COVID-IP: staring down the Bayh–Dole Act with 2020 vision

Jordan Paradise*

Beazley Institute for Health Law & Policy, Loyola University Chicago School of Law, Chicago, IL 60611, USA

ABSTRACT

As the human and economic toll of the COVID-19 coronavirus steadily escalates, there is extreme uncertainty regarding the timeframe for prevention, detection, and treatment.¹ There is also concern about the eventual costs associated with approved products and the barriers to access created by the patent system. Industry, government, and academic collaborations are leading the charge in the discovery race, partnerships which have triggered calls for the activation of the federal governments so-called “march–in rights” established in the Bayh–Dole Act.² The Bayh–Dole Act dramatically altered the patent protections available to federally funded institutions and initiated a 40-year debate over appropriate incentives for innovation and the scope of the government’s authority. The COVID-19 pandemic provides an opportunity to reflect on the purpose and impact of the historic legislation as well as contemplate the implications for our public health future. Patent rights for therapeutic compounds, methods of delivery, and medical diagnostics will significantly impact access to and cost of life-saving innovations. This article examines current calls for the U.S. government to utilize governmental march–in rights to quell concerns about patent monopolization and product pricing in the face of our current pandemic.

KEYWORDS: food and drug law, intellectual property

I. INVESTIGATIONAL MOBILIZATION

Pharmaceutical companies, academic institutions, and medical research entities have mobilized attention to identify new vaccines and treatments or repurpose old (and often unapproved) products to fight and treat coronavirus disease 2019 (COVID-19). Likewise, medical device sponsors are acquiring emergency use authorization (EUA) for diagnostic products that have yet to gain market authorization by the Food and Drug Administration (FDA) to detect the both the presence of the virus and antibodies. The FDA has also issued an EUA for use of the unapproved drug Remdesivir in the

* Georgia Reithal Professor of Law; Co-Director, Beazley Institute for Health Law & Policy, Loyola University Chicago School of Law. The author thanks Abby Higgins for research assistance.

¹ Bayh-Dole Act of 1980, Pub. L. No. 96–517 (1980).
² Id.
treatment of hospitalized patients suffering from COVID-19. The Lancet reports that as of April 21, 2020, there were over 500 COVID clinical trials that have been registered at the various international and national clinical trial registry sites exploring safety and efficacy of products for use to combat the novel coronavirus. The Wall Street Journal counts more than 140 new experimental drug treatments and vaccines were in development by the end of April, eleven of those already in clinical trials, and 254 clinical trials for re-purposing existing drugs for other diseases. For example, AbbVie and Gilead are both exploring the re-purposing of vaccines for human immunodeficiency virus (HIV) and Ebola, respectively, to be used in coronavirus trials.

There was an early frontrunner that maintains promise. The FDA issued Gilead a European Medicines Agency for the drug Remdesivir on May 1, 2020, meaning that the drug can be made available as soon as adequate manufacturing controls have been established prior to actual approval by the FDA. Gilead began clinical trials of Remdesivir in March 2020 and made it available through the FDA’s expanded access program. Remdesivir was originally manufactured as an Ebola drug, yet did not achieve FDA approval for that indication. Gilead has completed a limited clinical trial in Chicago, with 125 total patients, 113 of which were severe. The results demonstrated all but two patients were eventually discharged. Notably, Gilead recently asked the FDA to rescind the Orphan Drug status granted to the drug after public pushback.

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3 U.S. Food & Drug Admin., Emergency Use Authorization for Use of Remdesivir for the Treatment of Hospitalized 2019 Coronavirus Disease, May 1, 2020, https://www.fda.gov/media/137564/download (accessed Aug. 27, 2020).

4 Global Coalition to Accelerate COVID-19 Clinical Research in Resource-Limited Settings, 395 LANCET 1322, Apr. 2, 2020.

5 Joseph Walker, Peter Loftus & Jared S Hopkins, Scientists Rush to Find Coronavirus Cure—but It Still Isn’t Fast Enough, WALL STREET JOURNAL, Apr. 6, 2020, https://www.wsj.com/articles/inside-the-race-to-find-a-coronavirus-cure-11586189463 (accessed Aug. 11, 2020). The health, medicine and science media company STAT maintains a ‘COVID-19 Drugs and Vaccines Tracker’ on their website. COVID-19 Drug and Vaccine Tracker, STAT NEWS, https://www.statnews.com/feature/coronavirus/drugs-vaccines-tracker/?utm_campaign=stat_plans_today&utm_medium=email&utm_content=87463235&utm_source=hs_email (subscription required; accessed Aug. 11, 2020).

6 AbbVie, AbbVie's Update on COVID-19, https://www.abbvie.com/coronavirus.html?_ga=2.241135683.1112355514.1587332152-1790810423.1587332152 (accessed Aug. 11, 2020); Gilead, An Open Letter from our Chairman and CEO, Apr. 10, 2020. https://www.gilead.com/stories/articles/an-open-letter-from-our-chairman-and-ceo-april-10 (accessed Aug. 11, 2020).

