus-vaccine-operation-warp-speed.html [https://perma.cc/D4KN-3KSX].

[27] *Id.*

[28] *See Trump Administration Announces Framework and Leadership for 'Operation Warp Speed',* U.S. DEP'T OF HEALTH & HUM. SERVS. (hereinafter "HHS") (May 15, 2020), https://www.hhs.gov/about/news/2020/05/15/trump-administration-announces-framework-and-leadership-for-operation-warp-speed.html [https://perma.cc/U553-KFUS].

[29] *Id.*

[30] Sanger, *supra* note 26.

countermeasures and vaccines."[31] That Act was supplemented by additional appropriations in the Coronavirus Aid, Relief, and Economic Security Act, colloquially referred to as the CARES Act, signed into law on March 27, 2020.[32] In all, nearly $18 billion in federal funding was made available to be directed towards COVID-19 vaccine and therapeutic development efforts.[33] OWS utilized the Biomedical Advanced Research and Development Authority ("BARDA"), a subdivision of the U.S. Department of Health and Human Services ("HHS"), as the financial interface between the federal government and the biomedical industry.[34]

The theory underlying OWS was that the clinical development, process development, and manufacturing scale-up of vaccines could be "substantially accelerated by running all streams, fully resourced, in parallel."[35] Under normal circumstances, a vaccine's development would follow a sequential approach,[36] meaning a vaccine developer would complete Phase 1 clinical trials before moving on to Phase 2, and so on. Developers follow the sequential approach primarily because it limits the financial risk to the developer in the event the vaccine candidate fails at any level,

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[31] *See* Coronavirus Preparedness and Response Supplemental Appropriations Act of 2020, Pub. L. No. 116-123, 134 Stat. 146, 149 (2020).

[32] *See* Coronavirus Aid, Relief, and Economic Security Act of 2020, Pub. L. No. 116-136, 1345 Stat. 281 (2020).

[33] *See* John Tozzi, Riley Griffin, & Shira Stein, *Trump Administration Dips Into Protective Gear, CDC Funds to Fund Vaccine Push*, BLOOMBERG (Sep. 23, 2020), https://www.bloomberg.com/news/articles/2020-09-23/how-much-is-the-trump-administration-spending-on-a-vaccine [https://perma.cc/ER74-Y5H2].

[34] *See Explaining Operation Warp Speed*, HHS, https://www.nihb.org/covid-19/wp-content/uploads/2020/08/Fact-sheet-operation-warp-speed.pdf [https://perma.cc/2H2K-DVNC] (last visited Mar. 13, 2022).

[35] Moncef Slaoui & Matthew Hepburn, *Developing Safe and Effective Vaccines—Operation Warp Speed's Strategy and Approach*, NEW ENG. J. MED. (Oct. 29, 2020), https://www.nejm.org/doi/10.1056/NEJMp2027405 [https://perma.cc/7395-C4UZ].

[36] *See The Complex Journey of a Vaccine: The Steps Behind Developing a New Vaccine*, INT'L FED'N OF PHARM. MFRS. & ASS'NS 10, https://www.ifpma.org/wp-content/uploads/2019/07/IFPMA-ComplexJourney-2019_FINAL.pdf [https://perma.cc/9LPF-HBD9].

though it is also a means of accommodating any safety concerns.[37] By providing a substantial, up-front government investment for the vaccine developers, OWS sought to condense the timeframe needed to complete all the Phases of clinical trials and other steps necessary to secure the vaccine's approval for public use without "compromising safety, efficacy, or product quality" with the federal government bearing any financial risk of a vaccine candidate's failure.[38]

Vaccine candidates were selected for OWS funding based on a set of four criteria. First, candidates needed to have "robust preclinical data or early-stage clinical trial data supporting their potential for clinical safety and efficacy."[39] Second, with an infusion of OWS funding, candidates needed the potential to enter large Phase 3 field efficacy trials by the summer or fall of 2020 and "deliver[] efficacy outcomes by the end of 2020 or the first half of 2021."[40] Third, candidates needed to be "based on vaccine-platform technologies permitting fast and effective manufacturing, and their developers had to demonstrate the industrial process scalability, yields, and consistency necessary to reliably produce more than 100 million doses by mid-2021."[41] Fourth, and last, candidates needed to use one of four vaccine-platform technologies, including mRNA,[42] believed to be most likely to yield a safe and effective vaccine.[43]

The federal government selected a diverse portfolio of two candidates from each of the four vaccine-platform technologies to receive OWS funding in order to mitigate the risk of failure due to

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[37] *See generally* Aylin Sertkaya et al., *Key cost drivers of pharmaceutical clinical trials in the United States*, 13 CLINICAL TRIALS 117 (Feb. 8, 2016), https://journals.sagepub.com/doi/pdf/10.1177/1740774515625964 [https://perma.cc/N4U2-DSSS] (illustrating how Phase 1 is more expensive than Phase 2, and so on).

[38] Slaoui & Hepburn, *supra* note 35.

[39] *Id.*

[40] *Id.*

[41] *Id.*

[42] *See Understanding mRNA COVID-19 Vaccines*, CDC, https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/mrna.html [https://perma.cc/2GXJ-RTGT] (last visited Mar. 8, 2022) (explaining mRNA vaccine technology).

[43] Slaoui & Hepburn, *supra* note 35.

safety, efficacy, manufacturability, or scheduling factors.[44] By August 2020, OWS had directed approximately $11 billion to the eight companies selected for funding to expedite development and preparation for manufacture of their respective vaccine candidates.[45] Two vaccine candidates that received OWS funding for clinical trials received EUAs: Moderna's mRNA-1273 in December of 2020 and Johnson & Johnson's Ad26.COV2-S in February 2021.[46] As of February 13, 2022, more than 206 million doses of Moderna's vaccine and more than 18 million doses of Johnson & Johnson's vaccine had been administered in the United States alone.[47]

B. Moderna and the NIH's Development of mRNA-1273

Prior to the creation of OWS, and even prior to the outbreak of the COVID-19 pandemic, experts at the NIH and Moderna collaborated for over four years to study coronaviruses and determine how best to protect against them.[48] These scientists focused on one "prototype" coronavirus and created a vaccine that could then be customized to fight different coronaviruses in the event of an outbreak.[49] Consequently, when Chinese researchers

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[44] *Id.*

[45] *See* Noah Higgins-Dunn, *The U.S. Has Already Invested Billions in Potential Coronavirus Vaccines. Here's Where the Deals Stand*, CNBC (Aug. 8, 2020), https://www.cnbc.com/2020/08/14/the-us-has-already-invested-billions-on-potential-coronavirus-vaccines-heres-where-the-deals-stand.html [https://perma.cc/4LP2-SY77].

[46] *See* Letter from Jacqueline O'Shaughnessy, Ph. D., Acting Chief Scientists, FDA to Janssen Biotech, Inc. (Nov. 19, 2021), https://www.fda.gov/media/146303/download [https://perma.cc/HQD7-NWJU]; *Statement from NIH and BARDA*, NIH, *supra* note 6.

[47] *See* Matej Mikulic, *Number of COVID-19 Vaccine Doses Administered in the United States as of February 13, 2022, by Vaccine Manufacturer*, STATISTA (Feb. 14, 2022), https://www.statista.com/statistics/1198516/covid-19-vaccinations-administered-us-by-company/ [https://perma.cc/7PEU-VFAC].

[48] *See COVID-19 Vaccine Development: Behind the Scenes*, NIH, https://covid19.nih.gov/news-and-stories/vaccine-development [https://perma.cc/GYA3-6U5B] (last visited Feb. 20, 2022) [hereinafter "*COVID-19 Vaccine Development*, NIH"]; Christopher Rowland, *Moderna Took NIH Money and Help for its Covid Vaccine. Now it Wants to Leave Government Scientists off a Lucrative Patent.*, WASH. POST (Nov. 9, 2021), https://www.washingtonpost.com/business/2021/11/09/moderna-nih-patent-vaccine/ [https://perma.cc/4JJY-DZQA].

