ROPES & GRAY

CAN THEY REALLY DO THAT?

The Specter of Government-Authorized **Infringement of Pharmaceutical Patents**

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Introduction

DRUG PRICES HAVE DOMINATED HEADLINES in recent years, and reducing health care costs for the public has been a talking point for both President Trump and nearly every Democratic presidential campaign. The president has signaled that he believes health care issues will be important to his re-election campaign, and has vowed to lower drug prices.[1] Former Democratic candidates—many of whom hold positions in the federal government—have railed against pharmaceutical companies, suggesting drastic measures to reduce the cost of prescription drugs. Many of the proposed actions have involved targeting drug-related patents. For example, former Democratic Party presidential candidate Pete Buttigieg proposed exercising the government's "eminent domain" rights against the "worst offender" pharmaceutical companies.[2] Senators Cory Booker, Bernie Sanders and Kamala Harris introduced legislation to "void" drug patents.[3] In addition, Senator Sanders reportedly pledged to invoke "march-in rights" to "break drug companies' patents on a drug."[4] And although President Trump has yet to present a concrete plan related to drug patents, he has shown an affinity as president for taking unilateral executive actions on a wide range of issues.[5] Finally, the ongoing novel coronavirus pandemic has caused some to raise questions regarding whether the U.S. government should act to ensure that patent rights—especially those in the hands of non-practicing entities or those not capable of meeting demand—do not impede potentially life-saving treatments.[6]

But under what authority could either the current or a future administration take action on patents in an attempt to lower drug prices or make a pharmaceutical product more widely available? Some assume that presidential candidates and others are referring to the prospect of exercising the never-before-invoked "march-in rights" under the Bayh-Dole Act. But, in most instances, it appears that they are actually (implicitly or explicitly) proposing to exercise the government's power under 28 U.S.C. § 1498 to "take" a license to an otherwise-enforceable patent, effectively authorizing third-party drug manufacturers to infringe valid drug patents.

Under what authority could either the current or a future administration take action on patents in an attempt to lower drug prices or make a pharmaceutical product more widely available? Some assume that presidential candidates and others are referring to the prospect of exercising the never-before-invoked "march-in rights" under the Bayh-Dole Act.

Some commentators have proposed using § 1498 to lower drug prices,[7] and the potential use of this statute has gained the attention of policymakers over the past few years.[8] This white paper examines the government's authority under § 1498, how the government may employ § 1498 with respect to prescription drug pricing and what patent holders in the pharmaceutical space can do in response.

The Mechanics of § 1498, and Comparison with Bayh-Dole March-In Rights

SECTION 1498 GRANTS THE U.S. GOVERNMENT, or its contractors, the authority to use or manufacture any patented invention "without license."[9] In exchange, the patent owner has the right to sue the federal government in the Court of Federal Claims for "reasonable and entire compensation" for the use or manufacture of the patented invention.[10] The statute is sometimes described as an "eminent domain" provision for patents,[11] grounded in the Takings Clause of the Fifth Amendment, which expressly permits the government to take private property for public use so long as "just compensation" is paid to the property owner. In effect, § 1498 allows the United States to take, for itself or another, a compulsory license to use any patented invention without obtaining the permission of the patent owner in exchange for the constitutionally required payment of reasonable compensation.[12] From the perspective of contractors and subcontractors, § 1498 acts as an assumption of liability for infringement by the government, and shields them from liability. The federal government uses its § 1498 authority with some frequency, although it has not been used recently in the pharmaceutical context.[13]

There are important differences between § 1498 and "march-in rights." First, march-in rights apply only to patented inventions that were developed with the support of public funding. In contrast, § 1498 applies to every U.S. patent, even if developed wholly with private funds.