7 U.S. Food & Drug Administration, Emergency Use Letter of Authorization, May 1, 2020, https://www.fda.gov/media/137564/download (accessed Aug. 27, 2020).

8 Andrew Joseph, Remdesivir Surges Ahead Against Coronavirus, STAT NEWS, Mar. 16, 2020. https://www.statnews.com/2020/03/16/Remdesivir-surges-ahead-against-coronavirus/ (accessed Aug. 11, 2020).

9 Jason Gale, Gilead to Expand Access to Remdesivir, Its Promising Coronavirus Treatment, FORTUNE, Mar. 30, 2020.

10 Adam Feuerstein et al., Gilead Data Suggests Coronavirus Patients are Responding to Treatment, STAT, Mar. 16, 2020, https://www.statnews.com/2020/04/16/early-peek-at-data-on-gilead-coronavirus-drug-suggests-patients-are-responding-to-treatment/ (accessed Aug. 11, 2020).

11 Gilead, Gilead Sciences Statement on Request to Rescind Remdesivir Orphan Drug Designation, https://www.gilead.com/news-and-press/company-statements/gilead-sciences-statement-on-request-to-rescind-remdesivir-orphan-drug-designation (accessed Aug. 11, 2020). Orphan Drug status would have given Gilead seven years of exclusivity on the market, an incentive implemented to foster development of drug products for populations of 200,000 or less. 21 U.S.C. §526 (2016).
Federal funding infusions add to financial incentives for COVID innovations. Congress recently passed the $2 trillion Coronavirus Aid, Relief, and Economic Security (CARES) Act, allocating emergency funding support. The Act included $3.5 billion directed to the Biomedical Advancement Research and Development Authority (BARDA) to allocate resources for collaborative research into promising diagnostics, vaccines, and therapeutics. Additional related public-private coordinated efforts, such as Operation Warp Speed, are also supporting innovation. For example, Sanofi, Johnson & Johnson, and Moderna are part of the BARDA initiative in developing a new vaccine and have received funding directly from the CARES Act. BARDA maintains a list of COVID-19 projects they are funding across diagnostics, therapeutics, and vaccines. The awards are for either countermeasures or for analytics and modeling uses with the stated goal of agreement to:

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advance candidate medical countermeasures toward licensure or approval by the US Food and Drug Administration (FDA). This [agreement] will also serve to advance the knowledge and scientific understanding of candidates' platform technologies, modeling and forecasting, and visual analytics.
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A few examples illustrate the breadth of study of COVID-19 therapeutic candidates. AbbVie is testing Kaletra (lopinavir/ritonavir), a drug originally patented for HIV treatment, with assistance in part from BARDA and global partners. The clinical trial consisting of 199 randomized patients, with 99 given lopinavir-ritonavir twice a day for 14 days, garnered results in March finding no discernable benefit beyond standard care. However, AbbVie did identify signals from the clinical trial results that there may be a stronger positive benefit based on the timing of the treatment. Notably, AbbVie has announced it would not enforce patent rights against potential infringers in the race for a cure. This serves as one example of the drug sponsor proactively addressing an

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14 U.S. Department of Health & Human Services, BARDA’s Novel Coronavirus Medical Countermeasure Portfolio, https://www.phe.gov/emergency/events/COVID19/Pages/BARDA.aspx (accessed Aug. 11, 2020).
15 Id.
16 Office of Biomedical Advanced Research and Development Authority (BARDA) Broad Agency Announcement (BAA): BAA-18-100-SOL-00003, 7, https://research-authority.tau.ac.il/sites/resauth.tau.ac.il/files/BARDA_FINAL_BAA_2018.pdf (accessed Aug. 27, 2020).
17 Kyle Blankenship, *AbbVie Gives Up Patent Rights to HIV Med Kaletra Amid COVID-19 Tests: Report*, FiercePharma, Mar. 23, 2020. https://www.fiercepharma.com/pharma/abbvie-gives-up-patent-rights-to-hiv-med-kaletra-amid-covid-19-tests-report (accessed Aug. 11, 2020).
18 Bin Cao et al., *A Trial of Lopinavir–Ritonavir in Adults Hospitalized with Severe Covid-19*, N. Eng. J. Med. online, Apr. 14, 2020: DOI: 10.1056/NEJMoa2001282.
19 Angus Liu, *AbbVie’s HIV Drug Kaletra Stumbles in COVID-19 Trial, But One Analyst Bows to Differ*, FiercePharma, Mar. 19, 2020, https://www.fiercepharma.com/pharma-asia/does-abbvie-s-hiv-drug-kaletra-also-works-covid-19-maybe-not-nejm-study-finds (accessed Aug. 11, 2020).
20 Donato Paulo Mancini & Hannah Kuchler, *Abbvie Drops Patent Rights for Kaletra Antiviral Treatment*, Financial Times, Mar. 23, 2020, https://www.ft.com/content/5a7a9658-6d1f-11ea-89df-41bea055720b (accessed Aug. 11, 2020).
easing of patent rights in the face of the pandemic, even though it is unclear the scope of this nonenforcement pledge.

