§ 1498: A GUIDE TO GOVERNMENT PATENT USE

A PATH TO LICENSING AND DISTRIBUTING GENERIC DRUGS

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EXECUTIVE SUMMARY

This guide provides practical information on how the U.S. government can use a long-standing U.S. federal statute, 28 U.S.C. § 1498, to authorize use of any patented technology by or for the government and the American public.

The guide aims to clarify ambiguity and misperceptions surrounding the U.S. government's "government patent use" power under § 1498. It explains, in accessible language, the substantive powers that § 1498 provides to U.S. government officials, and it explains what effective and successful use of § 1498 looks like in practice. The guide takes a comprehensive approach, outlining what U.S. government officials should expect from contractors, patent holders, and courts before, during, and after "using" a patent pursuant to § 1498.

Together, the sections below highlight § 1498's broad scope and its highly flexible application to any and all patented technology, regardless of whether the technology was developed with public or private money. Section 1498 permits the U.S. government to use—and thereby expand public access to—any technology covered by a U.S. patent. Any time a patent stands in the way of government procurement—e.g., when a particular patent holder asks an unreasonable price, or is unable to manufacture enough of a patented product to meet the government's supply needs—§ 1498 can be used to procure the product from competitors, or to allow the government to manufacture the product itself. As a result, § 1498 has broad utility. In years past, the statute has been used in many different technological contexts—including, for example, pharmaceuticals, military equipment, and financial technology—and it could be applied in any number of technological contexts in the future.

SECTION 1 of this guide highlights some problematic features of the patent system, which § 1498—a core part of the U.S. patent system for over a century—is well suited to correct. While acknowledging the important role that patents play as economic incentives for innovation, Section 1 focuses on the enormous costs, both human and economic, that can result from healthcare corporations' strategic, profit-maximizing use of patents. For example, patents have sustained the high prices of life-saving drugs for hepatitis C infection and HIV/AIDS, prolonging these costly and deadly epidemics. Further, the U.S. has faced preventable shortages of treatments, tests, and other supplies throughout the COVID-19 pandemic. Shortages of one COVID-19 treatment in particular, remdesivir, grew so severe in the summer of 2020 that patients and doctors were forced to ration the drug; these were exacerbated by patents that blocked competition and expanded supply. Section 1498 can address such problems, as the remainder of the guide explains.

SECTION 2 provides a legal and historical overview of § 1498. It introduces the text of § 1498 and clarifies its meaning: the U.S. government has the authority to use or manufacture any patented invention, without the consent of the patent holder, in return for "reasonable and entire compensation" to the patent holder. Section 2 then summarizes how this authority functions in practice, describing when and how government patent use occurs and by providing brief historical examples of patent use under § 1498. It highlights the versatility of § 1498, including the law's value as leverage in a negotiation (where the mere prospect of government patent use, without actual exercise of the power, may bring patent holders to the negotiating table).

SECTION 3 describes in detail how § 1498 operates in practice. Section 3 begins by describing a first type of government patent use under § 1498: direct, independent government patent use, in which the U.S. government itself makes, sells, and/or distributes a patented invention. Section 3 then describes a second

type of government patent use: third-party use on behalf of the government, which is included within the statute as patent use "for" the U.S. government. Section 3 also explains the flexible "government use test" that courts have created to establish whether a third party's use of a patent is properly "for" the U.S. government and therefore covered by § 1498, and it provides a roadmap for U.S. government officials to meet the government use test.

SECTION 4 details litigation that may arise upon government patent use under § 1498. Section 4 focuses primarily on the "reasonable and entire compensation" paid to a patent holder when the U.S. government uses their patent: what constitutes "reasonable and entire compensation," and how is this value determined? Reasonable and entire compensation is determined by a federal court, the Court of Federal Claims, which has historically taken a conservative and even-handed approach that typically provides the patent holder with a "reasonable royalty" based on the market value of the patented invention. Section 4 provides specific examples and trends deduced from these data, which provide guidance to government policymakers on what to expect when using, pursuant to § 1498, a particular patent in a particular instance. Finally, Section 4 reiterates the value of § 1498 as leverage in negotiation and explains how § 1498's compensation structure creates much of this leverage.

SECTION 5 discusses government patent use under § 1498 in the specific context of prescription drugs. Special considerations apply to pharmaceuticals because they are heavily regulated by the Federal Drug Administration (FDA), and non-patent regulatory barriers to competition can affect the reach of government patent use. Section 5 explains, broadly, two distinct sets of facts that may apply to a given pharmaceutical. Under the first set of facts, patents are the only barriers to competition for a particular drug. Government patent use under § 1498 is likely to solve these "patent problems"—to accelerate competition and expand access—quickly and straightforwardly. Under the second set of facts, additional non-patent statutory exclusivities prevent generic competitors from entering the market. Government patent use under § 1498 cannot solve the latter sort of "non-patent problems." However, the government may be able to coordinate with generic manufacturers to work around such non-patent exclusivities.

§ 1498: A GUIDE TO GOVERNMENT PATENT USE

A PATH TO LICENSING AND DISTRIBUTING GENERIC DRUGS

This infographic illustrates the steps by which the U.S. Government can use 28 U.S.C. § 1498 to authorize and distribute a lower-cost generic version of a brand-name drug, even when the brand-name drug is still protected by patents.

CONTRACT

A U.S. government agency contracts with a generic drug manufacturer (or multiple) to begin making a generic version of a patent-protected brand-name drug. This contract includes explicit authorization under 28 U.S.C. § 1498 for the generic to use the brand-name company's patent(s) to manufacture on the government's behalf.

FDA APPLICATION

The manufacturer applies to the U.S. Food & Drug Administration for approval of its generic version, if it is not already approved.

POSSIBLE LITIGATION

The patent-holding brand-name drug company may sue the generic manufacturer for patent infringement. Because the generic has the government's authorization under § 1498 to use those patents on the government's behalf, the court will dismiss this litigation, and the generic manufacturer cannot be held liable for infringement.

APPROVAL + DISTRIBUTION

Once the FDA approves the authorized generic drug, the agency can immediately begin procuring and distributing the generic drug.

ADDITIONAL LITIGATION

The brand-name drug company may sue the U.S. government under § 1498 in a specialized court, the Court of Federal Claims, seeking compensation for the use of its patents to make the generic drug. Dedicated lawyers in the Department of Justice will step in to represent the government.

COMPENSATION

If and only if the Court of Federal Claims finds that the patents used are valid, enforceable, and infringed, it will require the Government to pay the brand name manufacturer a reasonable compensation for the use of its patents.

10 KEY TAKEAWAYS ON GOVERNMENT PATENT USE UNDER 28 U.S.C. § 1498

1. **PERMISSION NOT REQUIRED** Under existing federal statute, 28 U.S.C. § 1498, **the U.S. government can manufacture or use any patented product, without permission from the patent holder**, no matter who owns or who funded the patent. This legal authority is often referred to as the U.S. government's "government patent use" power.

2. **ALL PRODUCTS ELIGIBLE** **All patented products are eligible for government patent use under § 1498.** The U.S. government has, through the years, used § 1498 to obtain and deploy patented products as diverse as prescription drugs, military equipment, and financial software.

3. **USED FOR OVER A CENTURY** Government patent use has been **enshrined in federal statute for over a century**, and it has been used successfully by both Republican and Democratic administrations.

4. **IMMEDIATE USE** **Section 1498 can be used instantly.** There is no legal process the government must undertake before it uses a patent.

5. **NO LIMITATIONS** **There are no limitations on when the U.S. government can use a patent pursuant to § 1498.** The statute applies in both emergencies and non-emergencies.

6. **AVAILABLE TO ANY GOVERNMENT AGENCY** **Any U.S. government agency and any U.S. government official operating in their official capacities can use a patent pursuant to § 1498.** The government patent use power is not limited to the President or to senior government officials.

7. **COVERS GOVERNMENT CONTRACTORS** Under § 1498, the U.S. government can **extend its government patent use power to authorized contractors**, so long as the use is "for the United States."

8. **GOVERNMENT COMPENSATION** Whenever the U.S. government (or an authorized contractor) uses a patent, **the statute guarantees patent holders "reasonable and entire compensation" for the government's use**. The compensation is paid by the government directly to the patent holder. The compensation is typically a court-set royalty that approximates the fair market value of a license to the patent.

9. **COST SAVINGS** Even though the patent holder is guaranteed reasonable and entire compensation, **the government can nonetheless save significant, even enormous, amounts of money** by procuring patented products through § 1498. When the patent holder charges very high prices for its own patented products, the U.S. government can use § 1498 to procure those products from alternative manufacturers at much lower cost overall.

10. **PRICING AND SUPPLY LEVERAGE** Because the reasonable and entire compensation that patent holders collect under § 1498 is typically less than they can earn from selling their patented products at full price, **the government can use the prospect of government patent use under § 1498 as leverage** in pricing and supply negotiations with the patent holder.

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ABBREVIATIONS

§ 1498	28 U.S.C. § 1498
ABLA	Abbreviated Biologics License Application
ANDA	Abbreviated New Drug Application
BLA	Biologics License Application
BPCIA	Biologics Price Competition and Innovation Act
Brennan	Hannah Brennan et al., *A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health,* 18 Yale J.L. & Tech. 275 (2016)
CDC	Centers for Disease Control & Prevention
CMS	Centers for Medicare & Medicaid Services
DOD	Department of Defense
FDA	Food & Drug Administration
HHS	Department of Health & Human Services
HRSA	Health Resources & Services Administration
Kapczynski & Kesselheim	Amy Kapczynski & Aaron S. Kesselheim, *'Government Patent Use': A Legal Approach To Reducing Drug Spending,* 35:5 Health Affs. 791 (May 2016)
Lavenue	Lionel M. Lavenue, *Patent Infringement Against the United States and Government Contractors Under 28 U.S.C. § 1498 in the United States Court of Federal Claims*, 2 J. Intell. Prop. L. 389 (1995)
Morten & Duan	Christopher J. Morten & Charles Duan, *Who's Afraid of Section 1498? A Case for Government Patent Use in Pandemics and Other National Crises*, 23 Yale J.L. & Tech. 1 (2020)
NDA	New Drug Application
PrEP	pre-exposure prophylaxis

SECTION 1

SPOTLIGHT ON THE PROBLEM OF PATENTS IN AMERICAN HEALTHCARE

We open this guide to government patent use under 28 U.S.C. § 1498 with a spotlight on a particular sector of the economy—and a particular field of technology—in which patents create essential incentives to invent but also hinder competition, access, and, at least in some cases, public health. As such, healthcare is an illustrative sector in which government patent use under § 1498 could play a significant role in expanding access to patented medical technologies by lowering prices, addressing shortages, and serving the public interest.

To be sure, healthcare is far from the only area of the economy in which patents are important and in which government patent use could play an important policy role. In subsequent sections of this guide, we discuss numerous examples of government patent use outside the healthcare context; the lessons of those sections are applicable to all sectors of the economy and all fields of technology.

In a survey by the Harvard School of Public Health leading up to the 2020 election, the single most important domestic issue for Democrats and Republicans alike was access to affordable healthcare. The second-ranked priority for both groups—lowering the cost of prescription drugs—was also related to healthcare.[1]

These findings are not surprising. The United States currently spends more on healthcare than any other nation in the world,[2] due in part to its outsized spending on prescription drugs. While other countries have implemented health technology assessment and leveraged government buying power to reduce the cost of medicines, the U.S. government has largely declined to take serious action. As a result, Americans pay on average up to four times more for drugs than do patients in other countries,[3] and prescription drug spending is projected to rise faster than any other category of health spending over the next decade.[4] At a national level, this strains our public health systems, leading to drug rationing, substandard health outcomes, and the risk of insolvency for public insurance programs, including Medicare and Medicaid. For individuals, the high cost of medicines can lead to catastrophic outcomes: medical bankruptcy, nonadherence to treatment, sickness, and death.

These issues pervade despite the fact that the United States is—by a wide margin—the largest worldwide investor in medical research and development.[5] Of

[1] Harvard T.H. Chan School of Public Health & Politico, *Americans' Domestic Priorities for President Trump and Congress in the Months Leading Up to the 2020 Election* (Feb. 2020), https://cdn1.sph.harvard.edu/wp-content/uploads/sites/94/2020/02/PoliticoFeb2020.pdf.

[2] Johns Hopkins Bloomberg School of Public Health, *U.S. Health Care Spending Highest Among Developed Countries* (Jan. 7, 2019), https://www.jhsph.edu/news/news-releases/2019/us-health-care-spending-highest-among-developed-countries.html.

[3] Ways and Means Committee Staff, 117th Cong., *A Painful Pill to Swallow: U.S. vs. International Prescription Drug Prices* (Sept. 2019), https://waysandmeans.house.gov/sites/democrats.waysandmeans.house.gov/files/documents/U.S.%20vs.%20International%20Prescription%20Drug%20Prices_0.pdf.

[4] Andrea M. Sisko et al., *National Health Expenditure Projections, 2018-2027: Economic And Demographic Trends Drive Spending And Enrollment Growth*, 37(3) Health Affairs (March 2018), https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2018.05499.

WHAT, EXACTLY, IS A PATENT?

Patents are a government-granted property right in a technological "invention." Patents grant their holders the legal right to exclude others from making, using, and selling the invention, and importing into the United States, throughout the life of the patent, typically 20 years.[7] Patents are important in the pharmaceutical industry and other research-intensive industries, because they permit inventive companies to block "free-riding" competitors from using their inventive technologies without permission.

the 210 new drugs approved by the FDA from 2010-2016, the U.S. government funded research associated with every single one, totaling an investment of over $100 billion in U.S. tax dollars.[6] In spite of our extensive public investment in medicine, U.S. law and policy permit—actually encourage—drug companies to acquire patents on drugs developed with public funding, contributing to high drug prices overall.

