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2057
INTRODUCTION

On June 5, 1981, the United States Centers for Disease Control and Prevention (CDC) published a report detailing five cases of a rare lung infection in young, previously healthy, gay men living in Los Angeles.1 This marked the first official report of acquired immunodeficiency syndrome (AIDS).2 In the short time that followed, similar reports documented a rare form of cancer in gay men living in New York City and California.3 By year’s end, reports showed 337 individuals with AIDS in the United States; 130 of those individuals had died.4 The end of the decade saw the number of cases in the United States exceed one hundred thousand and the number of AIDS-related deaths exceed fifty-nine thousand.5

AIDS is caused by the human immunodeficiency virus (HIV), a retrovirus that attacks CD4-positive T cells, causing a progressive depletion of the immune system.6 After attaching to the cell surface and entering the cell, HIV integrates its genetic material into the host genome through a process known as reverse transcription.7 This integration into host DNA makes HIV impossible to eradicate with current therapies.8

5. CDC, First 100,000 Cases of Acquired Immunodeficiency Syndrome—United States, 38 MORBIDITY & MORTALITY WKLY. REP. 561, 561-63 (1989).
8. Deeks et al., supra note 6, at 4.
HIV remains a serious global health issue today. Since 1981, an estimated seventy-nine million people have become infected with HIV, and an estimated thirty-six million people have died from AIDS-related illnesses. In 2020, thirty-eight million people were living with HIV globally, and 1.5 million people became newly infected with the virus. In the United States alone, an estimated 1.2 million people are living with HIV/AIDS and, in 2019, an estimated 34,800 new HIV infections occurred.

Today, medicine treats HIV as a chronic illness. However, given the continued rate of new infections annually, there persists a critical need for effective methods to prevent the transmission and spread of the virus. Pre-exposure prophylaxis (PrEP) is one such method.

As its name suggests, PrEP is an HIV prevention medication that HIV-negative individuals take before exposure to the virus to reduce the risk of infection. PrEP decreases the risk of HIV infection across multiple at-risk populations, including gay and bisexual men, transgender women, mixed-status couples (meaning only one partner has HIV), and people who inject drugs. As of publishing, there are currently three FDA-approved medications for PrEP: pill-based Truvada and Descovy, as well as injectable

10. Id.
14. See id.
17. Id.
Apretude. Both Truvada and Descovy utilize fixed-dose combinations of the same two drugs—emtricitabine and tenofovir—manufactured and sold by the same company: Gilead Sciences. Truvada is highly effective at preventing new HIV infections—up to 99 percent effective in individuals who take the medication daily.

Despite this proven efficacy, PrEP remains underutilized by and inaccessible to the most at-risk populations. CDC estimates show that 1.1 million people in the United States would benefit from access to PrEP, but since 2012 only 10 percent of adults with PrEP indications have started taking the drug. Of those who take the

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22. Tenofovir has two distinct prodrug formulations that are metabolized into active tenofovir in the body. In Truvada, tenofovir consists of tenofovir disoproxil fumarate (TDF). See U.S. DEP’T OF HEALTH & HUM. SERVS., supra note 20. In Descovy, tenofovir consists of tenofovir alafenamide (TAF). Id. This Note will refer to both drugs as “tenofovir” or by their specific formulations. In the medical literature, Truvada is sometimes referred to as FTC/TDF while Descovy is sometimes called FTC/TAF. See NAT'L INSTS. HEALTH, supra note 21. This Note will refer to both drugs individually using their brand names or collectively as “PrEP.”


24. Peter L. Anderson et al., Emtricitabine-Tenofovir Concentrations and Pre-Exposure Prophylaxis Efficacy in Men Who Have Sex with Men, 4 SCI. TRANSLATIONAL MED. 1, 4-5 (2012).

25. PrEP is indicated for HIV-negative people who have condomless anal or vaginal sex, have shared injection or drug preparation equipment in the last six months, and/or had a bacterial STI in the last six months. CDC, Pre-Exposure Prophylaxis (PrEP) Care System (Nov. 18, 2021), https://www.cdc.gov/hiv/effective-interventions/prevent/prep/ [https://perma.cc/U9GP-WNND].

drug, the majority are white men who live in either the Northeast or West Coast and have sex with men. Researchers and activists have pointed to one obvious cause for these large disparities in PrEP use across race, geographic region, and sex: the cost.

Truvada for PrEP costs in excess of $1,900 a month in the United States. Accordingly, the cost of preventing HIV infection for at-risk individuals is greater than sixty dollars a pill—sixty dollars a day. Insurance should cover this cost, but the reality is more complicated.

The cost of Descovy, Gilead’s new PrEP medication, is similarly high. These price discrepancies and subsequent calls from activists sparked a flurry of political and legal attention for PrEP access. Partially in response to this pressure, and as part of the former Trump administration’s plan to end the HIV epidemic, the

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30. Id.
administration initiated a rare patent infringement lawsuit against Gilead in November 2019. In the suit, the government alleges that Gilead infringed on patents issued to the United States Department of Health and Human Services (HHS) and CDC. According to court documents, Gilead has refused HHS’s attempts to license these patents and collect royalties for years.

This approach greatly differs from Democratic lawmakers and PrEP activists’ proposals to reduce the cost of PrEP and expand access to the drug. PrEP4All, one such activist group, has specifically called for the government to utilize march-in rights under section 203 of the Bayh-Dole Act or the paid-up license under section 202. However, march-in rights have never been exercised in the forty years since the enactment of the Bayh-Dole Act.

This Note argues that both approaches are wrong. Instead of utilizing patent infringement litigation to recover damages from Gilead or invoking a never-utilized provision of the Bayh-Dole Act to grant a manufacturing license, this Note argues that 28 U.S.C. § 1498, also known as “use without license,” is the appropriate government action to rapidly expand access to PrEP and reduce costs to the individual patient.

Part I of this Note details the discovery of Truvada for PrEP and the ongoing patent infringement litigation brought by HHS, discusses the patents currently held by CDC and Gilead, and examines the shortcomings of infringement litigation as a means to expand access to the drug. Part II analyzes the mechanism of march-in rights under the Bayh-Dole Act and discusses two previously attempted applications for the HIV-management drug ritonavir to demonstrate why march-in rights will always fail to expand access to life-saving medications or reduce costs to consumers. Part III discusses the unique legal right conferred to the government under § 1498 and demonstrates why § 1498 is the correct course of action to expand access to PrEP. PrEP is a life-saving and life-altering

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36. Id.
37. Id.
medication. Patient access is an issue to address proactively—and prophylactically—through established intellectual property regimes.