Moderna has secured BARDA funding for investigations of a new messenger ribonucleic acid (mRNA) vaccine, which utilizes synthetic mRNA to encode for and stimulate the production of COVID-19 antibodies within the human body. The company was awarded $483 million to obtain FDA licensure for the vaccine and ultimately increase production as part of the CARES Act. A subsequent manufacturing contract with the US government for $1.5 billion in August for 100 million doses of the vaccine further backs the company’s endeavors. Johnson & Johnson, through their research branch Janssen, has also announced a partnership with BARDA that will total a combined $1 billion toward research of a vaccine and antiviral treatment. And Sanofi was awarded $226 million prior to the passage of the CARES Act to work in agreement on flu vaccines and will be using that platform to explore the use in Coronavirus vaccinations.

The flurry of clinical trials and federal funding aimed at diagnostics, vaccines, and therapeutics for the coronavirus have sparked important discussions about costs and licensing issues that may result from patent protection for eventual products. One targeted aspect of these discussions involves the scope and application of the Bayh–Dole Act’s ‘march-in-rights’ held by the federal government. Organizations like Doctors without Borders and Universities Allied for Essential Medicines have called for governments to utilize what are called ‘march-in rights’ to require the licensing of patents relevant to COVID-19. With respect to Remdesivir, recent investigations have uncovered documents and research publications suggesting that Gilead may have utilized federal funds and laboratories to isolate and test the chemical compound. However, the company failed to acknowledge the funding in their patent application filed in September 2015, nor was the government listed as a licensee on the patent for use of the compound to treat a variety of coronaviruses. Legislators have responded to this information with requests for the Department of Health and Human Services (HHS)

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25 Sanofi Press Release, Sanofi Joins Forces with U.S. Department of Health and Human Services to Advance a Novel Coronavirus Vaccine, Feb. 18, 2020, http://www.news.sanofi.us/2020-02-18-Sanofi-joins-forces-with-U-S-Department-of-Health-and-Human-Services-to-advance-a-novel-coronavirus-vaccine (accessed Aug. 11, 2020).
26 Ed Silverman, The U.S. Government Contributed Research to a Gilead Remdesivir Patent—But Didn’t Get Credit, PHARMALOT, May 8, 2020.
27 Id.
II. THE BAYH–DOLE ACT AND MARCH-IN RIGHTS

The Bayh–Dole Act is one of two pieces of legislation passed in 1980 that paved the way for the successful development of large-scale advances in biotechnology, including changes to intellectual property rights for academic institutions. The other is the Stevenson-Wydler Technology Innovation Act of 1980. Both laws supported patenting, licensing, and technology transfer efforts among various entities participating in research endeavors. Both before and after these laws, the US government has been a major funder of research at academic institutions, through federal grant programs supported through yearly Congressional appropriations. However, before these laws were enacted, if inventions resulted from government-funded research, the US government often retained ownership over the inventions subject to their own discretionary policies. The ownership status arose with the filing and issuance of patents covering the inventions by the US Patent and Trademark Office. The patents granted exclusive authority to the US government to either make and use the patented inventions or license those rights to a third party.

Critics of this arrangement highlighted the fact that many university-derived inventions were languishing under patents issued to the US government. In fact, the Government Accounting Office reported in 1978 that the US government had accumulated over 28,000 patents, but less than 5% of those patents were commercially licensed. Rather than stimulating the development of promising innovations and advancements in science and technology, federally funded inventions were not progressing to useful commercial products because the government lacked the capacity to pursue the inventions’ development potential. Of concern to many critics were inventions in the medical and health care realm that could have brought significant benefits to patients but were either stalled or stymied altogether by poor development efforts by the government.

Both laws were signed into law by President Carter. Each was named for the initiating sponsors in Congress: Senators Birch Bayh of Indiana and Bob Dole of Kansas; and Senators Adlai Stevenson of Illinois and Congressman John W. Wydler of New York. While targeting the same problem of stagnation in development of patented inventions, the laws focused on separate, although related, aspects of technology development. The Bayh–Dole Act created a mechanism for patent title to issue to federally funded academic institutions, while the Stevenson-Wydler Act created a mechanism to foster cooperative efforts between the US federal government laboratories and outside, private entities.

28 Id.
29 U.S. General Accounting Office, Technology Transfer: Administration of the Bayh-Dole Act by Research Universities, GAO/RCED-98-126, 3, May 1998.
30 The Stevenson-Wydler Technology Innovation Act and subsequent amendments facilitated cooperative research and development agreements (or CRADAs) between federal laboratories and industry to stimulate technology transfer. Under a CRADA, the federal lab may receive funds, services, personnel, and property from a private entity or organization, and may in return provide the private entity or organization with government personnel, services, and property. Like the Bayh-Dole Act, the law provides that the government retains a nonexclusive, nontransferable, irrevocable license to any invention resulting from the CRADA. Pub.L. 96–480, 94 Stat. 2311 (1980).
The Bayh–Dole Act deals with patent title status and licensing ability. This law effectively introduced the presumption that the legal title to an invention developed through federal funding goes to the contractor, who is also the inventor. This presumption means that rather than the US government automatically retaining title to any patent issued to the invention, the inventor affiliated with the federally funded institution is named as the inventor on the patent, and the assignee to the patent rights is the institution itself. Notably, the law does specify that there may be exceptional circumstances where this presumption can be rebutted. While the inventor and assignee institution are presumed to hold legal title, the US government retains a nonexclusive, nontransferable, and irrevocable license to the invention.

