

# Pandemics, Patents, and Price Controls

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## KEY TAKEAWAYS

Many Democrats and activists are exploiting the COVID-19 pandemic to push their political agenda to impose price controls on patented drugs.

In proposing price controls on patented drugs, Democrats and activists distort laws that do not authorize the government to impose price controls in the marketplace.

The response by the biopharma sector to the pandemic is unprecedented. Price controls would stifle the innovation that made these medical breakthroughs possible.

The second decade of the 21st century was bookended by two great crises—the Great Recession and the COVID-19 pandemic. In addition to the colossal impact these events have had on our daily lives, they resulted in *massive* increases in government power and spending. During the Great Recession, Rahm Emmanuel, Chief of Staff for President Barack Obama, infamously said, “You never want a serious crisis to go to waste. And what I mean by that is an opportunity to do things that you think you could not do before.”<sup>1</sup> This adage was applied in the Great Recession—and it certainly has been applied in the COVID-19 pandemic.<sup>2</sup>

Many areas of economic activity have been impacted during the pandemic, including, most obviously, medical research and development. As early as February 2020, before COVID-19 was officially declared to be a pandemic by the World Health

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Organization, Democrats in Congress were calling for price controls on any vaccines or drugs to treat this novel coronavirus.<sup>3</sup> They repeated their call for price controls in April 2020, long before the U.S. Food and Drug Administration (FDA) had authorized any vaccines or drugs to treat COVID-19.<sup>4</sup> The calls for price controls have only intensified since this time,<sup>5</sup> even as multiple vaccines and drugs were tested and delivered to patients in a historically unprecedented time.

## Section 1498 and the Bayh–Doyle Act

Politicians and activists invoke several federal laws to attempt to rationalize their belief that the federal government has the authority to impose price controls on drug patents. One is a century-old law, known as § 1498, that implements the constitutional right to compensation when the federal government exercises its eminent domain power over patents.<sup>6</sup> This law requires the government to pay patent owners “reasonable or entire compensation” if the government uses a patented invention without authorization.

Another is the Bayh–Dole Act of 1980, a law that made clear to inventors that they had the right to patent their innovations—regardless of whether federal funding of basic research contributed to the discovery or creation of this invention.<sup>7</sup> To ensure that these inventions do not lie fallow in university research labs, federal agencies are empowered by the Bayh–Dole Act to “march in” and license the patent if the patent owner is not actively deploying the invention in the marketplace.<sup>8</sup>

**Problems.** The problem with these price-control proposals is manifest. First, the Bayh–Dole Act and § 1498 do not authorize the government to impose price controls. This is clear by their statutory text—and by the interpretation of these laws by judges and other federal officials over many decades. Sensing this obvious legal problem may, perhaps, be one reason why House Speaker Nancy Pelosi (D–CA), Senator Bernie Sanders (VT–I), and others have introduced bills in Congress that would require the U.S. government to use drug prices set by foreign governments in their nationalized health care systems as a “reference” for what the U.S. government pays for drugs in its Medicare program.<sup>9</sup> This proposed law would simply import price controls set by other governments.

This raises the second, more important problem with these proposals. They are a solution in search of a problem, and, in fact, this “solution” creates far worse problems. There is *no* evidence that patents are undermining the creation and distribution of COVID-19 treatments. Indeed, the evidence all points to the opposite conclusion: Patents have been a launching pad

for creating vaccines and other drugs and in developing information-sharing and other commercial agreements that have brought vital treatments to patients.

This should come as no surprise: This is what property rights do. And price controls do the exact opposite: These statist controls kill innovation, destroy markets, and stymie or degrade economic development. The world is witnessing this occur (once again) in Venezuela, previously one of the most prosperous countries in South America—and now its poorest, with previously controlled diseases like malaria running rampant again.<sup>10</sup> This same story repeats itself again and again whenever governments impose price controls on markets.

This *Legal Memorandum* details the legal and policy problems in the proposals to impose price controls on drug patents.

1. It briefly describes a patent—a property right secured to an inventor in a new and useful invention. This property right is the platform for commercial development of these innovations, spurring new products and services in the marketplace, creating jobs, growing the economy, and ultimately contributing to a flourishing society.
2. It describes how current price-control proposals are not supported by existing federal laws—neither by § 1498 nor by the Bayh–Dole Act.
3. It explains why, as a policy matter, there is zero evidence that patents have blockaded or delayed the invention, development, and distribution of vaccines or other treatments for COVID-19. The exact opposite is the case, as reliable and effective patent rights have been a key driver of medical innovation and economic development for decades—and the incredible, unprecedented response of the biopharmaceutical sector to the pandemic confirms this fact. Price controls, on the other hand, will kill innovation and destroy markets, which is especially manifest in high-risk, high-cost industries, such as the pharmaceutical and biotech sectors of the U.S. innovation economy.

## The Nature and Economic Function of Patents as Property Rights

As long established in the patent laws and in court decisions, patents are property rights secured in a new invention.<sup>11</sup> The Constitution authorizes Congress to promote the “useful arts” (an 18th-century phrase for what

we now identify as “innovation,” broadly defined) by “securing for limited times to...inventors the exclusive right to their...discoveries.”<sup>12</sup> The First Congress immediately enacted the Patent Act of 1790 on April 10, 1790, defining and securing under federal law a property right issued to inventors in their new inventions. As fully explained in a prior *Legal Memorandum*, “The Constitutional Protection of Intellectual Property,” the majority of judges, legislators, and prominent scholars from the Founding Era through today defined patents as property rights and secured them accordingly under the Constitution.<sup>13</sup>

Although some judges and other officials at times loosely refer to patents as “monopolies,” they are property rights. As a property right, as opposed to a personal grant of a monopoly privilege, patents protect the exclusive rights to acquire, use, and sell products and services in the marketplace, just as other property rights do in land and other tangible goods.<sup>14</sup> Supreme Court Justice Levi Woodbury explained this point succinctly in a patent case in 1845: “[W]e protect intellectual property, the labors of the mind... as much a man’s own, and as much the fruit of his honest industry, as the wheat he cultivates, or the flocks he rears.”<sup>15</sup>

**Property Rights: 1790 to Present.** This is not an academic debate over definitions. The long-standing definition and legal protection of patents as property rights have fundamental implications in law, in innovation policy, and in promoting economic growth in an innovation economy. Legally speaking, as property rights, U.S. patents have functioned as commercial assets, like any other property rights, from 1790 through today. Thus, inventors were not merely incentivized to create new inventions by the promise of a patent; more importantly, patent owners were able to engage in innovative commercial practices by efficiently deploying their new products and services in the marketplace.<sup>16</sup> Economists, historians, and other scholars have recognized that patents have served a fundamental role in the explosive growth in the U.S. innovation economy from the Industrial Revolution in the 19th century through today’s biotech and high-tech mobile revolutions.<sup>17</sup>

In sum, patent owners are able to sell or license their property rights in the marketplace to create and maximize new value for themselves and for everyone else in society. Each week, people witness this key economic function of patents on the popular television show *Shark Tank*, where venture capitalists make clear that property rights (patents) are a core requirement in their investment decisions. Academic research has further confirmed a causal link between a start-up owning a patent and its success in receiving venture capital financing and ultimately succeeding in the marketplace.<sup>18</sup>

For economists, this is unsurprising; Adam Smith recognized in *The Wealth of Nations* that property rights enable specialization and division of labor in the marketplace, serving as a launching pad for innovation, economic growth, and ultimately a flourishing society. The Founders also recognized this basic truth in crafting their political system. James Madison stated in *Federalist No. 43* that patents and copyrights are clear examples in which “[t]he public good fully coincides in both cases with the claims of individuals.”<sup>19</sup>