I. PATENT INFRINGEMENT LITIGATION IS UNLIKELY TO EXPAND PATIENT ACCESS TO PRÉP

In November 2019, the United States initiated a lawsuit against Gilead Sciences and its parent company Gilead Sciences Ireland for patent infringement concerning four patents for PRÉP. The government’s complaint details a long history of drug development at CDC and repeatedly alleges that “Gilead’s only contribution to CDC’s patented research was providing samples of the drugs that CDC used for testing purposes.” The government alleges four counts of willful infringement of its patents. In response, Gilead denies all infringement claims and raises several affirmative defenses and counterclaims. As of publishing, the parties are completing discovery. The trial is not set to occur until 2023.

A. The Development of Truvada for PRÉP

The government argues that years of experimentation at CDC, including the creation and development of novel animal modeling techniques for HIV transmission, are prerequisite to the discovery of emtricitabine and tenofovir for PRÉP. Results published by CDC in 2008 showed the first evidence that PRÉP could effectively

40. See Vector, supra note 35.
42. Id. at 68-75.
43. Defs.’ 3d Am. Answer & Affirmative Defenses & Def. Gilead Scis., Inc.’s 2d Am. Countercls. at 66-109, United States v. Gilead Scis., Inc., No. 1:19-CV-02103 (Apr. 21, 2021) [hereinafter Answer]. Gilead’s affirmative defenses included noninfringement, invalidity, unclean hands, inequitable conduct, derivation, safe harbor, acquiescence, implied waiver, no willfulness, no exceptional case, no recovery of costs, failure to mitigate, no standing, and no constitutional authority. Id. at 66-91. Gilead also brought eight counterclaims: four counterclaims for noninfringement and four for invalidity for each patent-in-suit. Id. at 104-09.
45. Id. at 13.
46. Complaint, supra note 41, at 24-27.
prevent the transmission of HIV in humans. The study showed that in all test primates that received emtricitabine and tenofovir, either daily or immediately before exposure to SIV, PrEP protected them from infection. The five CDC scientists listed on the patents-in-suit authored this study. In one published report, CDC researchers concluded that the high efficacy of this drug combination supported similar PrEP trials in humans; other researchers completed the first such trial two years later.

The Preexposure Prophylaxis Initiative (iPrEx) study randomly assigned 2,500 HIV-negative men or transgender women who have sex with men to receive the emtricitabine/tenofovir combination or a placebo. Following the study's observation period, participants in the experimental group experienced a 44 percent reduction in the incidence of HIV infection. Participants in the experimental group who adhered to the daily dose experienced a relative reduction in HIV-infection risk of 92 percent. Based on this groundbreaking study and other subsequent trials, the FDA approved the use of emtricitabine/tenofovir as PrEP in 2012.

B. CDC’s Patents-in-Suit

Based off of this research, CDC obtained four patents: U.S. Patent Nos. 9,044,509 (’509), 9,579,333 (’333), 9,937,191 (’191), and 10,335,423 (’423). All four patents share the title “Inhibition of HIV

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48. SIV, or the simian immunodeficiency virus, “is a well-established model for HIV transmission” in macaques. Id. at 292.
49. Id. at 291.
50. Id.; see infra notes 56-57 and accompanying text.
51. García-Lerma et al., supra note 47, at 298; Grant et al., supra note 16, at 2587.
52. Grant et al., supra note 16, at 2587.
53. Id.
54. Id. at 2597. In a subsequent analysis of the iPrEx trial, two doses of emtricitabine/tenofovir a week resulted in a 76 percent reduction in HIV risk; four doses a week resulted in a 96 percent reduction; and daily doses resulted in a 99 percent reduction. Anderson et al., supra note 24, at 1.
Infection Through Chemoprophylaxis”, list CDC scientists Walid Heneine, Thomas M. Folks, Robert Janssen, Ronald A. Otten, and Jose Gerardo García Lerma as their inventors; and list the United States as assignee, via the Secretary of HHS. The government alleges Gilead infringed these four patents.

“Whoever invents or discovers any new and useful process may obtain a patent so long as that patent meets the conditions of novelty, nonobviousness, and delineated written specification requirements.

Although each of the four patents has different claim language, they all generally describe methods for PrEP use in humans or primates for some combination of emtricitabine, tenofovir, or a tenofovir prodrug. The '333, '191, and '423 patents all expire in 2027; the '509 patent expires in 2031. The '509 patent was the first filed and all subsequent patents are continuations of that application. The claims between the four patents vary slightly, but the '509 patent is exemplary.

The '509 patent describes and claims “[a] process of protecting a primate host from a self-replicating infection by an immuno-deficiency retrovirus [HIV]” by selecting a host not infected with the virus and administering a “pharmacologically effective amount” of both emtricitabine and tenofovir “prior to an exposure” and “administered orally.” The '509 patent also describes and claims a similar process in humans instead of all primates.

The '333 patent claims a similar process wherein the effective amounts of emtricitabine and tenofovir are “administered orally,

56. The '333 Patent is errantly called “Inhibition of HIV Infection Through Chemoprophylaxis [sic].”
58. Complaint, supra note 41, at 51-57.
60. Id. § 102.
61. Id. § 103.
62. Id. § 112.
63. Complaint, supra note 41, at 53, 56.
64. See, e.g., '191 Patent col. 1 ll. 7-13.
65. '509 Patent col. 12 ll. 35-53.
66. Id. at col. 13 ll. 17-25, col. 14 ll. 1-5.
subcutaneously or vaginally” in either humans or primates, as opposed to just orally.67 The patent claims use of either tenofovir generally or its TDF prodrug formulation.68

The ‘191 patent claims the process of administering the same agents in a “tablet” formulation and refers to HIV as “the human immunodeficiency retrovirus.”69 The patent also claims use of either tenofovir or its TDF prodrug formulation.70

In turn, the ’423 patent claims the process of administering the combination of emtricitabine and tenofovir or any “tenofovir prodrug.”71 If the court finds the ’423 patent valid and enforceable against Gilead, the government may allege Descovy for PrEP, which utilizes the TAF prodrug formulation of tenofovir, is as equally infringing as Truvada. This could stymie Gilead’s current marketing attempts to switch Truvada patients over to Descovy.72

C. Gilead’s Underlying Patents

The four patents-in-suit are not the only patents to consider in this analysis. Gilead owns and owned several patents surrounding the two component drugs of Truvada and Descovy. Gilead’s patents to the TDF formulation of tenofovir expired prior to the start of this litigation, but Gilead’s exclusive patents to emtricitabine did not expire until September 2021.73 These patents prevented generic versions of PrEP from entering the market until they expired—with one exception. In May 2019, Gilead announced that it would allow

68. Id. at col. 12 ll. 59-60, col. 14 ll. 9-10.
70. Id. at col. 12 ll. 41-42, col. 13 ll. 23-24.
one of its competitors, Teva Pharmaceuticals, to market a generic version of Truvada starting in late 2020. This decision to allow a limited license was met with much skepticism among PrEP activists out of fear that it “will do little to reduce price in a way that will increase access” to PrEP. This fear ultimately proved correct.