This means that the government’s license cannot be revoked by the inventor and assignee institution and the government may authorize others to practice the patented invention ‘for or on behalf of the United States’, which serves to shield any so authorized contractor from liability and does not require compensation. It is nonexclusive in that the inventor and assignee institution are free to grant additional licenses to third parties for use of the invention.

The law also provides the US government with so-called ‘march-in’ rights, meaning that under certain circumstances the government can step in and assert legal title to an invention. The Bayh–Dole Act allows for the government to retain rights to require the contractor, an assignee or exclusive licensee of a subject invention to grant a nonexclusive, partially exclusive, or exclusive license in any field of use responsible applicant or applicants upon terms that are reasonable for any government-funded research that has led to the patent. Under the law, these march-in rights may be executed where there has been no efforts to commercialize within an agreed upon timeframe—if a specific time frame for development was included in the original funding agreement between the government and the contractor – or ‘action is necessary to alleviate health or safety needs’. The law provides no guidance on when commercialization of an invention can be considered ‘necessary to alleviate health or safety needs’.

Although these march-in rights sound like an appealing way to keep institutional patent holders in check, the US government has never actually utilized this authority. A 2016 Congressional Research Service article states that the National Institutes of Health (NIH) has denied all six petitions to exercise march-in rights. One recent example of the government’s refusal to march-in based on ‘health or safety needs’ involved the patent on the FDA-approved drug Fabrazyme. Fabrazyme is approved to treat Fabry disease, which is a rare genetic disorder affecting a patient’s ability to properly metabolize fat, a condition that often leads to kidney failure and heart disease. The drug was manufactured by Genzyme under an exclusive patent license from Mount Sinai School of Medicine. Due to contamination issues and other serious manufacturing problems, Genzyme halted production of the drug for several years,

31 The Bayh-Dole Act was subsequently expanded by means of Executive Order to all recipients of federal government grants and contracts.
32 Bayh-Dole Act of 1980, Pub. L. No. 96–517 (1980).
33 35 U.S.C. §203.
34 John R. Thomas, March-In Rights Under the Bayh-Dole Act, Congressional Research Service, Aug. 22, 2016, 1, https://fas.org/sgp/crs/misc/R44597.pdf (accessed Aug. 27, 2020).
leading to strict rationing and ultimately a drug shortage because there were no other approved drugs on the market. Despite compelling petitions, the NIH declined to exercise march-in rights, stating that the situation did not fall within the scope and intent of the law.\textsuperscript{35} Most recently, during their presidential campaigns, Senators Bernie Sanders and Elizabeth Warren advocated for use of march-in rights to help curtail exorbitant drug prices.\textsuperscript{36}

Now forty years following the enactment of the Bayh–Dole Act, debates continue as to its effect on innovation, competition, and access. For example, Rebecca Eisenberg and Arti Rai have highlighted shortcomings in the Bayh–Dole Act, noting that the presumption of legal title and accompanying limited march-in provisions are in desperate need of revision. The authors call for additional authority to federal agencies to restrict patenting of publicly funded research when there is concern about appropriate commercialization of the invention for the public good.\textsuperscript{37} In a reflective article, Sara Boettiger and Alan Bennett further home in on problems and disputes arising from the Bayh–Dole Act twenty-five years after its implementation.\textsuperscript{38} They specifically discuss four implications of the Act: the lack of a research exemption that would allow scientists to use the patent invention in research where there was no commercial product development, the lack of access to research tools that are protected with a patent, the need for reform to address the anticommons effects of the law where pervasive patent rights deplete networks of related resources, and a need to provide access for humanitarian purposes.\textsuperscript{39}

There have been calls for broad governmental actions to curb the blunt force of patents that may impact development of a COVID-19 vaccine. In February, 46 members of Congress wrote to President Trump advocating for the use of every tool to assure the affordability and accessibility of an eventual vaccine, cautioning that the stifling impact of patent rights could result in expensive medicine and would threaten the public health.\textsuperscript{40} Media reports cite the sheer amount of federal funding being funneled into COVID-19 as reason to utilize march-in rights to ensure that companies who are receiving a substantial amount of money from the government mandate accessibility and affordability in their product manufacturing.\textsuperscript{41} Some commentators theorize that these general march-in powers will be used as a bargaining tactic by the government

\textsuperscript{35} National Institutes of Health, Office of the Director, Determination in the Case of Fabrazyme® Manufactured by Genzyme Corporation, Dec. 1, 2020, https://www.keionline.org/wp-content/uploads/francis_collins_rejection_fabrazyme_marchin_1dec2010.pdf, (accessed Aug. 11, 2020). Detailed coverage of the request can be found at Knowledge Economy International, 2010 Fabrazyme March-In Request. https://www.keionline.org/bayh-dole/fabrazyme (accessed Aug. 11, 2020).