Drug companies typically acquire a variety of patents covering different inventive aspects of their drugs—including the active ingredient (or ingredients, as a single drug may contain multiple active ingredients), methods of administration, and chemical compositions—creating a dense thicket of overlapping protections.[8] These patents give drug companies exclusive control of the market for a new drug, and the ability to prevent competition from lower-cost generic manufacturers—sometimes for decades. During this time, U.S. law and policy permit those companies to set prices as high as the market will bear (or, more precisely, as high as those companies determine U.S. insurers, patients, and their families are able to pay for the drug), rather than as a function of the drug company's investments in R&D or its manufacturing costs. Drugs that cost a few dollars or even pennies per pill to manufacture are commonly sold for tens or hundreds of thousands of dollars. The prices that brand-name drug companies charge for their products typically continue to rise, rather than fall, as long the products remain under patent protection.[9]

Ilt is true that the patent system plays an important role in U.S. innovation, including the development of groundbreaking new medical treatments. At its core, the patent system represents a quid pro quo between inventors and the U.S. government. Drug patents give pharmaceutical companies temporary market exclusivity—freedom from competition—and the chance to recoup the cost of research and development, while the U.S. public benefits from the creation of new treatments, vaccines, and cures, along with new scientific knowledge. However, the quid pro quo balance may tip too far in favor of drug companies when patents permit those companies to set and keep prices astronomically high—much higher than needed to fund future drug development, and much, much higher than the manufacturing cost. When companies charge sky-high prices for patent-protected medicines, those medicines become difficult for un- and underinsured patients to access, and the American people as a whole can suffer. This is particularly true when patented drugs are needed to treat communicable diseases and address other pressing public health concerns.

Treatment for hepatitis C virus infection provides a vivid example. Many hoped the disease was on its way to being eliminated when the very first direct-acting antiviral medications that cure most hepatitis C infections, with relatively limited side effects, were approved in 2011.[10] However, the cost of a cure—tens of thousands of dollars for a course of therapy[11]—has put these life-saving medicines out of reach for many everyday Americans. According to a bipartisan report by the U.S.

[5] Hamilton Moses et al., *The Anatomy of Medical Research U.S. and International Comparisons*, 313(2) JAMA 174-89 (2015).

[6] Ekaterina Galkina Cleary et al., *Contribution of NIH funding to new drug approvals 2010–2016*, 115(1) PNAS 2329-34 (2018).

[7] 35 U.S.C. § 154.

[8] *See, e.g.*, Kevin T. Richards, et al., Cong. Rsch. Serv., R46221, *Drug Pricing and Pharmaceutical Patenting Practices* (2020), https://fas.org/sgp/crs/misc/R46221.pdf.

[9] *See, e.g.*, Alfred Engelberg, *Unaffordable prescription drugs: the real legacy of the Hatch-Waxman Act*, STAT News (Dec. 16, 2020), https://www.statnews.com/2020/12/16/unaffordable-prescription-drugs-real-legacy-hatch-waxman-act/.

[10] *See* Liesl M. Hagan & Raymond F. Schinazi, *Best Strategies for Global HCV Eradication*, 33(1) Liver Int'l 68 (2013); *see also A Brighter Future in the Fight Against hepatitis*, 19(7) Nature Medicine 791 (2013).

[11] Brandy Henry, *Drug Pricing & Challenges to hepatitis C Treatment Access*, 14 J. Health Biomed. L. 265 (2018).

Senate's Committee on Finance, the manufacturer of one hepatitis C drug set the price "at a level where ultimately many patients would not receive treatment."[12] Public payers including Medicare and Medicaid have responded by imposing highly restrictive criteria to control costs, limiting access to the drug to only the sickest patients.[13] As a result, the number of new hepatitis C infections each year is increasing, and acute hepatitis C cases more than tripled between 2010 and 2016.[14]

The story of HIV/AIDS pre-exposure prophylaxis (PrEP) is distressingly similar. In 2012, the drug Truvada became the first FDA-approved medication for use as PrEP.[15] Taking Truvada as PrEP once a day reduces the risk of sexual HIV transmission in HIV-negative people by 99%.[16] However, the availability of PrEP has been severely limited by its high cost and the lack of affordable generic alternatives.[17] Years after the approval of the first medicine for PrEP, the U.S. Centers for Disease Control and Prevention (CDC) estimate that less than 20% of the 1.2 million people at substantial risk for HIV infection are using PrEP.[18] A recent publication by scientists at the CDC concluded that the high cost of PrEP "should promote action around ways to lower PrEP costs to the healthcare system to prevent coverage denials, eliminate prior authorization requirements, and increase access," and thereby ensure that PrEP fulfills its central role in the U.S. government's Ending the HIV Epidemic initiative.[19]

The coronavirus pandemic has brought new urgency to these issues, highlighting fundamental weaknesses in the United States' ability to respond to public health crises. Despite warnings as early as October 2019 about U.S. preparedness,[20] shortages of patented N95 masks, testing kits, personal protective equipment, and ventilators marred the U.S. response to the virus, contributing to the more than 300,000 deaths attributable to the virus as of writing in late 2020. The United States also failed to ramp up production of medicines, including remdesivir, currently (as of December 2020) the only antiviral drug approved by the FDA for treating COVID-19. In the summer of 2020, at a time when some developing countries (and their local generic drug manufacturers) reported surpluses of remdesivir,[21] U.S. hospitals faced severe shortages that led to rationing of the drug.[22] Despite these chronic shortages, the U.S. drug company holding the patent for remdesivir failed to produce more for the U.S. market, and the Trump administration declined to enlist generic manufacturers to step in and produce more of the drug for American hospitals.

Experts are now sounding the alarm about monoclonal antibodies—the treatment famously used by President Trump following his own COVID-19 diagnosis—which may be the next drug to run out as the U.S. faces another wave of COVID-19 hospitalizations in the winter of 2021.[23] The successful end of the coronavirus will also turn on the United States' ability to quickly produce and distribute a low-cost vaccine to millions of Americans, yet experts predict rationing of vaccines, too.[24] The U.S. government would thus be well-advised to consider its authority to assert greater control over manufacturing and distribution of drugs, vaccines, and other medical technologies.

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[12] U.S. Senate Committee on Finance Staff, 114th Cong., *The Price of Sovaldi and its Impact on the U.S. Health Care System*, S. Prt. No. 114-20, at 3 (Dec 2015), https://www.finance.senate.gov/imo/media/doc/1%20The%20Price%20of%20Sovaldi%20and%20Its%20Impact%20on%20the%20U.S.%20Health%20Care%20System%20(Full%20Report).pdf.

[13] *Id*. at 99.

[14] Centers for Disease Control and Prevention, *CDC Estimates Nearly 2.4 Million Americans Living with hepatitis C* (Nov. 6, 2018), https://www.cdc.gov/nchhstp/newsroom/2018/hepatitis-c-prevalence-estimates-press-release.html.

[15] Centers for Disease Control and Prevention, *CDC Statement on FDA Approval of Drug for HIV Prevention* (Jul. 16, 2012), https://www.cdc.gov/nchhstp/newsroom/2012/fda-approvesdrugstatement.html

[16] Centers for Disease Control and Prevention, *Pre-exposure Prophylaxis (PrEP)*, https://www.cdc.gov/hiv/risk/prep/index.html (last visited Nov. 11, 2020).

[17] The first generic medicine for PrEP costs $1,455 per month. Liz Highleyman, *First Generic Truvada Now Available in the United States*, Poz (Oct. 20, 2020), https://www.poz.com/article/first-generic-truvada-now-available-united-states.

[18] Rochelle P. Walensky & A. David Paltiel, *PrEP School: A Field Manual For The Battle Over HIV Prevention Drug Pricing*, Health Affairs Blog (Aug. 29, 2019), https://www.healthaffairs.org/do/10.1377/hblog20190826.11005/full.

[19] Nathan W. Furukawa, *National Trends in Drug Payments for HIV Preexposure Prophylaxis in the United States,* 2014 to 2018, 173(1) Annals of Internal Medicine 799 (Nov. 17, 2020).

[20] Joe Biden (@JoeBiden), Twitter, (Oct. 25, 2019) https://twitter.com/JoeBiden/status/1187829299207954437.

[21] Elizabeth Cohen, *Covid-19 Drug Rationed in the US is Plentiful in Developing Countries*, CNN Health (Sept. 9, 2020, 9:17 AM), https://www.cnn.com/2020/09/09/health/covid-remdesivir-us-vs-other-countries/index.html.

[22] Elizabeth Cohen, *Hospitals in Covid-19 Hotspots are Running out of Remdesivir*, CNN Health (Jul. 12, 2020, 4:08 PM), https://www.cnn.com/2020/07/12/health/remdesivir-distribution-covid-19-hotspots/index.html.

[23] Matthew Herper, *Antibody drugs seem to work. But the virus is moving faster than we can make them*, STAT (Oct. 29, 2020), https://www.statnews.com/2020/10/29/antibody-drugs-appear-effective-now-can-we-make-enough-of-them/.

[24] *See, e.g.*, Kevin Stankiewicz, Dr. Scott Gottlieb sees Covid vaccine in 'rationing type of environment' well into the spring, CNBC (Dec. 2, 2020), https://www.cnbc.com/2020/12/02/dr-scott-gottlieb-sees-covid-vaccine-in-rationing-type-of-environment-well-into-the-spring-.html.

SECTION 2

OVERVIEW OF 28 U.S.C. § 1498

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 owner thereof or lawful right to use or manufacture the same, the owner's 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...."

A. LEGAL OVERVIEW

1. WHAT IS 28 U.S.C. § 1498?

In a nutshell, 28 U.S.C. § 1498 is a federal statute that authorizes the U.S. government to use or manufacture any patented invention without the permission of the patent holder. In return for its use of a patent, the government pays "reasonable and entire compensation" to the patent holder.[25] Any use of a patent by a U.S. government agency, as well as any use of a patent by an authorized third party operating "by or for the United States" falls within the statute.[26] Section 1498 creates a compensation scheme for the patent holder, but, in contrast to private patent infringement claims, does not allow the patent holder to prevent government use of the patent through what is called, in legal terminology, an "injunction."[27] As a result, the statute affirms the government's power to use any patent—that is, make, use, import, sell, and/or distribute any patented invention—for its benefit while granting patent holders the right to demand reasonable compensation for any patents the government chooses to use.

WHAT IS AN "INJUNCTION"?

An "injunction" is simply a court order commanding someone to take, or preventing someone from taking, a certain action.[28] In "private" patent infringement cases (between private companies), a patent holder can sometimes obtain an injunction against an infringer, preventing ("enjoining") the infringer from using the patent. For example, in private patent infringement cases, patent-holding brand-name pharmaceutical companies often obtain injunctions against generic competitors, preventing the generic competitors from using the patents and consequently blocking their products from the market. In contrast to private patent infringement cases, injunctions are not available in § 1498 cases. A patent holder cannot obtain an injunction preventing the U.S. government from using a patent.

[25] 28 U.S.C. § 1498(a).

[26] Hannah Brennan et al., *A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health*, 18 Yale J.L. & Tech. 275, 330 (2016) ("Brennan").

[27] Christopher J. Morten & Charles Duan, *Who's Afraid of Section 1498? A Case for Government Patent Use in Pandemics and Other National Crises*, 23 Yale L.J. Tech 1, 45 (2020) ("Morten & Duan").

[28] Black's Law Dictionary (11th ed. 2019), available at Westlaw.

II. HOW DOES THE U.S. GOVERNMENT "USE" § 1498?

To use a patent, the government (or a third party authorized by the government, such as a generic drug manufacturer operating under contract with the government) need not take any special legal or administrative action. The statute creates no obligation for the government to notify the patent holder or anyone else before commencing use of the patent.[29] Rather, the government (or a third party authorized by the government, such as a generic drug manufacturer operating under contract with the government) can simply commence use or manufacture of a patented invention.

After the U.S. government or a third party authorized by the U.S. government has used a patent, the patent holder can then use § 1498 to seek compensation under the statute. Specifically, the patent holder formally invokes § 1498 by filing a lawsuit against the United States in a specialized federal court, the Court of Federal Claims, to demand the appropriate compensation from the government. (As such, in the narrowest, technical sense, it is patent holders, not the U.S. government, that "use" § 1498, by filing lawsuits that reference the statute.)

At the time the government decides to use a patent, there is no formal requirement for it to declare, or even know, that such use is made under § 1498.[30] The government's use of a patent by or for the United States and the patent holder's subsequent compensation are both automatically governed by § 1498 whether the government declares so at the outset or not. (As such, the government implicitly "uses" § 1498 any time it uses a patent.)

If the patent holder attempts to sue the government for patent infringement on any basis other than § 1498, the government can move to dismiss the claim quickly, because a suit under § 1498 is the patent holder's sole legal remedy for government patent use.[31] Similarly, a third-party company that is using a patent on behalf of the U.S. government—for example, to manufacture a patented invention under contract with the government—cannot be held liable for patent infringement and can quickly dismiss any infringement suit the patent holder files against it. For a more detailed discussion on why a § 1498 action is the patent holder's only cause of action in these cases, refer to Section 4.A below.

III. WHEN AND HOW CAN THE GOVERNMENT USE A PATENT?

Section 1498 itself places no limitations on when the government can use a patent or which patents it may use. There is also no limit on how many patents the government can use. The government can use many patents simultaneously, e.g., to procure and use or distribute a single product covered by many patents. The government can use a patent for a brief period, or for a period of years.[32]

Likewise, there are no circumstantial preconditions under the statute, besides the qualification that the use be "by or for the United States." [33] That is, emergency conditions are not required to justify government patent use under § 1498. (Of course, there are some emergency situations in which the policy justifications for government patent use might be particularly strong, such as insufficient access to life-saving medications in the midst of an epidemic, or wartime needs for competitive technologies.) Whether the government's goal in using the patent is to address a shortage, reduce prices, or simply obtain an invention for government use, if the use is by or for the government, § 1498 governs.

One point bears repeating: while government patent use "by or for the United States" includes use or manufacturing by the government directly, it also includes use or manufacturing by third parties authorized by the government.[34] Section 1498 protects these third parties, too. For a more detailed discussion on how the relevant courts have interpreted the "by or for the United States" requirement of § 1498, particularly with regard to non-government third parties, refer to Section 3 below.

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[29] Morten & Duan at 51.

[30] Morten & Duan at 52.

[31] *See Iris Corp. v. Japan Airlines Corp.,* 769 F.3d 1359, 1362 (Fed. Cir. 2014); see also *Advanced Software Design Corp. v. Fed. Reserve Bank of St. Louis,* 583 F.3d 1371 (Fed. Cir. 2009) (dismissing counts of patent infringement on the ground that the acts were "by or for the United States" and could only be pursued under 28 U.S.C. § 1498)

[32] Amy Kapczynski & Aaron S. Kesselheim, *'Government Patent Use': A Legal Approach To Reducing Drug Spending*, 35:5 Health Affs. 791, 794 (May 2016) ("Kapczynski & Kesselheim").