Meanwhile, some of Gilead’s patents for the TAF formulation of tenofovir used in Descovy are not set to expire until 2032. Activists and patients argue that these patents should be subject to stricter scrutiny and allege Gilead purposefully delayed the development of the TAF formulation of tenofovir and Descovy by five years in order to gain a monopoly on PrEP drugs for a longer period of time. The veracity of these allegations is beyond the scope of this Note and would be nothing more than inappropriate conjecture. But the end result remains the same—PrEP remains inaccessible due to the high cost resulting from this existing monopoly.

D. The Shortcomings of Patent Infringement Litigation to Expand Drug Access

The government’s attempt to lower drug prices and expand access to PrEP through patent infringement litigation is effectively a sledgehammer: unwieldy, unyielding, and unlikely to fix an issue


that requires a more delicate approach. To boot, the ultimate goal of infringement litigation remains unclear.

Analyzing the merits of the case would be little more than guesswork in this Note, but at least one patent law expert has speculated that CDC’s patents are both valid and enforceable. After analyzing the patent requirements of novelty, nonobviousness, and specification discussed above, the expert addressed Gilead’s potential infringement:

[It] appears that use of [Truvada for PrEP] tablets as instructed by the [Truvada for PrEP] prescribing information meets each and every limitation of claim 1 of the ’509 patent. Therefore, if claim 1 of the ’509 patent ... [is] found to be valid and enforceable, ... [there is] no reason to believe that a court would not find that use of [Truvada for PrEP] tablets ... directly infringes that claim.

However, despite this potential for success on the merits, pursuit of patent infringement litigation remains an ineffective way to reduce costs to consumers and expand access to the drug.

In its prayer for relief, the government sought a finding of infringement, enhanced damages for willful infringement, and royalties for continued infringement, as well as costs, attorneys’ fees, and any additional relief deemed appropriate by the court. What those damages may be is a difficult endeavor to calculate. Courts may award “damages adequate to compensate for the infringement, but in no event less than a reasonable royalty.” Generally, courts have interpreted this provision to award two categories of damages: the reasonable royalties explicitly mentioned or lost profits. Courts require plaintiffs to satisfy a high burden of


80. Id. at 9.

81. 35 U.S.C. § 284 (“[T]he court may increase the damages up to three times the amount found or assessed.”).

82. Complaint, supra note 41, at 75.


proof to recover lost profits, the least of which is actually bringing the product to market.\textsuperscript{85} Neither HHS, CDC, nor any branch of the United States government ever sought to bring an emtricitabine/tenofovir combination to market for PrEP. As such, lost profits are an unlikely damage award.

Reasonable royalties, meanwhile, serve as a "backstop" for plaintiffs who cannot prove lost profits as the result of infringement.\textsuperscript{86} In fact, "reasonable royalty law is designed with the nonmanufacturing patentee in mind."\textsuperscript{87} Rationally, an infringed patent has some value, especially to the infringer. As such, violators should pay some licensing fee to utilize that patent, even in an underserved market.\textsuperscript{88}

The question then becomes: What is a reasonable royalty for use of CDC's patents? Truvada earned Gilead $3 billion in sales in 2018.\textsuperscript{89} According to Gilead's annual reports, the drug has earned the company $36 billion since 2004.\textsuperscript{90} While it is unclear what portion of those sales is attributable to CDC's patents,\textsuperscript{91} at least one industry estimate found the government could claim $1 billion in royalties, or up to $3 billion if the court finds willful infringement.\textsuperscript{92} While both of these assessments are much higher than the average award in a patent infringement case,\textsuperscript{93} neither is unheard of for

\textsuperscript{85} Id. at 656-67.
\textsuperscript{86} Id. at 655.
\textsuperscript{87} Id. at 661.
\textsuperscript{88} See id. at 655-56.
\textsuperscript{90} Id.
\textsuperscript{91} The government estimates that 60 percent of Truvada sales were for Truvada for PrEP and that Gilead has received approximately $6.7 billion in revenue since the '509 patent was issued. Complaint, \textit{supra} note 41, at 61.
Gilead.94 A court’s attempt to answer this question, however, would require expert testimony, speculation, guesswork, and an attorney’s attempt at math.95 This uncertainty in the amount of damages available to the government is just one of the infringement litigation strategy’s shortcomings.

Assuming that the goal of this litigation is to reduce the price of and expand access to PrEP,96 it remains unclear how damages awarded to HHS will benefit patients. PrEP activists have called for the government to use any damages awarded to help uninsured Americans gain access to the drug, but whether the government will meet these demands is another unknown.97

The list of indeterminate factors does not end there. Assuming the government prevails in this suit, it is unclear whether access to PrEP will actually change. The government may take a finding of validity and license the PrEP patents to other manufacturers in an attempt to increase competition and drive down the cost. Notably, this step to expand PrEP access does not require preemptive victory in the ongoing patent infringement suit, raising further questions as to government priorities.98 Assuming instead that Gilead prevails on its counterclaims of nonvalidity or noninfringement, what comes next? Gilead’s near-monopoly on Truvada continues, Teva’s generic version of the drug remains equally expensive, and patients are left in the lurch. All of which assumes the litigation ever meets a final valid judgment on the merits.99 The current trial date is not until 2023.100 A plethora of factors may change before that date,

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95. See Jackson v. Pollion, 733 F.3d 786, 788 (7th Cir. 2013) (“Innumerable are the lawyers who explain that they picked law over a technical field because they have a ‘math block.’”).