[49] *See COVID-19 Vaccine Development*, NIH, *supra* note 48.

discovered and published the DNA sequence of SARS-CoV-2, the coronavirus that causes COVID-19, two weeks after the outbreak was first publicly reported,[50] scientists at the NIH and Moderna used this information in conjunction with their prior work to quickly customize the prototype vaccine to the SARS-CoV-2 spike protein.[51] By early February 2020, a COVID-19 vaccine candidate had been designed, manufactured, and was ready to enter clinical trials.[52]

BARDA issued a $430 million grant on April 16, 2020, to "advance the vaccine candidate into expanded clinical studies."[53] Though OWS had not formally come into existence, this grant represented an early iteration of the strategy behind a public-private partnership to hasten vaccine development and manufacture. The initial investment was bolstered by an additional $470 million grant from BARDA in July of 2020[54] to "expand[] an existing partnership with Moderna . . . to support the Phase 3 clinical trial of [its] vaccine candidate for COVID-19."[55] These grants, totaling more than $900 million, were crucial investments by the government that permitted the rapid pace at which the vaccine could proceed through the various Phases of clinical trials.

Once the vaccine entered Phase 3 trials in mid-August 2020, the federal government, through BARDA, placed an advance order for 100 million doses of mRNA-1273, paid for up-front.[56] The

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[50] *Id.*

[51] *Id.*; *see also* CDC, *supra* note 42 (explaining how mRNA vaccines work).

[52] *COVID-19 Vaccine Development*, NIH, *supra* note 48.

[53] *See HHS Engages Moderna's mRNA Technology to Accelerate Development of a COVID-19 Vaccine*, HHS, https://www.medicalcountermeasures.gov/newsroom/2020/moderna-covid-19-mrna/ [https://perma.cc/C5DL-5CGN] (last visited Mar. 8, 2022).

[54] *See BARDA Continues to Partner with Moderna for the First Phase 3 Clinical Trial of a COVID-19 Vaccine to Start in the United States*, HHS, https://www.medicalcountermeasures.gov/newsroom/2020/moderna-Phase-3/ [https://perma.cc/CU28-VF4L] (last visited Mar. 8, 2022).

[55] *Id.*

[56] *See Trump Administration Collaborates with Moderna to Produce 100 Million Doses of COVID-19 Investigational Vaccine*, HHS, https://www.medicalcountermeasures.gov/newsroom/2020/modernamanufacturing/ [https://perma.cc/CMR4-J9V9] (last visited Mar. 8, 2022).

purpose of this prepaid order (as opposed to previous grants facilitating clinical trials) was to fund the advance manufacture of the vaccine doses in parallel with conducting clinical trials so the vaccine doses would be ready to ship and be administered to Americans as soon as its expected EUA was finalized.[57] Another advance order, valued at over $1.6 billion and paid in full, was placed on December 11, 2020, for an additional 100 million doses, one week before the FDA issued the EUA for the vaccine.[58] In sum, Moderna, in 2020 alone, received over $4.1 billion for the development and manufacture of mRNA-1273. Furthermore, Moderna believes that over 2021, sales from the vaccine most likely grossed between $15 billion and $18 billion and anticipates sales of up to $22 billion in 2022.[59]

C. NIH-Moderna Dispute Over the mRNA-1273 Patent

Although Moderna and the NIH partnered for years to develop the underlying technology for the mRNA-1273 vaccine, the current dispute over the core vaccine patent can be traced back to a single weekend in January 2020 when each had a team of scientists working in parallel to "zero in on the gene for the virus's spike protein."[60] Each team independently identified the same gene over that weekend.[61] Subsequently, Moderna and the NIH discussed including the team of three NIH scientists as co-inventors on the

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[57] *Id.*

[58] *See News Release from HHS.GOV: Trump Administration purchases additional 100 million doses of COVID-19 investigational vaccine from Moderna*, HHS, https://www.medicalcountermeasures.gov/newsroom/2020/moderna/ [https://perma.cc/P5ZH-MXCG] (last visited Mar. 8, 2022).

[59] *See* Julie Steenhuysen, *Moderna COVID-19 Vaccine Patent Dispute Headed to Court, U.S. NIH Head Says*, REUTERS (Nov. 10, 2021), https://www.reuters.com/business/healthcare-pharmaceuticals/moderna-covid-19-vaccine-patent-dispute-headed-court-us-nih-head-says-2021-11-10/ [https://perma.cc/4MWQ-FDAM] (noting that mRNA-1273 is the first and only product Moderna has ever brought to market).

[60] Stolberg & Robbins, *supra* note 16. This gene sequence is the necessary component to allow for customization of the prototype vaccine to produce immunity to COVID-19. *See* CDC, *supra* note 42 (explaining how mRNA vaccines work).

[61] Stolberg & Robbins, *supra* note 16.

patent application for the genetic sequence, the most important aspect of the vaccine.[62] Moderna, however, rebuffed the NIH's efforts in its filing with the USPTO, claiming that it had "reached the good-faith determination that [the NIH scientists] did not co-invent" the genetic sequence, which caught the Agency by surprise.[63] Moderna acknowledges that the NIH scientists played a "substantial role" in developing the vaccine, but the company disagreed with the Agency's patent claims.[64] To note, Moderna has acknowledged the NIH scientists in its other patent applications concerning the vaccine, such as those related to dosing, but the principal, and most important, patent only lists Moderna scientists as the inventors.[65]

Appearing on the patent as a co-inventor concerns more than mere egos and accolades for the NIH scientists involved. Including the NIH scientists on the patent as co-inventors would give the government equal ownership status in the patent.[66] The government would secure an effectively unhindered right to license the vaccine technology.[67] This right could bring millions, or potentially billions, of dollars into the federal treasury, allowing the government to recover its investments in the vaccine's development through royalties.[68] It could also ensure sufficient

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[62] *Id.*; *see also* Steenhuysen, *supra* note 59 (naming the three excluded scientists as Dr. John R. Mascola, the center's director; Dr. Barney S. Graham, who recently retired; and Dr. Kizzmekia S. Corbett, now at Harvard).

[63] Stolberg & Robbins, *supra* note 7.

[64] *Id.*

[65] Steenhuysen, *supra* note 59.

[66] *See* 37 C.F.R. § 501.6(a)(1) ("The Government shall obtain . . . the entire right, title and interest to any invention made by any Government employee."). As co-inventors, the NIH scientists would be required to be included on the patent application and would be co-owners. 35 U.S.C. § 116 ("When an invention is made by two or more persons jointly, they shall apply for patent jointly . . . .").

[67] *See* 35 U.S.C. § 262 ("In the absence of any agreement to the contrary, each of the joint owners of a patent may make, use, offer to sell, or sell the patented invention within the United States, without the consent of and without accounting to the other owners.").

[68] *See generally* Caroline Banton, *Royalty*, INVESTOPEDIA (Mar. 26, 2021), https://www.investopedia.com/terms/r/royalty.asp [https://perma.cc/7AXZ-3B35] (explaining royalties).

access to the vaccine at home and abroad and help regulate the price of the vaccine by introducing competition into the market. Accordingly, it becomes clear why Moderna would seek to exclude these scientists from the patent.

III. THE CURRENT STATE OF PUBLIC RIGHTS TO FEDERALLY FUNDED INVENTIONS, INCLUDING MODERNA'S COVID-19 VACCINE

If the NIH scientists are excluded from Moderna's principal patent for mRNA-1273, the Bayh-Dole Act grants the government, and thereby the public, limited rights in the vaccine that, in practice, do little to alleviate concerns about the vaccine's future pricing and distribution, among other concerns. In addition, it would fail to acknowledge the substantial investment the public made towards its development.

The Bayh-Dole Act governs the disposition of rights to inventions derived under federal funding agreements.[69] The Bayh-Dole Act gives the public certain, limited rights to inventions derived under federal funding agreements, but grants ownership in any "subject invention" to the private entity that receives funding from the government.[70] In other words, the government does not retain the right to partial ownership of any patent on the invention.[71] The rights to these inventions the government retains, instead, are narrowly tailored and are effectively aimed solely at promoting the commercialization of the invention and therefore only ensure that Americans have the opportunity to be consumers. Importantly, these rights do not aim to compensate the federal government for the taxpayer dollars spent on developing the invention. Accordingly, the Act's primary flaw, particularly for inventions created in the public interest—like vaccines—is that it

[69] 35 U.S.C. § 201(e) ("[A]ny invention . . . conceived or first actually reduced to practice in the performance of work under a [federal] funding agreement . . . .").