[33] *Id.* at 794 (contrasting the lack of circumstantial requirements in § 1498 with political resistance to using march-in rights under the Bayh-Dole Act).

[34] Brennan at 330.

§ 1498 VS. "MARCH IN" UNDER THE BAYH-DOLE ACT

Government patent use under 28 U.S.C. § 1498 is sometimes confused or conflated with separate legal rights that the U.S. government holds over certain patents: "march-in rights" under 35 U.S.C. § 203, a section of the Bayh-Dole Act. In fact, these are entirely distinct laws, and they operate differently.

Section 1498 and the Bayh-Dole Act are broadly similar in that both statutes recognize and formalize the U.S. government's legal authority to use privately held patents and, under some circumstances, to authorize third parties to use those patents, too. But Section 1498 and the Bayh-Dole Act also differ in fundamental and important ways.

A detailed overview of the Bayh-Dole Act is beyond the scope of this guide, [35] but a few key differences between § 1498 and the Bayh-Dole Act are these:

- → As outlined above and explained in more detail in Section 3, there are no formal or procedural requirements for government patent use under § 1498. The government can simply and instantly begin using a patent, or alternatively authorize third parties to do so, so long as the use is "for the United States." By contrast, the U.S. government can also exercise march-in rights under Bayh-Dole to authorize third parties to use a patent, but only after making certain factual findings—e.g., that the "action is necessary to alleviate health or safety needs which are not reasonably satisfied by" the patent holder—and only after the patent holder exhausts or waives its right to an administrative appeals procedure and to petition the Court of Federal Claims.[36]
- → While the U.S. government has legal authority under § 1498 to use *any* U.S. patent, no matter who owns it and how it was generated, the Bayh-Dole Act only applies to "subject inventions"—patented inventions created with federal funding.[37] As a result, only a minority of patents are subject to the Bayh-Dole Act and to the possibility of march-in.
- → Government patent use under § 1498 has been used repeatedly by the U.S. government for over a century, creating a deep body of case law. By contrast, the U.S. government's march-in authority under the Bayh-Dole Act has never been used, although public interest groups have called for its use. [38]

IV. HOW DOES § 1498 BENEFIT BOTH PATENT HOLDERS AND THE GOVERNMENT?

Section 1498 provides a benefit to patent holders by creating a right to compensation in exchange for government use when, without § 1498, there would be none.[39] Prior to the enactment of § 1498, a patent holder would be entitled to no remedy for government patent use because such use was unchallengeable under the principle of "sovereign immunity." [40] "Sovereign immunity" refers to the legal doctrine preventing the government from being sued in its own courts or otherwise held legally liable. The government is "immune" from suit unless it waives its immunity.[41]

[35] For more thorough overviews of the Bayh-Dole Act, see Cong. Res. Serv., RL32076, *The Bayh-Dole Act: Selected Issues in Patent Policy and the Commercialization of Technology* (2012), https://www.everycrsreport.com/files/20121203_RL32076_836129be0e45a4049a32a64c143ec94df38236be.pdf and John R. Thomas, Cong. Res. Serv., RL44597, *March-In Rights Under the Bayh-Dole Act* (2016), https://fas.org/sgp/crs/misc/R44597.pdf.

[36] 35 U.S.C. § 203.

[37] Cong. Res. Serv., RL32076, *The Bayh-Dole Act: Selected Issues in Patent Policy and the Commercialization of Technology* (2012), at 7, https://www.everycrsreport.com/files/20121203_RL32076_836129be0e45a4049a32a64c143ec94df38236be.pdf

[38] John R. Thomas, Cong. Res. Serv., RL44597, March-In Rights Under the Bayh-Dole Act (2016), at 8, https://fas.org/sgp/crs/misc/R44597.pdf.

[39] Morten & Duan, *Who's Afraid of Section 1498? A Case for Government Patent Use in Pandemics and Other National Crises*, 22 Yale L.J. Tech, 13 (Forthcoming 2020) (explaining that the statute preceding the current version of § 1498 expanded patent holder rights when previously, due to sovereign immunity, there was no available remedy); *see also Golden v. United States*, 955 F.3d 981, 987 (Fed. Cir. 2020) (explaining that constitutional principles of sovereign immunity bar suits against the U.S. government for patent infringement but that § 1498 "added the right to sue the United States in the court of claims for patent infringement" (internal quotation marks, alteration, and citation omitted).

[40] Brennan at 299.

[41] Black's Law Dictionary (11th ed. 2019), available at Westlaw.

The passage of § 1498 effected a limited waiver of sovereign immunity. Consequently, patent holders may receive compensation from the sovereign—the United States government—under § 1498, although they still may not seek to prevent government use through an injunction.[42] For a more detailed discussion of how courts determine appropriate compensation under § 1498, refer to Section 4.C below.

The statute also produces benefits for the government. If the government uses a patent and the patent holder subsequently brings and wins a § 1498 claim, the government will owe the patent holder compensation, but what the government owes will typically be lower than what it would have paid to purchase the patented invention directly from the patent holder.[43] In particular, when the government elects to use a patent because it concludes that the price the patent holder charges for the patented invention is so excessively high that it causes substantial harm to the public, the compensation the court orders will likely reflect a price that is effectively significantly lower.[44] Beyond lowering prices, government use under § 1498 can also produce the public benefit of increasing public access to patented inventions in short supply. This is because the government could manufacture the patented invention itself or authorize non-government third parties to manufacture it, thereby increasing supply in cases where it might otherwise be restricted by the patent holder.[45]

Finally, the government will only owe compensation to the patent holder if the patent is determined to be valid, enforceable, and infringed, according to the standard elements of a patent infringement claim.[46] If the court deciding a § 1498 case determines that a patent is invalid, unenforceable, or not infringed, then the government will owe the patent holder no compensation.

B. HISTORICAL EXAMPLES

Government patent use in exchange for compensation to patent holders under § 1498 has a long history. On many occasions through the past century, U.S. government procurement officers have used § 1498—or the prospect of § 1498—to obtain lower prices or greater supply for goods needed by the government. Section 1498 has also been used to immunize certain non-governmental parties from patent infringement liability when those parties use others' patented inventions to provide some benefit to the U.S. government (and the American people). This subsection presents some historical examples that show government patent use under § 1498 in action, which span a wide range of technologies, including pharmaceuticals, software, and military supplies.

Green Bullets[47,48]

In the 1990s, the U.S. Department of Defense (DOD) identified a need for more reliably lethal bullets, and an executive order from President Clinton called for replacing standard-issue ammunition with lead-free bullets to reduce environmental impact. Years later, following the 9/11 attacks, an inventor developed a lead-free bullet with increased lethality and brought his invention to a U.S. Army official. The Army subsequently declined to use the inventor's bullet and developed its own instead, which the inventor alleged to infringe on his patent. The patent holder then filed suit in the Court of Federal Claims for patent infringement under § 1498, and the court found that the U.S. government had in fact used the inventor's patent. In awarding the patent holder "reasonable and entire compensation" under § 1498 in exchange for the government's patent use, the court determined that a hypothetical negotiation, had it occurred, would have yielded a price of $0.014 per ammunition round and ordered compensation to the patent holder from the government accordingly.

Night Vision Goggles[49]

In the late 1980s, the U.S. Army contracted a third party, American Optical, to produce several thousand pairs of night vision goggles. Gargoyles, Inc. sold and held a patent on a particular design of night vision goggles. Gargoyles alleged that American

[42] Brennan at 299.

[43] Kapczynski & Kesselheim at 794. *See also infra* Section 4.

[44] Kapczynski & Kesselheim at 793.

[45] *Id.* at 793.

[46] For explanation of the concepts of validity, enforceability, and infringement in patent law, see Section 4.B below.

[47] *Army Ammunition Goes Green and Infringement Free*, IP Update Vol 19, No. 9 (Sep. 2016), https://www.mwe.com/insights/ip-update-september-2016/.

[48] *Liberty Ammunition, Inc. v. United States*, 119 Fed. Cl. 368, 383 (2014).

[49] *Gargoyles, Inc. v. United States*, 113 F.3d 1572, 1576-77 (Fed. Cir. 1997).

Optical's goggles infringed its patent and filed suit against the government under § 1498. The court found the patent to be valid and used by the government and compensated the patent holder with its "reasonable and entire compensation": a reasonable royalty, calculated based on a hypothetical negotiation between a willing buyer and seller. The court also affirmed that Gargoyles was not entitled to any lost profits (an additional type of monetary compensation that Gargoyles had sought in addition to the reasonable royalty). The fact that the Army subsequently decided to deploy a different night vision goggle design, rather than Gargoyles' patented design, did not prevent the court from finding that this government use was properly "by and for" the government and therefore covered by § 1498. the government and therefore covered by § 1498.

Cipro[50]

In the midst of growing concern about potential anthrax attacks in the U.S. in 2001, the U.S. Department of Health and Human Services (HHS) sought to build a massive national stockpile of the antibiotic ciprofloxacin (Cipro), a treatment for the effects of anthrax. Bayer, a major pharmaceutical and chemical company, manufactured ciprofloxacin and held at least one in-force patent on the drug. Bayer initially told HHS that it was unable to make and sell a sufficient amount of ciprofloxacin to meet the government's needs, or to sell the drug at a price the government deemed reasonable. The HHS Secretary at the time, Tommy Thompson, announced that the government was prepared to purchase additional ciprofloxacin from generic manufacturers under § 1498, at a price lower than Bayer's. In response, Bayer agreed to ramp up production and cut its prices in half, close to what generic manufacturers offered. [51]

In 2002, shortly after the successful negotiation with Bayer, Alex Azar (who was then General Counsel of HHS and later became its Secretary under President Trump) wrote, "yes [Thompson] did save public health; yes, he saved taxpayers money; and yes, he really drove down the price and avoided litigation. And he did all of this with full knowledge of and while fully respecting patent law and food and drug law."[52]

For a more detailed account of this example, refer to Section 4.D.

Software[53]

In the early 2000s, the Federal Reserve Banks contracted with Fiserv, Inc. to purchase check fraud detection software. The software turned out to be covered by another company's patents. The Banks and Fiserv were subsequently found to be immune from patent infringement liability because their use of the patents was authorized under § 1498 by the U.S. Department of the Treasury. Although the Treasury was itself not party to the contract between the Banks and Fiserv, the Banks' use of the seal encoding technology was found to be "for the Government" and "with the authorization or consent of the Government." Therefore, Advanced Software, the patent holder, was entitled only to compensation from the government under § 1498, precluding any other claim of patent infringement against the Banks or Fiserv.

C. § 1498 IN THE CONTEXT OF NEGOTIATION

Government patent use under § 1498 is formally understood as the government actually using or manufacturing a patented invention by or for the United States. But even if the government does not formally use a patent under the statutory scheme of § 1498, the statute's existence may still be useful to achieve government goals, such as procuring needed goods, expanding overall supplies, or lowering prices for the government and consumers. In a situation involving high prices or critical shortages in which the government's primary goal is to improve accessibility of the patented invention to the American public, simply raising § 1498 in conversation with patent holders may prove useful to accomplishing that goal. The bargaining power of § 1498 in this context was illuminated in the ciprofloxacin (Cipro) example above, in which the HHS Secretary raised the possibility of government procurement of generic ciprofloxacin under the statute and Bayer responded by dramatically increasing supply and lowering prices. Section 1498 provides the U.S. government with significant leverage in bargaining with an intransigent patent holder.

[50] Kapczynski & Kesselheim at 794.

[51] Keith Bradsher & Edmund L. Andrews, *A NATION CHALLENGED: CIPRO; U.S. Says Bayer Will Cut Cost of Its Anthrax Drug*, New York Times (Oct. 24, 2001), https://www.nytimes.com/2001/10/24/business/a-nation-challenged-cipro-us-says-bayer-will-cut-cost-of-its-anthrax-drug.html.

[52] Alex Azar II, *Cipro: Good Deal, Good Policy*, Am. Law., Apr. 2002, at 141.

[53] *Advanced Software Design Corp. v. Fed. Reserve Bank of St. Louis,* 583 F.3d 1371 (Fed. Cir. 2009).

Why? In such a negotiation, the patent holder is motivated to work with the government to lower prices and increase supply because it knows that the government can always simply go ahead with using the patent under § 1498, in which case the patent holder's compensation would be limited to the "reasonable and entire compensation" determined by the Court of Federal Claims. The patent holder might prefer to avoid the time, expense, and uncertainty of litigating under § 1498 (which necessarily triggers the possibility of its patent being found legally void, as invalid or unenforceable) and instead agree to mutually acceptable price and supply terms. As we explain below in Section 4, the likely result of negotiation in the "shadow" of § 1498 is an agreed-upon price for the patented invention that is lower than what the government or its authorized third party would have to pay the patent holder absent any negotiation.

SECTION 3

APPLYING § 1498 TO PATENT USE "BY" AND "FOR" THE GOVERNMENT

As mentioned in Section 2(a)(i), § 1498 authorizes use or manufacture of patented products or technology by entities other than the patent holder, when done "by or for the government."[54] In this Section, we outline what conditions, if any, the government and third parties need to meet for the courts to confirm that § 1498 applies to their use of a patent.

In short, when the government uses a patent directly, things are simple. That use is "by" the government and therefore automatically authorized under § 1498, so there is nothing the government needs to do to ensure that § 1498 applies.[55]

When a non-government third party uses a patent, however, things are somewhat more complicated. Third-party patent use is covered by § 1498 only when it is both "authorized" by and undertaken "for" the government.[56] We explain in detail in subsection 3.B below how the government and its authorized third-party contractors can take steps to ensure that those contractors' use is properly covered by the statute.

A. "BY" THE GOVERNMENT: DIRECT, INDEPENDENT PATENT USE BY THE U.S. GOVERNMENT

If the government itself is the direct user or manufacturer of a patented technology, and acts completely independently, without the involvement of a third party, the technology is inherently "used or manufactured by or for the United States."[57] For example, the government could choose to manufacture patented defense technology or pharmaceuticals in a government-owned, government-operated facility.[58] If the production process and use are performed without any third party involvement, there are no grounds for a patent holder to challenge whether § 1498 applies.[59]

Because all direct patent use by the U.S. government is automatically within the realm of § 1498, the law will apply whether the government uses the patented technology intentionally or does so unintentionally.[60] The law also applies regardless of whether the government provides notice to the patent holder that its patent will be used pursuant to § 1498, and regardless of whether the government makes an official statement of how it will benefit from the use.[61] However, there are

[54] 28 U.S.C. § 1498(a).