96. The government stated this goal as part of the former Trump administration’s plan to eradicate new cases of HIV/AIDS by 2030. See Fauci et al., supra note 34, at 844-45.


98. See infra Parts II-III.

99. It is axiomatic of litigation that more than 95 percent of cases settle. E.g., Marc Galanter & Mia Cahill, “Most Cases Settle”: Judicial Promotion and Regulation of Settlements, 46 STAN. L. REV. 1339, 1339-40 (1994).

100. Scheduling Order, supra note 44. Further, the average patent infringement case takes 2.4 years to go to trial. ANSULL ET AL., supra note 93, at 14.
including continued court delays from the COVID-19 pandemic\(^{101}\) and the strong likelihood of appeal.\(^{102}\)

In the meantime, patients' lives remain unchanged. The government's current path via litigation offers no short-term benefits to patients without access to PrEP. The nature of litigation and appeals makes any long-term benefits unpredictable. Further, the government's path forward if it loses is unclear. With these drawbacks, the ongoing infringement litigation is unlikely to achieve its purported goal to expand access to PrEP.

**II. A First Time for Everything: The Bayh-Dole Act**

PrEP activists, as well as some politicians, have called for the government to utilize one of two provisions in the Bayh-Dole Act to expand access to PrEP: “march-in rights” or a “paid-up license.”\(^{103}\) For reasons discussed in this Part, neither of these options is the appropriate method for proactively expanding patient access to PrEP as both come with major drawbacks.

**A. How March-In Authority Works in Theory**

The Bayh-Dole Act provides, in part, that for “any subject invention” acquired with the grant support of a federal agency, that agency “shall have the right ... to grant a nonexclusive, partially exclusive, or exclusive license” to any responsible applicant upon reasonable terms.\(^{104}\) In other words, if government funding supports research that culminates in a patent, the government has a right to create a license to that patented invention, so long as it pays a

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102. Seventy-eight percent of patent infringement litigation is appealed in some capacity. ANSELL ET AL., supra note 93, at 15.


reasonable royalty.\textsuperscript{105} Interested third parties can petition the government to exercise this right on their behalf.\textsuperscript{106} Should the patent holder refuse such a request, the federal agency can authorize the license itself so long as the application meets one of four conditions.\textsuperscript{107} One, the patent holder has not taken effective steps, “within a reasonable [amount of] time,” to “achieve [a] practical application” of the invention.\textsuperscript{108} Two, such a license is “necessary to alleviate health or safety needs” not currently met by the patent holder.\textsuperscript{109} Three, such action is necessary to meet a specified federal regulation not currently satisfied.\textsuperscript{110} Or four, breach of an agreement under § 204 of the Act requires that the patented invention be manufactured substantially in the United States.\textsuperscript{111}

The Act further provides that “any contractor, inventor, assignee, or exclusive licensee adversely affected” by this section may appeal a march-in rights petition in the United States Court of Federal Claims.\textsuperscript{112} By design, the statute permits the patentee to challenge the government’s grant of a license to a potential competitor or other third party.\textsuperscript{113} Further, for any case granted under options (1) or (3) above, “the agency’s determination shall be held in abeyance pending the exhaustion of appeals or petitions.”\textsuperscript{114} When the government grants a march-in license due to a failure to take effective steps or out of necessity to meet a federal regulation, the license will not take effect until the patentee has had their day in court.\textsuperscript{115}

The use of march-in authority under the Act does not invalidate or void the patent anyway; instead, the march-in right grants an effective license to an enterprise chosen by the government or to the government itself.\textsuperscript{116} Notably, the patent holder retains the ability to enforce the patent and bring infringement actions against any

\textsuperscript{105} See id.
\textsuperscript{106} See id.
\textsuperscript{107} Id.
\textsuperscript{108} Id. § 203(a)(1).
\textsuperscript{109} Id. § 203(a)(2).
\textsuperscript{110} Id. § 203(a)(3).
\textsuperscript{111} Id. § 203(a)(4).
\textsuperscript{112} Id. § 203(b).
\textsuperscript{113} See id.
\textsuperscript{114} Id.
\textsuperscript{115} See id.
\textsuperscript{116} See THOMAS, supra note 39, at 7-8.
other entity not granted rights under the government’s march-in authority, while receiving reasonable compensation for government-sanctioned use under the Act. March-in rights are distinct from the “nonexclusive, nontransferable, irrevocable, paid-up license” granted to the United States government under § 202(c)(4) of the Act and as discussed in Part II.D below. 118

At the time of its passage, the Bayh-Dole Act marked a major departure from the federal government’s prior “practice of retaining title to nearly all the inventions it funded.”119 The Act was designed to incentivize new research by granting titles to inventions created under federal grants. Some scholars have argued that the Act was meant as a “powerful price-control” mechanism, mandating that “inventions resulting from federally funded research ... be sold at reasonable prices.”121 However, the Act has never been used in this capacity.122

The Act defines the “practical application” necessary to prevent march-in rights authorization under § 203(a)(1) to mean the “manufacture ... under such conditions as to establish that the invention is being utilized and that its benefits are ... available to the public on reasonable terms.” For example, a patent holder wishing to avoid government march-in under this mechanism would need to bring the patented invention to market to some “reasonable” degree and at a “reasonable” price. However, what “reasonable terms” means in this context is not clearly defined.

117. Id. at 7.
118. Id. at 8 (quoting 35 U.S.C. § 202(c)(4)).
120. Id.; 35 U.S.C. § 200 (“It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development ... [while] ensuring that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions.”).
121. E.g., Arno & Davis, supra note 119, at 631.
122. See id. at 642-44.
123. 35 U.S.C. § 201(f) (emphasis added).
124. See id.
To be sure, courts have interpreted "reasonable terms" to include reasonable prices in other contexts, allowing some to argue that "[t]erms may be considered unreasonable if the unit price is too high" for purposes of § 203(a)(1). This may include, for example, a unit price of sixty dollars per day.

However, the drafters of the Act, for whom it bears its name, disagree:

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. This omission was intentional; the primary purpose of the act was to entice the private sector to seek public-private research collaboration rather than focusing on its own proprietary research.

Despite academic and activist pressure to interpret the Act to include reasonable price controls, and some judicial precedent that indicates the potential favorability of this interpretation, the National Institutes of Health (NIH) has repeatedly refused to consider high drug prices across multiple applications for march-in rights.