[70] 35 U.S.C. §§ 202–03.

[71] Importantly, this is the case when the private partner independently invents the subject matter in question, not when a government employee is a co-inventor, as NIH claims with respect to mRNA-1273.

treats the American taxpayer as a donor and not an investor in R&D.

A. The Purpose and Relevant Provisions of the Bayh-Dole Act

Passed in 1980, the Bayh-Dole Act was intended to promote the utilization and commercialization of inventions arising from federally funded R&D.[72] Congress hoped that providing patent rights to the federal funding recipients would encourage greater commercialization of inventions because, otherwise, firms would be reluctant to engage in the development process without the ability to protect any potential earnings to which a costly development process could lead.[73] Before the Bayh-Dole Act, patent rights clauses in federal funding agreements were determined on an agency-by-agency basis but predominantly favored the federal agency that funded the research (e.g., the NIH), even when the federal agency had provided only a small proportion of the total funding in an R&D endeavor.[74] The issue with this framework was that the federal agencies often neglected their ownership rights, leaving patents undeveloped.[75] Essentially, "federally funded inventions were not progressing to useful commercial products because the government lacked the capacity to pursue the inventions' development potential."[76]

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[72] *See* 35 U.S.C. § 200.

[73] *See The University and Small Business Patent Procedures Act: Hearing on S. 414 Before the S. Comm. on the Judiciary*, 96th Cong. 28–29 (1979) [hereinafter *Senate Hearing*] (statement of Sen. Birch Bayh).

[74] *See* Ryan Whalen, *The Bayh-Dole Act & Public Rights in Federally Funded Inventions: Will the Agencies Ever Go Marching In?*, 109 NW. U. L. REV. 1083, 1087–88 (2015).

[75] *See* Michael Sweeney, *Correcting Bayh-Dole's Inefficiencies for the Taxpayer*, 10 NW. J. TECH. & INTELL. PROP. 295, 295–96 (2012). Supporters of Bayh-Dole pointed to a statistic reported by the Government Accounting Office in 1978 stating that the federal government had accumulated over 28,000 patents, of which less than five percent were commercially licensed. U.S. GEN. ACCT. OFF., TECH. TRANSFER: ADMINISTRATION OF THE BAYH-DOLE ACT BY RESEARCH UNIVERSITIES GAO/RCED-98-126, 3 (1998), https://www.gao.gov/assets/rced-98-126.pdf [https://perma.cc/V2G4-HXJ3].

[76] Jordan Paradise, *COVID-IP: Staring Down the Bayh-Dole Act with 2020 Vision*, 7 J.L. & BIOSCIENCES 1, 5 (2020).

The Bayh-Dole Act's authors felt that confidence in the patent system had declined and that the United States was falling behind its foreign competitors, primarily West Germany and Japan.[77] Accordingly, the Bayh-Dole Act was designed to confront these concerns about the lagging rate of innovation in the United States at the time.[78] Congress's solution was to enact a uniform rule whereby the organizational recipient of federal funding presumptively retained the title to the patents on any inventions created under a federal funding agreement.[79] The hope was that the new collaboration regime would encourage even more R&D agreements.[80]

Therefore, by its own terms as originally enacted, the Bayh-Dole Act sought to ease the ability of small businesses and nonprofit organizations, specifically universities, to obtain ownership of patents to inventions developed with federal funding to promote the commercialization of these inventions.[81] However, the Act's reach was then extended in 1983 when President Ronald Reagan expanded its scope to cover large corporations when he issued a presidential memorandum to treat all federal research funding recipients the same, regardless of the type or size of the entity.[82]

To avoid the pitfalls of the pre-Bayh-Dole Act regime, the Act's drafters sought to penalize entities that failed to pursue

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[77] *See* 126 CONG. REC. 29,897 (1980).

[78] *See, e.g.*, *id.* ("Technological innovation in the United States is declining at an alarming rate . . . .").

[79] *See* 35 U.S.C. § 202(a).

[80] *See* 126 CONG. REC. 29,896 (1980).

[81] *See* Herbert J. Zeh, Jr., *The Federal Funding of R&D: Who Gets the Patent Rights?*, 42 JOM 69 (1990) https://www.tms.org/pubs/journals/JOM/matters/matters-9004.html [https://perma.cc/MB5E-GXYC].

[82] *See* Gerhard Peters & John T. Woolley, *Ronald Regan, Memorandum on Government Patent Policy Online*, AM. PRESIDENCY PROJECT, https://www.presidency.ucsb.edu/node/262502 [https://perma.cc/5QQL-P7YS] (last visited Apr. 3, 2022). This was despite the fact that the initial version of the Bayh-Dole Act, which included patent protections for larger corporations, had faced overwhelming resistance, leading Sens. Bayh and Dole to offer a more limited version of the bill focused on funding agreements between universities, nonprofit organizations, and small businesses. *See* Whalen, *supra* note 74, at 1090.

patent protection and commercialization of inventions stemming from federal funding agreements. Thus, the modern, amended version of the Act gives the federal agency that provides the funding "a nonexclusive, nontransferable, irrevocable, paid-up license" to utilize or designate another entity to utilize the patented invention "for or on behalf of the United States."[83] To clarify, because this license allows the invention to be utilized solely "for the United States," it would not permit a third party designated by the government to utilize the license for its own pecuniary benefit.

Most significantly, however, the Act also grants the federal agency that provided the funding the right to compel the recipient of federal funding, hereinafter referred to as "inventor,"[84] to grant a license to a "responsible applicant" to utilize the patented invention under terms that are reasonable.[85] Colloquially referred to as "march-in rights," this right to march-in on the inventor's presumptive ownership rights is available to the federal government in four limited circumstances, in which it is "necessary," as defined by the statute.[86] Those four circumstances include: (1) when the inventor fails to take effective steps to achieve practical application of the invention; (2) when it is necessary to "alleviate health or safety needs *which are not reasonabl[y] satisfied*" by the inventor; (3) when it is "necessary to meet requirements for public use specified by [f]ederal regulations," which "*are not reasonably satisfied by*" the inventor; and, (4) if the mandated agreement to substantially manufacture the subject invention in the United States is not obtained, not waived, or is being breached by the inventor.[87] Notably, as it relates to Moderna, the law does not explain the scope of the "necessary to alleviate health or safety needs" clause, nor have "march-in" rights ever been exercised under any circumstance to provide guidance for the scope of the right.[88]

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[83] 35 U.S.C. § 202(c)(4).
[84] Or the recipient's assignee, or exclusive licensee.
[85] 35 U.S.C. § 203(a).
[86] *Id.*
[87] *Id.* § 203(a)(1)–(4) (emphasis added).
[88] *See* Paradise, *supra* note 76, at 6.

By all accounts, the Bayh-Dole Act succeeded in unleashing American innovation, with one commentator going so far as to describe the Act as "[p]ossibly the most inspired piece of legislation to be enacted in America over the past half-century."[89] Advocates of the Act will point out that, since its implementation, the Bayh-Dole Act is believed to have contributed "$1.3 trillion in U.S. economic growth, more than 4.2 million jobs, and over 11,000 new startup companies."[90] Additionally, the Bayh-Dole Act is viewed as foundational to the American biotechnology industry.[91] However, even before the COVID-19 pandemic, the Act was not free from criticism.[92] For example, one notable criticism involves how taxpayers must "double pay" for products, once through tax dollars used in the R&D of the product, and again when the invention is purchased by taxpayers on the market.[93] Additionally, the structure of the march-in rights has been criticized, particularly in the case of the NIH, as allowing agencies to "advance the interests of researchers and patent rights holders, rather than making decisions that advance the public interest."[94] Despite these criticisms, however, the Act, by all accounts, appears to have succeeded in achieving its goal of increasing commercialization of federally funded inventions.

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[89] *Innovation's Golden Goose*, ECONOMIST (Dec. 14, 2002), https://www.economist.com/technology-quarterly/2002/12/14/innovations-golden-goose [https://perma.cc/GC5Y-HNSX].