\textsuperscript{36} Dylan Scott, How a Democratic President Could Reduce Drug Prices Without Congress, Vox, Nov. 25, 2019, https://www.vox.com/policy-and-politics/2019/11/25/20982374/2020-democratic-presidential-candidates-prescription-drug-prices (accessed Aug. 11, 2020).

\textsuperscript{37} Rebecca Eisenberg & Arti K. Rai, Bayh-Dole Reform and the Progress of Medicine, 66 J. L. & CONTEMPORARY PROBLEMS 289 (2002).

\textsuperscript{38} Sara Boettiger & Alan B. Bennett, Bayh-Dole: If We Knew Then What We Know Now, 24 Nat. BIOTECH. 320 (2006).

\textsuperscript{39} \textit{Id.}, at 321–23.

\textsuperscript{40} Letter to President Trump, http://freepdfhosting.com/20bf1d75af.pdf (accessed Aug 27, 2020).

\textsuperscript{41} Varoon Mathur et al., Will Bayh-Dole be Needed to Get Affordable Covid-19 Treatments?, STAT, Apr. 2, 2020. https://www.statnews.com/2020/04/02/invoking-bayh-dole-may-be-needed-to-get-affordable-covid-19-treatments/ (accessed Aug. 11, 2020).
to control prices and access.\textsuperscript{42} Many others recognize that the scope of the march-in-rights is open to interpretation as to when they may be triggered by the government, which could lead to protracted litigation.

Calls for the use of march-in-rights are tempered by a range of positions. Former President of the Association of University Technology Managers (AUTM) penned an opinion letter in May 2020 that denounced advocate urgings to seize patents, noting that such stance is misguided and would serve to stifle innovation.\textsuperscript{43} Perhaps the most emphatic resistance to march-in-rights emanates from the pharmaceutical trade and lobbyist group Pharmaceutical Research and Manufacturers of America, or PhRMA. They have created an online presence to celebrate the Bayh–Dole Act, reiterate the original intent of its ‘Founding Fathers’,\textsuperscript{44} and publish and promote those opposed to the usage of march-in-rights.\textsuperscript{45} Democratic candidate Joe Biden has not publicly supported march-in-rights as applied to COVID-19 but has instead advocated for explicit authority for the HHS Secretary to approve commercial vaccine prices that are developed through federally funded research.\textsuperscript{46} Others urge the government to utilize a different statutorily reserved governmental power to use any patent if the government provides reasonable and entire compensation to the patent owner.\textsuperscript{47} This benefit of this approach is that the authority applies to all patents rather than just those achieved with federal governmental funding. Congress is also contemplating significant changes to patent law in the face of COVID-19 through the \textit{Facilitating Innovation to Fight Coronavirus Act}, which proposes a different approach.

\section*{III. THE FACILITATING INNOVATION TO FIGHT CORONAVIRUS ACT}

In the face of calls to exercise march-in rights to ensure widespread access and reasonable costs for COVID-19 therapeutic products, there are other ideas being put forth to harness patent rights in a different manner in order to foster drug and vaccine innovation. Senator Ben Sasse (R-NE) introduced the \textit{Facilitating Innovation to Fight Coronavirus Act} addressing patent term length and patent infringement in the face

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\textsuperscript{42} Ryan Davis, \textit{How COVID-19 Could Spur the Gov’t To Seize Patents}, Law360, Mar. 31, 2020, https://www.law360.com/articles/1258140/how-covid-19-could-spur-the-gov-t-to-seize-patents (accessed Aug. 11, 2020).

\textsuperscript{43} Fred Reinhart, \textit{Exercising Bayh-Dole March-in Rights Would Handicap Covid-19 Innovation}, STAT, May 4, 2020, https://www.statnews.com/2020/05/04/bayh-dole-march-in-rights-handicap-covid-19-innovation/?utm_campaign=stat_plus_today&utm_source=hs_email&utm_medium=email&utm_content=87392643&_hsenc=p2ANqtz-9Q0MbdhIVw4FI7_Zyb9sBnVz9q6_gLlZDxjI9SPAHwWX56g3duvwXmn0TZLFlgdAg-JjKcuiqRdGSwxHmzB1JpbyQ6&_hsmi=87392643 (accessed Aug. 27, 2020).

\textsuperscript{44} BayhDole 40, \textit{About}. https://bayhdole40.org/about/ (accessed Aug. 11, 2020). ‘By ensuring that academic institutions and companies would own inventions they make with government-support, Senators Birch and Bayh spurred the transformation of laboratory discoveries into new products benefitting the American taxpayer— and citizens throughout the world.’ Id.

\textsuperscript{45} Joseph P. Allen, \textit{New Study Shows Bayh-Dole is Working as Intended—and the Critics Howl}, BayhDole 40, Mar. 12, 2020, https://bayhdole40.org/category/news/march-in-rights/ (accessed Aug. 11, 2020).