125. For example, courts routinely determine what constitutes reasonable royalties and rates in the patent infringement context. See supra notes 83-88 and accompanying text.

126. Arno & Davis, supra note 119, at 651.

127. See supra note 30 and accompanying text.


**B. March-In Petitions Have Failed Repeatedly**

In the forty-year history of the Bayh-Dole Act, the government has never utilized march-in rights. NIH remains the only federal agency to ever receive a petition to utilize its march-in authority. In total, NIH has received six march-in petitions; all were denied. Two of those denials were for HIV medications and serve as convenient examples of why a march-in petition for PrEP will also result in denial.

1. **Ritonavir (2004)**

In 2004, members of Congress requested that NIH exercise march-in rights to expand access to the antiretroviral therapy ritonavir under § 203(a)(1) of the Act. NIH expressly declined to do so, determining that drug manufacturer Abbott Laboratories had made the drug sufficiently available to the public.

In its denial, NIH responded to concerns related to drug pricing: “the extraordinary remedy of march-in [rights] is not an appropriate means of controlling prices.” Citing market concerns, existing licensing arrangements, and international implications of exercising march-in rights in this context, NIH punted the issue, stating this “is appropriately left for Congress to address legislatively.” NIH “has the responsibility to exercise its march-in authority deliberately and with great care.” But it ultimately appears that no circumstance exists in which NIH, or any government agency, will exercise this authority at all.

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130. THOMAS, supra note 39, at 8.
131. Id.
132. Id.
133. Ritonavir is sold under the brand name Norvir. 2004 Opinion Letter, supra note 129, at 1.
134. Id.
135. Id. at 6.
136. Id. at 5-6.
137. Id. at 6.
138. Id.
2. Ritonavir (2012)

When asked again in 2012 to exercise march-in rights for ritonavir, NIH yet again declined. Applicants specifically raised the issue that prices for ritonavir were greatly disparate between the United States and other countries. NIH flatly rejected this concern, stating: “We do not think that AbbVie pricing policies and pricing disparities between the United States and other countries trigger any of the four Bayh-Dole march-in criteria.”

Applicants further requested that NIH exercise march-in authority under § 203(a)(2) in order to “alleviate health or safety needs which are not reasonably satisfied” by the patent holder. Here, NIH again declined, citing the stable price of the drug in the United States, as well as the Patient Assistance Program AbbVie offered. NIH further declined to utilize paid-up license authority under 35 U.S.C. § 202(c)(4), citing the future ability of generics to come to market under the Hatch-Waxman Act. Taken collectively, the government has resisted authorization of march-in rights to combat high-drug prices and refused to utilize such rights in any other context.

C. The Shortcomings of March-In Authority

The Bayh-Dole Act’s march-in authority is an inefficient and inappropriate means to reduce PrEP prices and expand drug access for patients. An infrequently discussed weakness of march-in rights exists within the statutory scheme itself and stymies any potential effort to expand patient access to PrEP. The statute plainly states

140. Id. at 6.
141. Id.
142. Id. at 4-5.
143. Id. Gilead also maintains a patient-assistance program for PrEP. PrEP Assistance Programs, NASTAD, https://www.nastad.org/prepcost-resources/prep-assistance-programs [https://perma.cc/6BA2-HDGK].
144. See infra Part II.D.
that march-in applications predicated on § 203(a)(1) or § 203(a)(3) “shall be held in abeyance pending the exhaustion of appeals or petitions.” 146 This means that any exercise of march-in authority due to high drug prices must be fully litigated before licensed use can begin. Such litigation can take years, leaving drug prices unaffected in the interim. Litigation as a means to reduce drug price disparity is generally fraught, regardless. 147

NIH declined to grant a license in each of the six march-in petitions it received. As such, no litigation, appeals, or adjudication on the merits has occurred. How the Court of Federal Claims, which has original jurisdiction on such matters, would rule is not guided by any directly applicable precedent. If a federal agency were to grant a march-in petition for the first time, litigation and appeal would be certain to follow. As an issue of first impression, how a court would rule on any march-in license is unpredictable. The culmination of unknowns is staggering.

Regardless, these shortcomings are mainly hypothetical as administrative agencies remain hesitant to exercise their statutory authority in this way. NIH has repeatedly shown that price disparities are not a significant factor in its decisions to deny march-in authority. 148 In 2004, the price of ritonavir increased by 400 percent prior to the march-in application. 149 Yet, this price jump was not sufficient for NIH to act. 150 In 2012, Abbott sold the same drug at exorbitant prices in the United States as compared to markets worldwide. 151 Again, NIH declined authorization. 152 The current demand for march-in authorization for PrEP revolves around the same facts: the drug is too expensive in the United States and is priced discordantly worldwide. Any future march-in application is

146. 35 U.S.C. § 203(b).
147. See supra Part I.D.
150. See id.
151. Id.
152. Id.
as likely to face denial as the six that came before it.\textsuperscript{153} Administrative agencies instead turn to Congress, hoping for a legislative fix to the broken march-in mechanism. Following the least productive Congress in decades, it is unclear if hope for legislative action remains reasonable.\textsuperscript{154}

\textit{D. Paid-Up Licenses Are No Different}

While march-in rights are unlikely to succeed at reducing the price of PrEP, the Bayh-Dole Act includes a second government licensure method. Section 202(c)(4) of the Act provides: "[T]he Federal agency shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world."\textsuperscript{155} This means, for any invention made and patented under a federal research grant, the government maintains a royalty-free license to use that invention.\textsuperscript{156}

PrEP activists have called on the government to utilize this authority in addition to its march-in rights, as it does not suffer the similar malady of abeyance pending litigation.\textsuperscript{157} But just like the march-in rights discussed above, § 202(c)(4) has several drawbacks.