[90] Walter Copan, *Reflections on the Impacts of the Bayh-Dole Act for U.S. Innovation, on the Occasion of the 40th Anniversary of this Landmark Legislation*, IPWATCHDOG (Nov. 2, 2020) https://www.ipwatchdog.com/2020/11/02/reflections-on-the-impacts-of-the-bayh-dole-act-for-u-s-innovation-on-the-occasion-of-the-40th-anniversary-of-this-landmark-legislation/ [https://perma.cc/TB75-7BZN].

[91] *See True Impact of the Bayh-Dole Act*, RICE UNIV.'S BAKER INST. FOR PUB. POL'Y (Dec. 6, 2016), https://blog.bakerinstitute.org/2016/12/06/true-impact-bayh-dole-act/ [https://perma.cc/4E23-K7UN].

[92] *See, e.g.*, Sweeney, *supra* note 75, at 295–97 (outlining various criticisms raised regarding Bayh-Dole).

[93] *See* Gary Pulsinelli, *Share and Share Alike: Increasing Access to Government-Funded Inventions Under the Bayh-Dole Act*, 7 MINN. J.L. SCI. & TECH. 393, 410–11 (2006).

[94] Whalen, *supra* note 74, at 1110 (explaining how possible conflicts of interest have impacted decisions to not utilize march-in rights).

B. Illustrating How Bayh-Dole's March-In and Government License Provisions Offer Little Recourse to the Public

Neither Bayh-Dole's march-in provision nor the license it confers to the government, alone, would help the public address various concerns, such as pricing and availability, that could arise regarding Moderna's COVID-19 vaccine. It is unlikely that any one of the four circumstances where the government is allowed to exercise march-in rights would be satisfied.[95]

As a preliminary matter, Moderna produces doses of the vaccine that are available in the United States at facilities within the United States, and there are no allegations that Moderna is running afoul of any federal regulations.[96] As such, justification for the NIH to use march-in rights would hinge on an expansive interpretation of two phrases: "practical application" and "reasonably satisfied."[97] "Practical application" means "that the invention is being utilized and that its benefits are . . . available to the public on reasonable terms."[98] The vaccine is quite clearly being "utilized," as hundreds of millions of doses have been manufactured, delivered, and administered to people in the United States and around the world.[99] As such, the interpretation of "reasonable terms" likely determines whether the government would be justified in exercising its march-in rights.

Advocates of marching-in on the mRNA-1273 patent or aggressively utilizing the government's license would likely justify

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[95] Those four circumstances include: (1) when the inventor fails to take effective steps to achieve practical application of the invention; (2) when it is necessary to "alleviate health or safety needs *which are not reasonabl[y] satisfied*" by the inventor; (3) when it is "necessary to meet requirements for public use specified by [f]ederal regulations" which "*are not reasonably satisfied by*" the inventor; and, (4) if the mandated agreement to substantially manufacture the subject invention in the United States is not obtained, not waived, or is being breached by the inventor. 35 U.S.C. § 203(a)(1)–(4) (emphasis added).

[96] *See Frequently Asked Questions*, MODERNA, INC., https://www.modernatx.com/covid19vaccine-eua/recipients/faq [https://perma.cc/LP38-F5NX] (last visited Feb. 21, 2022).

[97] *See* 35 U.S.C. § 203(a)(1), (3).

[98] *Id.* § 201(f).

[99] *See* Mikulic, *supra* note 47.

such action as necessary to promote the affordability of the vaccine or its availability at home and abroad.[100] However, without a significant change to the law or the current state of affairs, neither of these proffered justifications would be sufficient. The inability of the government to use the Bayh-Dole Act to address these types of concerns broadly illustrates the futility of march-in rights and the license the government retains.

1. Ensuring the Vaccine's Availability

Under a scenario where Moderna is unable to fulfill orders for doses of the vaccine for the government, there could be justification for the federal government to exercise its march-in rights. However, given the availability of other COVID-19 vaccines and the impact such a decision would have on the stated goals of the Bayh-Dole Act generally,[101] this scenario is highly unlikely. As of the writing of this Article, Moderna has not had trouble fulfilling the federal government's orders for doses of the vaccine.[102] If Moderna continues to fulfill orders placed by the government, surely the NIH cannot argue that Moderna is not reasonably "alleviat[ing] health or safety needs" for Americans.[103]

Hypothetically, if the government could prove that Moderna was unable to provide the needed doses of vaccine domestically, the government could argue it is justified in exercising its march-in rights. Even so, defending such a decision would be less controversial if mRNA-1273 was the only available vaccine, which

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[100] *See infra* pp. 916–17 (discussing recent calls to march-in on Gilead's remdesivir to expand access and lower costs); *see also* Rebecca Robbins, *Moderna, Racing for Profits, Keeps Covid Vaccine Out of Reach of Poor*, N.Y. TIMES (Nov. 9, 2021), https://www.nytimes.com/2021/10/09/business/moderna-covid-vaccine.html [https://perma.cc/3UPL-KQZF] (criticizing Moderna's apparent reluctance to ship vaccine doses to poorer countries).

[101] To promote collaboration with the public and private sector in research initiatives. *See* 35 U.S.C. § 200.

[102] *See Moderna says shipped 100 million COVID-19 vaccine doses to United States*, REUTERS (Mar. 29, 2021), https://www.reuters.com/article/us-health-coronavirus-moderna/moderna-says-shipped-100-million-covid-19-vaccine-doses-to-united-states-idUSKBN2BL1QI [https://perma.cc/W49Z-JVMK].

[103] 35 U.S.C. § 203(a)(2). Here, 35 U.S.C. § 203(a)(1) would not apply because the availability of the vaccine is independent from the terms under which it is offered.

it is not. In fact, mRNA-1273 is not even the most widely used COVID-19 vaccine in the United States; Pfizer Inc.'s ("Pfizer") vaccine is.[104] Under this scenario, so long as Moderna, though unable to completely fulfill orders, was making reasonable efforts to provide the adequate number of doses, and other vaccine producers could make up any shortcomings, it is not likely that a move to exercise march-in rights would succeed. As an illustration, the NIH previously refused to march-in on Genzyme's patent for Fabrazyme, the only approved treatment for Fabry's disease, which was created under a federal funding agreement, despite a documented shortage that required rationing for those suffering from the disease in the United States.[105] Accordingly, since federal agencies have yet to exercise march-in rights and seem reluctant to do so, unless the vaccine was wholly unavailable to the American public, the risk to Moderna that the government would exercise these rights is quite low.[106]

Additionally, the license granted to the government via the Act is limited "to practice or have practiced for or on behalf of the United States," which greatly diminishes the license's value in the mRNA-1273 context.[107] This license would not allow the United States or any potential designee of the United States to utilize the mRNA-1273 vaccine patent for commercial purposes. Despite previous calls to establish an Office of Drug Manufacturing within

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[104] Mikulic, *supra* note 47.

[105] *See* Whalen, *supra* note 74, at 1104–06. As a tangential matter, some have criticized Moderna's apparent unwillingness at times to distribute its vaccine to less-developed countries. *See* Robbins, *supra* note 100. However, the Act's march-in justification for the purpose of alleviating "health and safety needs" would likely not extend to those outside the borders of the United States. Therefore, the government would not be justified in exercising its march-in rights to provide doses of the vaccine to other countries. Treating a rare genetic disorder, as was the in the case of Fabrazyme, is different than confronting a pandemic of a highly contagious respiratory virus. However, if the NIH has refused to march-in on a clearly documented shortage of a drug *in the United States*, it is hard to imagine it justifying marching-in on the mRNA-1273 patent to alleviate the health needs of people outside of America's borders.

[106] *See* Roger Kuan et al., *Life Sciences Considerations Regarding Compulsory Licensing, March-In Rights, and the Defense Production Act During COVID-19*, 33 INTELL. PROP. & TECH. L.J. 11, 13 (2021).

[107] 35 U.S.C. § 202(c)(4).

the HHS, no such office exists, meaning the federal government does not have the capability of manufacturing the vaccine on its own.[108] Since the government lacks the manufacturing capacity to produce the vaccine on its own, theoretically, it would need to find a willing partner that would manufacture and sell doses to the government, and only the government, at no more than the production cost. The prospect of finding a partner willing to engage in such an endeavor is nearly nonexistent, making the government's license in mRNA-1273 effectively useless under the current state of affairs. Moreover, with no existing precedent of the federal government's march-in rights being exercised,[109] and Moderna making "reasonable efforts" to supply the requested number of doses, it is unlikely that the government would be justified in exercising its march-in rights.