[55] Brennan at 330.

[56] *Id.*

[57] *See* Alex Wang & Aaron S. Kesselheim, *Government Patent Use to Address the Rising Cost of Naloxone: 28 U.S.C. § 1498 and Evzio*, 46 J.L. Med. & Ethics 472 (2018).

[58] Senator Elizabeth Warren and Representative Jan Schakowsky have proposed legislation that would establish a federal "Office of Drug Manufacturing" within the Department of Health and Human Services that would "manufactur[e] select generic drugs and offer[] them to consumers at a fair price that guarantees affordable patient access." *See Schakowsky, Warren Reintroduce Affordable Drug Manufacturing Act, Legislation to Radically Reduce Drug Prices through Public Manufacturing of Prescription Drugs* (Dec. 20, 2019), https://www.warren.senate.gov/newsroom/press-releases/schakowsky-warren-reintroduce-affordable-drug-manufacturing-act-legislation-to-radically-reduce-drug-prices-through-public-manufacturing-of-prescription-drugs. Direct manufacturing of patented drugs by this proposed federal office would constitute "use" by the government itself.

[59] Morten & Duan.

[60] *Advanced Software*, 583 F.3d at 1377.

[61] Morten & Duan at 51-52.

sound policy reasons for the government to provide notice to the patent holder and to the public of its plans to use a patent, when possible, including to maintain open communications and relationships with patent holders.

B. "FOR" THE GOVERNMENT: AUTHORIZED THIRD-PARTY PATENT USE ON BEHALF OF THE GOVERNMENT

Section 1498 also expressly applies to third-party activity, including the government's many dealings with contractors and subcontractors.[62] Although the government is not the direct user of a patent in situations like this, its contractors' and subcontractors' use of the patent may still be within the scope of § 1498.[63] For example, the government can use § 1498 to contract with a generic drug manufacturer to produce and supply the government with a patented pharmaceutical, and has done so in years past.[64]

A third party's use of a patent is within the scope of § 1498 when the use is (1) "for the government" and (2) "with the authorization or consent of the government".[65] We refer to this two-part legal test as the "government use test" of § 1498. The government use test can be fulfilled in a number of ways.[66] The focus of this subsection is explaining precisely how.

First, though, a few important foundational principles of authorized third-party patent use on behalf of the government under § 1498: As was the case for direct patent use by the government, the government may "activate" its powers under § 1498 either before or after third-party use occurs, and whether it originally intended the third-party use or did not know of it.[67]

Accordingly, neither notice to the patent holder nor any official announcement of § 1498 is *necessary*; however, performing those actions—as described below in Section 3.B—will help the government more easily meet the government use test.[68] In addition, there may be good policy reasons for the government to provide official notice to the patent holder and to the public that it is authorizing a third-party contractor to use a patent, such as to maintain open relationships with patent holders and to assure the third-party contractor that its authorization is official.

When the government use test is met, the third party's use of the patent is brought within the scope of § 1498 and all the normal rules of § 1498 apply. That means that the patent holder's only legal remedy for the third party's use of the patent is a § 1498 suit against the government in the Court of Federal Claims. The patent holder cannot bring a standard patent infringement suit directly against the third party. (If the patent holder does bring such a suit against the third party, the court will dismiss it and direct the patent holder to file a § 1498 suit instead.[69]) In effect, by authorizing the third party to use the patent on its behalf, the government assumes the third party's liability for using the patent.[70]

(1) "FOR THE GOVERNMENT"

To meet the first part of the two-part government use test, the third party's use of a patent must be "for the government."

A government agency may designate use by a third party as "for the government" either explicitly or implicitly.[71]

If the government is procuring patented goods or services for its own consumption—as, for example, the

[62] 28 U.S.C. § 1498(a) ("For the purposes of this section, the use or manufacture of an invention described in and covered by a patent of the United States by a contractor, a subcontractor, or any person, firm, or corporation for the Government and with the authorization or consent of the Government, shall be construed as use or manufacture for the United States.").

[63] *Id. See also* Morten & Duan at 52.

[64] Brennan at 303-07.

[65] 28 U.S.C. § 1498(a); Madey v. Duke Univ., 307 F.3d 1351, 1359 (Fed. Cir. 2002); Brennan at 300.

[66] Brennan at 332.

[67] Morten & Duan at 52.

[68] Brennan at 332.

[69] 28 U.S.C. § 1498(a). *See, e.g., Advanced Software*, 583 F.3d at 1379 (affirming dismissal of patent holder's infringement suit against Federal Reserve Banks and a private company, Fiserv Inc., because both were using a patent for the U.S. government and with the government's authorization); *Saint-Gobain Ceramics & Plastics, Inc.* v. II-VI Inc., 369 F. Supp. 3d 963, 983 (C.D. Cal. 2019) (dismissing a patent holder's infringement suit against manufacturers of synthetic gemstone sheets because those manufacturers were manufacturing for the U.S. government and with the government's authorization).

[70] *Crozier v. Krupp*, 224 U.S. 290, 305 (1912); *Tektronix, Inc. v. United States*, 552 F.2d 343, 351 (Ct. Cl. 1977); *modified*, 557 F.2d 265 (Ct. Cl. 1977).

[71] *Hughes Aircraft Co. v. United States*, 534 F.2d 889, 901 (Ct. Cl. 1976).

Department of Defense does with military equipment—the "for the government" condition will almost certainly be fulfilled; courts typically will not inquire further into details of the use or how the government benefits from using the goods procured.[72] If possible, the procurement contract should specifically mention § 1498 and the patent in question, but this is not required, as was evidenced in many government contracts during World War II. [73]

If the government is not directly consuming the patented goods or services, the third party can instead establish that the use is "for the government" by showing that the production was for the "benefit" of the government, in a way that is not "merely incidental" to private benefits.[78] A federal agency or third-party contractor can demonstrate that the benefit is more than incidental in a number of ways.[79]

For one, when the government itself is the primary beneficiary of the patent use, that fact alone is strong evidence of public benefit sufficient to meet the legal test.[80] For example, if a government agency procures drugs and then distributes them to Americans who qualify for certain government benefits in so-called direct purchasing programs—as, for example, the Veterans Health Administration,[81] Department of Defense,[82] CDC, [83] and Health Resources and Services Administration (HRSA)[84] do—the government might use its § 1498 authority to contract with a generic drug manufacturer to supply a generic version of a costly patented drug at a lower price. In this scenario, if the government agency uses its savings under § 1498 to redirect spending toward other lawful agency priorities, then the primary beneficiary is the agency, even though the ultimate consumer of the drug is not the agency itself. The benefits to the agency should easily constitute a sufficient "non-incidental" government benefit under the government use test.[85] (In the 20th Century, multiple

SPECIAL CONSIDERATIONS FOR PROCUREMENT CONTRACTS SUBJECT TO THE FEDERAL ACQUISITION REGULATION (FAR)

Many government procurement contracts are subject to the Federal Acquisition Regulation (**FAR**),[74] which establishes guidelines and default rules for these contracts. Contracts governed by the FAR create a default rule under which the contractor (vendor) must "indemnify"—reimburse—the U.S. government in the event that the goods or services procured infringe patents.[75]

This does not mean that § 1498 cannot apply to procurement contracts subject to the FAR. If the government wishes to exercise its § 1498 authority in relation to such a FAR contract, the relevant agency head can simply execute a standardized document called a "Waiver of Indemnity."[76] As the name suggests, the Waiver of Indemnity waives the contractor's obligation to reimburse the government in the event of patent infringement and therefore ensures that any liability for patent infringement will be borne by the government, pursuant to the normal rules of § 1498.[77]

[72] *Sevenson Envtl Servs., Inc. v. Shaw Envtl, Inc.*, 477 F.3d 1361, 1366 (Fed. Cir. 2007).

[73] Brennan at 300.

[74] 48 C.F.R. Chapter 1.

[75] Brennan at 346-47. According to Black's Law Dictionary, to "indemnify" is "to reimburse (another) for a loss suffered because of a third party's or one's own act or default" or "to promise to reimburse (another) for such a loss." Black's Law Dictionary (11th ed. 2019), available at Westlaw.

[76] 48 CFR § 52.227-5.

[77] Brennan at 346 n.334.

[78] *Advanced Software*, 583 F.3d at 1378.

[79] For more detailed analysis of how various federal agencies could establish that generic manufacturing of patented drugs authorized under § 1498 is properly "for the government," *see* Brennan at 345-53.

[80] *Id.*

[81] Mike McCaughan, Veterans Health Administration, Health Affairs (Aug. 10, 2017), https://www.healthaffairs.org/do/10.1377/hpb20171008.000174/full/.

[82] Tricare Pharmacy, https://www.tricare.mil/CoveredServices/Pharmacy.

[83] CDC Drug Service, https://www.cdc.gov/laboratory/drugservice/index.html.

[84] HRSA, About the Ryan White HIV/AIDS Program, https://hab.hrsa.gov/about-ryan-white-hivaids-program/about-ryan-white-hivaids-program.

[85] Brennan at 334-35.

federal agencies, including the Department of Defense and Veterans Administration, successfully used § 1498 in this manner to supply themselves with low-cost generic drugs.[86])

When the government's own programs are not the primary beneficiary of the patent use, the government can still fulfill the "for the government" requirement indirectly if the use serves a "national interest," for example, to avert financial fraud throughout the United States.[87] Important aid to the national interest as a whole suffices to establish a government benefit.[88]

Whenever the government explains the purpose of its use of § 1498 and articulates how the use serves the national interest, courts tend to defer to that assertion.[89] The government's assertion of benefit to the national interest can be made in a number of ways, such as through a contract with or letter to the authorized third party or through direct communication between the government and the court in which the third party appears.[90]

For example, imagine that, pursuant to § 1498, the HHS contracts with a generic manufacturer of drugs not just to supply its own agencies that distribute such drugs directly but also to supply low-cost drugs to non-governmental private insurers that HHS reimburses under contracts administered through Medicare Part D. The "for the government" test can be met under these circumstances. To meet the test, the HHS should explain, through a press release or other statement, how the authorized sales to third parties serve a substantial national interest.[91] HHS could bolster its case by using the cost savings it enjoys (from lowered reimbursement costs arising from lower drug costs) to expand the health coverage HHS and its constituent agency, the Centers for Medicare & Medicaid Services (CMS), provide the nation—e.g., by providing funding to improve healthcare in rural hospitals.[92] Redirecting the cost savings in this manner would strengthen HHS's argument that these third party sales serve the national interest and could even lead a court to find that HHS is a primary beneficiary of those sales.[93]

What if the third-party patent use is *entirely* private? For example, what if the U.S. government authorizes a generic manufacturer to use a patent to make and distribute drugs to other third parties with which the government does *not* have any direct relationship, such as wholly private health insurers? In this scenario, the government would not obtain any cost savings (though those private health insurers would).[94] This context is the most attenuated and least likely to fulfill the requirements of the government use test,[95] although there may be circumstances where simply lowering the cost of and/or expanding access to a patented technology for private purchasers would serve the national interest—e.g., where the patented technology is a diagnostic test or a vaccine in the midst of a crisis of infectious disease.

(2) "WITH THE AUTHORIZATION OR CONSENT OF THE GOVERNMENT"

To meet the second part of the two-part government use test, the third party's use of a patent must be "with the authorization or consent of the government."

Courts are generous in finding that the government has provided authorization or consent; authorization or consent can be explicit or implied, and can be provided in advance of the patent use or after the use has already occurred.[96,97]

The most reliable way for a government agency to provide authorization is to explicitly authorize or consent to third-party production of patented technology, acknowledging that it is aware of the relevant patent and that the third party is not the patent holder, before or while the use occurs. As with the

[86] *Id.* at 304.

[87] *Advanced Software,* 583 F.3d at 1376.

[88] *Iris v. Japan Airlines*, 769 F.3d at 1362, *Advanced Software*, 583 F.3d at 1376; *see also Larson v. United States*, 26 Cl. Ct. 365, 369 (1992).

[89] *Iris v. Japan Airlines* 769 F.3d at 1362, *Advanced Software,* 583 F.3d at 1376.

[90] Advanced Software, 583 F.3d at 1377-78.

[91] Brennan at 336; see also Larson, 26 Cl. Ct. at 369.

[92] Mallory Hackett, *CMS is now accepting grant applications from rural communities to improve healthcare*, Healthcare Finance News (Sep. 16, 2020), https://www.healthcarefinancenews.com/news/cms-now-accepting-grant-applications-rural-communities-improve-healthcare.

[93] Brennan at 336.

[94] *Id.* at 337.

[95] *Id.* at 332-33.

[96] *Hughes Aircraft*, 534 F.2d at 901; Brennan at 333.

[97] Throughout this subsection, the term "authorization and consent" is captured in the abbreviated term "authorization."

"for the government" part of the test described in the preceding Section 3.B, authorization is best and most often given in a third-party contract, but may also be given through other types of documents or statements, such as a letter of instruction to the third party or through communication with a court where the third party appears.[98] Furthermore, the assertion of government benefit discussed in Section 3.B can itself serve as such authorization; it is therefore very efficient for the government to articulate both benefit and authorization in a single document, such as a contract.[99]

However, there are many ways in which, in the absence of explicit communication, the government can grant authorization implicitly. For example, the government may give the third party instructions, such as in a government-made blueprint, that necessitate the use of patented technology.[100]

Furthermore, if the government provides neither explicit nor implicit authorization *prior* to use, it can do so *after* the use occurs.[101] Such retroactive authorization is particularly beneficial to both the government and the third party in instances of accidental use, where either the government or the third party does not realize the third party is using patented technology. The third party's use need not be accidental for retroactive authorization, and the government need not make an "excuse" for not providing authorization beforehand.[102]

WHO WITHIN THE U.S. GOVERNMENT CAN USE § 1498?

Any U.S. government official can use § 1498 in their official capacity. There are no restrictions on which government actors—individual officials, administrative agencies, or other government entities—may exercise the government's authority under § 1498.

When the government authorizes a third party to use a patent, there are likewise no restrictions on who within the government may supply the third party with various forms of authorization. Any government official acting in their official capacity can provide the necessary authorization.

In fact, in many of the historical examples of government patent use under § 1498 mentioned in Section 2.B, the decisions to procure patented technology from third-party vendors were made by relatively junior officials, such as procurement officers. (For example, in the night vision goggle case summarized in Section 2, it was apparently a U.S. Army optometrist, Colonel Francis LaPiana, and other relatively low-level Army officials who issued the request for proposals that led the Army to procure patent-infringing goggles. The procurement was squarely covered by § 1498.[103]) A government employee need not be a Cabinet-level official or an agency director to make use of § 1498.