To begin, this paid-up license is only available to the federal government.\textsuperscript{158} No generic drug companies may attempt to utilize this mechanism.\textsuperscript{159} Instead, the government must utilize the patent itself

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\textsuperscript{155} 35 U.S.C. § 202(c)(4).
\textsuperscript{156} See id.
\textsuperscript{157} \textit{PrEP4ALL}, supra note 33, at 38-39.
\textsuperscript{158} \textit{THOMAS}, supra note 39, at 8.
\textsuperscript{159} Id.
\end{flushright}
or authorize a specific manufacturer to produce the patented product on the government’s behalf.\textsuperscript{160}

However, given that government researchers, not a third-party federal grant recipient, invented and patented PrEP, it is unclear how a paid-up license applies in this context. A paid-up license under this scenario would require the government to pay twice for the same medication.\textsuperscript{161} If the government asserts its rights to Truvada for PrEP via CDC’s patents, a paid-up license is still necessary for the underlying patent to emtricitabine.\textsuperscript{162}

Assuming a paid-up license was a potential avenue (and putting aside any issues with the governmental origin of the PrEP patents), concerns remain. Under this approach, the government maintains responsibility to determine what constitutes a reasonable royalty for use of PrEP—a similarly complicated analysis to the patent infringement damages analysis the District of Delaware is currently being asked to calculate.\textsuperscript{163}

If the government took a tailored approach instead and sought only to license or march-in on emtricitabine prior to its patent expiration, the calculation may be clearer, but litigation is unlikely to reach a result before the ’396 patent expires. If the government sought to license Descovy and its component drugs prior to TAF’s patent expiration in 2032, the calculation of royalties is similarly complex and would likely rely on the results of the ongoing ’423 patent infringement litigation discussed in Part I. Collectively, the exercise of march-in rights or paid-up licensure under the Bayh-Dole Act is wrapped up in the same complications as patent infringement litigation and leaves patients waiting. In the face of these barriers, another means of expanding access to PrEP while reducing prices for patients remains available, one that Congress has already “address[ed] legislatively”\textsuperscript{164}—28 U.S.C. § 1498.

\begin{footnotesize}
\begin{enumerate}
\item[160.] See 35 U.S.C. § 202(c)(4). This would not transfer the paid-up license to that specific manufacturer. See id.
\item[163.] See supra notes 81-97 and accompanying text.
\item[164.] 2004 Opinion Letter, supra note 129, at 5-6.
\end{enumerate}
\end{footnotesize}

Legislators and activists have called for amendments to the current patent law regime to expand access to PrEP and other life-saving medications. In her 2020 bid for the Democratic nomination for president, Senator Elizabeth Warren campaigned on a promise to publicly manufacture PrEP through a new law that would allow HHS to manufacture the drug following failure to reach certain threshold accessibility requirements. Then-Senator Kamala Harris, in her bid for the presidential nomination, touted her own bill that would require health insurance providers to cover PrEP. Senator Bernie Sanders campaigned on his Medicare-for-All platform as well as legislation he introduced that would create a prize model for HIV/AIDS medications, as opposed to the current patent system. But neither Warren’s Affordable Drug Manufacturing Act nor Harris’s PrEP Access and Coverage Act are necessary to achieve these policy goals. A tool for expanding access to PrEP and allowing for government or third-party manufacturing is already on the books in the United States and is regularly utilized outside of the pharmaceutical context.

A. Legislative History and Prior Use

28 U.S.C. § 1498 allows the United States government, or authorized third parties, to manufacture and use any patented invention so long as the inventor is paid “reasonable and entire compensation for such use and manufacture.” While the Bayh-Dole Act only

165. Securing LGBTQ+ Rights and Equality, WARREN DEMOCRATS, https://elizabethwarren.com/plans/lgbtq-equality [https://perma.cc/9D34-LALN] (“[The] Affordable Drug Manufacturing Act [would] allow[] HHS to manufacture generic drugs when no company is manufacturing a drug, ... there is a shortage of the drug, or the drug is a WHO essential medicine.”).


167. Id.

168. 28 U.S.C. § 1498(a) (“Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the
applies to inventions made with government funding, § 1498 can apply to any and every patented invention. 169 Under § 1498, government use of the patent is immediate, the patent owner’s only remedy is to bring suit in the Court of Federal Claims, and the patentee cannot seek injunctive relief. 170 There is no procedure to activate this statutory provision; instead, rightsholders possess the authority to recoup losses resulting from government use and infringement. 171 Terminology for this statute section varies—commentators sometimes refer to § 1498 as “use without license” or simply “government patent use”—but the effect is clear: the government may use and infringe a valid patent, so long as it compensates the owner.

While this conception frames the government use of patented inventions as a limitation on the rights of a patent holder, the origin of the statute is quite the opposite. 172 In response to a Supreme Court case barring a patent infringement suit against the United States under a theory of sovereign immunity, 173 Congress enacted a statute allowing a patent owner to “recover reasonable compensation for [government] use” of their invention without license. 174 This law served as the predecessor to § 1498 and, at the time, expanded patent protection to provide a remedy against government use where none had previously existed. 175 Although Congress considered national security implications when the law was first enacted, such scenarios did not become a reality until World War I. 176 During

169. Id.
170. Id.
171. See Richmond Screw Anchor Co. v. United States, 275 U.S. 331, 344 (1928) (noting that the statute effectuates “a waiver of immunity and effects an assumption of liability by the Government”).
174. An Act to Provide Additional Protection for Owners of Patents of the United States, and for Other Purposes, ch. 423, 36 Stat. 851 (1910); see also Morten & Duan, supra note 172, at 13-14.
175. Morten & Duan, supra note 172, at 14-15.
176. Id. at 15.
wartime, Congress amended the act to “expedite the manufacture of war material” for the navy. During World War II, Congress amended the act again. At a Senate committee hearing on the proposed amendment, Senator Homer T. Bone summarized the legislation’s goal:

No right fashioned by law is superior to the public welfare or national interest. The very fact that men are to die to preserve our system and way of life leaves only one conclusion; that is, that patent rights and every other form of property right must be subordinated to the all-out effort confronting us. It is crystal clear that in this hour of trial the profit motive cannot be accented without inviting ... destruction.

Section 1498 took on new interest in the wake of the terrorist attacks on September 11, 2001, and subsequent anthrax threats. At the time, the only approved antibiotic to treat the biothreat was ciprofloxacin, owned by German pharmaceutical giant Bayer AG. When Bayer was unable to meet government stockpile demands, Senator Chuck Schumer called for generic manufacture of the antibiotic under § 1498. Schumer, Bayer, and HHS Secretary Tommy Thompson waged a public fight on § 1498, and following threats to amend that statute to remove any reasonable compensation requirement, Bayer relented. No branch of the government invoked the statute for the drug. This rather public fight over § 1498 has had large implications for the statute’s public image, converting the “routine” and “commonplace” “government power” into “an ‘exceptional’ remedy to be used only in a vanishingly small
In contrast, some academics argue that § 1498 should be “viewed as [an] ordinary and integral policy tool[] with which the U.S. government can face emergencies of national dimension, including public health crises.”