Compulsory licensing is also available for inventions created with federal funding under the provisions of the Bayh-Dole Act.[14] In general, the Bayh-Dole Act permits certain entities to obtain patents on inventions produced with federal funding.[15] However, the federal government retains the authority to "march in" and grant compulsory licenses to third parties for federally funded inventions under certain specified circumstances, such as a failure by the patent owner to practice the patented invention, or certain health or safety needs.[16] A license granted pursuant to Bayh-Dole's march-in provisions must be "upon terms that are reasonable under the circumstances," which may require the licensee to pay some compensation to the patent owner.[17] However, despite many periodic requests to invoke march-in rights—especially in the pharmaceutical space—the federal government has never exercised its rights under Bayh-Dole.[18]

There are important differences between § 1498 and "march-in rights."[19] First, march-in rights apply only to patented inventions that were developed with the support of public funding. In contrast, § 1498 applies to every U.S. patent, even if developed wholly with private funds. Second, march-in determinations are governed by specific implementing regulations,[20] which provide for a petitioning process to allow private enterprises to request march-in rights from the government. By contrast, §1498 has no formal requesting process; it is triggered when the federal government practices a patented invention or authorizes a contractor to do so

on its behalf. Third, to exercise march-in rights, the government must follow strict procedures codified in the Federal Regulations, which provide for an adversarial process that includes formal fact-finding, after which the agency seeking to march in must find that granting a license "is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees."[21] Section 1498 has no explicit statutory limitation or "hoops" to jump through; the use need only be by or for the federal government with the government's consent or authorization, and even includes situations where the government gives its authorization *after* the infringement has occurred. Finally, recipients of march-in rights are awarded licenses, granted by the patent owner, "upon terms that are reasonable under the circumstances." Even if granted a license under march-in rights, a private party needs to pay royalties to the patent owner.[22] In contrast, under § 1498, the patent owner must commence litigation at the Court of Federal Claims and may be awarded damages, payable by the government to the patent owner, to compensate for the use by the government or its contractors after the patent has been infringed. And, although an action against the government under § 1498 is essentially the same as an infringement claim, the remedies differ: Injunctive relief is not available, and the compensation due under § 1498 has generally been limited to reasonable royalties.[23]

Due to the restrictions, limitations and lack of precedent associated with Bayh-Dole march-in rights, the government may view it as an indolent tool for reducing drug prices. Indeed, "march-in rights" have never been invoked. The NIH has also taken the position in the past that drug pricing issues alone are insufficient to invoke them,[24] and the three previous administrations have rejected the argument that "march-in rights" can or should be used to control drug prices.[25] In contrast, § 1498 has been used, albeit sparingly, in the past by the federal government to authorize or obtain generic versions of patented drugs[26]—though the statutory and regulatory regime governing generic drugs has changed significantly in the years since.

Considerations and Potential Justifications for Government Use of § 1498 in Connection with Pharmaceutical Patents

GOVERNMENT ATTEMPTS TO USE § 1498 to bypass patent protections for pharmaceuticals in an effort to lower drug prices would not come without hurdles. In order to use § 1498 in the pharmaceutical context, the government must 1) show that the use is "by or for the United States" and with the consent or authorization of the United States, and 2) resolve administrative or other regulatory issues in procuring the sought-after drugs. Here, we present a brief overview of how the government could potentially make use of § 1498.

LEGAL CONSIDERATIONS UNDER § 1498

For contractors and subcontractors, § 1498 can best be understood as an assumption of liability, by the government, for patent infringement.[27] But for a private company to be immunized by the statute, there are two requirements: 1) The use of the patent must be "with the authorization or consent of the Government," and 2) the use of the patent must be "for the Government."[28] Any plan that uses § 1498 to lower the cost of prescription drugs would likely either involve the U.S. Government

contracting with U.S. generic drug manufacturers to produce generic versions of patented drugs, or contracting with foreign generic manufacturers to import versions of patented drugs.[29] Either way, we assume for the purposes of this white paper that the infringing activity would be done with sufficient authorization and consent from the government. However, because of the fractured nature of the health care system in the United States, the question of whether the infringing activity is "for the Government" is more nuanced, and will likely depend on the specifics of the plan, as well as ambient circumstances.