**Compulsory Licensing.** For these legal and policy reasons, Congress has consistently rejected proposals to impose special restrictions on patent owners’ rights to sell, license, or otherwise commercialize their property rights in the marketplace. From 1790 to the present, Congress has rejected proposals to enact compulsory licensing provisions in its patent laws.<sup>20</sup> (“Compulsory licensing” is the legal term in intellectual property law for when the government permits another person to produce or sell a patented invention without the consent of the patent owner.<sup>21</sup>) This is in stark contrast to the patent laws in other countries, which have long granted their governments compulsory licensing powers.<sup>22</sup>

In addition to compulsory licensing, another “prominent example of weaker foreign patent systems is that many governments mandate in their patent systems that the state may use and sell a patent without permission from the patent owner.”<sup>23</sup> One example is the “Crown’s right” in England,<sup>24</sup> which confirms again how much the U.S. patent system is part and parcel of American exceptionalism. Despite England long permitting unauthorized and uncompensated uses by the government of the patents the Crown bequeathed to its subjects, U.S. courts have secured patents as “private property” under the Takings Clause of the Constitution.<sup>25</sup> This is the legal and historical context necessary for understanding the legally unprecedented and politically unsound calls for price controls today.

## Misrepresentation of Federal Laws in Advancing a Price-Control Agenda

Politicians and activists have invoked two federal statutes as the primary legal bases for imposing price controls on drug patents—the right to compensation for exercises of the eminent domain power in § 1498 and the “march in” licensing power in the Bayh–Dole Act. Neither of these laws is a price-control statute—nowhere in these laws does one find the phrases “price” or “reasonable price” as triggering conditions or justifications to coercively interfere in private transactions in the marketplace by directly or indirectly imposing

price mandates on private transactions between private persons. Judges and other federal officials have repeatedly confirmed this fact in their consistent interpretation and application of these laws over many decades.

**Theory vs. Law.** What then is the source of the belief by politicians and activists that § 1498 or the Bayh–Dole Act authorizes the federal government to dictate the prices set by private companies for drugs or vaccines sold to patients? The answer is unsurprising: articles published in academic law journals in which professors have imposed their preferred price-control theories on these laws—even though it is clear these laws provide no such authority.

Unfortunately, these academic price-control theories have been repeated by activists and politicians in the policy debates innumerable times over the past two decades, perhaps hoping that their false theories will become true simply by dint of repetition. In this context, confusion about these laws is understandable. Thus, this section describes these two statutes and how the plain meaning of the statutory text does *not* support the ongoing calls for the federal government to impose price controls on the patented drugs sold by private companies in the health care market.

## Section 1498 and the Federal Government's Eminent Domain Power

Congress enacted § 1498 in the early 20th century in response to some inadvertent confusion created by the Supreme Court of the time concerning the long-standing constitutional right of patent owners to seek relief from the unauthorized use of their property rights by government officials.<sup>26</sup> Thus, Congress codified the decisions reached by many 19th-century courts, that, as one court stated in 1876, “[i]nventions secured by letters-patent are property in the holder of the patent, and as such are as much entitled to protection as any other property.... Private property, the constitution provides, shall not be taken for public use without just compensation.”<sup>27</sup> The statutory language in § 1498 thus mandates that a patent owner shall have a “remedy...by action against the United States...for the recovery of his reasonable and entire compensation” whenever “an invention...covered by a patent of the United States is used or manufactured by or for the United States without license of the owner.”

**Takings Clause.** The express function of § 1498 was to definitively resolve any doubt as to a patent owner’s constitutional right to sue the government under the Takings Clause for compensation following an unauthorized use of the patented invention by the federal government (or

one of its authorized agents, such as a contractor). As a result, the Supreme Court and lower federal courts have long recognized this statute as a grant of jurisdiction to courts to hear lawsuits when the federal government uses its eminent domain power in using a patent without authorization.<sup>28</sup>

More important, though, § 1498 reflects the historical understanding of the Takings Clause as limiting the exercise of the eminent domain power by the federal government to only when the federal government takes property for “public use.”<sup>29</sup> Thus, § 1498 requires payment of reasonable and entire compensation—the patent law version of just compensation, as provided in the Takings Clause—when a patented invention is “*used or manufactured by or for the United States* without license of the owner.”<sup>30</sup> Thus, § 1498 expressly limits the government’s power to directly using a patented invention for the federal government itself or authorizing another party (such as a contractor) to manufacture a patented invention for the federal government.

**Codifying Legal Precedent.** Since the legislative history is clear that § 1498 codified the earlier court decisions affirming patent owners’ constitutional rights, its limitation of the eminent domain power to the direct use by or manufacture of patented inventions for the government follows faithfully the circumstances that occurred in these 19th-century cases. All of the 19th-century cases involved unauthorized use of a patented invention by the government, unauthorized manufacture of a patented invention for the federal government, or both. Two such cases, for instance, arose from the U.S. Army making and using without authorization patented tents and patented cartridge (bullet) cases worn by soldiers.<sup>31</sup> Another famous 20th-century case arose from the U.S. Army’s unauthorized use of a patented battery during World War II. (The case is *United States v. Adams*, and it is in all patent textbooks used to teach patent law in law school.)<sup>32</sup> Thus, § 1498’s plain text—“used or manufactured by or for the United States”—is clear that it is not a grant of power to impose price controls on patented inventions sold by private parties in the marketplace.

**A Cunning Interpretative Tactic.** In 2016, this well-established understanding of the clear statutory text in § 1498 was challenged in an article published in the *Yale Journal of Law and Technology* called “A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health.”<sup>33</sup> The four authors—three Yale professors and a then-judicial clerk (now policy activist)—imposed a price-control theory on § 1498 to rationalize their argument that the federal government should mandate lower prices of drugs sold by private parties in the health care market. Their price-control theory was pushed into the broader policy debates by a *New York Times* editorial in 2018.<sup>34</sup>



Their idea is simple: A federal agency passes a regulation (or Congress enacts a law) that directs a private company to make and sell patented drugs at lower prices in the health care market in competition with the owner of the drug patent. According to their argument, since the government directly authorizes the private company to sell the infringing drug at the lower price in the marketplace, the patent owner must *sue the federal government* under § 1498 for compensation, not the private company for patent infringement. In a regular patent infringement lawsuit between private parties, this would be a clear case of willful infringement—and the patent owner would receive an injunction to stop the ongoing infringement in the future and compensatory damages representing its lost profits up until that date.

But not so when a patent owner is forced to sue the federal government under § 1498. No property owner can receive an injunction against the federal government to stop an unauthorized taking or use of private property; instead, the patent owner receives only “reasonable and entire compensation” (or “just compensation” when other property owners sue the government for an unauthorized taking). Of course, “reasonable and entire compensation” is whatever a federal judge deems it to be. In sum, the article authors concocted a plan for the federal government to impose price controls on drugs sold in the health care market—with the price being set by whatever federal judges think is “reasonable and entire compensation” for the patent owner.

**“My Theory, Your Facts.”** This academic price-control theory of § 1498 is a perfect example of the classic adage, “My theory says your facts are wrong.” The private company directed to infringe the patented drug by making and selling the drug in the health care market in direct competition with the patent owner has not “manufactured [the patent]...for the United States” nor is the patent being “used...by...the United States,” per the text of § 1498. For instance, the company is not making a drug for use by the U.S. Army or another federal department or agency, such as the U.S. Postal Service or Veterans Administration—the classic situations in the historical cases of manufacture for the United States.<sup>35</sup>

The private company is instead acting solely as a private actor in the marketplace, making and selling a product to consumers in direct competition with another private company (the owner of the drug patent) for private profit. This situation is what a price-control statute or regulation would do, such as the setting of rents by public officials in rent-control regimes in which the rents are charged to tenants and collected by the private landlords. This is not what § 1498 provides in its clear text, nor was this the public understanding of its clear text at the



time it was enacted. The consistent interpretation of § 1498 by courts and officials in the ensuing decades confirms this understanding of the plain meaning of its text.