That said, while not legally necessary, it may be best for public policy reasons—such as to ensure public perception of legitimacy—that official authorization of government patent use under § 1498 comes from senior officials in some cases. (For example, in the 2001 anthrax response, it was a Cabinet Secretary (HHS Secretary Tommy Thompson) who negotiated directly with a patent holder (Bayer) and threatened to authorize competitors to use its patent on ciprofloxacin (Cipro).) When undertaking large-scale manufacturing or procurement under § 1498, an executive agency might collaborate with the White House to issue a joint press release announcing the decision to exercise the government patent use power and explaining the expected benefits.

Any agency or agency official considering whether to make use of their government patent use authority under § 1498 should do so in accordance with the agency's internal practices and procedures. Each agency has its own laws and policies governing agency decision-making, and agency officials should, of course, comply with those laws and policies.

[98] *Sevenson Envtl Servs., Inc. v. Shaw Envtl, Inc.,* 477 F.3d 1361, 1366 (Fed. Cir. 2007).

[99] Brennan at 333.

[100] *Hughes Aircraft*, 534 F.2d at 901.

[101] *Id.*

[102] *Advanced Software*, 583 F.3d at 1377-78.

[103] *See Gargoyles*, 113 F.3d at 1574.

UNIQUE CONTEXTS FOR THIRD-PARTY PATENT USE

Beyond direct government patent use and indirect government patent use by a single authorized third party, there are other ways in which the government can employ § 1498. We discuss two in this short subsection. First, the government can authorize multiple third parties, or even an entire field of industry, to use a patent. Additionally, there are contexts in which the government may wish to use § 1498 in conjunction with other statutes, specifically the Defense Production Act.

§ 1498 as a Shield for General Production: industry-wide government patent use "for the government, with the authorization or consent of the government"

The government might be able to use § 1498 very broadly, to provide sweeping patent use authorization to an entire industry, rather than to a specific third party.[104] This ability would be useful if the government wishes to ask an entire industry to develop a much-needed product or to solve a specific technological problem and wants to ensure that potential liability for patent infringement does not slow the industry's efforts.

For example, the U.S. government might authorize the pharmaceutical industry to use patents in a wide-ranging effort to develop life-saving drugs in the face of a pandemic or epidemic. Individual pharmaceutical companies would then be empowered to use any and all existing technologies in their effort to develop new drugs, even if those technologies are covered by others' patents and even if the relevant patents are not yet known.

Because the government has not yet used § 1498 in this industry-wide fashion, there is no clear roadmap to fulfilling the government use test in these situations. Authorizing the relevant third parties to use patents and establishing that their use is "for" the United States may be more challenging than when dealing with a single third party, because there will not be a single contract and the public benefit might be vague or uncertain. However, the test may still very well be met, if (1) the authorization from the government is clear, and explicitly mentions § 1498 and an intended government benefit; and (2) the resulting technologies will be used or distributed by the government in some fashion, for public benefit. The government should also be prepared to communicate all of the above to a court that hears any patent infringement claims against members of the industry that act upon the government's invitation.

§ 1498 and the Defense Production Act

Under the Defense Production Act (DPA), a law distinct from § 1498, the government is authorized to take control of private manufacturing when doing so is "necessary or appropriate to promote the national defense."[105] Such authority enables the government to meet a demand quickly by compelling manufacturers to ramp up production of needed supplies. The needed supply might be patented, and the patent holder alone might not be able or willing to meet demand. Further, the patent holder may not be willing to license to other producers to help meet demand, or other producers might not want to do so. In these instances, the government can address the supply issue by using § 1498 and the DPA simultaneously, to compel a manufacturer to manufacture needed technology that is patented by another party.[106] (For example, in the midst of the COVID-19 pandemic, President Donald Trump ordered 3M to prioritize orders from the Federal Emergency Management Agency for 3M's N95 respirators.[107] To scale up production, President Trump could have—but did not—authorized competing manufacturers to use 3M's patents to manufacture similar N95 respirators.[108])

Use of § 1498 together with the DPA can be justified on two distinct legal bases. First, such patent use is arguably done directly "by" the government, despite the involvement of third parties, as those third parties are under the control of the government at the time of use. Second, if deemed to be third-party patent use rather than direct use by the government, such patent use is almost certainly "for" the government. While third-party facilities, personnel, and other assets may be involved, a court is highly likely to conclude that any action undertaken by the third party under government control is action "for" the United States and that meets the "government use test," as described in Section 3.B.

[104] Morten & Duan at 60.

[105] Defense Production Act of 1950, 50 U.S.C. § 4511(a).

[106] Morten & Duan at 47.

[107] 3M, *3M Response to Defense Production Act* Order (Apr. 3, 2020), https://news.3m.com/English/press-releases/press-releases-details/2020/3M-Response-to-Defense-Production-Act-Order/default.aspx.

[108] 3M apparently holds patents on its N95 respirators, which it had not licensed to competitors as of April 2020. *See* Morgan Watkins, *Kentucky Gov. Andy Beshear Calls on 3M to Release Patent for N95 Respirator Amid Pandemic*, Louisville Courier J. (Apr. 3, 2020), https://www.courier-journal.com/story/news/2020/04/03/beshear-calls-3-m-release-patent-n-95-respirator-amid-pandemic/5112729002/.

SECTION 4

LITIGATION UNDER § 1498 AND THE DETERMINATION OF "REASONABLE AND ENTIRE COMPENSATION"

What happens after a U.S. government agency uses a patent, whether directly or through a third party with appropriate authorization or consent? The patent holder is likely to sue for compensation.[109] Consistent with the statutory language of § 1498, the patent holder is owed "reasonable and entire compensation" from the government for the use, which is generally calculated as a reasonable royalty on the patented technology.[110]

This section addresses litigation under § 1498 and a court's determination of the "reasonable and entire compensation" the government owes under the statute. The section proceeds in four subsections. The first subsection, "'Reasonable and entire' compensation is the patent holder's exclusive remedy for patent use by or for the government," explains that a lawsuit under § 1498 is generally a patent holder's only legal avenue to obtain compensation for use of its patent. Any other litigation brought by the patent holder will be dismissed. The second subsection, "A patent holder may only collect compensation if the patent is valid and enforceable and the government's use is deemed to infringe the patent," explains that the relevant court often finds that the government is not liable for using a particular patent under § 1498—and accordingly will not owe *any* compensation to the patent holder. The third subsection, "Determination of 'reasonable and entire' compensation," explains in detail how the relevant court calculates the appropriate compensation—usually a reasonable

WHAT IS A "ROYALTY"?

A royalty is a payment made to a patent holder for each copy of a patented invention—e.g., $1 per patented pill or 10% of an authorized third-party contractor's revenues on patented night-vision goggles.[111]

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[109] Depending on the particular U.S. government agency that uses a patent, and the nature of that use, a patent holder could conceivably attempt some kind of administrative redress before proceeding to court. See Lionel M. Lavenue, *Patent Infringement Against the United States and Government Contractors Under 28 U.S.C. § 1498 in the United States Court of Federal Claims*, 2 J. Intell. Prop. L. 389, 453 (1995) ("Lavenue"). Whether an avenue for administrative redress exists depends on the agency and the nature of its use, but in general, federal administrative bodies, including the Comptroller General and the Boards of Contract Appeals, have rejected patent holders' administrative challenges and directed those patent holders to file § 1498 lawsuits in court instead. See id. at 453-58.

[110] *Hughes Aircraft Co. v. United States,* 86 F.3d 1566, 1572 (Fed. Cir. 1996) ("Generally, the preferred manner of reasonably and entirely compensating the patent holder is to require the government to pay a reasonable royalty for its license").

[111] Black's Law Dictionary defines an intellectual property royalty as follows: "A payment—in addition to or in place of an up-front payment—made to an author or inventor for each copy of a work or article sold under a copyright or patent. Royalties are often paid per item made, used, or sold, or per time elapsed." Black's Law Dictionary (11th ed. 2019), available at Westlaw.

royalty calculated at market rate—in the event that the government is found liable. Finally, the fourth subsection, "Bargaining in the shadow of 'reasonable and entire' compensation," explains how the liability and compensation rules laid out in the first three subsections inform bargaining between the U.S. government and a patent holder, in the event that the government chooses to approach the patent holder to negotiate a direct purchase of patented goods or a license to the patent.

Before we dive in, a few foundational points. First, all § 1498 lawsuits are taken up by a specialized federal court, the Court of Federal Claims, which determines the appropriate measure of "reasonable and entire" compensation. Second, any federal agency that uses a patent and becomes involved in litigation under § 1498 receives legal help from the U.S. Department of Justice, which includes a dedicated section—the Intellectual Property Section of the Commercial Litigation Branch—expert in representing the U.S. government in § 1498 suits.[112] These DOJ lawyers represent the U.S. government in multiple § 1498 suits every year.[113] Third, any court-ordered compensation ultimately paid by the government to the patent holder is paid from the U.S. Treasury's Judgment Fund, not from the budget of the agency that uses the patent. [114]

KEY TAKEAWAYS ON THE "REASONABLE AND ENTIRE COMPENSATION" PAID FOR GOVERNMENT PATENT USE UNDER § 1498

While there is no one-size-fits-all solution for determining "reasonable and entire compensation" under § 1498, there are a few things we can say for certain:

- → "Reasonable and entire" compensation to the patent holder under § 1498 will generally be less than the cost of acquiring the patented technology on the open market—sometimes significantly so.[115]
- → At the same time, § 1498's compensation structure is not unduly punitive to patent holders. The compensation paid—usually a "reasonable royalty"—generally reimburses the patent holder for the fair market value of the patent rights over the life of the patent.
- → Beyond the "reasonable and entire compensation," use of patented technology under § 1498 generally does not result in **any** additional legal liability for the government **or** its authorized third-party contractors.

[112] U.S. Department of Justice, Intellectual Property Section (Aug. 14, 2017), https://www.justice.gov/civil/intellectual-property-section ("Litigation forms the majority of the Intellectual Property Section's workload. Section attorneys represent the United States in suits in the Court of Federal Claims under Title 28, section 1498 of the United States Code (28 U.S.C. § 1498).").

[113] In the 1990s, Lavenue calculated that "[s]ince the enactment of 28 U.S.C. § 1498, the Court of Federal Claims and its predecessor courts have decided an average of five and one-half cases a year." Lavenue at 496. Morten and Duan reported over 100 § 1498 cases decided in the 2010s. Morten & Duan at 68 n.288.

[114] *See* Jenna Greene, *Judgment Fund: Feds Paid $87M in Patent Cases; The largest infringement award came in a dispute over night-vision goggles*, Nat'l. L. J. (2015) (describing the U.S. government's payment from the Treasury's Judgment Fund to settle infringement lawsuits against the government); Lavenue at 456 n.377.

[115] *Leesona Corp. v. United States*, 599 F.2d 958 (Ct. Cl. 1979), *cert. denied*, 444 U.S. 991 (1979) (considering the price the patent holder bid to produce the patented goods a "ceiling" on the awardable amount); *see also Tektronix*, 552 F.2d at 351 (under § 1498, the "goal of 'complete justice' implies that only a reasonable, not an excessive, royalty should be allowed where the United States is the user—even though the patentee, as a monopolist, might be able to exact excessive gains from private users").

A. "REASONABLE AND ENTIRE" COMPENSATION IS THE PATENT HOLDER'S EXCLUSIVE REMEDY FOR PATENT USE BY OR FOR THE GOVERNMENT

When patented technology is used "by or for" the government, the patent holder's sole remedy is a suit for "reasonable and entire" compensation at the Court of Federal Claims.[116] Section 1498 provides broad immunity to the government and its contractors from traditional forms of infringement liability falling outside of the scope of § 1498. Patent holders are barred from bringing separate claims of patent infringement against the government (e.g., claims of infringement under § 271(a) and claims of induced infringement under § 271(b)), and are foreclosed from seeking additional remedies such as punitive damages.[117] In addition, courts cannot issue injunctions to prevent or cease government use of patented technology.[118] "Reasonable and entire" compensation is the sole remedy for patent holders under § 1498.[119]

No separate liability exists for government contractors or third-party manufacturers who make or use patented technology on behalf of the government.[120] When claims are brought against third parties in federal district courts, courts are quick to dismiss them so long as the infringing use satisfies the "by and for" analysis described in Section 3.[121] This is particularly straightforward when the government expressly indicates that the third-party patent use was authorized for a particular government benefit. In one example, the government submitted an amicus brief (i.e., a legal brief from an outside party) during a patent litigation brought by a patent holder against third-party contractors to confirm that it had authorized the contractor's patent use; the court subsequently dismissed the infringement claims against those contractors.[122] Even when a third party's infringement is unwitting and serves only an attenuated government purpose, § 1498 can be used so long as the government provides retroactive authorization and can demonstrate retroactively a benefit to the government.[123]

If the court finds that the third-party use falls within § 1498, any lawsuits against the third party in federal district courts will be dismissed, and the patent holder will be able to bring separate claims against the government under § 1498 at the Court of Federal Claims. The third parties using patents under the government's authorization may then participate as third-party defendants in § 1498 suits and can submit evidence to aid in the determination of reasonable royalties.

As an additional backstop against third-party liability for patent use, the government may choose to indemnify third party government contractors.[124] Indemnification provides third parties with an explicit promise that the government will pay for any judgment against them. Indemnification provisions can be included in contracts with third parties before litigation occurs, so that third parties can use patents freely under § 1498 without concerns of future financial liability. In other situations, third-party contractor's may alternatively choose to indemnify in the opposite direction, indemnifying the U.S. government to limit the government's financial liability for the third party's patent use.

[116] Courts have repeatedly affirmed that patent holders may not pursue a separate Fifth Amendment "takings" claim against the government for the government's patent use. If any ambiguity had previously existed, the Court of Appeals for the Federal Circuit extinguished it with its recent holding in Golden v. United States. See Golden v. United States, 955 F.3d 981 (Fed. Cir. 2020) ("the Claims Court does not have jurisdiction to hear takings claims based on alleged patent infringement by the government. Those claims . . . are to be pursued exclusively under 28 U.S.C. § 1498," "[1498] provides the only avenue for a patent holder to bring an action against the government for patent infringement.") The Supreme Court denied certiorari in Golden in December 2020, meaning the Federal Circuit's decision remains the law. See Golden v. United States, No. 20-5532, 2020 WL 7132384 (U.S. Dec. 7, 2020).