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There are two modern cases that illustrate how broadly the government assumption of liability has been interpreted under § 1498: *Advanced Software Design Corp. v. Fed. Reserve Bank of St. Louis*[30] and *IRIS Corp. v. Japan Airlines Corp.*[31]

In *Advanced Software Design,* the plaintiff brought an infringement suit against three regional Federal Reserve Banks and Fiserv, Inc. based on a method patent for detecting fraudulent bank checks. The method was used in a pilot program with the Philadelphia Reserve Bank.[32] The bank of first deposit, as opposed to the Treasury, almost always bears the loss from fraudulent Treasury checks.[33] But despite the fact that the U.S. Government was not the primary beneficiary of the infringement, the Federal Circuit found that the use of the patented method was still "for the Government" under § 1498. The court found that "the national interest in averting fraud in Treasury checks," "the resources Treasury has saved by adopting this efficient technology" and the "the financial benefits accruing to the member banks and the Reserve Banks" was sufficient under § 1498.[34] In addition, the court rejected the argument that the benefit to the government was merely an incidental effect of the private parties, the member banks and the reserve banks acting in their private interests because the government was actively participating in the use of the patent.[35]

In *IRIS Corp.,* the patent at issue was a method for making documents that contained an embedded computer chip, which stored biographical or biometric data. IRIS claimed that Japan Airlines was infringing its patent by using electronic passports in the processing of passengers.[36] The Federal Circuit found that the United States had assumed liability under § 1498.[37] The Federal Circuit found that the airline's use of the patented method was "for the United States" because it "improve[d] the detection of fraudulent passports and reduce[d] demands on government resources."[38] This had the effect of "directly enhanc[ing] border security and improv[ing] the government's ability to monitor the flow of people into and out of the country."[39] The court explained that "[w]hen the government requires private parties to perform quasi-governmental functions, such as this one, there can be no question that those actions are undertaken "for the benefit of the government."[40] In addition, the court noted that the U.S. Government had intervened in the litigation

and "unequivocally stated" that § 1498 applied, and though the government's statement was not dispositive, it reinforced the court's conclusion.[41]

Moreover, § 1498 may apply even in circumstances where the U.S. Government itself is not the primary beneficiary of the infringement. The Federal Circuit has noted that "[t]he coverage of § 1498 should be broad so as not to limit the Government's freedom in procurement by considerations of private patent infringement," and noted the "Congressional intent to allow the Government to procure whatever it wished regardless of possible patent infringement."[42] Given tht the Federal Circuit takes into account the government's view of whether it benefits from the use of a patent, in the pharmaceutical context, the government would likely assert that lowering the cost of prescription drugs "reduce[s] demands on government resources."[43] And as expressed in the mission of the U.S. Department of Health & Human Services (HHS), the government sees a national interest in enhancing and protecting the well-being of all Americans.[44] Under a maximalist view of § 1498, the government could assert that these considerations are sufficient for action by the government.

However, § 1498 only applies to use by or for the *federal* government, and public health has long been understood to be an area where individual states have significant power as well.[45] Furthermore, the United States health care system comprises multiple different systems, with both public and private providers and payers, and with the federal government, state governments and the private sector playing different roles, depending on the system. Where, for example, private payers are purchasing patented drugs under contract with a state, and the federal government's role is limited to regulation and providing indirect subsides, it may be less likely that the use of these drugs is either "for the government" or "for the benefit of the government." Ultimately, the specific case for whether § 1498 applies will vary depending on a number of factors, including the health care sector in which the government may intervene and the specific role of the federal government within the sector.

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Although the analysis will be fact dependent, it is likely that the more federal control and direct federal involvement in the health care sector, the more likely a use would be deemed "for the Government." For example, drug procurement for the Veterans Health Administration (VHA), where the federal government is both the payer and the health care provider, is more likely to be accepted as an action falling under the umbrella of § 1498. In contrast, a government argument that it can use § 1498 to distribute generic drugs into the private health care market, where the federal government's role is primarily regulatory, would be less likely to succeed.

A particularly impactful, but uncertain, case would be for Medicaid and Medicare, which together insure more than 34 percent of Americans.[46] Under these programs,

the federal government heavily regulates the sale of prescription drugs, but generally does not act as a payer or provider of prescription drugs. Medicaid is primarily run by states, with complex systems of rebates and reimbursements for prescription drugs, and Medicare provides outpatient prescription drugs through Medicare Part D private insurance. Because of the government's indirect role in these programs, and because of the many different ways in which the federal government interacts with state and private entities, any use of § 1498 would likely rest on uncertain legal ground, and any analysis would likely depend on the specific details of the government's plan.