**An End Run Around the Statute.** In an attempted end run around the clear statutory text in § 1498, the academic advocates for this price-control theory assert that the government used § 1498 to impose lower prices of drugs in the health care market in the 1950s and 1960s. The *New York Times* repeated their assertion that this has all happened before, and thus it can happen again. The *New York Times* asserted that it was merely an historical accident that the price-control function of § 1498 “fell out of use.”<sup>36</sup>

This is patently false. In an essay responding to the *New York Times* editorial in which two co-authors and I dug into the alleged historical record relied on by the journal article authors and the *New York Times* to advance their price-control theory, we concluded: “The historical record is absolutely clear that government agencies and courts have all applied § 1498 only to situations of government procurement and its own direct use. It has never been used to authorize private companies infringing patents for the sole purpose of selling the patented innovation to consumers in the free market.”<sup>37</sup>

In sum, the federal government has never invoked § 1498 to direct a private company to lower the market price of a product or service that it sells to private persons in the commercial marketplace. Despite academic obfuscation, the government has *never* invoked its eminent domain power under § 1498 on the ground that drugs sold to consumers in the commercial marketplace are “too expensive” in order to impose a “reasonable price” on the marketplace. The reason is simple and straightforward: This is not what § 1498 says it can do.

## The Bayh–Dole Act and the “March In” Power to License Patents

In addition to § 1498, activists and politicians have invoked a provision in the Bayh–Dole Act of 1980 to further their policy agenda to impose price controls on patented drugs. The problem is that this is not the function of the Bayh–Dole Act, which Congress enacted to incentivize the commercialization of valuable inventions resulting from research supported by federal grants. Just as with § 1498, academics imposed a cunningly devised price-control theory on a statute whose text and function do not support this theory—and as with § 1498, this price-control theory was born of a law journal article written by two professors in 2001.

**The Bayh–Dole Act.** Before addressing the price-control theory superimposed on the Bayh–Dole Act, it is first necessary briefly to summarize the Bayh–Dole Act. This legislation was enacted in 1980 in response to an unintended problem in innovation policy resulting from the substantial increase in federal funding of basic research in the post–World War II era. Scientists, especially those working at universities and research institutions, were uncertain if they could obtain patents for their discoveries or inventions when their inventive labors were supported by federal research grants, such as those provided by the National Institutes of Health (NIH).

Congress held hearings and received evidence of many innovations, especially medical discoveries, that were metaphorically sitting on the shelf due to lack of certainty about their ownership status (in legal terms, there was a cloud on the title).<sup>38</sup> Thus, Congress enacted a law that definitively declared that such inventions were patentable by their inventors, regardless of upstream federal research funding. The result over the ensuing decades has been an explosion in university licensing, start-ups, and valuable inventions—especially drugs and other biotech innovations—being made available to patients in the health care market.<sup>39</sup>

**A Second Academic Theory.** Just as with § 1498, an academic price-control theory was superimposed on the Bayh–Dole Act statutory regime in 2001—many years after its enactment in 1980.<sup>40</sup> This argument focused on the “march-in right” created in the Bayh–Dole Act, which is a set of four conditions in which a federal agency that had provided research funds could “march in” and license a patented product or service if the product or service was not being commercialized in the marketplace.<sup>41</sup>

In a 2001 article in the *Tulane Law Review*, titled “Why Don’t We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed Upon Patents Deriving in Whole or in Part from Federally Funded Research,” Professors Peter Arno and Michael Davis announced that the (previously unrealized) primary purpose of the march-in power was to impose price controls on the marketplace. It bears emphasizing how much Arno and Davis’ price-control theory is completely divorced from the statutory language and the legislative record.

To take one small example: Arno and Davis assert that, in enacting the Bayh–Dole Act, “Congress’s concern with march-in rights focused exclusively on maintaining competitive conditions, controlling profits, and doing so through price control.”<sup>42</sup> They produce a myriad of quotes from the legislative record allegedly supporting this factual claim. Not one of the quoted sources refers to either “price” or “price control” as the purpose of the march-in power.<sup>43</sup>

Before 2001, some petitions submitted to the NIH asked it to invoke its march-in power utilizing an expansive, policy-driven “interpretation” of the statute, but these petitions were uniformly rejected as lacking authorization in the Bayh–Dole Act.<sup>44</sup> It was not until Professors Arno and Davis’ 2001 law journal article that their price-control theory captured the imaginations of academics and activists. Just as with the price-control theory of § 1498, a subsequent op-ed written by Arno and Davis and published in 2002 in the *Washington Post* pushed their theory into the policy debates.<sup>45</sup> Organizations have since filed at least 10 petitions with the NIH demanding that it invoke the march-in power for the sole purpose of imposing price controls in the health care market (lowering prices). The NIH has rejected all of these petitions, observing repeatedly that the march-in power cannot be used to lower prices, as it is not authorized by the statute, and it contradicts its key innovation and commercialization policies.<sup>46</sup>

Encouraged by the Arno and Davis article, however, activists and politicians zeroed in on some generalized language in the Bayh–Dole Act to create an elaborate “interpretation” of the statute to continue to push this price-control theory. As noted earlier, § 203 is the “march-in” provision in the Bayh–Dole Act, and it specifies four conditions that authorize a federal agency to “march in” and license other companies to make and sell a patented product or service: All four conditions address circumstances in which the patent owner is not effectively commercializing the patented invention in the marketplace.<sup>47</sup> (As with almost all statutes, the legalese used in § 203 is not easy to quote or summarize, but if one is interested in these four commercialization conditions, some of the operative language is quoted in endnote 41 in the introductory paragraph to this section.)

Among these four conditions, they focused on the first authorizing condition in § 203(a)(1), which covers a patent owner or licensee who “has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use.”<sup>48</sup> The phrase “practical application” is further defined in § 201(f) to “mean manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms.”

**Interpretative Legerdemain.** Advocates for the price-control theory of the march-in power engage in an act of complicated, interpretative legerdemain of § 203(a)(1) and § 201(f). They claim that “available to the public on reasonable terms” in the final clause of the lengthy definition in § 201(f)

as applied to the phrase “practical application” in § 203(a)(1) supports their price-control theory. In sum, they argue that “reasonable terms” in § 201(f) as applied to “practical application” in § 203(a)(1) means the government can mandate “reasonable prices” in the marketplace. Voila, price controls on drug patents.

The problem with this cunning “interpretation” of the Bayh–Dole Act is that the law simply does not say it authorizes the government to impose price controls on patented products like drugs. Nowhere in § 203 (nor in § 201(f)) does one find any reference to “market price” as a condition authorizing a federal agency to march in and license the patent without authorization from the patent owner. Congress can enact a price-control statute if it wishes to do so, and this would be clear by the statutory language, such as, among others, the Emergency Price Control Act of 1942.<sup>49</sup> Even if one were to look at classic rate regulation laws enacted by states, the power to set “prices” or “rates” is expressly stated in the statutes.<sup>50</sup>

*The Bayh–Dole Act does not do this.* Its terms are entirely about effective commercialization of inventions, and rules of statutory interpretation tell us this is sufficient for construing the plain meaning of this statute.<sup>51</sup> In fact, additional legal rules used by courts to interpret statutes expressly prohibit myopically taking phrases out of context to create an alleged ambiguity simply to impose a pre-existing policy on a statute.<sup>52</sup> In the statutory context of the Bayh–Dole Act, “practical application” means that the invention is being deployed in the market, and a license contains “reasonable terms” if it achieves this commercialization goal, such as not unduly preventing a licensee in producing or selling the product.