**B. Strengths of § 1498**

Section 1498’s greatest utility is “in the context of a national crisis.” The continued rate of HIV infection in the United States is such a crisis. In the United States alone, 1.2 million people are living with the virus and 34,800 new infections occurred in 2019. PrEP, the most effective drug available for preventing the spread of the virus, is used only by 10 percent of adults at risk for contracting HIV. The most at-risk populations, including the homeless, transgender women, and those of low socioeconomic status, are those with the least access to this life-altering, life-saving medication. The exorbitant price of PrEP is the largest barrier to its widespread use. Despite the approval of Truvada for PrEP in 2012, rates of new HIV infection in the United States have not meaningfully decreased. The HIV/AIDS epidemic in the United States remains a national crisis. In the words of Senator Bone: “[P]atent rights ... must be subordinated to the ... effort confronting us.”

However, if the scale of the crisis is somehow not large enough to be of concern, those advocating for the expanded use of § 1498 are the first to concede that “government patent use does not need to be reserved for extraordinary circumstances.” Section 1498 is a flexible, customizable policy tool capable of achieving public health

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185. Id. at 32.
186. Id. at 33. Morten & Duan then argue, in convincing detail, that § 1498 should be readily used in the wake of the COVID-19 pandemic to expand access to medications such as remdesivir and vaccines. Id. at 69-90.
187. Id. at 12.
188. U.S. DEP’T OF HEALTH & HUM. SERVS., supra note 11.
190. See id.
191. See supra notes 25-33 and accompanying text.
192. See U.S. DEP’T OF HEALTH & HUM. SERVS., supra note 11.
193. 1942 Hearing, supra note 179, at 3.
194. Morten & Duan, supra note 172, at 12.
benefits regardless of the size of the problem.195 Its first and most important benefit is its speed of utilization.196 Government invocation of § 1498 rights is immediate, instantaneous, and without any pomp or circumstance.197 Patent holders cannot delay government use or implementation of their inventions, nor can they seek an injunction.198 And, in stark contrast to march-in rights, there is no requirement that government use “be held in abeyance pending the exhaustion of appeals or petitions.”199 Instead, rightsholders may bring litigation to recoup costs only after the infringing use has begun.200 As such, patients will see an immediate benefit in terms of drug accessibility and prescription pricing, benefits not present in either patent infringement litigation or either arm of the Bayh-Dole Act discussed above. While infringement litigation takes years to recover damages and march-in rights may take just as long to receive judicial approval, use rights under § 1498 offer immediate and clear benefits.

The statute also allows for flexibility in government use.201 While historic examples concerned short-term drug shortages (such as ciprofloxacin during the anthrax threats or Tamiflu during a flu outbreak), the applicability of § 1498 to PrEP is equally abundant.202 The government can tailor the scope of PrEP usage to whatever extent necessary to achieve access goals. For example, the government could provide PrEP on a short-term basis until more generics enter the market, to only those covered by Medicare, or to qualified persons most in need. Section 1498’s strength comes, in part, from the flexibility of its possible usage.

Section 1498 is further strengthened by its ability to encourage a negotiated remedy. News reports indicate that the current

195. See id. at 12-13.
196. Id. at 51-53.
197. Id. at 51 (“[E]lection’ or ‘invocation’ of government patent use are perhaps the wrong terms to use—the U.S. government’s power to use privately held patents is always on, by default.”).
198. See id.
200. 28 U.S.C. § 1498(a) (“The owner’s [only] remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture.”).
201. Morten & Duan, supra note 172, at 54-60.
202. See id. at 54.
infringement litigation only began after failed licensing negotiations between HHS and Gilead. Section 1498 may overcome this barrier. In 2001, following the threatened invocation of § 1498, Bayer came back to the negotiating table, promising to manufacture the necessary antibiotic en masse and at reduced prices. As far back as 1917, the threat of condemnation under § 1498’s precursor was enough to bring the Wright brothers to the negotiating table to aid in the war effort. The threat of § 1498, or its temporary utilization, may be the push necessary to restart negotiations between Gilead and the government.

Finally, and perhaps most importantly, § 1498 provides for an ex post remedy determination. While the rightsholder remains entitled to reasonable compensation for the government’s infringing use, an injured party must bring a claim to receive said compensation. Although that judicial determination of reasonable compensation may be as complicated and fraught—especially in the case of PrEP—as the infringement remuneration determinations discussed in Part I.D above, that concern is offset by the delay in litigating that calculation. In the meantime, that delay of years provides the government time to reasonably negotiate a license or settlement. All the while, patient access to PrEP increases. Section 1498 proactively provides for increased drug access while prophylactically addressing the potential harms of prolonged litigation: a cure arrives before disease takes hold.


206. Id. at 61-65.

207. Id. at 61.

208. Whereas patent infringement litigation requires a linear progression to the questions of validity, infringement, and reasonable compensation before rewarding any monetary damages or changing drug accessibility, see supra Part I.D, § 1498 allows for the change to drug accessibility to come before the damages calculation. See Morten & Duan, supra note 172, at 61-65. The ex post remedy calculation occurs after any government patent use. See id.

209. As demonstrated by Bayer in 2001, the mere threat of § 1498 is enough to encourage a settlement or reignite negotiations. See supra notes 180-83 and accompanying text.
This feature pairs well with some of the unique facts concerning PrEP, CDC’s patents, and the ongoing infringement litigation. By combining § 1498 with an infringement suit, patients gain access to treatment now, while the litigation and appeals process resolves compensation issues in the background. If the court finds Gilead infringed CDC’s patents, the government will owe a reduced rate of reasonable compensation (if Gilead does not owe the government damages for patent infringement in the first place). What was a weakness for both infringement litigation and march-in rights on their own becomes a strength when combined with § 1498. Both patients and the government enjoy benefits in the immediate and long-term contexts.

In contrast, no plaintiff has litigated, and no court has ruled on, march-in rights under the Bayh-Dole Act. It will be an issue of first impression and immediately appealed regardless of the outcome. And, as discussed, patients are left waiting for a final decision before drug access becomes a reality. Section 1498, meanwhile, has been litigated in courts for over a century; the case law is robust and clear. Overall, the utility of § 1498 extends beyond its applicability to public health crises, as it offers a range of benefits to patients and patent holders that both infringement litigation and Bayh-Dole strategies lack.