FDA REGULATIONS AND MARKETING EXCLUSIVITIES

There is another obstacle to the potential use of § 1498 by the federal government in the modern health care system. In general, all drugs (including generic drugs) must be approved by the FDA in order to be legally sold in or imported into the United States, and this would include any generic drug the government attempts to procure using § 1498. However, the generic still must be approved by the FDA under the Federal Food, Drug, and Cosmetic Act (FDCA). Amendments to the FDCA over the past several decades, including the Drug Price Competition and Patent Term Restoration Act (commonly known as the Hatch-Waxman Act), the Orphan Drug Act, and the Biologics Price Competition and Innovation Act, significantly changed the FDA's regulatory scheme for pharmaceuticals and biologics since the last time the government used § 1498 to procure drugs in the 1960s and 1970s.

For non-biologic drugs,[47] the § 1498 generic drug would have to be approved through one of three avenues: a New Drug Application (NDA),[48] an Abbreviated New Drug Application (ANDA)[49] or a 505(b)(2) application.[50] The NDA process requires the submission of clinical investigations to establish the safety and efficacy of the drug and is expensive,[51] while the ANDA and 505(b)(2) processes permit reliance on the safety and efficacy data submitted by the original NDA applicant for its product (also known as the "reference product").[52] But, no matter which avenue is employed, the § 1498 drug manufacturer would have to demonstrate to the FDA the ability to properly manufacture the drug.[53]

The FDCA provides various data and marketing exclusivities to NDA applicants that can serve to restrict generic competition. One such example is New Chemical Entity (NCE) exclusivity, which lasts five years and is granted to an active ingredient the first time it is approved in a drug.

In addition, the FDCA provides various data and marketing exclusivities to NDA applicants that can serve to restrict generic competition.[54] One such example is New Chemical Entity (NCE) exclusivity, which lasts five years and is granted to an active ingredient the first time it is approved in a drug.[55] During this five-year period, no ANDA or 505(b)(2) applications for the drug may be submitted to FDA, except that an ANDA or 505(b)(2) application containing a certification of patent invalidity or non-infringement may be submitted after four years.[56]

Importantly, the exclusivities provided under the FDCA are distinct from patent rights, and § 1498 would not allow the government, or any government contractors, to circumvent any of these exclusivities.

Moreover, the Hatch-Waxman Act requires the § 1498 generic ANDA or 505(b)(2) manufacturer to make certain certifications regarding patents covering the innovator's drug, which are listed in what is colloquially referred to as the Orange Book.[57] Under the Hatch-Waxman Act, should an innovator pharmaceutical company bring suit within 45 days of receipt of a certification challenging its Orange Book patents (here, presumably the challenge would be based on the government's rights under § 1498), a 30-month stay of FDA approval of the generic drug is triggered.[58] It is possible that at least some of this 30-month stay may be used by the innovator pharmaceutical company to challenge the propriety of the federal government's actions, as discussed in more detail below.

The FDA approval requirements for drugs and the regulatory exclusivities that may protect NDA-approved drugs from competition would undoubtedly complicate any potential § 1498 prescription drug proposal. Moreover, any specific government proposal would have to account for these regulatory issues, or it would potentially be vulnerable to legal challenges.

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How Drug Companies Can Respond

POLICY ARGUMENTS

Some commentators have argued that, under the current state of law and policy, there are insufficient incentives for pharmaceutical companies to engage in meaningful drug development activities.[59] The threat of § 1498 action, however well intentioned for the "public good," would likely exacerbate this problem; potential profits associated with successful drugs could be limited, as § 1498 may only provide for a reasonable royalty. Furthermore, not every potential drug is successful, and the economics of pharmaceuticals is such that the blockbuster drugs pay for the many drugs that fail in development.