**The Senators’ Response.** Lastly, any ambiguity created by the interpretative gymnastics of academics and lawyers is further cut short by Senators Birch Bayh (D–IN) and Robert Dole (R–KS)—the legislative sponsors of the Bayh–Dole Act. Similar to what the *New York Times* did for the academic price-control theory of § 1498, in their 2002 *Washington Post* op-ed, Arno and Davis summarized their novel price-control theory of the Bayh–Dole Act. Senators Bayh and Dole immediately responded. They explained in no uncertain terms that Arno and Davis’ academic price-control theory was unjustified given the clear statutory text that Congress enacted into law in 1980.

Bayh–Dole did not intend that government set prices on resulting products. The law makes no reference to a reasonable price that should be dictated by the government.... The [Arno and Davis] article also mischaracterizes the rights retained by the government under Bayh–Dole. The ability of the government to revoke a license granted under the act is not contingent on the pricing of the resulting

product or tied to the profitability of a company that has commercialized a product that results in part from government-funded research. The law instructs the government to revoke such licenses only when the private industry collaborator has not successfully commercialized the invention as a product.<sup>53</sup>

When one sets aside the myopic, out-of-context focus on isolated phrases in the Bayh–Dole Act, such as “reasonable terms” in § 201(f) or “practical application” in § 203(a)(1), the meaning of the march-in power is clear: It refers to efforts, or the lack thereof, to achieve the commercial development and successful market deployment of a patented product or process. This is why federal officials—spanning bipartisan administrations over the course of several decades—have interpreted and applied the Bayh–Dole Act in exactly this sense. In 1997, for instance, the NIH rejected a petition requesting it to invoke the march-in power and license a patented medical device used in organ transplant procedures.<sup>54</sup> In denying this petition, the NIH was emphatic that the march-in power was not created for the purpose of “*forced attempts to influence the marketplace*,” concluding that “such actions may have far-reaching repercussions on many companies’ and investors’ future willingness to invest in federally funded medical technologies.”<sup>55</sup> This conclusion is not merely a policy choice by the NIH, it is necessitated by the plain meaning of the Bayh–Dole Act and its express function to secure patents in the fruits of federally funded research that can be effectively licensed in the marketplace. Even if one invokes extra-statutory sources of meaning, such as agency interpretations or the interpretation of its legislative sponsors, the Bayh–Dole Act and its commercialization function is clear. It is not a price-control statute.

**Summary.** In sum, neither § 1498 nor the Bayh–Dole Act authorizes the federal government to license private companies—such as a generic drug company—to make and sell a patented drug in the health care market for the purpose of lowering prices paid by private purchasers of this drug. Both laws serve functions that have nothing to do with imposing price controls on private companies selling products and services in the marketplace in competition with other private companies. Academics, activists, and politicians have crafted clever price-control theories and sought to rationalize these theories in § 1498 or the Bayh–Dole Act.

Despite their sleight-of-hand legal arguments and rhetorical gimmicks, these laws do not support their theories. They are, at the end of the day, policy arguments masquerading as “legal analyses.” To turn a phrase from Justice Antonin Scalia, sometimes an issue arises in sheep’s clothing—but this wolf comes as a wolf.<sup>56</sup>

## The Pandemic and Price Controls: A Solution in Search of a Problem

Aside from the foundation of sand on which these price-control theories rest in the law, there are strong policy reasons for rejecting proposals to impose price controls on patented drugs and vaccines. Before the COVID-19 pandemic, there were numerous legislative bills introduced that would impose price controls on drugs.<sup>57</sup> The pandemic merely provided a crisis to push further the pre-existing arguments for price controls.

On February 20, 2020, almost a month before COVID-19 was declared to be a pandemic, 46 Democratic Members of Congress wrote to the President, demanding that the federal government revoke pharmaceutical companies' rights to "set prices and determine distribution" of any drugs or other treatments for COVID-19.<sup>58</sup> In April 2020, Representative Jan Schakowsky (D-IL) and other Democratic congressional leaders announced their "principles on COVID-19 drug pricing," declaring that "we must mandate up front that manufacturers agree to a reasonable price" for all COVID-19 drugs—drugs and vaccines that had not even been authorized yet by the FDA for use by patients.<sup>59</sup>

**Pre-Existing Political Commitments.** As Schakowsky's proposal makes clear, these are not evidence-based policy proposals for addressing the pandemic: The calls for price controls are rooted in pre-existing beliefs and political commitments about an alleged lack of availability or access to medical care. The evidence during the pandemic has demonstrated the exact opposite: The biopharmaceutical sector has responded to the pandemic with unprecedented speed and an unprecedented marshalling of resources and development of information-sharing and other commercial agreements. There is *no* evidence that patents have delayed or blocked any vaccines, drugs, or other COVID-19 treatments. In sum, the calls for price controls are a classic example of a solution in search of a problem.

**The Unprecedented COVID-19 Response.** It is important to remember the historically unprecedented response by the biopharmaceutical sector to the COVID-19 pandemic. In May 2020, the online COVID-19 Therapeutic Development Tracker created by the Biotechnology Innovation Organization listed 430 unique compounds in development to treat COVID-19, a virus that was unknown to the world just five months earlier at the start of 2020.<sup>60</sup> As of October 2020, the number of unique compounds in development was 762.<sup>61</sup> This is a massive mobilization of research and development (R&D) resources based on (1) a pre-existing foundation of technical know-how; (2) numerous existing commercial agreements across



the industry involving information sharing and other similar R&D synergies; and (3) manufacturing and distribution capacities. These pre-existing capabilities were developed during the previous decades on a foundation of reliable and effective patent rights protecting the fruits of productive labors in the biopharmaceutical sector.

Gilead Science's Remdesivir was the first drug approved by the FDA to treat severe respiratory symptoms caused by COVID-19. This drug was first developed by Gilead scientists over a decade ago to treat hepatitis C and Ebola, although it was unsuccessful in both cases and was ultimately shelved. Scientists discovered it could be repurposed to treat severe cases of respiratory illness caused by COVID-19. Scientists at Gilead labored for more than a decade to develop this drug, and Gilead will ultimately spend more than \$1 billion in total R&D expenditures on it.<sup>62</sup> After numerous calls over many months for the NIH to exercise Bayh–Dole march-in rights on Remdesivir, the U.S. Government Accountability Office (GAO) reported on March 31, 2021, what everyone already knew: There was no basis to exercise march-in rights under Bayh–Dole because the “federal contributions to the research did not generate new inventions” in this drug.<sup>63</sup>

The vaccines are another roaring success story. Moderna developed its vaccine using mRNA technology within *two days* after Chinese researchers published the genome of the coronavirus on January 11, 2020.<sup>64</sup> BioNTech—the biotech company that commercially partnered with Pfizer to develop another mRNA-based vaccine for COVID-19—created its vaccine in a *couple of hours*.<sup>65</sup> Prior to the COVID-19 pandemic, the average time to invent and develop vaccines was four years. Both Moderna and Pfizer had delivered their vaccines to the FDA to start the regulatory approval process by February 2020. As of February 2021, a GAO report identified that, in addition to Moderna, Pfizer, and other vaccines, several more vaccines developed by Sanofi, GSK, and others are in various phases of the FDA's testing process.<sup>66</sup>

**Regulatory Delay.** The one-year delay between the creation of the vaccine and its delivery to patients was the result of the FDA's regulatory process for determining if the vaccines met its safety and efficacy requirements, as well as setting up manufacturing and distribution capacities. This regulatory bottleneck usually is unacknowledged in the complaints about lack of patient access to drugs; instead, one hears only about patents and high prices.