[117] *Astornet Technologies Inc. v. BAE Systems, Inc.,* 802 F.3d 1271 (Fed. Cir. 2015).

[118] *Leesona*, 599 F.2d at 969 ("injunctive relief of 35 U.S.C. § 283 could not be awarded, of course, since this court lacks the power to grant such relief").

[119] *Id*. ("An aggrieved party is entitled to receive only reasonable and entire compensation, not more than that.").

[120] See *Richmond Screw Anchor Co. v. United States*, 275 U.S. 331 (1928) ("Congress, in passing [1918 amendment to 1910 Act], was also accepting government liability for the patent infringement of its contractors"); *see also Crozier v. Krupp*, 224 U.S. at 305.

[121] *See Iris v. Japan Airlines*, 769 F.3d at 1362; *see also Advanced Software*, 583 F.3d at 1379 (dismissing counts of patent infringement on the ground that the acts were "by or for the United States" and could only be pursued under 28 U.S.C. § 1498).

[122] Advanced Software, 583 F.3d at 1377-78 (finding authorization and consent from correspondence from a government agency to the infringer and from statements of the government acting as amicus curiae).

[123] See Japan Airlines, 769 F.3d 1359, 1362 (Fed. Cir. 2014).

[124] Administrative Conference of the United States, Federal Government Indemnification of Government Contractors (Jun. 9, 1988), https://www.acus.gov/recommendation/federal-government-indemnification-government-contractors.

B. A PATENT HOLDER MAY ONLY COLLECT COMPENSATION IF ITS PATENT IS *VALID* AND ENFORCEABLE AND THE GOVERNMENT'S USE IS DEEMED TO *INFRINGE* THE PATENT

When the Court of Federal Claims takes up a § 1498 claim against the government, the court does not proceed immediately to calculation of the "reasonable and entire compensation" owed to the patent holder. Instead, the court first determines whether the U.S. government is actually liable for using the patent. Specifically, the court may determine (i) whether the patent in question is valid and enforceable and will always determine (ii) whether the government's use constitutes infringement.[125] If the Court of Federal Claims determines that a patent is invalid or unenforceable at step (i), or if it determines that the government's use does not actually infringe the patent at step (ii), then no compensation will be owed to the patent holder.[126]

Validity, enforceability, and infringement of patents used by the government under § 1498 are generally analyzed similarly to private patent infringement lawsuits and offer the government most of the same legal defenses available to private parties accused of infringing a patent.[127]

I. VALIDITY AND ENFORCEABILITY

To be valid, a patent must meet all of the statutory requirements outlined in the 1952 Patent Act. Not all issued patents are valid; many invalid, legally defective patents are granted incorrectly by the U.S. Patent & Trademark Office. These fatal defects may be exposed during litigation. For instance, the Court of Federal Claims may conclude that a patent is invalid for failing to meet the "enablement" requirements of 35 U.S.C. § 112(a), or perhaps for not being "novel" (§ 102) or "non-obvious" (§ 103) at the time of filing. If the court finds a patent invalid, the patent functionally ceases to exist, and the government is not liable for its use.

Patents issued by the USPTO enjoy a "presumption of validity."[128] This means that an issued patent will be deemed valid by the court unless the government proves by "clear and convincing" evidence that the patent is invalid. Challenges to a patent's validity are commonplace in patent litigation, and more than 40% are successful.[129] Accordingly, a defense of invalidity provides a key opportunity for the government to avoid owing compensation for use of a patent that is not valid under U.S. patent law.

A patent's enforceability is less about whether the patent meets the statutory requirements of the Patent Act, and more based on the equity and fairness of asserting the patent against the alleged infringer—in a § 1498 case, the U.S. government or an authorized third party. For instance, a patent may be held unenforceable as a result of inequitable conduct during prosecution of the patent, fraud, or "unclean hands."[130] As with validity, the Court of Federal Claims presumes that all patents issued by the USPTO are enforceable, but the government may prove otherwise. If the government proves that a patent is unenforceable, it will not owe any compensation for using the patent.

II. INFRINGEMENT

If the Court of Federal Claims concludes that the patent is valid and enforceable, the court will address the question of infringement. Under § 1498, infringement occurs whenever "an invention described in and covered by a patent of the United States is ***used*** or

[125] When defending a § 1498 suit, in addition to arguing that the patent is invalid, unenforceable, or not infringed, the U.S. government can raise other arguments in a § 1498 suit to establish that it is not liable. For example, a statute of limitations applies to § 1498 suits: the patent holder must bring suit within six years of the government's use or its suit will be dismissed. *See, e.g., Filler v. United States*, 148 Fed. Cl. 123, 144 (2020). An exhaustive list of all of these potential arguments is beyond the scope of this guide.

[126] Morten & Duan at 69.

[127] *Id.* ("Like any defendant in standard infringement litigation, the government owes no compensation whatsoever if the asserted patent turns out to be invalid, unenforceable, or not infringed."); *see also* Lavenue at 458.

[128] 35 U.S.C. § 282.

[129] When patents are challenged as invalid, district courts find them invalid 42.6% of the time. Josh Landau, *A Little More Than Forty Percent: Outcomes At The PTAB, District Court, and the EPO, Patent Progress* (May 1, 2018), https://www.patentprogress.org/2018/05/01/a-little-more-than-forty-percent.

[130] The doctrine of "unclean hands" can result in the dismissal of a patentee's infringement case when "particularly egregious misconduct [is discovered], including perjury, the manufacture of false evidence, and the suppression of evidence," during prosecution. Inequitable conduct embraces a broader scope of misconduct, including "both egregious affirmative acts of misconduct intended to deceive both the PTO and the courts but also the mere nondisclosure of information to the PTO." *See Therasense Inc. v. Becton Dickinson and Co.*, 649 F.3d 1276, 1288 (Fed. Cir. 2011).

manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same."[131]

Infringement is determined with respect to a patent's claims, and requires that the patent holder demonstrate that every element of its patented invention is present in the government's allegedly infringing use. For instance, if a patent claims a product containing ingredients A, B, and C, the government will only be deemed to infringe if it purchases, distributes, or otherwise "uses" a product that contains ingredients A, B and C (or equivalents thereof)—a product that contains ingredients A and B without ingredient C will not infringe. (In one recent case, the Court of Appeals for the Federal Circuit—the federal court that decides appeals in § 1498 cases and generally shapes patent law in the United States—determined that a generic formulation of the prescription drug cinacalcet (Sensipar) did not infringe the brand-name drug company's patent on the drug, even though the active ingredients were identical, because the generic formulation did not contain specific ingredients claimed in the brand-name drug company's patent. *See Amgen Inc. v. Amneal Pharms. LLC*, 945 F.3d 1368, 1380 (Fed. Cir. 2020).)

Patent holders often have an over-expansive view of what sorts of activities and technologies are covered by their patents, and judges frequently construe a patent's claims more narrowly than the patent holder desires. Accordingly, the Court of Federal Claims may absolve the government of liability for damages if it concludes that the government's use falls outside the scope of the patent claims. Unlike validity and enforceability—which are presumed unless the government shows otherwise—it is the patent holder's burden to show that its patent has been infringed. If the patent holder is unable to show that the government's use falls within the scope of its patent rights, the government will bear no liability for infringement and will not owe § 1498's "reasonable and entire" compensation to the patent holder.

C. DETERMINATION OF "REASONABLE AND ENTIRE" COMPENSATION

Only if the Court of Federal Claims concludes that the patent is valid, enforceable and infringed will it then turn to the question of compensation.

"Reasonable and entire" compensation is paid by the U.S. government to the patent holder and typically takes the form of a reasonable royalty on the patented product. Royalties under § 1498 generally represent a reasonable valuation of the patent rights, and are premised upon a nonexclusive license for the government's procurement and use of the patented technology, rather than the value of an exclusive license or total appropriation of the patent.[132] (The appropriate royalty for a nonexclusive license is always less than the appropriate royalty for an exclusive license, because under a nonexclusive license, the patent holder remains free to license the patent to other users and thereby generate additional revenue from the patent.[133]) The precise amount of the royalty is calculated by the Court of Federal Claims based on the past dealings of the patent holder, the nature of the patent rights, industry norms, common sense, and considerations of policy.[134] The award may include prejudgment interest,[135] but does not include "enhanced," punitive damages.[136]

I. PRIOR AGREEMENTS ESTABLISHING A BENCHMARK ROYALTY RATE

In general, the Court will first look to the patent holder's prior dealings to determine a reasonable valuation of the patent rights. If a previously-established royalty rate is available for the same or similar patent rights, the Court of Federal Claims will

[131] Infringement under 35 U.S.C. § 1498(a) is often analogous to infringement for private parties under 35 U.S.C. § 271(a), but does not exactly match the latter statute. *See FastShip, LLC v. United States*, 892 F.3d 1298, 1305 (Fed. Cir. 2018) (interpreting "manufactured" in § 1498 in accordance with its plain meaning instead of its meaning in the context of § 271(a), which the court dismissed as "a different word in a different statute"). *See also Zoltek Corp. v. United States*, 672 F.3d 1309, 1319 (Fed. Cir. 2012) (describing § 1498 as a waiver of the government's sovereign immunity that "makes no reference to direct infringement as it is defined in § 271(a).")

[132] *See Motorola, Inc. v. United States*, 729 F.2d 765, 768 n.3 (Fed. Cir. 1984) (describing the government as "a compulsory, nonexclusive licensee").

[133] *See Mark A. Lemley, Patenting Nanotechnology*, 58 Stanford L. Rev. 601, 626-27 (2005) ("royalty rates for exclusive licenses are significantly higher than the rates for nonexclusive licenses").

[134] Courts in § 1498 cases can consider a broad array of factors. *See, e.g., Liberty Ammunition, Inc. v. United States*, 119 Fed. Cl. 368, 386 (2014) ("The determination of a reasonable royalty requires a highly case-specific and fact-specific analysis, relying upon mixed considerations of logic, common sense, justice, policy and precedent.")

[135] *Hughes Aircraft*, 86 F.3d at 1572 (approving "damages for [the U.S. government's] delay in paying the royalty").

[136] *Leesona*, 599 F.2d at 970 (declining to grant attorney's fees and reversing increased damages, emphasizing that "this is a punitive award not necessary to provide just compensation.").

begin there.[137] Prior commercial license agreements from the patent holder are considered the best measure for "reasonable and entire" compensation under § 1498.[138] However, the court will also give considerable weight to settlement agreements,[139] unconditional offers to license the product by the patent holder,[140] licenses for foreign patents corresponding to the U.S. patent,[141] and license agreements involving related patents owned by the patent holder or its competitors.[142] In Saulnier v. United States, for example, the court used a royalty negotiated in "an arm's length transaction" between a patent holder and the U.K. national government as a benchmark for determining the appropriate royalty for the U.S. government to pay for use of the same patent.[143] (In future pharmaceutical cases, one might imagine the Court of Federal Claims looking to the drug prices that the U.K. and other foreign governments negotiate with patent-holding drug companies as a reference point.)

Once a reasonable benchmark has been established, the royalty rate may be adjusted up or down by the court depending on the circumstances.[144] For instance, if the established royalty rate was not the result of a fair negotiation between two willing parties, the court may compensate for large differences in bargaining power, or the fact that the royalty was negotiated to avoid litigation.[145] Similarly, if the patent holder is reliant on the patent for business purposes, the court may adjust the royalty upward to account for the commercial importance of the patent rights to the patent holder.[146]

II. GEORGIA-PACIFIC AND THE "WILLING BUYER-WILLING SELLER" RULE

In most § 1498 cases, the Court of Federal Claims has applied the "willing buyer-willing seller" rule to arrive at a reasonable royalty.[147] This rule is particularly useful when the court lacks evidence of prior commercial agreements, but it may also be used to evaluate the reasonableness of an award established through prior license agreements or some other form of analysis.[148] As outlined in *Georgia-Pacific Corp. v. U.S. Plywood*, the "willing buyer-willing seller" rule attempts to simulate a hypothetical negotiation between willing parties before the time the infringement occurred. The goal of the Court of Federal Claims in applying the rule is to arrive at a royalty rate that is agreeable to both a willing licensee (the government) and a willing licensor (the patent holder), and strives to ensure that the patent holder makes a reasonable profit on its investment in the patented invention.

To guide this hypothetical negotiation, courts have outlined several factors to consider, called the *Georgia-Pacific* factors.[149] Among these are the nature of the patented invention, the character of commercial embodiments of the invention, the duration of the

[137] An established royalty rate is the best measure of reasonable and entire compensation where such a rate exists. *See Tektronix*, 552 F.2d at 347 ("Where an established royalty rate for the patented inventions is shown to exist, that rate will usually be adopted as the best measure of reasonable and entire compensation."); *see also Hughes Aircraft*, 86 F.3d at 1572.

[138] *Decca Ltd. v. United States*, 640 F.2d 1156, 1167 (Ct. Cl. 1980), *cert. denied*, 454 U.S. 891 (1981) ("Where (a) prior to the time as of which the license taken by the Government is to be valued, the patentee has licensed the infringed patent commercially and (b) the rights of such a commercial licensee are the same or substantially similar to the rights taken by the Government, the court uses, virtually without exception, the reasonable royalty method to value the license taken by the Government.").

[139] *Pitcairn v. United States*, 547 F.2d 1106, 1118 (Ct. Cl. 1976), *cert. denied*, 434 U.S. 1051 (1978) ("mere surmise that a bargained license may possibly include some discount for litigation-avoidance does not per se preclude use of an accepted commercial rate as establishing reasonable and entire compensation.").

[140] *Id.* ("[T]here is no reason why the owner himself should not be held to his own offer.").

[141] *Van Veen v. United States*, 386 F.2d 462 (Ct. Cl. 1967); *Saulnier v. United States*, 314 F.2d 950 (Ct. Cl. 1963).

[142] *Leesona*, 599 F.2d at 976 (considering a competitor's 1.5% royalty rate, but deeming it too low in the circumstances).

[143] *Saulnier*, 314 F.2d at 952.

[144] *See Hughes Aircraft*, 86 F.3d at 1572 ("The facts of a particular case may call for a reasonable royalty that is more, less or the same as the offered royalty."), citing *Pitcairn*, 547 F.2d at 1118. *See also Tektronix*, 552 F.2d at 347 n.5 ("Even an established royalty may be modified upward ... or downward ... depending on the circumstances of the case.").