Investment in pharmaceutical research is driven in part on an expected rate of return, and if the use or potential use of § 1498 decreases the expected return, some amount of capital will likely be shifted to other investments. This decrease in research investment would likely lead to a decrease in pharmaceutical advancements. Furthermore, the use of § 1498 may also have the effect of actually *raising* drug prices. If the return on investment for a successful drug is undermined by the potential that the government invokes § 1498, a rational response may be to raise all drug prices so as to offset this loss and continue to adequately fund research. This response could lead to a zero-sum game, however: increased drug prices leading to further use of § 1498 leading to further price increases. Such a cycle would undermine the pharmaceutical industry and research, and harm, rather than help, the public.

In addition, increased use of § 1498 may also affect the types of drugs that are being researched. It is likely that § 1498 would be reserved for the most advanced drugs lacking a generic alternative. This again could create perverse incentives, leading to companies being penalized for their most groundbreaking and beneficial discoveries. A company attempting to minimize the risk of § 1498 may, in turn, prioritize researching drugs that provide only incremental improvements over the status quo.

In sum, the government should tread carefully in deciding whether to exercise § 1498 in the pharmaceutical realm, whether it is seeking to reduce drug prices or even in addressing the current pandemic.

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LEGAL ARGUMENTS BEYOND § 1498

An obvious tool in the innovator pharmaceutical company's arsenal is to argue that § 1498 does not apply—i.e., the use is not "by or for" the government, or the infringer does not have the government's authorization or consent. However, there are additional legal avenues as well, including the following potential arguments:

Potential Due Process Clause Challenge

If the government invokes § 1498, a patent holder may assert a violation of the Fifth Amendment's Due Process Clause, which prohibits depriving a person of property without due process of law. Indeed, the Supreme Court has stated that because patents are a species of property, they are protected under the Due Process Clause.[60] However, the Supreme Court has also stated, in the context of patent rights, that a deprivation of due process results only when there is "no remedy, or only inadequate remedies, to injured patent owners for infringement of their patent."[61] Patent owners bringing a due process challenge would need to show that the forum and/or remedies provided by § 1498 are inadequate under the Constitution.

Furthermore, if the government were to take aggressive steps to avoid otherwise-applicable FDA regulatory requirements, the Due Process Clause may create a cause of action for a separate reason. For example, the government might contract with a generic drug manufacturer to create a generic version of a drug and have the FDA (a federal government agency) approve it on an expedited basis, even if that drug is subject to an FDA marketing exclusivity. Although the manufacturing and distribution of an unapproved generic drug in these circumstances would technically violate the FDCA, it is possible that the Department of Justice and the FDA would take no action against the generic drug manufacturer, and the FDCA itself does not provide a private right of action.62 Under these circumstances, the innovator pharmaceutical company would have to look beyond the FDCA to bring a cause of action. They may bring an action under the APA (discussed below), bring an action seeking a writ of mandamus to force the FDA to act or bring a suit asserting a constitutional violation—where injunctive relief would potentially be available.

Challenge Government or FDA Action (or Inaction) Under the Administrative Procedures Act (APA)

As mentioned above, the FDCA and FDA regulations place strict constraints on the marketing and manufacture of generic drugs. Any generic drug would also need to be manufactured in accordance with FDA good manufacturing practice requirements.[63] Additionally, any proposed generic drug is subject to FDA approval processes prior to marketing, and approval of a particular generic drug may be blocked by an FDA regulatory exclusivity applicable to the branded reference product—and these exclusivities and regulatory requirements are distinct from patent rights. If the government attempted to fast-track any generic approval or work around any exclusivity, the administration may open itself up to a challenge under the APA. The APA prohibits government agencies from taking actions that are arbitrary, capricious, an abuse of discretion or otherwise not in accordance with law. Notably, APA suits can also be brought for a "failure to act"—for example, as may be the case should the FDA fail to enforce a regulatory exclusivity period.

ADDITIONAL CONSIDERATIONS: WHO BEARS THE RISK?