Even with these regulatory restrictions, as of April 19, 2021, over 25 percent of the U.S. population (85 million) were fully vaccinated, and 40 percent (132 million) had received at least one dose.<sup>67</sup> As of April 25, more than



1 billion people worldwide were vaccinated, according to the Bloomberg COVID-19 Vaccine Tracker.<sup>68</sup> Again, patents have not been the cause of any obstacles in drug development or delays in distribution.

Regulatory delays are certainly not the only bottleneck in the distribution and delivery of vital vaccines and drugs. Another GAO report published in February 2021 found COVID-19 vaccine distribution was held up by manufacturing bottlenecks, supply chain issues, and lack of a skilled workforce.<sup>69</sup> Aside from the regulatory state blinders—the GAO apparently does not consider regulatory delays to be a factor that affects the distribution and delivery of vaccines to patients—there was one factor noticeably absent in this GAO report: patents. Yet, if one listened only to the politicians and activists calling for price controls and other restrictions on vaccines and drugs for COVID-19, one would understandably believe that patents were the only factor causing delays or restrictions on receiving medical care for COVID-19.

**Patent Successes.** Snafus aside, the response by the biotech and pharmaceutical sectors has been nothing short of miraculous, deploying cutting-edge technologies that were invented, developed, and commercialized on the foundation of reliable and effective property rights—patents. In the early 1980s, the U.S. led the world as the first country to provide patent protection in cutting-edge biotech innovations, and the result is that the biotech revolution occurred in the U.S. first, with the rest of the world following suit decades later, if at all.<sup>70</sup> Today, the U.S. accounts for about 5 percent of the world’s population and approximately one-quarter of its economic output, but well over half of all new biotech innovations are created in the U.S.<sup>71</sup> This technological and commercial foundation was key to the biopharmaceutical sector’s response to COVID-19, which is miraculous by historical standards and past responses to pandemics.

**Price Controls Destroy Markets and Innovation.** The price-control political agenda being pursued by Democrats and activists would kill this innovation and stymie ongoing R&D. It would also hinder the development of new treatments for COVID-19 in the same way that regulatory controls have already delayed delivery of vital medicines—and it would prevent the new development of knowledge, technology, and commercial infrastructure necessary to address the next pandemic.

As a matter of economics, this is almost a truism. There is virtually universal agreement among economists, for instance, that price controls on apartments (that is, rent control) has destructive effects on housing markets and harms everyone—poor and rich alike.<sup>72</sup> Whenever large-scale price controls are imposed on whole countries and entire sectors of the economy,

the effects are the same. The price controls imposed by President Richard Nixon in 1971 were, according to Nobel-prize-winning economist, Milton Friedman, an “utter failure and [led to] the emergence into the open of the suppressed inflation.”<sup>73</sup> Markets in the U.S. were also massively disrupted: “Ranchers stopped shipping their cattle to the market, farmers drowned their chickens, and consumers emptied the shelves of supermarkets.”<sup>74</sup> If price controls consistently destroy markets for housing, food, and other tangible goods—resulting in rampant shortages and economic decay—the effect that price controls will have on high-risk, high-cost innovation markets like the biopharmaceutical sector will only be worse.

## Conclusion

The pandemic has brought to the forefront of public awareness the incredible achievements of the patent-based biopharmaceutical industry. Medical care based on biopharmaceutical innovation is a relatively recent phenomenon in human life; in fact, it is less than 100 years old.<sup>75</sup> In 1924, President Calvin Coolidge’s 16-year-old son died after injuring his toe playing tennis on the White House lawn.<sup>76</sup> He developed a blood infection that killed him within a week. Antibiotics that are easily, cheaply, and routinely prescribed today to treat this common staph infection were not discovered until several years later, and it was more decades still before these antibiotics were commonplace treatments in medical care.

Approximately 100 years later, we are benefiting from multiple vaccines that were designed by scientists at pharmaceutical companies using mRNA-based technology to address a virus that is barely one year old and which caused a worldwide pandemic. We are also benefiting from innumerable other drugs, medical devices, and other treatment technologies that have saved millions of lives. The COVID-19 pandemic will not repeat the Spanish Flu Pandemic of 1918–1919 in which an estimated 50 million people died across the globe—at a time when the world population was approximately 15 percent of today’s world population.<sup>77</sup>

These medical innovations and the life-enhancing impact they have had on hundreds of millions of people around the world were built on the legal foundation of reliable and effective property rights—patents. As a matter of moral principle, there is no difference between the farmer who labors for a year to create crops to sell in the market—armed with the knowledge that the fruits of his labors will be secured to him as his property—and the scientists, engineers, and physicians who engage in inventive labors for years knowing that patents will secure the fruits of their productive labors. These

vital property rights also serve the critical legal and economic function of launching innumerable commercial agreements and other mechanisms to translate an invention or discovery in the lab into a real-world medical treatment used by patients. In facilitating this commercial development based on hundreds of billions of dollars in risky R&D endeavors,<sup>78</sup> patents are the launching pad of real-world medical innovations like mRNA vaccines.

Price controls threaten to stifle this innovation. If the government twists its own laws and arbitrarily threatens price controls on the patented vaccines and drugs created by pharmaceutical innovators, this innovation will not happen. This is not conjecture. Economists who have studied how the free market functions and why it is so successful in driving economic growth have long recognized that price controls destroy markets.<sup>79</sup>

Crises like worldwide pandemics prove the wisdom of how reliable and effective property rights, secured by stable legal institutions governed by the rule of law, make possible the innovation necessary to move beyond the emergency and return to thriving and flourishing life. The COVID-19 pandemic has shown the world what decades of patent protection has made possible in the biopharmaceutical sector of the U.S. innovation economy. We should not let politicians and activists exploit this crisis and undermine both patents and innovation—harming people today and preventing an effective response to the next pandemic.