2. Ensuring the Vaccine's Affordability

Currently in the United States, mRNA-1273 and all other COVID-19 vaccines are "free to the public,"[110] but there is concern regarding their cost in a post-pandemic world. For example, Pfizer executives have already discussed hiking the price of its COVID-19 vaccine once the pandemic transitions to an endemic phase.[111] Whether the government intends on providing the vaccine free-of-charge forever remains unanswered. Moreover, whatever limited

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[108] *See* Tim Wright, *A Government-Run Drug Manufacturer?*, CONT. PHARMA (Jan. 25, 2019), https://www.contractpharma.com/issues/2019-01-01/view_editorials/a-government-run-drug-manufacturer/ [https://perma.cc/7LPS-9AAA].

[109] *Id.*

[110] *COVID-19 Vaccines Are Free to the Public*, CDC, https://www.cdc.gov/coronavirus/2019-ncov/vaccines/no-cost.html [https://perma.cc/YN2D-NHSN] (last visited Feb. 21, 2022). Free of out-of-pocket charges, that is. The federal government is buying doses by the hundreds of millions to be administered to Americans using tax dollars. *Id.*; *see also* Audrey Carlsen, *How is the COVID-19 vaccination campaign going in your state?*, NPR, https://www.npr.org/sections/health-shots/2021/01/28/960901166/how-is-the-covid-19-vaccination-campaign-going-in-your-state [https://perma.cc/TUF9-5CS6] (last visited Feb. 21, 2022) (collecting data on vaccine doses administered on a state-by-state basis).

[111] Audrey McNamara, *Pfizer Execs Discuss Hiking Vaccine Price After Pandemic Wanes*, CBS NEWS (Mar. 17, 2021), https://www.cbsnews.com/news/pfizer-covid-vaccine-price-hike-post-pandemic/ [https://perma.cc/K7JY-SSY6].

ability the federal government has to cap the price it pays for COVID-19 vaccines could evaporate if the free guarantee expires or companies feel less inclined to exhibit displays of altruism concerning the vaccine. People certainly will continue to need these vaccines, as the virus has shown to be resilient, mutating into new, vaccine-resistant variants.[112] However, as a preliminary matter, the federal government is incapable of addressing any pricing concerns related to the vaccine. This inability is for the same reasons that the government's license in the mRNA-1273 patent fails to promote the vaccine's accessibility—namely, its lack of manufacturing capabilities and its inability to find a designee willing to produce the vaccine under the required terms of the license, as discussed above. All evidence suggests that using march-in rights to regulate the pricing of mRNA-1273 would be an overextension of the Bayh-Dole Act.

First, commercialization, not price control, is the Act's intent.[113] The law, as enacted, was never intended to have the government set prices on the products that are developed with federal funds; any reference to a reasonable price provision was omitted intentionally because it would directly undermine the purpose of the Act.[114] Proponents of utilizing Bayh-Dole's march-in provision to regulate pricing of drugs created under federal funding agreements rely on an expansive interpretation of the phrase "reasonable terms" in the definition of "practical application."[115] In response, commentators have cautioned that

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[112] *See* Herb Scribner, *Omicron Variant is Resistant to Vaccines, Antibody Treatments and Boosters, Study Says*, DESERET NEWS (Dec. 20, 2021), https://www.deseret.com/coronavirus/2021/12/20/22841212/omicron-variant-covid-vaccines-antibody-treatments-boosters [https://perma.cc/4JWD-B7GQ].

[113] Birch Bayh & Bob Dole, *Our Law Helps Patients Get New Drugs Sooner*, WASH. POST (Apr. 11, 2002), https://www.washingtonpost.com/archive/opinions/2002/04/11/our-law-helps-patients-get-new-drugs-sooner/d814d22a-6e63-4f06-8da3-d9698552fa24/ [https://perma.cc/XV25-Z2ES]. Further bolstering this point, Sens. Birch and Bayh stated that they would have included statutory guidance if they intended for the government to be able to march-in and set prices. *Id.*

[114] *Id.*

[115] *See* Peter Arno & Michael Davis, *Paying Twice for the Same Drugs*, WASH. POST (Mar. 27, 2002), https://www.washingtonpost.com/archive/

changes in the law should come from the legislative process and not through "torturing the words [of the Act] into an entirely different meaning than Congress intended."[116]

Second, the NIH has explicitly declined invitations to march-in on federally funded drugs to regulate price[117] because the NIH, under both Republican and Democratic administrations, believes regulating price is beyond the scope of its march-in rights under Bayh-Dole.[118] Moreover, the NIH appears to be building a body of march-in precedent by relying on its previous determinations to inform decisions on new petitions.[119] If the NIH is indeed building a body of precedent to justify rejecting petitions to march-in on drugs over concerns related to pricing, it would be anomalous for the Agency to abruptly reverse course.

Lastly, the National Institute of Standards and Technology ("NIST") proposed a rule in the final weeks of the Trump Administration intended to "clarify" that march-in rights shall not be exercised by an agency exclusively on the basis of the pricing of goods and services arising from the practical application of an

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opinions/2002/03/27/paying-twice-for-the-same-drugs/c031aa41-caaf-450d-a95f-c072f6998931/ [https://perma.cc/3622-8CLU].

[116] Joseph Allen, *New Study Shows Bayh-Dole is Working as Intended—and the Critics Howl*, IPWATCHDOG (Mar. 12, 2019), https://www.ipwatchdog.com/2019/03/12/new-study-shows-bayh-dole-working-intended/id=107225/ [https://perma.cc/H8J3-ETUJ]. Mr. Allen, who served as a Professional Staff Member on the U.S. Senate Judiciary Committee with former Senator Bayh and was instrumental in working behind the scenes to ensure the passage of the Bayh-Dole Act, has written extensively on how the Act, as written, does not contemplate government price regulation. *Id.*

[117] *See* Whalen, *supra* note 74, at 1101–04.

[118] *See id.*; *see also* Joseph Allen, *President Biden: Don't Misuse Bayh-Dole March-In Rights*, STAT (Sep. 17, 2021) https://www.statnews.com/2021/09/17/president-biden-dont-misuse-bayh-dole-march-in-rights/ [https://perma.cc/FK2G-9B9U].

[119] *See* Determination in the Case of Norvir, Francis S. Collins, Nat'l Insts. of Health, Office of the Dir. 2, 4–6 (Nov. 1, 2013), http://www.ott.nih.gov/sites/default/files/documents/policy/March-In-Norvir2013.pdf [https://perma.cc/R7JX-62M7] (relying on much of the same reasoning from its 2004 petition rejection to reject the second petition to march-in on the Norvir patent owned by Abbott Laboratories).

invention.[120] Although the rule has not been adopted, and there are questions about the propriety of the NIST promulgating a rule that takes away discretion allocated to funding agencies via the Statute, the rule states in clear terms the position of the government on this issue (at least as of January 2021).[121] Importantly, however, President Biden issued what can adequately be described as a "colossal" Executive Order on July 9, 2021, which, buried in section 4(r)(ii), called on the Secretary of Commerce, acting through the Director of the NIST, to "consider not finalizing any provisions on march-in rights and product pricing" in the above-mentioned proposed rule.[122] Given the language of the Executive Order, the proposed regulation was not stopped in its entirety; it only orders the NIST Director to "consider" not finalizing it. However, it will be important to watch whether it nonetheless becomes the official position of the federal government that undesirable pricing is not a proper justification for marching-in. If the rule is adopted, any petition or calls to march-in and regulate the price of mRNA-1273 or any other drug falling under Bayh-Dole would effectively be dead-on-arrival.

Accordingly, the government's rights to mRNA-1273 if the NIH scientists are excluded as co-inventors of the patent—the right to march-in or utilize its license—would do very little, if anything, to vindicate the public interest in the vaccine. Under the current framework and state of affairs, neither of these rights would alleviate the two most likely concerns that could arise regarding the vaccine: pricing and availability.