\textsuperscript{46} The Biden Plan to Combat Coronavirus (COVID-19) and Prepare for Future Global Health Threats, Joe Biden for President. https://joebiden.com/covid19/ (accessed Aug. 11, 2020).

\textsuperscript{47} 28 U.S.C. §1498(a).
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of COVID-19. The three page bill has two sections: limitations on liability for health care providers and terms for patents. The first section removes liability for health care providers when: using or modifying medical devices without approval or indication, practicing without a license or outside of a specialty if instructed by a licensed physician or specialist, and conducting testing or treatment on a patient outside of a health care facility if in the name of COVID-19 prevention or treatment while the national emergency exists. These provisions alone are controversial, as are similar legal immunity provisions contained within proposed state and federal bills. The second section temporarily halts patent rights for ‘eligible patents’ for the duration of the national emergency, sets the effective date of a patent filed during the national emergency as the date the national emergency terminates, and adds ten years to the patent term as long as the patent is filed to aid in the treatment of COVID-19. The bill defines an eligible patent as any ‘new or existing pharmaceutical, medical device, or other process, machine, manufacture, or composition of matter, or any new and useful improvement thereof used or intended for use in the treatment of the Coronavirus Disease 2019.’

The bill faces heavy criticism. Some intellectual property commentators are flagging the definition of ‘eligible patent’ as a concern as it may incentivize inventors to direct patent claims toward COVID-19 in order to achieve the lucrative 10-year extension. There are also concerns that the bill would foster broad patent infringement during the pandemic, alter the dynamic between inventors and licensees, and introduce a barrage of post-pandemic infringement litigation. Other critics insist that the mechanism to accelerate COVID product innovation is to improve the patent process itself, providing a clearer patent for inventors. There is also confusion on exactly how the provisions would operate in practice.

As to the immunity from liability for health care providers, Senator Sasse has noted that this provision is to give emergency rooms and intensive care units a ‘common-sense liability shield so that they don’t have to worry about lawsuits while they’re scrambling to save lives.’ The provisions address use of medical devices beyond authorization or against intended use but also expand liability coverage much more broadly. However, states are already acting to provide more flexible liability standards for physicians during the pandemic and shortage of health care providers by either enacting existing emergency orders to remove liability for out of state licensed physicians. New York,

48 Foley & Lardner, LLP, Proposed Legislation to Delay, Then Extend Coronavirus Patents, The National Law Review, Apr. 13, 2020, https://www.natlawreview.com/article/proposed-legislation-to-delay-then-extend-coronavirus-patents (accessed Aug. 11, 2020).
49 Facilitating Innovation to Fight Coronavirus Act, S. 3630, 116th Congr. (2020).
50 Id., at §2.
51 Id., at §3.
52 Id., at §3(c).
53 James Edwards and Gene Quinn, Facilitating Innovation to Fight Coronavirus Act- Legislation That’s A Mixed Bag, IPWatchdog.com, Apr. 8, 2020, https://www.ipwatchdog.com/2020/04/08/facilitating-innovation-to-fight-coronavirus-act-legislation-mixed-bag/id=120483/ (accessed Aug. 11, 2020).
54 Stephen Adams et al., IP Bill to Fight COVID-19, JD Supra, Apr. 15, 2020. https://www.jdsupra.com/legalnews/ip-bill-to-fight-covid-19-87903/ (accessed Aug. 11, 2020).
55 U.S. Senator for Nebraska—Ben Sasse, U.S. Senator for Nebraska—Ben Sasse (2020), https://www.sasse.senate.gov/public/index.cfm/press-releases?ID=047637F8-19E1-498F-809E-2BC966E58CA9 (accessed Aug. 11, 2020).
for example, has implemented expansion of the Good Samaritan laws to provide civil immunity for health care professionals who cause injury or death while providing medical services. The Centers for Medicare and Medicaid Services has also announced that it has granted a temporary waiver of some regulations to encourage responses and remove liability concerns. The proposed bill, however, would go further than most of the state and federal laws so far in that it would allow practicing without a license under the direction of a practicing physician or practicing outside of specialty area rather than merely practicing outside of the licensed state. The bill’s likelihood of success seems low given the intense opposition. It has been read twice in early May and referred to the Senate Committee on the Judiciary where it currently stands. Despite its low likelihood of enactment, the bill serves as an example of the resistance to any efforts to diminish patent rights in the quest to identify a candidate to treat COVID-19. Rather than march-in to assure widespread access and fair and reasonable costs as is the mission of advocates for the exercise of the Bayh–Dole Act, the bill would extend eventual patent rights in return for an interim hiatus during the declared national emergency. Critics of the bill lament the difficulty in implementing the provisions governing the timeframe of the patent right hiatus as coupled with across-the-board ten years additional patent term, the extent of application of the bill, and the procedure for the reactivation of patent rights in light of the termination of the national emergency. It is also unclear whether the bill would ultimately provide any lucrative value to the patent holder as the worth of a vaccine is typically limited to the term of its need in the time of a global pandemic. Once the emergency subsides, the value may be significantly diminished.