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## Endnotes

1. This infamous statement was made at a conference with corporate executives hosted by the *Wall Street Journal* on November 19, 2008. There are surprisingly many different versions of the quote in newspaper articles and in other sources, but the quote in the main text is the actual statement. The recording of Emmanuel's remarks is available at the *Wall Street Journal* website, see [podcast.mktw.net/wsj/audio/20081120/pod-wsjemmanuel/pod-wsjemmanuel.mp3](http://podcast.mktw.net/wsj/audio/20081120/pod-wsjemmanuel/pod-wsjemmanuel.mp3) (quote at 3:06–3:14) (last visited May 6, 2021).
2. See Nikolai G. Wenzel, *Biden's Economic Trojan Horse*, Law & Liberty (April 14, 2021), <https://lawliberty.org/bidens-economic-trojan-horse/> (last visited May 4, 2021) (“[The American Rescue Plan Act], like its predecessors, is not an economic stimulus bill, nor is it carefully targeted at providing relief to those who really need it. It is much better classified with Roman patronage, as a pre-emptive purchase of votes before the midterm election. Alas, President Biden is merely following in the footsteps of his predecessor, as President Trump did the same in March 2020.”).
3. See Letter from 46 Members of Congress to the President (Feb. 20, 2020), <http://freepdfhosting.com/20bfd75af.pdf> (last accessed May 4, 2021).
4. See *Congressional Progressive Leaders Announce Principles on COVID-19 Drug Pricing for Next Coronavirus Response Package* (April 15, 2020), <https://schakowsky.house.gov/media/press-releases/congressional-progressive-leaders-announce-principles-covid-19-drug-pricing> (last accessed May 4, 2021) (stating that “we must mandate up front that manufacturers agree to a reasonable price” on “any potential vaccine or treatments for COVID-19”).
5. See, e.g., Ed Silverman, *This Academic Published a Manual for Using a Little-Known Federal Law for Lowering Drug Prices*, STAT+ (Jan. 26, 2021), <https://www.statnews.com/pharmalot/2021/01/26/patents-drug-prices-morten-1498-march-in/> (last accessed May 4, 2021); Warren Identifies Key Priorities for the Incoming Biden-Harris Administration's Response to the COVID-19 Public Health Crisis (Jan. 13, 2021), <https://www.warren.senate.gov/newsroom/press-releases/warren-identifies-key-priorities-for-the-incoming-biden-harris-administrations-response-to-the-covid-19-public-health-crisis> (last accessed May 4, 2021) (“Use existing compulsory licensing and march-in authorities for vaccines and treatments”); Letter from 34 State Attorneys General to Secretary Alex Azar et al. (Aug. 4, 2020), <https://www.oag.ca.gov/system/files/attachments/press-docs/Remdesivir%20Letter%2020200804.pdf> (last accessed May 4, 2021) (calling for federal agencies to invoke “march-in” power to impose compulsory licensing on Remdesivir to lower its price).
6. See 28 U.S.C. § 1498.
7. See University and Small Business Patent Procedures Act of 1980, 35 U.S.C. §§ 200–212.
8. See 35 U.S.C. § 203(a)(1)–(4).
9. See Sally Pipes, *Pelosi's Drug Price Controls Are Dangerous—But So Are Trump's*, FORBES (Jan. 29, 2020), <https://www.forbes.com/sites/sallypipes/2020/01/29/pelosis-drug-price-controls-are-dangerous-but-so-are-trumps/> (last accessed May 4, 2021); Sarah Karlin-Smith, *The Bernie Sanders–Trump Mind Meld on Drug Costs*, POLITICO (Nov. 20, 2020), <https://politi.co/2Bh8751> (last accessed May 4, 2021). On April 22, 2021, Representative Frank Pallone (D–NJ) reintroduced Speaker Pelosi's 2019 bill mandating that a “fair price” be paid for patented drugs purchased for the Medicare program by importing price controls set by foreign governments (The bill is known as HR 3.). See <https://www.congress.gov/bill/117th-congress/house-bill/3?s=1&r=36> (last accessed May 4, 2021). For The Heritage Foundation's analysis of this bill, see Doug Badger, *How Congress Can Make Real Progress on Drug Prices*, Heritage Foundation Issue Brief (No. 5016, December 9, 2019), [https://www.heritage.org/sites/default/files/2019-12/IB5016\\_1.pdf](https://www.heritage.org/sites/default/files/2019-12/IB5016_1.pdf) (last accessed May 4, 2021).
10. See Gideon Long, *Venezuela Crisis: Malaria Spreads as Economy Implodes*, FINANCIAL TIMES (Apr. 24, 2019), <https://www.ft.com/content/d980c25a-4fbc-11e9-8f44-fe4a86c48b33> (last accessed May 4, 2021).
11. See, e.g., 35 U.S.C. § 261 (“patents shall have the attributes of personal property”); Adam Mossoff, *Institutional Design in Patent Law: Private Property Rights or Regulatory Entitlements*, 92 SO. CAL. L. REV. 921 (2019); Adam Mossoff, *Who Cares What Thomas Jefferson Thought About Patents? Reevaluating the Patent “Privilege” in Historical Context*, 92 CORNELL L. REV. 953 (2007).
12. U.S. Const. art. 1, § 8, cl. 8.
13. See Adam Mossoff, *The Constitutional Protection of Intellectual Property*, Heritage Foundation Legal Memorandum (No. 282, March 8, 2021), <https://www.heritage.org/economic-and-property-rights/report/the-constitutional-protection-intellectual-property> (last accessed May 5, 2021).
14. See Mossoff, *Institutional Design Choice in Patent Law*, *supra* note 11, at 924–33.
15. Davoll v. Brown, 7 F. Cas. 197, 199 (C.C.D. Mass. 1845).
16. See generally Adam Mossoff, *Patent Licensing and Secondary Markets in the Nineteenth Century*, 22 GEO. MASON L. REV. 959 (2015); Christopher Beauchamp, *Invented By Law: Alexander Graham Bell And The Patent That Changed America* 49–51 (Harvard University Press, 2015) (detailing Bell's use of licensing and the franchise business model); Adam Mossoff, *The Rise and Fall of the First American Patent Thicket: The Sewing Machine War of the 1850s*, 53 ARIZ. L. REV. 165, 194–202 (2011) (detailing the creation of the first cross-licensing “patent pool” and its impact on the innovation market in sewing machines).
17. See, e.g., Jonathan M. Barnett, *Innovators, Firms, and Markets: The Organizational Logic of Intellectual Property* (Oxford University Press, 2020); Stephen Haber, *Patents and the Wealth of Nations*, 23 GEO. MASON L. REV. 811 (2016); B. Zorina Khan, *The Democratization of Invention: Patents and Copyrights in American Economic Development, 1790–1920*, at 9–10 (Cambridge Univ. Press, 2005) (“[P]atents and...intellectual property rights facilitated market exchange, a process that assigned value, helped to mobilize capital, and improved the allocation of resources.... Extensive markets in patent rights allowed inventors to extract returns from their activities through licensing and assigning or selling their rights.”).