IV. RECOMMENDATIONS FOR AMENDING BAYH-DOLE SO IT BECOMES A BETTER BARGAIN FOR THE PUBLIC

There may be genuine questions as to whether the NIH scientists did, in fact, co-invent the mRNA-1273 genetic sequence

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[120] Rights to Federally Funded Inventions and Licensing of Government Owned Inventions, 86 Fed. Reg. 35 (proposed Jan. 4, 2021) (to be codified at 37 C.F.R. pts. 401, 407).

[121] *Id.*; *see also* Rebecca Eisenberg, *Whether and How the U.S. Government Should Exercise Its Compulsory Licensing Authority Under 28 U.S.C. § 1498 and the Bayh-Dole Act*, 11 N.Y.U. J. INTELL. PROP. & ENT. L. 38, 40–41 (2021).

[122] Exec. Order No. 14,036, 86 Fed. Reg. 36,987, 36,998 (Jul. 9, 2021).

for Moderna's COVID-19 vaccine. Consequently, unless Moderna and the NIH can resolve the dispute amicably, the possibility of a protracted legal battle with broad implications for the vaccine's long-term distribution and billions of dollars in future profits looms large.[123] If the NIH scientists are not found to be co-inventors of the main genetic sequence in the vaccine, they will have no right to be listed as such in the patent, and Moderna would retain the right to manufacture, price, and distribute the vaccine largely as it sees fit. This possibility highlights that the current state of the law is inequitable to the public and should be changed. The public should have stronger rights to inventions developed using taxpayer dollars, particularly inventions created for public health purposes. The best place to start is to begin treating taxpayers as investors in publicly funded R&D and not simply as donors. This is particularly true in the case of mRNA-1273, whose development, alongside scientists from the NIH, was almost exclusively funded by the federal government[124] and will likely result in billions of dollars in profits for Moderna, who was able to capitalize on the availability of federal funding.[125]

Any proposed change to the current framework established by the Bayh-Dole Act inherently involves balancing the interests of the public with the interests of the funding recipient contracting with the government for the R&D project. The public certainly has strong interests in the technological developments financed using taxpayer dollars. In fact, within the context of COVID-19, the public's interest is even more clear, as the virus's pervasiveness, transmissibility, and higher mortality rate in unvaccinated individuals demonstrate the importance of having access to Moderna's mRNA-1273 vaccine. Moreover (and more in line with

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[123] *See* Stolberg & Robbins, *supra* note 7.

[124] *See* Allie Clouse, *Fact Check: Moderna Vaccine Funded by Government Spending, with Notable Private Donation*, USA TODAY (Nov. 24, 2020), https://www.usatoday.com/story/news/factcheck/2020/11/24/fact-check-donations-research-grants-helped-fund-moderna-vaccine/6398486002/ [https://perma.cc/9JAU-CMX6].

[125] *See* Matt Grossman & Peter Loftus, *Moderna Beats Profit Estimates, Fueled by COVID-19 Vaccine Sales*, WALL ST. J. (Feb. 24, 2022), https://www.wsj.com/articles/moderna-beats-profit-estimates-fueled-by-vaccine-sales-11645707646?mod=pls_whats_news_us_business_f [https://perma.cc/237T-DP8H].

the commercial focus of the Bayh-Dole Act), the public has a financial interest in this federally funded vaccine. Americans will be paying for COVID-19 vaccines for the foreseeable future, be it indirectly through their tax dollars or health insurance premiums, or directly out of their pockets.

On the other hand, funding recipients also have strong interests in the technology they research and develop and need a certain degree of protection of their rights to the resulting inventions. Though the government provides the funding, these recipients typically are the ones putting the funding to use by carrying out the research and inventing something new and useful or discovering something previously unknown.[126] Lastly, as an overarching principle, the United States government wants to facilitate collaborations between the private and the public sector, such as funding agreements to conduct research to create useful inventions that can improve the lives of Americans and people around the world. However, encouraging private partners to accept funding from the government to undertake research projects should not entail the public ceding all rights to the private partner. To maintain public support for funding R&D the public needs to trust that it is receiving a fair deal. But this trust is undermined when, for example, Americans see that they pay considerably more for drugs than people in other countries,[127] some of which received federal funding for their development. Accordingly, amending the Bayh-Dole Act to adequately consider the public's financial interest in inventions it funds the development of will serve the goal of promoting continued support for funding such collaborations.

Regarding Moderna's mRNA-1273 vaccine, the primary issue under the current Bayh-Dole framework is that Moderna is double-dipping on public funding—it used public funds, almost exclusively, to develop the vaccine and is now selling the product

[126] Highlighting the NIH's involvement in the development of the vaccine is not intended to discount work undertaken by Moderna scientists.

[127] *See* Andrew Mulcahy et al., *International Prescription Drug Price Comparisons: Current Empirical Estimates and Comparisons with Previous Studies*, RAND CORP. 36 (2021), https://www.rand.org/pubs/research_reports/RR2956.html.

back to the government to be distributed to Americans. In effect, Moderna has received a risk-free business enterprise by piggy-backing off American taxpayers who funded the development of its vaccine and is now profiting handsomely by pricing the vaccine as it pleases and selling it back to the government.[128] This can hardly be described as a "fair deal" to the taxpaying public.

In light of these findings, the Bayh-Dole framework should be amended to grant the public clearer and stronger financial rights to R&D projects funded by the federal government. These amendments should specifically focus on the public's ability to recoup its investment in projects that result in profitable, commercialized inventions and limit private companies' ability to price such inventions however they see fit when selling the inventions back to the public, whether directly or through the government, as is the case currently with mRNA-1273.

A. Public Return of Investment in Profitable Inventions

The key to resolving the unfair economic proposition created by the Bayh-Dole Act and fairly compensating the public is to allow the government to recoup any investment it makes in profitable, commercialized products. This subpart proposes two solutions to achieve this goal. First, it proposes enacting a "Return of Government Investment" provision, which was included in the original bill but ultimately left out. Second, it suggests amending the license that the government retains in the patented invention so that the license is transferrable.

1. Enact a "Return of Government Investment" Provision

The simplest and most obvious solution that would allow the public to recoup its investment in federally funded R&D is to amend Bayh-Dole to contain a "Return of Government Investment" provision. Section 204 of the original draft of the Bayh-Dole bill required the return of all or part of the government's investment after a subject invention generated a

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[128] *See* Matina Stevis-Gridneff et al., *A European Official Reveals a Secret: The U.S. is Paying More for Coronavirus Vaccines*, N.Y. TIMES: THE UPSHOT (Dec. 18, 2020), https://www.nytimes.com/2020/12/18/upshot/coronavirus-vaccines-prices-europe-united-states.html [https://perma.cc/6Q6F-UK8Z].

specified amount of profit.[129] Senator Thurmond, an original sponsor, considered this provision "[p]erhaps the most significant feature of th[e] bill."[130] Drafters of the Act were concerned that granting private ownership to the resulting inventions of publicly funded research ran the risk of appearing as a wealth transfer to private interests.[131] However, the drafters decided to hang their hat on the hunch that the improved rate of development and commercialization would generate a net social benefit without a return of investment requirement.[132] This hunch ultimately informed the decision to rely on march-in rights as the way to preserve the public's interest in the inventions the federal government funded.[133] It is unclear whether the drafters contemplated something such as OWS when writing the various provisions of the bill.

Drawing from the original draft of the Act, this Article proposes to add a provision requiring entities that *profit* from inventions falling under Bayh-Dole to share a portion of those profits with the government in perpetuity, or at least until the government's initial investment is repaid. Accordingly, the government would recoup much of the cost of subsidizing research that leads to a profitable, commercialized product. Moreover, an exceptionally successful product could supply additional funding

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[129] *See* S. REP. NO. 96-480, at 34 (1979); S. 414, 96th Cong. § 204 (1980); *see also* 126 CONG. REC. 8739 (1980) (statement of Sen. Dole) ("The Government payback provision guarantees that the Government's investment, paid for by the taxpayers of this country, is returned to the Federal coffer.").

[130] *Senate Hearing*, 96th Cong. 34 (1979) (statement of Sen. Strom Thurmond, Member, S. Comm. on the Judiciary).