IV. REMDESIVIR FUNDING AND PATENTS AND CALLS TO ‘MARCH-IN’

Remdesivir appears poised to be the first treatment in the US to achieve FDA approval. Already approved in several countries and the subject of an EUA issued in May by the FDA, Gilead reportedly filed its product application for the review of Remdesivir late-stage clinical trials with the FDA on August 10, 2020. The company has assigned the innovator name Veklury to the vaccine. The US government has contracted for much of Remdesivir’s supply through September 2020 and Gilead has entered into several manufacturing and supply deals with pharmaceutical manufacturers to ensure a global supply chain. In early May 2020, the Institute for Clinical and Economic Review projected the eventual market cost of Remdesivir to treat COVID-19 to be $4460 based on measures of cost effectiveness. Gilead is now representing the eventual market cost

56 American Medical Association, Liability Protections for Health Care Professionals During COVID-19, Apr. 8, 2020, https://www.ama-assn.org/practice-management/sustainability/liability-protections-health-care-professionals-during-covid-19 (accessed Aug. 11, 2020).
57 Center for Medicare and Medicaid, Fact Sheet Additional Background: Sweeping Regulatory Changes to Help U.S. Healthcare System Address COVID-19 Patient Surge, https://www.cms.gov/newsroom/fact-sheets/additional-backgroundsweeping-regulatory-changes-help-us-healthcare-system-address-covid-19-patient (accessed Aug. 11, 2020).
58 Manojna Maddipatla, Gilead Seeks U.S. Approval for COVID-19 Treatment Remdesivir, Aug. 10, 2020, https://in.reuters.com/article/us-health-coronavirus-gilead-sciences-re/gilead-seeks-u-s-approval-for-covid-19-treatment-Remdesivir-idINKCN2561WY (accessed Aug. 27, 2020).
59 Id.
60 Id.
61 Angus Liu, Fair Price for Gilead’s COVID-19 Med Remdesivir? $4,460, Cost Watchdog Says, FIERCE PHARMA, May 4, 2020.
at $3120 for a five day course of the product, which many believe is cost prohibitive and unjust given the presence of such a public health emergency and prior governmental support for Remdesivir clinical development in other contexts.62

While frequent commentary on the ability of the federal government to assert legal ownership rights to Remdesivir through the utilization of the Bayh–Dole Act has circulated in the popular media and academic circles, the topic has recently garnered the attention and action of the states.63 On August 4, 2020, the State of California and State of Louisiana Office of the Attorneys General submitted a letter to HHS Secretary Azar, Doctor Francis Collins as Director of the National Institutes of Health (NIH), and FDA Commissioner Stephen Hahn that requests the government to exercise it march-in rights pursuant to the Bayh–Dole Act, 35 U.S.C. §§200–212, to increase supply and lower cost of Remdesivir.64 The letter, signed by the Attorneys General of thirty-four states, urges that Gilead has ‘fail[ed] to achieve a reasonable price or fail[ed] to reasonably ‘alleviate health or safety needs’ of consumers.’65 The request follows the June announcement by Gilead of the projected $3120 price tag for patients with private insurance, Medicare, and Medicaid, and a slightly reduced $2340 cost for coverage through the Indian Health Services and Department of Veterans Affairs.66 In comparison, findings from academic studies indicate that the manufacturing cost of Remdesivir is a mere 93 cents per day, or a total of $12.50 per patient.67 The letter cites $30-million funding for a clinical trials supplied to Gilead by the NIH in 2020 as the basis for the government to march-in under the terms of the law.68

Although the letter makes no reference to them, there are at least two preexisting patents claiming the molecular structure of Remdesivir held by Gilead that are involved in the debate. The patents were awarded by the US Patent and Trademark Office in 2017 and 2018 to individual inventors with the identified assignee Gilead Sciences.69 Both patents were filed and issued years prior to the current pandemic. Neither of the patents list the US government as an assignee, although they reference the scientific contributions of scientists as the Centers for Disease Control and Prevention and the US Army

62 Valerie Bauman, States Demand Gilead Drug Seizure Misread Law, Attorneys Say, BLOOMBERG LAW, Aug. 6, 2020, https://news.bloomberglaw.com/health-law-and-business/states-demanding-gilead-drug-seizure-misread-law-attorneys-say#:~:text=%20States%20Demanding%20Gilead%20Drug%20Seizure%20Misread%20Law%2C,In%20fact%2C%20Gilead%20has%20already%20voluntarily...%20More%20(accessed Aug. 27, 2020).

63 Commentators have also suggested that the federal government utilize legal authority under 28 U.S.C. §1498, which allows the government to seize a patented invention without a license and require the production and fair cost while giving the manufacturer reasonable costs as determined by a court. Theora Tiffney, Americans Are Paying Twice for Remesivir, SLATE, July 20, 2020, https://www.msn.com/en-us/health/medical/americans-are-paying-twice-for-Remesivir/ar-BB16YE6P (accessed Aug. 27, 2020).