18. See Joan Farre-Mensa, Deepak Hegde & Alexander Ljungqvist, *What Is a Patent Worth? Evidence from the U.S. Patent "Lottery,"* 75 J. FINANCE 639, 642, 649 (2020) (demonstrating a causal link between a start-up owning a patent and its increased chances of securing venture capital financing, and further demonstrating a causal link of these patent-based start-ups with higher rates of success as commercial enterprises).
19. *Federalist No. 43*, in *The Federalist Papers* 271–272 (Clinton Rossiter ed., Penguin, 1961).
20. See BRUCE W. BUGBEE, *GENESIS OF AMERICAN PATENT AND COPYRIGHT LAW* 143 (Public Affairs Press, 1967) (describing how Congress considered and rejected a compulsory licensing provision before enacting the Patent Act of 1790).
21. See *Compulsory Licensing of Pharmaceuticals and TRIPS*, World Trade Organization, [https://www.wto.org/english/tratop\\_e/tripos\\_e/public\\_health\\_faqs\\_e.htm](https://www.wto.org/english/tratop_e/tripos_e/public_health_faqs_e.htm) (last visited Apr. 23, 2021).
22. See Adam Mossoff, *Institutional Design Choice in Patent Law*, *supra* note 11, at 937 (discussing historical proposals in U.S. as compared to other countries).
23. Adam Mossoff, *Why We Don't Want to Import Weak Intellectual Property Systems*, Daily Signal (Aug. 18, 2020), <https://www.dailysignal.com/2020/08/18/why-we-dont-want-to-import-weak-intellectual-property-systems/> (last accessed May 4, 2021).
24. See Sean O'Connor, *Taking, Tort, or Crown Right? The Confused Early History of Government Patent Policy*, 12 JOHN MARSHALL REV. INTELL. PROP. L. 145, 168 (2012) ("The [Supreme] Court also strengthened its comments from *Burn's Case* that there would be no equivalent in U.S. patent law to British Crown Rights.").
25. See Mossoff, *supra* note 13; see also Adam Mossoff, *Patents as Constitutional Private Property: The Historical Protection of Patents under the Takings Clause*, 87 BOSTON UNIV. L. REV. 689, 700–11 (2007).
26. See Mossoff, *Patents as Constitutional Private Property*, *supra* note 25, at 711–14 (quoting from legislative history to the legislation enacted in the early 20th century, noting that it clarified the procedural ability of patent owners to seek a remedy in court given a long-standing, pre-existing constitutional liability).
27. *Brady v. Atlantic Works*, 3 F. Cas. 1190, 1192 (C.C.D. Mass. 1876) (Clifford, Circuit Justice), *rev'd on other grounds*, 107 U.S. 192 (1883).
28. See, e.g., *Crozier v. Fried. Krupp Aktiengesellschaft*, 224 U.S. 290, 307 (1912) (holding that a suit under the predecessor statute to § 1498(a) provides all the requirements necessary to sustain the statute as an exercise of the federal government's eminent domain power); *Decca Ltd. v. United States*, 544 F.2d 1070, 1082 (Ct. Cl. 1976) ("It is [the government's] taking of a license, without compensation, that is, under an eminent domain theory, the basis for a suit under § 1498."); *Carter-Wallace, Inc. v. United States*, 449 F.2d 1374, 1390 (Ct. Cl. 1971) (Nichols, J., concurring) (assessing a claim under § 1498 as a claim "to recover just compensation for a taking under the power of Eminent Domain"); *Irving Air Chute Co. v. United States*, 93 F. Supp. 633, 635 (Ct. Cl. 1950) ("The Government urges, rightly, that 28 U.S.C.A. § 1498, is in effect, an eminent domain statute, which entitles the Government to manufacture or use a patented article becoming liable to pay compensation to the owner of the patent."). Recently, some trial courts and appellate courts have become confused again, but in these recent opinions, courts did not acknowledge these earlier decisions, and they certainly could not overrule the Supreme Court's earlier decisions. See, e.g., *Christy v. United States*, 141 Fed. Cl. 641, 658–59 (2019) (holding that Congress has not provided for protection of patents under the Takings Clause), *aff'd*, 971 F.3d 1332 (Fed. Cir. 2020).
29. See U.S. Const. V amend. ("nor shall private property be taken for public use, without just compensation").
30. § 1498(a) (emphasis added).
31. See, e.g., *United States v. Burns*, 79 U.S. 246 (1870) (patented tents used during Civil War); *McKever v. United States*, 14 Ct. Cl. 396 (1878) (patented cartridge boxes).
32. See *United States v. Adams*, 383 U.S. 39 (1966).
33. See Hannah Brennan, Amy Kapczynski, Christine H. Monahan & Zain Rizvi, *A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health*, 18 YALE J. L. & TECH. 275 (2016).
34. See *How the Government Can Lower Drug Prices*, N.Y. TIMES (June 20, 2021), <https://www.nytimes.com/2018/06/20/opinion/prescription-drug-costs-naloxone-opioids.html> (last accessed May 5, 2021).
35. See *supra* notes 29 and 30. See also *Campbell v. James*, 4 F. Cas. 1168 (C.C.S.D.N.Y. 1879) (No. 2,361), *rev'd on other grounds*, *James v. Campbell*, 104 U.S. 356 (1881) (unauthorized use of patented device for postmarking and canceling stamps by U.S. postal officials).
36. *Supra* note 32.
37. Adam Mossoff, Sean O'Connor & Evan Moore, *Proposal for Drug Price Controls Is Legally Unprecedented and Threatens Medical Innovation*, Center for the Protection of Intellectual Property, Antonin Scalia Law School, George Mason University (Nov. 5, 2018), <https://cpip.gmu.edu/2018/11/05/proposal-for-drug-price-controls-is-legally-unprecedented-and-threatens-medical-innovation/> (last visited May 5, 2021).
38. Joseph Allen, a congressional staff member who worked for Senator Birch Bayh in the legislative process that led to the enactment of the Bayh–Dole Act and who was later appointed as Director of the new Office of Technology Commercialization in the U.S. Department of Commerce to implement this law, recently wrote about "the pre-Bayh–Dole era" in which "federally funded inventions were micromanaged from Washington.... The result: less than 5% of 28,000 inventions were licensed. Even worse, the Comptroller General found that not a single new drug had been developed under this policy despite billions of taxpayer dollars invested in the National Institutes of Health (NIH)." Joseph Allen, *Bayh–Dole Rocks While the Critics Play the Same False Note*, IPWatchdog (June 11, 2019), <https://www.ipwatchdog.com/2019/06/11/bayh-dole-rocks-critics-play-false-note/id=110254/> (last accessed May 5, 2021).

39. See Joseph Allen, *Academic Patent Licensing Helps Drive the U.S. Economy*, IPWatchdog (June 20, 2017), <https://www.ipwatchdog.com/2017/06/20/academic-patent-licensing-helps-drive-u-s-economy/id=84778/> (last accessed May 5, 2021).
40. See Peter S. Arno & Michael H. Davis, *Why Don't We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed Upon Patents Deriving in Whole or in Part from Federally Funded Research*, 75 *TULANE L. REV.* 631 (2001).
41. See 35 U.S.C. § 203(a)(1)–(4) (2011). These four statutory conditions are: (1) if the assignee or licensee “has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use”; (2) “to alleviate health or safety needs which are not reasonably satisfied”; (3) to meet requirements for public use set forth by regulatory mandates that are not “reasonably satisfied”; or (4) “a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of its agreement.”
42. Arno & Davis, *supra* note 40, at 659.
43. *Id.* The term used is “public interest”—and it is only in the minds of leftist academics that “public interest” is a synonym for “price control.”
44. See, e.g., NIH Office of the Director, *Determination in the Case of Petition of CellPro, Inc.* (Aug. 1, 1997), <https://www.ott.nih.gov/sites/default/files/documents/policy/cellpro-marchin.pdf> (last accessed May 5, 2021) (rejecting petition in part to invoke march-in power, given argument that company was too slow in bringing a medical device to market).
45. See Peter Arno & Michael Davis, *Paying Twice for the Same Drugs*, *WASH. POST* (March 27, 2002), <https://www.washingtonpost.com/archive/opinions/2002/03/27/paying-twice-for-the-same-drugs/c031aa41-caaf-450d-a95f-c072f6998931/> (last accessed May 5, 2021) (“Bayh–Dole is a provision of U.S. patent law that states that practically any new drug invented wholly or in part with federal funds will be made available to the public at a reasonable price.”).
46. See *Return on Investment Initiative for Unleashing American Innovation* 29 (NIST Special Publication 1234, April 2019) (“NIH determined that the use of march-in to control drug prices was not within the scope and intent of its authority.”).
47. See § 203(a)(1)–(4).
48. § 203(a)(1).
49. See Pub. L. No. 77–421, 56 Stat. 23. See also Economic Stabilization Act of 1970, Pub. L. No. 91–379, § 202, 84 Stat. 799, 799–800 (“The President is authorized to issue such orders and regulations as he may deem appropriate to stabilize prices, rents, wages, and salaries at levels not less than those prevailing on May 25, 1970.”); Housing and Rent Act of 1947, Pub. L. No. 129, 61 Stat. 193, 198 (imposing rent controls on existing structures set at levels permitted to be charged under the Economic Price Control Act of 1942).
50. See, e.g., *Nebbia v. People of New York*, 291 U.S. 502, 515 (1934) (“The Legislature of New York established by chapter 158 of the Laws of 1933, a Milk Control Board with power, among other things to ‘fix minimum and maximum...retail prices to be charged by...stores to consumers for consumption off the premises where sold.’”); *Stone v. Farmers’ Loan & Trust Co.*, 116 U.S. 307, 308 (1886) (reviewing “the statute of Mississippi passed March 11, 1884, entitled ‘An act to provide for the regulation of freight and passenger rates on railroads in this state, and to create a commission to supervise the same, and for other purposes’”).
51. See *INS v. Phinpathya*, 464 U.S. 183, 189 (1984) (stating that “in all cases involving statutory construction, our starting point must be the language employed by Congress...and we assume that the legislative purpose is expressed by the ordinary meaning of the words used”) (quotations and citations omitted).
52. See, e.g., *Samantar v. Yousuf*, 560 U.S. 305, 319 (2010) (“We do not...construe statutory phrases in isolation; we read statutes as a whole.”) (quoting *United States v. Morton*, 467 U.S. 822, 828, (1984)).
53. Birch Bayh and Robert 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/> (last accessed May 5, 2021).
54. See *supra* note 42.
55. *Id.* at 7 (emphasis added).
56. *Morrison v. Olson*, 487 U.S. 654, 699 (1988) (Scalia, J., dissenting) (“Frequently an issue of this sort will come before the Court clad, so to speak, in sheep’s clothing: the potential of the asserted principle to effect important change in the equilibrium of power is not immediately evident, and must be discerned by a careful and perceptive analysis. But this wolf comes as a wolf.”).
57. See also *Drug Pricing and Intellectual Property: The Legislative Landscape for the 117th Congress* 30–33 (Congressional Research Service, March 31, 2021) (identifying numerous bills just introduced in 2019 and 2020 that would impose various price controls on drugs).
58. See *supra* note 3.
59. *Supra* note 4.
60. COVID-19 Therapeutic Development Tracker, <https://www.bio.org/policy/human-health/vaccines-biodefense/coronavirus/pipeline-tracker> (visited May 12, 2020) [webpage on file with author].
61. COVID-19 Therapeutic Development Tracker, <https://www.bio.org/policy/human-health/vaccines-biodefense/coronavirus/pipeline-tracker> (visited Oct. 28, 2020) [webpage on file with author].
62. See Adam Mossoff, *U.S. Should Not Confiscate Gilead’s Remdesivir Patent*, *LAW360* (Aug. 21, 2020), <https://www.law360.com/articles/1303214/us-should-not-confiscate-gilead-s-remdesivir-patent> (last accessed May 5, 2021).