[131] Whalen, *supra* note 74, at 1097; *See* 126 CONG. REC. 29,898 (1980) (statement of Rep. Brown) ("I am aware of the concern that granting contractors exclusive rights to federally funded inventions is a 'give-away' of the taxpayers' property."); 126 CONG. REC. 8738 (1980) (statement of Sen. Long) ("It is dismaying, therefore to find that S. 414 provides for contractors . . . to receive gifts of ownership of taxpayer-financed research, and according to S. 414's chief sponsor, this is to be only a first step.").

[132] *See* 126 CONG. REC. 29,898 (1980).

[133] "It is unclear whether Bayh-Dole's drafters envisioned that the [march-in] provisions would ever be used, or, if their inclusion was more strategic in nature, intended to preemptively counter allegations of wealth transfer." Whalen, *supra* note 74, at 1098.

to the government to dedicate to other research initiatives it wishes to pursue.[134] In other words, it would present the opportunity for the public to receive a return on its investment in R&D, much like any other investor in a business would expect.

Moreover, this amendment would also protect those private entities that accept federal funding because repayment would be conditioned on the invention in question being profitable. In the event of a failed R&D endeavor, the private entity would have no obligation to pay the government back. In other words, everyone makes out when federally subsidized R&D results in a commercially successful product. Consider this quote from Professor Ritchie de Larena:

> From an equity perspective, surely partial, if not full, payback of the funding public seems eminently fair. If indeed the intent of the patent system at large is to reward—and thereby encourage—investment in the creation of new inventions, then it naturally follows that the reward for inventions created with federal research funds should inure to the federal taxpayers who paid for them.[135]

Requiring the funding recipient to return the government's investment once it has successfully invented and commercialized a product that is profitable balances the interests of both the public and the private entities involved. The public, like any investor, is rewarded for investing in promising research by receiving that investment back and reaping the social benefit of the invention's availability on the market. The inventor receives the investment on a risk-free basis because it is only required to return the funding if the product is profitable. The inventor also retains exclusive ownership rights to the patent on the invention. Importantly, the public can then reinvest those funds in other promising research that will generate more social benefits.

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[134] *See generally* Peter Kotecki, *In Focus: As Lyrica profits dry up, Northwestern seeks another 'blockbuster" drug*, DAILY NORTHWESTERN (Apr. 10, 2016) https://dailynorthwestern.com/2016/04/10/in-focus/in-focus-as-lyrica-profits-dry-up-northwestern-seeks-another-blockbuster-drug/ [https://perma.cc/C5KA-WM8S] (noting how Northwestern University had received about $1.4 billion towards its endowment by licensing its discovery of the compound pregabalin, whose brand name is Lyrica).

[135] Lorelei Ritchie de Larena, *The Price of Progress: Are Universities Adding to the Cost?*, 43 HOUS. L. REV. 1373, 1389 (2007).

2. Amend the License Granted to the Government to a Transferrable License

Amending the type of license granted to the government in any subject invention via the Bayh-Dole Act so that the license is transferable would provide another mechanism for the public to recoup its investment. Accordingly, the government would be able to sell (transfer) this license, subject to certain restrictions. Under this framework, after the federal government provides research funding resulting in a successfully commercialized product, the funding agency retains a transferable license allowing for the invention to be used for commercial purposes. The government would give the inventor, or whoever has since been assigned the rights to the invention, the option to "buy-out" the government's license. Exercising this "buy-out" option would grant the party exclusive rights to operate under the patent, subject to existing march-in rights.

In fact, the NIH settled a patent dispute with Myriad Genetics ("Myriad") in 1995 by effectively tracking this framework. Two NIH researchers in North Carolina assisted Myriad in isolating and sequencing the *BRCA* genes associated with breast and ovarian cancer.[136] Myriad failed to list the two NIH scientists as inventors on the patents it filed soon after the discovery, to which the NIH responded by filing its own competing patent applications.[137] The parties settled the dispute with the NIH agreeing to withdraw its patent application and Myriad agreeing to amend its application to include the NIH scientists, giving the NIH partial ownership of the patent.[138] The NIH was additionally entitled to royalties from Myriad's patent earnings and shares of Myriad's stock, but in return the NIH ceded full control of the patent's commercialization by granting Myriad the exclusive right to operate under the

[136] *See* Contreras, *supra* note 24; *see also Hereditary Breast Cancer and BRCA Genes*, CDC (explaining BRCA genes), https://www.cdc.gov/cancer/breast/young_women/bringyourbrave/hereditary_breast_cancer/index.htm [https://perma.cc/HP6G-CUCH] (last visited Mar. 8, 2022).

[137] *See* Contreras, *supra* note 24.

[138] *Id.*

patent.[139] In other words, Myriad effectively bought out the NIH's right to license the patented technology.

The value of this proposed "buy-out" option could be set as the amount of research funding the government disbursed, with an adjustment for inflation. Unlike the proposed aforementioned "Return of Government Investment" provision, the decision to "buy-out" the government and return the investment would fall completely under the discretion of the federal funding recipient. In the event the funding recipient does not wish to "buy-out" the government's license, the agency holding the license could auction it off to whoever is willing to pay the most. The minimum bidding price would be the adjusted "buy-out" cost of the initial federal funding recipient, meaning the party purchasing the license would not receive a better deal to "buy-out" the government than what was offered to the funding recipient.

Research funding recipients could use their discretion and make a business determination as to whether they believe they can successfully compete with a potential competitor-licensee or whether they wish to monopolize the invention for the life of the patent. Either way, the government can recoup its investment in the successful research. If the inventor believes it can produce the invention more affordably than any would-be competitor, it can decline to buy the license and proceed to compete against whoever purchases the license. The inventor would be at an advantage, having not needed to provide the upfront research investment, while a would-be competitor would need to make a significant investment, either up front or over time through licensing fees, to purchase the license. Healthy competition could keep prices down and the public would receive the investment back, while having the opportunity to buy the product on the market.

Currently, there is no investment threshold that the government must meet in order for the Bayh-Dole Act's provisions to apply generally.[140] Accordingly, to protect the interests of the funding

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[139] *Id.*

[140] *See* 35 U.S.C. § 201(e) ("[A]ny invention of the contractor conceived or first actually reduced to practice in the performance of work under a [federal] funding agreement . . . .").

recipient, a minimum government investment threshold should be established to trigger this public right. Granting an unencumbered, transferrable license to the government in a situation where its investment was negligible would not be inherently fair to the parties partnering with the government. As such, this provision should only apply to inventions that received funding comprising a certain, appropriate percentage of total investment in the research endeavor, as determined by Congress or other policymakers. In the event such funding does not meet the requisite threshold, the license would retain the features it has under the current state of the law[141] and the proposed "Return of Government Investment" would govern by default.

These proposed amendments to the Bayh-Dole Act are squarely concerned with permitting the public to recoup its investment in public research. Essentially, the key to improving Bayh-Dole is to treat the American taxpayer as an investor, not a donor, regarding federally funded R&D. If the government is already providing a risk-free investment in the research, incentivizing private entities to collaborate with the government should not require unhindered monopolization of the economic gains of the fruits of such research by the entity partnering with the government.

B. Price Regulation: Confer Most-Favored-Nation Status to the United States

"Spiraling" drug prices remain a constant concern in the United States.[142] This subpart outlines how conferring "most-favored-nation status" on the United States regarding drugs developed under federal funding agreements could help alleviate such concerns. Additionally, this subpart cautions against overextending the current provisions of the Bayh-Dole Act to regulate drug pricing.

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[141] The statute describes the license as "nonexclusive, nontransferable, [and] irrevocable . . . ." 35 U.S.C. § 202(c)(4).

[142] *See, e.g.*, Margot Sanger-Katz, *Democrats Choosing Less Risky Path on Drug Prices*, N.Y. TIMES: THEUPSHOT (Nov. 6, 2021), https://www.nytimes.com/2021/11/06/upshot/democrats-drug-prices.html [https://perma.cc/DZM6-HTCM].

The best way to achieve drug pricing regulation, regardless of whether the drug was invented under a federal funding agreement, is for Congress to separately establish a comprehensive regulatory scheme. However, in the absence of such a scheme, Congress should amend Bayh-Dole to confer upon the United States a "most-favored-nation status" when it comes to the pricing of drugs developed under a federal funding agreement.