64 The State of California Office of the Attorney General Xavier Becerra and The State of Louisiana Office of the Attorney General Jeff Landry to Secretary Alex M. Azar, Director Francis S. Collins, and Commissioner Stephen Hahn, Aug. 4, 2020. The letter also urges use of additional legal authority under the Defense Product Act. Id., at 5.

65 Id., at 2.

66 Id., at 4.

67 Id., at 4.

68 Id., at 3.

69 U.S. Pat. No. 9,724,360, Methods for Treating Filoviridae Virus Infections (Aug. 8, 2017); U.S. Pat. No. 9,949,994, Methods for Treating Filoviridae Virus Infections (Apr. 24, 2018).
Medical Research Institute for Infectious Disease. Scientific publications also reveal collaborations between Gilead and federal government scientists on research leading to the patents. It is unclear the extent of governmental funding, if any, that Gilead received in support of the patent, nor is it clear that the involvement of federal scientists would amount to ‘funding’ as contemplated in the Bayh–Dole Act’s march-in rights.

The federal government under direction of the Trump Administration has initially taken a very narrow view of the Bayh–Dole Act with respect to Remdesivir. A spokesperson for the HHS was quoted in response to the Attorneys General letter:

We can only exercise march-in rights where the IP to make the product, as a whole was funded by the federal government. . . . In short, all of the patents underlying the product have to have been conceived or reduced to practice with federal funds for Bayh–Dole’s march-in provision to be of any practical significance. We do not believe that to be the case here.

There is similar rebuke of the letter by legal experts for different reasons. The situation raises several questions about the scope and applicability of the Bayh–Dole Act’s march-in rights. First, the relevant patents held by Gilead issued years before the current application for COVID-19, in that the patent claims did not contemplate the utility in the treatment of the novel coronavirus. Issued in 2017 and 2018, the key patents claim the chemical compound as well as methods of use. Although the patents and publications mention the assistance of federal scientists and federal laboratories, this assistance is not necessarily ‘funding’ by the federal government as contemplated by the Bayh–Dole Act. The patents neither identify the scientists as inventors nor identify a federal governmental agency as assignee. There has not been the identification of specific federal funding that supported the research leading to the patents. The federal government would need to prove that aspect if there is an effort to invalidate the patents or assert patent rights to the inventions. Revising the patents to reflect coinventorship of the governmental scientists would be entirely possible as patent regulations allow the correction of a patent to identify inventors originally left off the application by inadvertent mistake. The addition of an assignee is also allowed under the patent regulations as a regular matter of administrative procedure in the event an entity was omitted from the original application and issuing patent, or there is a new assignment of the patent.

Perhaps more importantly than the patent and funding technicalities, as a general matter, the full scope of the Bayh–Dole Act’s language is yet uninterpreted by the federal government and untested in the courts. The current administration has seemingly

70 For a discussion of the contributions by federal researchers, see James Krellenstein & Christopher J. Morten, *The U.S. Government’s Ownership of Patents Protecting Remdesivir*, NYU School of Law Clinical Law Center, Technology Law & Policy Clinic White Paper, May 22, 2020.

71 Justin Hughes & Arti K. Rai, *Acknowledging the Public Role in Private Drug Development: Lessons From Remdesivir*, STAT, May 8, 2020.

72 Bauman, *supra* note 61.

73 Bauman, *supra* note 61; Joseph Allen, *No, You Can’t March In on Remdesivir*, IP WATCHDOG, Aug. 6, 2020, https://www.ipwatchdog.com/2020/08/06/no-cant-march-Remdesivir/id=123868/ (accessed Aug. 27, 2020).

74 Certificate of correction of inventorship, 37 C.F.R. §1.48.
taken the position that the Bayh–Dole Act’ march-in provisions do not apply for a number of reasons, including that the development of Remdesivir was not ‘as a whole’ funded by the US government and not all of the patents claiming the drug. This initial HHS spokesperson statement is subject to further clarification and follow up, which is hopefully forthcoming as the approval of Remdesivir is impending and the toll of COVID-19 on the American people continues to escalate. Legal experts urge that the Bayh–Dole Act, the Executive Order that subsequently expanded the scope of march-in rights, and regulations are clear that any amount of federal funding triggers the ability of the government to assert march-in rights. The terms of existing funding contracts will also likely confirm this legal position.

V. CONCLUSION
Scientific advancements to address COVID-19 are progressing at warp speed, fueled with federal funding incentives and the promise of patent rights for the ensuing diagnostics, vaccines, and therapeutics. With increasing calls for the federal government to utilize their march-in authority under Bayh–Dole or assure reasonable costs and widespread access through other legal mechanisms such as compulsory licensing, something must be done proactively to resolve the inevitable barriers that will face the public health. We must interrogate the legislative history and practical scope of the Bayh–Dole Act, the financial relationships underlying the original Remdesivir patents (and other patents achieved with federal assistance), and the role of federal COVID-19 funding as it applies to existing legal authority of the federal government to assert ownership rights through the march-in mechanism. After all, what good is a cure if only the wealthy can afford it?