[145] *Meurer Steel Barrel Co. v. United States*, 85 Ct. Cl. 554 (1937), *cert. denied*, 302 U.S. 754 (1937) (increase in royalty rate "is supported by the fact that the lesser royalty fixed by plaintiff was so fixed to avoid the expense of litigation and other factors involved in the same.").

[146] *See Leesona*, 599 F.2d at 976 (adjusting the royalty rate upward because Leesona intended to use the patents "as a springboard for entry into the battery manufacturing business" making their worth to Leesona greater than conventional battery patents were worth to competing battery manufacturers).

[147] *Tektronix*, 552 F.2d at 349 n.7 ("This willing-buyer/willing-seller technique in determining a reasonable royalty has not been a stranger to the Court of Claims."); *see also Amerace Esna Corp. v. United States*, 462 F.2d 1377, 1380 (Cl. Ct. 1972) ("In the absence of an existing royalty rate, courts often resort to a 'willing seller-willing buyer' approach to establish what a reasonable royalty should be under the particular facts with which they are faced; *Hughes Aircraft*, 86 F.3d at 1573; *Decca*, 640 F.2d at 1169 & n.22.

[148] *Leesona*, 599 F.2d at 973.

[149] *Georgia-Pacific Corp. v. United States Plywood-Champion Papers Inc.*, 446 F.2d 295 (2d. Cir. 1971).

patent term, the territorial and temporal scope of the license, the value of the invention to the licensor, and any previously established royalties for licensing of the patent at issue.[150]

Logically, this hypothetical negotiation is bounded by a "floor" below which no rational patent holder would accept the deal and a "ceiling" above which the government would rationally pursue other means of acquiring the patented technology. In the context of § 1498, courts have generally interpreted the "willing buyer-willing seller" rule to require that the awarded royalty at least fairly compensate the patent holder for the risk-adjusted development costs for the invention, plus a reasonable profit, allocated over the life of the patent.[151] If the government has contributed to the development of the patented technology, any government expenditures can be subtracted from this "floor."[152] Ultimately, the patent holder bears the burden of showing its expenditures related to the patented technology. "[T]he party having the burden of proof must suffer if a scantiness of record fails to support a fully informed and reasoned determination."[153] Accordingly, royalties under § 1498 do not unfairly undercompensate the patent holder for the government's use of its patented technology, unless the patent holder fails to document the full value of the patent and its investments in it.

The most obvious "ceiling" for a willing licensee is the price of acquiring the patented goods directly from the patent holder (i.e., by paying the patented monopoly price). Because compensation under § 1498 is not intended to be punitive, courts will not order the government—i.e., U.S. taxpayers—to pay a patent holder more than the patented goods would fetch on the open market. When the government has received multiple bids to produce the patented technology—for instance, a bid from the patent holder and a bid from a lower-cost third-party manufacturer—courts have concluded that the difference between these bids is a fair indicator of the upper limit of what the government would be willing to pay for the patent rights—the "ceiling."[154]

Accordingly, the "willing buyer-willing seller" rule specifically and § 1498's broader statutory guarantee of "reasonable and entire compensation" to the patent holder work to ensure that the government generally saves money under § 1498 while paying fair compensation to the patent holder.[155]

LEESONA, A CASE STUDY ON HOW THE COURT OF FEDERAL CLAIMS CALCULATES A REASONABLE ROYALTY

A major 1979 case, ***Leesona Corp. v. United States***, provides a good model for judicial application of the "willing buyer-willing seller" rule to set a reasonable royalty, the "reasonable and entire compensation" typically owed under § 1498 for the government's use of patented technology.[156]

In *Leesona*, the government sought to produce mechanically rechargeable metal-air batteries, which were protected by three patents owned by Leesona. After initially striking a deal with Leesona to produce the patented batteries, the government reneged and instead awarded the contract to the lowest bidding manufacturer, whom the government authorized to use Leesona's patents to manufacture the batteries at a lower price.

[150] For a full listing of the *Georgia-Pacific* factors, see *Georgia-Pacific Corp. v. U.S. Plywood Corp.*, 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970).

[151] *Leesona*, 599 F.2d at 973.

[152] *Id.* at 978 (citing *Olsson v. United States*, 25 F. Supp. 495 (Ct. Cl. 1938), for the proposition that when the U.S. government undertakes some of the risk of researching, developing, and/or manufacturing a patented invention, the government's contributions should result in a lower royalty paid under § 1498); *see also Fauber v. United States*, 112 Ct. Cl. 302 (1948), *cert. denied*, 337 U.S. 906 (1949) (rate adjusted downward because "the Government contributed its own research and development work in adapting the Fauber invention to its hydroplane hulls").

[153] *Leesona*, 599 F.2d at 979.

[154] *Id.* at 978 (finding the government's savings as "a ceiling on the awardable royalty" and *Leesona*'s adjusted development expenses as a floor).

[155] *Id.* at 971 ("[While] savings to the government may be considered in determining reasonable compensation," its best use "is in estimating what royalty willing buyers and sellers would agree to. It has been done infrequently in the past and generally only when the calculation of a reasonable royalty was difficult. . . . Even where savings to the government are used as an acceptable measure of just compensation, no court has awarded the total savings to the infringer as just compensation.").

[156] Id. at 973.

During litigation at the Court of Claims, the government and Leesona each submitted evidence to support widely varying royalty rates. After deciding that "none of the licenses discussed in the record are based on a situation directly comparable to the case at hand," the court found that an increased royalty would be appropriate because the patents were critical to Leesona's entry into the battery market. The Court found that a royalty of 10% of the authorized low-cost manufacturer's revenues appeared consistent with the "special value" of the patent rights to Leesona's future business.[157]

The Court then tested the reasonableness of the 10% royalty under the "willing buyer-willing seller" rule. The court began by computing the government's cost savings in authorizing the use of Leesona's patent under § 1498—the difference between Leesona's original bid to produce the patented batteries and the procurement costs from the lower-cost rival manufacturer. To the court, this figure represented "a ceiling on the awardable royalty, but not a floor."

From the perspective of the hypothetical willing seller, the court determined that any royalty award should be sufficient to recoup Leesona's development costs over the life of the patent, plus a reasonable profit:

> "A floor on the royalty would be provided by the expense incurred by Leesona in developing its invention, less any compensation received from defendant in its pre-1969 development contracts. The figure, with a reasonable profit, could be amortized by the royalty attributable to the [government's third-party] procurement in the proportion such procurement bore to the anticipated sales of the invention during the patent life."

Because a 10% royalty fell comfortably between this "ceiling" and "floor," the court deemed the 10% royalty appropriate for compensating Leesona for the government's use of its patents.

III. EMPIRICAL ANALYSIS OF COMPENSATION UNDER § 1498

No matter what logical framework the judge uses to arrive at an award, in practice, royalties in § 1498 cases rarely exceed 10% of an authorized third-party manufacturer's revenues.[158] Courts have consistently found that a royalty of 10% or less represents "reasonable and entire compensation" fair to both the patent holder and the government.

D. BARGAINING IN THE SHADOW OF "REASONABLE AND ENTIRE" COMPENSATION

The U.S. government can also use § 1498's "reasonable and entire" compensation to bring patent holders to the negotiating table instead of the courtroom. Knowing the typical bounds of "reasonable and entire" compensation, and knowing that not all patent holders successfully establish liability in § 1498 suits, rational patent holders bargaining with the U.S. government in the shadow of § 1498 will be incentivized to accept a deal that represents a discount from the "normal," "open market" price of the patented product.

The ciprofloxacin (Cipro) example introduced in Section 2 is a good example of bargaining in the shadow of § 1498—then-HHS Secretary Tommy

[157] The court found an increased royalty appropriate because Leesona's battery patents were critical to its entry into the battery market. *See id.* at 976.

[158] See Kapczynski & Kesselheim at 793 ("Royalties are commonly set at 10 percent of sales or less" in § 1498 cases involving the Department of Defense); Brennan at 310; Richard J. McGrath, *The Unauthorized Use of Patents by the United States Government or Its Contractors*, 18 AIPLA Q.J. 349, 352 (1991) ("Historically, the highest royalty rate that the United States Claims Court has awarded is 10%.").

Thompson apparently used the "threat" of government patent use under § 1498 to obtain a better deal for the U.S. government and the American people—so we revisit it here, in more detail:

In the aftermath of the attacks on September 11, 2001, the administration of President George W. Bush learned of a credible threat of anthrax attacks against the United States.[159] The public quickly began panic-buying ciprofloxacin (Cipro), the only antibiotic then approved for treating anthrax, and the Bush administration moved to create a national stockpile of the drug.

Yet Bayer AG, which held the patent on ciprofloxacin, informed Secretary Thompson that it would require almost two years to manufacture enough ciprofloxacin to fill the stockpile. Bayer also indicated that it was unwilling to license generic competitors to sell the drug in the United States. Meanwhile, one of those generic manufacturers estimated that it could fulfill the government's request in three months. Secretary Thompson then threatened to "bypass Bayer's patent"[160] —apparently a veiled reference to government patent use under § 1498. In the wake of Thompson's threat, and in the face of increasing public outrage, Bayer responded by ramping up production of ciprofloxacin. It also agreed to sell HHS a large order of ciprofloxacin at a substantially discounted price of $0.95 per pill, compared to the $1.83 that the government normally paid and Bayer's wholesale price of $4.67 per pill.

Thompson and other Bush administration officials later denied threatening use of § 1498 to bring Bayer to the negotiating table—perhaps because the Bush administration was then embroiled in an effort to prevent countries in the Global South from using their own government-patent-use-like powers on patents owned by U.S. drug companies[161]—but most accounts agree that § 1498 provided the necessary leverage to obtain the concessions from Bayer.[162] Notably, Bayer's nearly 50% discount, while representing a significant decrease from the market price, did not make the deal unprofitable for Bayer. Rather, it allowed Bayer—instead of a competing generic manufacturer—to fulfill the United States' demand for its vital, patented drug while also turning a profit on the sale.

Negotiations like those for ciprofloxacin can take place at any time, including up to and during litigation. Even after the government has begun using a patent without the patent holder's approval, triggering § 1498, the government and patent holder can continue negotiating with the goal of either agreeing on a license prior to litigation or coming to an agreeable settlement once litigation has already commenced. Thus, government officials should feel empowered to acquire and use patented technology even before commencing negotiations with the patent holder. Either negotiations will produce a reasonable licensing agreement, or a judge will do the same after the fact by adjudicating "reasonable and entire" compensation owed to the patent holder.

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[159] Morten & Duan at 26 (describing HHS Secretary's response to the anthrax crisis); *see also* Brennan at 303.

[160] Keith Bradsher, *Bayer Agrees to Charge Government a Lower Price for Anthrax Medicine*, N.Y. Times, Oct. 25, 2001, at B8, https://www.nytimes.com/2001/10/25/business/nation-challenged-cost-bayer-agrees-charge-government-lower-price-for-anthrax.html; see also Dan Ackman, *A New Deal on Cipro*, Forbes (Oct. 24, 2001), https://web.archive.org/web/20040907005526/ http://www.forbes.com:80/2001/10/24/1024topnews_print.html (quoting Thompson saying that Bayer is "going to meet our price, which is less than $1, or else we're going to go to Congress and ask for some support to go in and do some other business").

[161] Morten & Duan at 29.

[162] *See, e.g.*, Brennan at 303.

SECTION 5

SPECIAL CONSIDERATIONS FOR USE OF § 1498 TO EXPAND ACCESS TO PHARMACEUTICALS

A. INTRODUCTION TO THE UNIQUE REGULATORY LANDSCAPE FOR PHARMACEUTICALS

As is true for patents on any useful invention, patents on pharmaceuticals are both an incentive to innovate and a barrier to public access and competition. The above sections demonstrate that government patent use governed by § 1498 can be an effective way to bypass patent barriers and provide public benefit through increased availability to such useful inventions. Likewise, in the pharmaceutical context, in which patents are the primary barrier to access and competition, government patent use under § 1498 can be a powerful tool.

However, the regulatory landscape of pharmaceutical inventions is unusually complex and merits some additional consideration. For pharmaceuticals, regulatory barriers can be as important as patent barriers and can affect the reach of government patent use. (The same is true for other heavily regulated, R&D-driven industries, such as medical devices and aerospace. We focus in this guide on pharmaceuticals because pharmaceuticals are fundamental to the national economy and to public welfare. *See* Section 1.)

Pharmaceutical manufacturers must clear regulatory hurdles at the FDA before they can sell their product in the U.S. marketplace, and should the government opt to use a pharmaceutical patent to increase public access to life-saving medication, it, too, must be aware of the regulatory landscape in this area. Like all drugs, patented drugs procured under § 1498 must obtain FDA approval before they can reach patients. Furthermore, the government must take care to ensure its proposed patent uses will not conflict with any non-patent-

TWO KINDS OF PRESCRIPTION DRUGS: "SMALL MOLECULE" AND "BIOLOGIC"

"Small molecule" drugs are drugs that are manufactured from chemical synthesis. As the name suggests, they tend to be small (chemically speaking) and they tend to have well defined chemical structures. Most drugs prescribed and consumed in the United States are small molecule drugs. Examples of small molecule drugs include aspirin, loratadine (Claritin), atorvastatin (Lipitor), and lenalidomide (Revlimid).

Biologics are drugs derived from living organisms. Biologic drugs tend to have larger, more complex chemical structures that may not be well defined. Vaccines fall into the category of biologic drugs. Examples of biologic drugs include insulin, adalimumab (Humira), and interferon beta-1a (Avonex).

related "statutory exclusivities." (We discuss these non-patent statutory exclusivities below.)

Under federal statute, a drug must be reviewed by the Food & Drug Administration (FDA) for safety and efficacy and subsequently approved before it can enter the U.S. market.[163] The typical road to FDA approval for an "originator" company's new drug involves pre-clinical evaluations, clinical testing, and finally the submission of a New Drug Application (NDA) (for small molecule drugs) or Biologics License Application (BLA) (for biologic drugs) to the FDA. The FDA will approve an application if it determines the drug to be sufficiently safe and effective for its proposed use, appropriately labeled, and reliably manufactured in such a way as to preserve the drug's integrity. After a new drug has been approved by the FDA, competitor manufacturers can file "follow-on," "abbreviated" generic (for small molecule drugs) and biosimilar (for biologic drugs) applications that rely on the original application for proof of safety and efficacy to obtain FDA approval.