It is important to understand that in almost any situation, the government would need manufacturing partners, and would be the manufacturer of the generic drug that bears the ultimate risk of § 1498 not applying (and, therefore, payment of substantial damages for patent infringement). If an innovator pharmaceutical company brings an infringement action against a generic manufacturer—and the court finds the patent valid and infringed, and that § 1498 does not apply—the generic manufacturer would be liable for the full extent of infringement remedies. Moreover, importing drugs into the United States under a § 1498 plan may breach existing licensing or supply agreements between innovator pharmaceutical companies and generic pharmaceutical companies, potentially leading to various contract-related causes of action.

Conclusion

Policymakers at both the state and federal level have considered the use of § 1498 as a means to attempt to lower drug prices and expand access to generic drugs. The current administration, or a future one, may see § 1498 as a way to unilaterally "solve" a political problem. Although the Federal Circuit has interpreted § 1498 to provide the federal government with relatively broad powers to use patented technology for its own benefit, because of the regulatory framework and the structure of health care in the United States, the government should tread carefully—and pharmaceutical patent holders have many tools to use to fight back.

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ENDNOTES

[1] *See, e.g.,* Josh Wingrove and Riley Griffin, "Trump Eyes Drug-Price Cuts After His Health-Care Record Is Attacked," *Bloomberg,* Feb. 10, 2020, https://www.bloomberg.com/news/articles/2020-02-10/trump-eyes-drug-price-cuts-after-his-health-care-record-assailed; Robert Pear, "Trump Promises Lower Drug Prices, but Drops Populist Solutions," *New York Times,* May 11, 2018, https://www.nytimes.com/2018/05/11/us/politics/trump-prescription-drugs-plan.html.

[2] PETE FOR AMERICA, "Affordable Medicine for All: A Plan to Slash Drug Prices and Boost Medical Innovation," https://peteforamerica.com/policies/affordable-medicine/ (last visited Feb. 18, 2020).

[3] Prescription Drug Affordability and Access Act, S. 3166, 116th Cong. (2020). Senator Booker's bill would create the Bureau of Prescription Drug Affordability and Access to conduct reviews of drug prices and determine an appropriate list price. "If companies don't comply with the Bureau-reviewed list price, the Secretary of Health and Human Services (HHS) would allow other entities to produce the drug, thereby voiding the companies' government-granted exclusivity and ensuring patients have access to the drug at a lower and more reasonable price determined by the Bureau." Press Release, Senator Cory Booker, "Booker Unveils Groundbreaking Bill Establishing National Drug Pricing Agency to Lower Costs, Increase Access," Nov. 15, 2019, https://www.booker.senate.gov/?p=press_release&id=1019.

[4] Peter Sullivan, "Sanders Pledges to Allow Prescription Drug Imports on First Day in Office," *The Hill*, Aug. 1, 2019, https://thehill.com/policy/healthcare/455794-sanders-pledges-to-allow-imports-of-cheaper-prescription-drugs-on-first-day.

[5] *See* Kevin Freking, "Trump outstripping Obama on pace of executive orders," *Associated Press*, Oct. 19, 2019, https://apnews.com/25ca8d3b39024f9e828df7ebeb718274.

[6] *See, e.g.,* Alex Moss and Elliot Harmon, "The Feds Can Stop Patent Trolls from Endangering COVID-19 Testing and Treatment," Mar. 25, 2020, https://www.eff.org/deeplinks/2020/03/feds-can-stop-patent-trolls-endangering-covid-19-testing-and-treatment.

[7] *See, e.g.,* Brennan, et al., "A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health," 18 *Yale Journal of Law & Technology* 275 (2016).

[8] *See* Letter from Matthew Eyles, President and CEO, America's Health Insurance Plans, to Health and Human Services Secretary Alex Azar (July 16, 2018) (suggesting that HHS exercise authority under § 1498 "to introduce market competition"); Letter from Robert Weissman, President, Public Citizen, and Dr. Leana Wen, Commissioner, Baltimore City Health Department, to Kellyanne Conway, Counselor to the President of the United States (May 3, 2018) (requesting that the government "authorize use of any and all patents necessary to allow for the production of generic naloxone treatments and delivery systems to respond to the opioid epidemic"); Sarah Jane Tribble, "Louisiana Proposes Tapping a Century-old Patent Law to Cut Hepatitis C Drug Prices," *Washington Post,* May 2, 2017, https://www.washingtonpost.com/national/health-science/louisiana-proposes-tapping-a-century-old-patent-law-to-cut-hepatitis-c-drug-prices/2017/05/02/fc611990-2f76-11e7-9534-00e4656c22aa_story.html (the secretary of health for Louisiana urged the federal government to invoke § 1498 to treat underserved populations with Hepatitis C).