Under the current regime, citizens of foreign countries receive drugs at significantly lower prices than Americans, even when Americans have subsidized the R&D of the drugs.[143] Conferring a most-favored-nation status would resolve this unfair bargain for American taxpayers by requiring that "subject inventions be brought to market in the [United States] on terms at least as amenable as the terms in similarly economically developed countries."[144] Drug companies would simply need to have rough uniformity on the terms in which they offer their products to Americans and people in countries that are economically similar. This provision would help manage the pricing of drugs on the market in the United States. Americans would be able to capitalize on the drug pricing regulatory policies of European countries, the most likely peer countries, under such a provision. This would remove the concern that a government agency would march-in on an invention over a pricing dispute regarding what would be a "reasonable price" without any guidance.

Calls for the federal government to utilize the Bayh-Dole Act to regulate drug pricing has been the basis for multiple march-in petitions in recent years.[145] More recently, in the context of COVID-19, in August 2020, Attorneys General Xavier Becerra of California and Jeff Landry of Louisiana authored a letter to federal agency representatives at the HHS, the NIH, and the FDA, signed by thirty-four other states' attorneys general.[146] The letter

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[143] *See* Mulcahy, *supra* note 127, at 36.

[144] Whalen, *supra* note 74, at 1114.

[145] *See id.* at 1101–1104.

[146] Letter from Xavier Becerra, Att'y Gen. of the State of California, and Jeff Landry, Att'y Gen. of the State of Louisiana, to Alex Azar, Sec'y of HHS, Dr. Francis Collins, Dir. of NIH, and Stephen Hahn, Comm'r of FDA, (Aug. 4,

demanded that the federal government utilize its authority under the Bayh-Dole Act to march-in against Gilead Sciences to make its COVID-19-fighting drug, Remdesivir, more widely available at a lower cost.[147] The government denied the invitation.[148] However, the desire by state officials for the federal government to regulate prices using Bayh-Dole certainly has caught the pharmaceutical industry's attention—so much so that the industry has created an online presence to celebrate the Act, reiterate the original intent of the drafters, and promote those opposed to the usage of march-in rights to regulate drug prices.[149]

If Congress wants to grant agencies the power to regulate drug prices under Bayh-Dole, Congress must amend the Act to explicitly grant that power and, moreover, define what constitutes a "reasonable price."[150] However, history serves caution to adopt such a measure. For instance, in 1989, the NIH imposed a reasonable pricing clause for its patent licenses and its cooperative R&D agreements ("CRADAs").[151] Instead of lowering drug prices as intended, the primary effect of the clause was that the number of CRADAs between the NIH and the private sector plummeted.[152] In response, the acting NIH director, concluded that "the pricing clause has driven industry away from potentially beneficial

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2020), https://www.oag.ca.gov/system/files/attachments/press-docs/Remdesivir%20Letter%2020200804.pdf.

[147] *Id.*

[148] A spokesperson for the HHS was quoted as saying that Bayh-Dole provisions did not apply to remdesivir, therefore the government lacked the ability to march-in at all, let alone over pricing concerns. *See* Paradise, *supra* note 76, at 12.

[149] *See About*, BAYH-DOLE COALITION, https://bayhdole40.org/about/ [https://perma.cc/3UE3-QUKG] (last visited Feb. 21, 2022) ("By ensuring that academic institutions and companies would own inventions they make with government-support, Senators [Bayh and Dole] spurred the transformation of laboratory discoveries into new products benefitting the American taxpayer—and citizens throughout the world.").

[150] *See* Allen, *supra* note 116.

[151] Press Release, NIH, NIH Notice Rescinding Reasonable Pricing Clause 4 (Apr. 11, 1995), https://www.ott.nih.gov/sites/default/files/documents/pdfs/NIH-Notice-Rescinding-Reasonable-Pricing-Clause.pdf [https://perma.cc/C9WC-K77C].

[152] *Id.* at 1.

scientific collaborations with [government] scientists without providing an offsetting benefit to the public," and the clause was rescinded.[153] Subsequently, the number of CRADAs with the NIH skyrocketed.[154]

A company's hesitation to enter into agreements with a "reasonable pricing" clause makes sense: What company would risk investing money in an R&D endeavor alongside the government if the government could simply turn around and hand it to a rival just because someone did not like the price set by the company for the invention? Nevertheless, a "reasonable pricing" provision was on the minds of several members of Congress, even though, ultimately, the provision was not included in the final version of the Act.[155]

Though there have been calls for the federal government to use its authority established under the Bayh-Dole Act to regulate drug pricing, these calls remain unanswered—and for good reason. In effect, regulating pricing would cut directly against the goals of the Bayh-Dole Act because of the likely chilling effect such action would have on the private sector's willingness to collaborate with the government. If the government wishes to regulate prices, the government should enact a comprehensive regulatory scheme for all drugs, not just those invented via a federal funding agreement. Absent such a regulatory scheme, the Bayh-Dole Act should at least be amended to confer most-favored-nation status to the

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[153] *Id.*

[154] *See generally* Stephen Ezell, *The Bayh-Dole Act's Vital Importance to the U.S. Life-Sciences Innovation System*, INFO. TECH. & INNOV. FOUND. (Mar. 4, 2019), https://itif.org/publications/2019/03/04/bayh-dole-acts-vital-importance-us-life-sciences-innovation-system#_Ref536611880 [https://perma.cc/8RVZ-SKT9] (displaying the number of private-sector CRADAs with NIH from 1987–2017 in Figure 5).

[155] *See Patent Policy: Hearings on S. 1215 Before the Subcomm. on Sci., Tech., & Space of the S. Comm. on Com., Sci., & Transp.*, 96th Cong. 392 (1979) (statement of Sen. Russell B. Long, Member, S. Comm. on Com., Sci., & Transp.) ("Is this bill providing a limitation on just how much the successful contractor can charge the public for what the public has already paid for? . . . Is there any limitation in this proposal as to how much he could charge the public to have the benefit of what the public has already paid for when they paid for the research?").

United States but not to impose a "reasonable pricing" provision. Most-favored-nation status would largely solve the inherently unfair circumstance of Americans paying more for drugs developed using their tax dollars than other people around the globe.

V. CONCLUSION

Moderna's mRNA-1273 COVID-19 vaccine was the result of years of collaboration with the NIH and substantial upfront investments by the federal government through Operation Warp Speed.[156] Now, the NIH and Moderna are embroiled in a dispute over who should be listed on the vaccine's principle patent as a "co-inventor." The NIH claims three of its scientists co-invented the key vaccine technology; Moderna disagrees. The outcome of that legal battle, should it continue, will have tremendous implications for the future accessibility of the vaccine and the distribution of the vaccine's potentially billions of dollars in future profits.

When an invention is developed under a federal R&D agreement, the Bayh-Dole Act grants the entity that received the funding and created the invention the exclusive right to own and license any patents to that invention. In the case of Moderna's mRNA-1273 vaccine, if it is determined that the NIH scientists did not co-invent the vaccine technology, the Bayh-Dole Act provides little recourse to the American public. In effect, the Bayh-Dole framework is an unfair proposition for the American taxpayer as it currently stands because it treats the American taxpayer as a donor in R&D and not an investor.

The NIH-Moderna vaccine patent dispute has exposed the Bayh-Dole framework, showing its unfairness towards American taxpayers when federal funds are used for public health R&D. Therefore, it is time to reevaluate what rights the public should have to the profits of federally funded research. Promoting cooperation with the federal government on R&D projects should not require ceding all economic rights to the private party willing to capitalize on the availability of federal funds. The Bayh-Dole

[156] *See supra* Part II.

Act must be amended to make it a better deal for the taxpayer. Foremost, it must be amended to require research partners to return any public investment in profitable inventions. Ancillary considerations, such as regulating the pricing of drugs developed under a federal funding agreement, can similarly be addressed by conferring "most-favored-nation" status to the United States. Addressing the Bayh-Dole Act's unfair proposition for American taxpayers will help to facilitate the continued public support of federally funded R&D collaborations with private entities, while recognizing sufficient public rights to the inventions derived from those collaborations.