210. This Note is not arguing that § 1498 offers a speedy alternative to infringement litigation—in fact, its relative legal novelty is nearly certain to raise issues ripe for appeal. Cf. ANSELL ET AL., supra note 93, at 14. However, by utilizing § 1498, the problems associated with lengthy litigation are experienced after patients receive the benefit of increased drug access.

211. See supra notes 89-94 and accompanying text.

212. Patent infringement litigation can take years to positively impact patients’ lives. See supra Part I.D. March-in rights, meanwhile, “shall be held in abeyance pending the exhaustion of appeals or petitions.” 35 U.S.C. § 203(b); see also supra Part II.C. Instead, § 1498 places patient impact first. Legal challenges remain available but cannot be used as roadblocks.

213. See supra Part II.B.

214. See supra Part II.C.D.

215. See supra Parts I.D, II.C-D.

216. See, e.g., Richmond Screw Anchor Co. v. United States, 275 U.S. 331, 345 (1928) (“We must presume that Congress in the passage of § 1498 intended to secure to the owner of the patent the exact equivalent of what it was taking away from him.”).
C. Potential Drawbacks of § 1498

It would be naïve to claim that the use of § 1498 comes without any reasonable concern. It is the core tenant of patent law that patents are necessary to incentivize invention and innovation.\(^{217}\) The patent strikes a bargain between the inventor and the public: in exchange for a limited period of monopoly, the public learns how to use an invention. In some ways, a patent allows the patentee to build a “security fence” around a novel idea, protecting the value and profitability of the invention.\(^{218}\) It follows that this incentivized monopoly and inherent protection are what enable research and development investments, especially in the pharmaceutical space.\(^{219}\) The patent system protects more than the discovered invention; it protects the investment.\(^{220}\) What happens when that protection weakens? While legal and economic scholars have debated the veracity of this core tenet,\(^{221}\) the application to § 1498 in the pharmaceutical context requires a closer examination.

In the case of PrEP, private industry innovation did not lead to its discovery.\(^{222}\) Instead, a public health crisis, government funds, and government labor created a miracle of medicine.\(^{223}\) In the years that followed, private companies have profited off that innovation, without the initial research and development investment that the patent system supposedly incentivizes.

Putting aside the question of who invented PrEP, § 1498 nonetheless ensures profitability. The patentee retains the right to “reasonable and entire compensation.”\(^{224}\) Although government use and the


\(^{219}\) Id. at 42-43.

\(^{220}\) Id. at 43.


\(^{222}\) See supra Part I.

\(^{223}\) See supra Part I.A-B.

\(^{224}\) 28 U.S.C. § 1498(a).
resulting litigation delay compensation by a number of years, that investment will still see a just return. If this delay in compensation puts the rightsholder in a dire situation, the patentee can negotiate a license instead. 225 In the interim, short- and long-term public health interests and the need for life-saving medication counterbalance a patent holder’s short-term profit interests. Further, the government has established other incentive regimes besides patents. Inventors can innovate and recoup research and development costs under grants, prizes, and patent buyouts with similar success. 226

PrEP is not the only drug that addresses an ongoing health crisis. Section 1498 has only grown in popularity as a potential avenue for expanded drug access and reduced drug cost in the wake of the COVID-19 pandemic. 227 Academics, doctors, patients, and politicians have all called for government use of current and future vaccines. 228 The development of a COVID-19 vaccine within one year of sequencing the virus demonstrates what sufficient research and development investment can achieve. But this argument highlights the misplaced concerns about incentives. When faced with a global pandemic, profit is no longer the sole driver of innovation. Regardless, the statutory scheme of § 1498 ensures inventors receive compensation (albeit eventually) for their innovations.

Concerns regarding government overreach extend beyond the application of § 1498 to other drug products. Some critics argue that government patent use under § 1498 constitutes a taking under the Fifth Amendment, likening government patent use to eminent domain. 229 Under this argument, government use under § 1498 constitutes a taking of “private property ... for public use,” which in turn requires “just compensation.” 230 Courts have grappled with this question, concluding that § 1498 does not implicate the Fifth Amendment. 231 Unlike “taking” or condemning real property, courts equate the “taking” of a patent with the effective “creation” of a patent.
licensure.\textsuperscript{232} As part of that license, Congress created a cause of action for patentees to recover losses.\textsuperscript{233} The government’s ability to use a patent under § 1498 does not constitute a seizure, a taking, or a revocation of patent rights; if anything, § 1498 states a promise to compensate for infringing use by the government.\textsuperscript{234}

Other critics, including some government actors, point to the need for Congress to address drug prices directly.\textsuperscript{235} When NIH rejected march-in rights as an avenue for drug-price control, the agency called on “Congress to address [this issue] legislatively.”\textsuperscript{236} By passing, and then repeatedly amending § 1498, Congress has done so. Congress’s other attempt to address drug pricing, namely the Bayh-Dole Act, created a statutory mechanism that remains hypothetical in application. Instead, Congress enacted the legal mechanisms for government patent use, and subsequently drug price control, over a century ago.\textsuperscript{237}

It is unlikely that § 1498 will actually stifle innovation, cause a wave of government overreach, or further exacerbate legislative inactivity. The statutory design of § 1498, particularly the ability of rightsholders to recover damages, proactively mitigates these concerns.

\textbf{CONCLUSION}

The United States must address its continued HIV/AIDS epidemic. Ongoing disputes over patent rights are ripe for appeal, prolonging the epidemic and offering no clear benefit to patients. March-in rights or paid-up licenses offer a potential remedy but have repeatedly failed to achieve price control. If the government utilizes march-in rights for the first time in history, litigation delays lurk around the corner and again leave patients waiting. Instead, 28 U.S.C. § 1498 provides the strongest legal way to confront this crisis. The existing law offers fast, flexible, and fine-tuned actions

\textsuperscript{232} Id.
\textsuperscript{233} Id. at 1352 ("Congress provided a specific sovereign immunity waiver for a patentee to recover for infringement by the government.").
\textsuperscript{234} See Morten & Duan, supra note 172, at 14.
\textsuperscript{235} See supra Part II.B.1.
\textsuperscript{236} 2004 Opinion Letter, supra note 129, at 5-6.
\textsuperscript{237} See supra Part III.A.
to address patients' needs while preserving rightsholders' interests. When combined with the other approaches, § 1498's strength only increases. Section 1498 offers the patent prophylaxis HIV/AIDS patients and at-risk individuals need to expand access to this life-saving medication.

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