[9] 28 U.S.C. § 1498(a).

[10] *Id.*

[11] *See Motorola, Inc. v. United States,* 729 F.2d 765, 768 (Fed. Cir. 1984); *Leesona Corp. v. United States,* 599 F.2d 958, 964 (Ct. Cl. 1979).

[12] Amanda Mitchell, "Tamiflu, the Takings Clause, and Compulsory Licenses: An Exploration of the Government's Options for Accessing Medical Patents," 95 *California Law Review* 535, 541-42 (2007) (analogizing § 1498 to a compulsory license).

[13] Brennan, *supra* note 6, at 302 (characterizing the government use of section 1498 as "routine" and citing a number of examples).

[14] *See* Pub. L. No. 96-517, § 6, 94 Stat. 3015, 3019-27 (1980).

[15] 35 U.S.C. § 203(a).

[16] Id. § 203(a)(1)-(4).

[17] *Id.* § 203(a).

[18] *See, e.g.,* William O'Brien, "March-In Rights Under the Bayh-Dole Act: The NIH's Paper Tiger?," 43 *Seton Hall Law Review* 1403 (2013); JOHN R. THOMAS, CONG. RES. SERV., R44597, MARCH-IN RIGHTS UNDER THE BAYH-DOLE ACT at 1 (Aug. 22, 2016).

[19] Thomas, *supra* note 17, at 11.

[20] *See* 37 C.F.R. § 401.6

[21] *See id;* 35 U.S.C. § 203(a)(2).

[22] 35 U.S.C. § 203(a).

[23] *See* Donald S. Chisum, 7 *Chisum on Patents* § 20.03 (2015) ("There is some doubt whether lost profits is a permissible basis for recovery against the United States."). *Honeywell Int'l Inc. v. United States,* 107 Fed. Cl. 659, 679 (2012) (relying upon the *Georgia-Pacific Corp. v. U.S. Plywood Corp.,* 318 F. Supp. 1116 (S.D.N.Y. 1970) factors to calculate the reasonable royalty rate).

[24] *See* Thomas, *supra* note 17, at 8-9 ("A common theme of each of the denials was the agency's views that concerns over drug pricing were not, by themselves, sufficient to provoke march-in rights.").

[25] *See* Joseph Allen, "The Washington Post Misses the Mark on March-In Rights," ipwatchdog.com, Apr. 22, 2019, https://www.ipwatchdog.com/2019/04/22/washington-post-misses-mark-march-rights/id=108499/.

[26] *See* Brennan, *supra* note 6, at 280.

[27] *See Advanced Software Design Corp. v. Fed. Reserve Bank of St. Louis,* 583 F.3d 1371, 1375 (Fed. Cir. 2009) (quoting *Richmond Screw Anchor Co. v. United States,* 275 U.S. 331, 344 (1928)) ("[35 U.S.C § 1498] 'is more than a waiver of immunity and effects an assumption of liability by the government.'"). However, in some cases, the relevant contract may include an indemnification provision requiring the contractor or subcontractor to reimburse the government any or all "reasonable compensation" paid to a patent owner as part of a § 1498 action.

[28] 28 U.S.C. § 1498(a); *see also IRIS Corp. v. Japan Airlines Corp.,* 769 F.3d 1359, 1362 (Fed. Cir. 2014).

[29] *See also supra* Section I.

[30] 583 F.3d 1371 (Fed. Cir. 2009).

[31] 769 F.3d 1359 (Fed. Cir. 2014).

[32] *Id.* at 1373–74.

[33] *Id.* at 1378.

[34] *Id.*

[35] *Id.* at 1379.

[36] 769 F.3d at 1361.

[37] *Id.* at 1363.