63. See Christopher Rowland, *United States Spent \$162 Million on Remdesivir Development But Holds No Patents, Review Finds*, WASH. POST (April 1, 2020) (quoting the GAO report), <https://www.washingtonpost.com/business/2021/04/01/covid-drug-remdesivir-gilead/> (last accessed May 5, 2021).
64. See John Bonifield, *Moderna's Covid-19 Vaccine Was Designed in Just Two Days*, CNN (Nov. 30, 2020), [https://edition.cnn.com/world/live-news/coronavirus-pandemic-11-30-20-intl/h\\_e33ae1918c88b1167f7f858cd728ae10](https://edition.cnn.com/world/live-news/coronavirus-pandemic-11-30-20-intl/h_e33ae1918c88b1167f7f858cd728ae10) (last accessed May 5, 2021).
65. See Susie Neilson, *The Co-Founder of BioNTech Designed the Coronavirus Vaccine It Made With Pfizer in Just a Few Hours Over a Single Day*, Business Insider (Dec. 12, 2020), <https://www.businessinsider.com/pfizer-biontech-vaccine-designed-in-hours-one-weekend-2020-12> (last accessed May 5, 2021).
66. Jeff Craven, *GAO: COVID-19 Vaccine Production Falls Short of January 2021 Goal* (Feb. 15, 2021), <https://www.raps.org/news-and-articles/news-articles/2021/2/gao-covid-19-vaccine-production-falls-short-of-jan> (last accessed May 5, 2021).
67. Centers for Disease Control and Prevention, "COVID-19 Vaccinations in the United States," <https://covid.cdc.gov/covid-data-tracker/#vaccinations> (last accessed May 5, 2021).
68. Bloomberg COVID-19 Vaccine Tracker (visited April 25, 2021), <https://www.bloomberg.com/graphics/covid-vaccine-tracker-global-distribution/>.
69. *Supra* note 66.
70. See Kevin Madigan & Adam Mossoff, *Turning Gold to Lead: How Patent Eligibility Doctrine Is Undermining U.S. Leadership in Innovation*, 42 GEO. MASON L. REV. 939, 943–44 (2017) (summarizing this development).
71. See Ross C. DeVol, Armen Bedroussian & Benjamin Yeo, *The Global Biomedical Industry: Preserving U.S. Leadership* 19 (Milken Institute, Sep. 2011).
72. See Megan McArdle, *Opinion: The One Issue Every Economist Can Agree Is Bad: Rent Control*, WASH. POST (June 14, 2019), <https://www.washingtonpost.com/opinions/2019/06/15/comeback-rent-control-just-time-make-housing-shortages-worse/> (last accessed May 5, 2021); MILTON FRIEDMAN & ROSE FRIEDMAN, *FREE TO CHOOSE* 219 (Harvard, 1990) ("[Rent control] is what New York City and, more recently, other cities have done for rental dwellings, and that is why they all suffer...from housing shortages."); THOMAS SOWELL, *BASIC ECONOMICS* 51 (Basic Books, 5th ed. 2015) ("One of the reasons for the political success of price controls is that part of their costs are concealed. Even the visible shortages do not tell the whole story. Quality deterioration, such as already noted in the case of housing, has been common with many other products and services whose prices have been kept artificially low by government fiat.").
73. See Gene Healy, *Remembering Nixon's Wage and Price Controls*, WASH. EXAMINER (Aug. 15, 2011), <https://www.washingtonexaminer.com/remembering-nixons-wage-and-price-controls> (last accessed May 8, 2021).
74. *Id.* (quoting DANIEL YERGIN & JOSEPH STANISLAW, *THE COMMANDING HEIGHTS: THE BATTLE FOR THE WORLD ECONOMY*).
75. See THOMAS HAGER, *THE DEMON UNDER THE MICROSCOPE: FROM BATTLEFIELD HOSPITALS TO NAZI LABS, ONE DOCTOR'S HEROIC SEARCH FOR THE WORLD'S FIRST MIRACLE DRUG* (Harmony, 2006).
76. See Jared Rhoads, *The Medical Context of Calvin Jr.'s Untimely Death*, Calvin Coolidge Presidential Foundation (July 7, 2014), <https://www.coolidgefoundation.org/blog/the-medical-context-of-calvin-jr-s-untimely-death/> (last accessed May 5, 2021).
77. See *1918 Pandemic (H1N1)*, Centers for Disease Control and Prevention (visited April 14, 2021), <https://www.cdc.gov/flu/pandemic-resources/1918-pandemic-h1n1.html> (last accessed May 5, 2021).
78. For each drug approved by the FDA for use by patients, there is, on average, R&D expenditures of \$2.6 billion incurred over 10–15 years. See Joseph A. DiMasi, Henry G. Grabowski, & Ronald W. Hansen, *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECON. 20 (2016). Total private investment in biopharmaceutical R&D in 2018 was estimated to be \$129 billion. See *U.S. Investments in Medical and Health Research and Development 2013–2018*, at 7 (Research America, 2019).
79. See, e.g., Sowell, *supra* note 72, at 573 ("Often related to the notion of reasonable or affordable prices is the idea of keeping 'costs' down by various government policies. But prices are not costs. Prices are what pay for costs. Where the costs are not covered by the prices that are legally allowed to be charged, the supply of the goods or services simply tends to decline in quantity or quality, whether these goods are apartments, medicines, or other things."); FRIEDMAN & FRIEDMAN, *supra* note 72, at 219 ("Economists may not know much. But we know one thing very well: how to produce surpluses and shortages.... Do you want a shortage? Have the government legislate a maximum price that is below the price that would otherwise prevail."); HENRY HAZLETT, *ECONOMICS IN ONE LESSON* 117–26 (Crown Publishers, 1979) (describing the impact of legally mandating lower prices than market level is to increase demand, decrease supply, and "marginal producers are driven out of business," creating a "shortage of that commodity").