[38] *Iris Corp. v. Japan Airlines Corp.,* 769 F.3d 1359, 1362 (Fed. Cir. 2014).

[39] *Id.*

[40] *Id.*

[41] *Id.* at 1363.

[42] *TVI Energy Corp. v. Blane,* 806 F.2d 1057, 1060 (Fed. Cir. 1986) (finding that § 1498 applied where the defendant infringed in order to meet the government specifications for a product in hopes of securing a defense contract).

[43] *Iris Corp.,* 769 F.3d at 1362.

[44] *See also Madey v. Duke University,* 413 F. Supp. 2d 601, 607 (M.D.N.C. 2006) (quotations and citations omitted) ("A use is 'for the Government' if it is in furtherance and fulfillment of a stated Government policy which serves the Government's interests and which is for the Government's benefit.").

[45] *See e.g. New Orleans Gas Co. v. Drainage Comm,* 197 U.S. 453, 460 (1905) (The public health and welfare "is one of the most important purposes for which the police power can be exercised.").

[46] *See* Health Insurance Coverage of the Total Population, https://www.kff.org/other/state-indicator/total-population/.

[47] While this white paper focuses on non-biologic drugs, many of the same issues regarding marketing exclusivity apply to biologics approved under the BPCIA. *See* 42 U.S.C. § 262.

[48] 21 U.S.C. § 355(b)(1).

[49] *Id.* § 355(j).

[50] *Id.* § 355(b)(2).

[51] *Id.* § 355(b)(1)(A).

[52] *Id.* § 355(j)(2)(A)(i); *Id.* § 355(b)(2) .

[53] *See* 21 U.S.C. §§ 355(d), (j).

[54] The FDA must enforce many different regulatory exclusivities including terms of 12 years for biologics, seven years for orphan drugs, five years for drugs that qualify as an NCE, three years for certain clinical investigations and 180 days for generic drug companies that challenge relevant patents under certain conditions. *See* JOHN R. THOMAS, CONG. RES. SERV., R44951, REGULATORY EXCLUSIVITY REFORM IN THE 115TH CONGRESS (Sept. 15, 2017).

[55] *See* 21 C.F.R. § 314.108.

[56] *See Id.* § 314.107(d). The 505(b)(2) application or ANDA may be submitted after four years if it contains a certification of patent invalidity, non-infringement or unenforceability.

[57] See 211 U.S.C. § 355(j)(7)(A)(iii); *see also* 21 U.S.C. § 355(b)(1); 21 C.F.R. § 314.53(b)(1).

[58] *See* 21 U.S.C. § 355(j)(5)(B)(iii).

[59] Erika Lietzan & Kristina M.L. Acri née Lybecker, "Distorted Drug Patents," *Washington Law Review* (forthcoming) (Sept. 23, 2019), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3458588.

[60] *See Fla. Prepaid Postsecondary Educ. Expense Bd. v. Coll. Sav. Bank,* 527 U.S. 627, 642 (1999) ("[Patents] are surely included within the 'property' of which no person may be deprived by a State without due process of law.").

[61] *Id.* at 643.

[62] *See* 21 U.S.C. § 337(a).

[63] *See* 21 U.S.C. § 351(a)(2)(B); 21 C.F.R. Part 211. The quality of generic drugs has been a significant policy concern in recent years, particularly for foreign-manufactured drugs. In recent years, government officials have called into question the adequacy of FDA's oversight of foreign drug manufacturers and raised quality and security concerns with the heavy reliance in the drug supply chain on foreign-manufactured drugs. *See* Mary Denigan-Macauley, U.S. Government Accountability Office, Drug Safety: Preliminary Findings Indicate Persistent Challenges with FDA Foreign Inspection, Testimony Before the Subcom. on Oversight and Investigations, H. Com. On Energy and Commerce 2 (Dec. 10, 2019).; Letter from Sen. Chuck Grassley to Alex Azar, Secretary of Health and Human Services (June 27, 2019).; *see generally Securing the U.S. Drug Supply Chain: Oversight of FDA's Foreign Inspection Program: Hearing Before the S. Comm. On Oversight and Investigations of the Committee on Energy and Commerce,* 116th Cong. (2019).

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