The relevant law of drug approval at the FDA creates complications for patent terms and also creates certain types of FDA-granted non-patent exclusivity. § 1498 can cut through some, but not all, of these complications. Patent term extensions are an example of a "patent problem," where the barrier to competitors entering the market is solely or largely the existence of a current patent; generally speaking, such "patent problems" are ones the government can solve through use of § 1498. Conversely, non-patent exclusivities, which create independent restrictions on how and when the FDA is permitted to approve a generic or biosimilar drug, are not "patent problems," and thus proceeding with government patent use under § 1498 is not a clear solution in these cases. Below, we describe these implications in more detail and explain which are "patent problems" readily solvable by § 1498.

I. THE HATCH-WAXMAN ACT[164]

The Drug Price Competition and Patent Term Restoration Act of 1984, known colloquially as the "Hatch-Waxman Act," is a federal law that provides regulatory pathways to market for generic drug manufacturers and patent term extensions for the "originator" drug companies that first bring new drugs to market.[165] This guide does not purport to provide a comprehensive overview of the Hatch-Waxman Act. Instead, it focuses on just two features of the Act especially relevant to government patent use: (1) patent term extensions, which extend patent protection on originator drugs but can be overcome through exercise of § 1498 and (2) the 30-month stay, which may delay FDA approval of generic drugs.

Patent Term Extensions

The Hatch-Waxman Act's patent term extensions are particularly relevant in the context of government patent use under § 1498 because, although patent term extensions might pose a barrier to generic manufacturers entering the market with follow-on drugs, the government can proceed with using the patent without running afoul of either statute.

The Hatch-Waxman Act created patent term extensions that, under certain conditions, give pharmaceutical patent holders up to five years of patent protection beyond the standard 20-year patent term.[166] These extensions seek to "restore" patent term "lost" due to time spent in the FDA approval process, during which time the patent holder may not market its drug.

Government patent use under § 1498 during the period of patent term extension should work no differently than it does during the standard term of a patent. Patent term extension under the Hatch-Waxman Act does not change the nature of the patent; it simply extends the patent's term.[167] For the duration of the patent term extension, the patent holder enjoys the exclusive right to make, use, sell, and import the patented invention, and it can sue others who infringe on these rights, either for damages or an injunction. However, nothing in the text of the Hatch-Waxman Act states that the government or its authorized third-party contractors may not use patented inventions pursuant to § 1498 during the extension, if such use meets the normal requirements of § 1498. The statutory text of § 1498 makes it clear that the government and

[163] Technically, small molecule drugs are legally "approved" by the FDA, while biologic drugs are "licensed." See U.S. Food and Drug Administration Frequently Asked Questions About Therapeutic Biological Products, https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/frequently-asked-questions-about-therapeutic-biological-products. We use the terms "approved" and "approval" broadly, to cover both approval of small molecule drugs and licensure of biologic drugs.

[164] *The Hatch-Waxman Act: A Primer, Congressional Research Service* (Sep. 28, 2016), https://www.everycrsreport.com/files/20160928_R44643_1c2fafad2efe96d4c0fe44f2f23308dcfc059f83.pdf.

[165] *Id.*

[166] *See* 35 U.S.C. § 156.

[167] *See* 35 U.S.C. § 156(a) ("The term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended in accordance with this section from the original expiration date of the patent . . . .").

its authorized contractors may use any patent, which must necessarily include patents with extended terms. The patent holder cannot enjoin such use but can, of course, seek compensation from the government under § 1498 by filing a suit at the Court of Federal Claims.

30-month stay

The Hatch-Waxman Act also creates a legal mechanism by which an originator drug manufacturer can prevent generic competition for a period of time known as the "30-month stay."

To understand the 30-month stay, some context is necessary. The Hatch-Waxman Act creates a formal legal procedure by which generic drug manufacturers can apply for approval of follow-on drugs—that is, drugs that are shown to be "bioequivalent" to the previously approved originator drug, called a "reference product" under the Act—through an Abbreviated New Drug Application (ANDA). The ANDA is "abbreviated" in the sense that it can rely on safety and efficacy data submitted by the original manufacturer and does not need to contain a complete set of clinical trial data establishing safety and efficacy. Upon filing, the ANDA applicant must submit a statement regarding any patents associated with its application that are published in the Orange Book, the FDA's annual publication listing patents on FDA-approved drugs. If the ANDA applicant asserts in this statement that the listed patents are invalid, unenforceable, or will not be infringed, then it must notify the patent-holding originator company, and the originator may in turn file suit for patent infringement in federal district court. If the originator files suit within 45 days of notice from the generic manufacturer, a 30-month stay of the ANDA goes into effect. The stay prevents the FDA from approving the ANDA until all of the relevant patents expire, the court finds them invalid, unenforceable, or not infringed, or 30 months passes—whichever comes first.

This "30-month stay" is *not* an extension of the patent term; rather, it is a legislatively-created period of marketing exclusivity during which a generic application cannot be approved by the FDA—and thus cannot come to market. Consequently, the practical utility of government patent use under § 1498 could be affected by the 30-month stay.

In the event that a government-authorized generic contractor's application is affected by a 30-month stay, the best course for the generic contractor and the government is for the generic to seek a judgment dismissing the case, which will end the 30-month stay.[168] In this scenario, the generic manufacturer could argue that its authorization from the U.S. government constitutes a license to use the patent, thereby leading to a finding of non-infringement.[169] Alternatively, or additionally, the generic manufacturer could argue that because its use of the asserted patent is authorized by the U.S. government, the patent holder's sole legal remedy is a § 1498 suit at the Court of Federal Claims, and the district court must therefore dismiss the case for lack of jurisdiction.[170] "If a patented invention is used or manufactured for the government by a private party, that private party cannot be held liable for patent infringement."[171] (Either way, the 30-month stay will be extinguished.)

In addition, some experts have argued that the FDA could and should simply ignore the 30-month stay in the event of government patent use of a pharmaceutical patent.[172] They observe that the 30-month stay effectively constitutes an injunction—a court order—preventing the government from using the drug patent, and they reason that because no patent holder can enjoin government patent use (a core principle of § 1498—see Section 2), the 30-month stay must not block the government or its authorized third parties.[173] However, this interpretation of the interaction between government patent use and the Hatch-Waxman Act's 30-month stay has not been tested in court. Any government agency seeking to use a patent covering a small molecule drug currently or potentially subject to a 30-month stay should seek counsel before proceeding.

The 30-month stay under the Hatch-Waxman Act is one example of a marketing exclusivity that presents a potential barrier to government patent use under § 1498, but it is not the only one. Before commencing with government patent use of a drug under § 1498,

[168] 21 CFR 314.107.

[169] 21 CFR 314.107(b)(3)(viii).

[170] 21 CFR 314.107(b)(3)(ii).

[171] *Crater Corp. v. Lucent Techs., Inc.*, 255 F.3d 1361, 1364 (Fed. Cir. 2001). *See also Saint-Gobain Ceramics & Plastics, Inc. v. II-VI Inc.*, 369 F. Supp. 3d 963, 983 (C.D. Cal. 2019) (holding that "defendants are immune from" patent infringement suits in district court when authorized to practice those patents under § 1498).

[172] Brennan at 343.

[173] *Id.*

the government should investigate to see if the drug is currently covered by any other non-patent statutory exclusivities.

II. PATENT TERM EXTENSIONS AND NON-PATENT STATUTORY EXCLUSIVITIES FOR BIOLOGICS AND BIOSIMILARS[174]

The FDA regulates the class of drugs known as biologics and biosimilars slightly differently from small molecule drugs. "Biosimilars" are "follow-on" biologic drugs which are shown to be highly similar or interchangeable with an already approved biologic drug. The Biologics Price Competition and Innovation Act (BPCIA) provides an abbreviated path to approval for biosimilars that is analogous to the ANDA process for follow-on small molecule generic drugs created by the Hatch-Waxman Act. Under the BPCIA, biosimilar drugs can apply for approval with an abbreviated application known as an Abbreviated Biologics License Application (ABLA) by demonstrating high similarity or interchangeability with an already-approved biologic drug.

The BPCIA also creates a 12-year period of exclusivity for biologics, meaning that the FDA cannot approve a biosimilar until 12 years after approval is granted for the reference biologic.[175] Since this non-patent statutory exclusivity is not a "patent problem," the government cannot use § 1498 to bypass this barrier to market. However, if the patent term continues after the period of non-patent statutory exclusivity ends, thereby continuing to block competitors from manufacturing a biosimilar, the government or its authorized third parties can use the patent during that time pursuant to § 1498.

The patent term extension provisions of the Hatch-Waxman Act also apply to biologics. That is, a biologic covered by patent can also have its patent term extended, creating a "patent problem" solvable by government patent use under § 1498. However, the 30-month stay provision from the Hatch-Waxman Act does not apply to biologics. This is because the 30-month stay is only triggered by filing of a small molecule ANDA, and biosimilars follow a different approval process.

B. GUIDANCE ON THE USE OF § 1498 IN CONNECTION WITH PHARMACEUTICALS: FOUR SCENARIOS

To illustrate potential uses of § 1498 to expand access to prescription drugs by making generic and biosimilar versions available (including vaccines), we explore four distinct potential factual scenarios. These scenarios are delineated based on the FDA approval status of drug in question:[176]

- **SCENARIO A**, in which a generic or biosimilar product has obtained full approval from the FDA but is nonetheless being kept off the market by patents;
- **SCENARIO B**, in which a generic or biosimilar product has obtained tentative (not full) approval from the FDA but is being kept off the market by patents;
- **SCENARIO C**, in which an application for approval of a generic or biosimilar product has been filed with the FDA but has not yet received any kind of FDA approval;
- **SCENARIO D**, in which no generic or biosimilar application has yet been filed with the FDA.

Scenario A is the simplest, in legal and policy terms, from the perspective of the U.S. government: in Scenario A, patents are the sole barrier to generic or biosimilar entry to the marketplace, so exercise of § 1498 is likely to suffice to permit that entry. The same may or may not be true in Scenario B. In Scenarios C and D, non-patent barriers are more significant, but they may nonetheless be possible to overcome through cooperation with a generic drug maker.

This subsection focuses on the Department of Health and Human Services (HHS) as a U.S. government body likely to use § 1498 to procure drugs because HHS is the executive department primarily entrusted with managing and providing healthcare, including prescription drugs and vaccines. While this section refers generally to "HHS," the term

[174] Congressional Research Service, *Biologics and Biosimilars: Background and Key Issues* (June 2019), https://fas.org/sgp/crs/misc/R44620.pdf.

[175] U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER), *Guidance for Industry: Reference Product Exclusivity for Biological Products Filed Under Section 351(a) of the PHS Act* (Aug. 2014), https://www.fda.gov/media/89049/download.

[176] The FDA publishes the approval status of drugs on the public Drugs@FDA website. See Drugs@FDA: FDA-Approved Drugs, https://www.accessdata.fda.gov/scripts/cder/daf/.

should be understood to encompass not just HHS at the department level, but also its constituent agencies—including the Health Resources and Services Administration (HRSA), CDC, and Centers for Medicare & Medicaid Services (CMS)—that procure and distribute prescription drugs and vaccines. However, the same scenarios apply equally to other federal agencies that procure pharmaceuticals, such as the Department of Defense (which provides healthcare, including prescription drugs, for many service members and their families through the Tricare program) and the Department of Veterans Affairs (which does the same for veterans through the Veterans Health Administration).

SCENARIO A

In Scenario A, a generic or biosimilar drug has received full FDA approval, but the generic or biosimilar maker is nonetheless holding its product off the U.S. market.

How does this scenario arise? Sometimes the generic or biosimilar maker delays its launch because of ongoing patent litigation with the originator.[177] Other times, such patent litigation will end in a settlement agreement, and the generic or biosimilar maker will agree not to enter the U.S. market until some date in the future. These agreements can delay launch for years.

Any time Scenario A applies and a generic or biosimilar drug has full FDA approval, § 1498 can clear the way for a generic to enter the market: this is a solvable "patent problem." Once properly authorized by the U.S. government to use the relevant patents (as described above in Section 3), the generic or biosimilar maker is immunized from patent infringement liability and should be able to proceed to market immediately.

Scenario A is quite common and covers many prescription drugs, including some of the most commercially important drugs in the U.S.: adalimumab (Humira), etanercept (Enbrel), rituximab (Rituxan), and emtricitabine/tenofovir disoproxil fumarate (Truvada).[178] As of December 2020, the FDA has granted full approval of a generic or biosimilar version of each of these drugs, and only patents and patent settlement agreements between the originator drug company and its competitors prevent generic or biosimilar entry into the U.S. market.[179]

TRUVADA (emtricitabine and tenofovir disoproxil fumarate): An example of Scenario A

The drug emtricitabine/tenofovir disoproxil fumarate, sold under the brand name Truvada, is an illustrative example of Scenario A.

The drug is vital to public health, as it is highly effective at preventing HIV infections in HIV-negative people.[180] As of December 2020, at least four generic drug companies—Teva, Aurobindo, Amneal, and Zydus—have received full FDA approval for generic versions of Truvada.[181] Yet only one of those four companies—Teva—is actually selling its generic product,[182] and, at a price of $1,455 a month, it is only slightly cheaper than the brand-name drug sold by the originator company, Gilead.[183] Other generic manufacturers also signed settlement agreements with Gilead after patent litigation, under which each of those generic

[177] Barbara Boughton, *FDA approves Teva's generic copy of Truvada*, BioPharmaDive (Jun. 14, 2017) https://www.biopharmadive.com/news/teva-truvada-fda-generic-approval-gilead/445006/.

[178] These four drugs were all among the top 20 most commercially significant drugs in the United States in 2018, with combined sales of over $20,000,000,000. See Kyle Blankenship, *The top 20 drugs by 2018 U.S. sales*, Fierce Pharma (Jun. 17, 2019), https://www.fiercepharma.com/special-report/top-20-drugs-by-2018-u-s-sales.

[179] For a complete list of all biosimilars approved by the FDA, including adalimumab, etanercept, and rituximab, *see generally* US Food and Drug Administration, *Biosimilar Product Information*, (Jul. 7, 2020) https://www.fda.gov/drugs/biosimilars/biosimilar-product-information. For details on these three drugs, see *AbbVie Announces Global Resolution of HUMIRA® (adalimumab) Patent Disputes with Sandoz* (AbbVie Press Release, Oct 11, 2018), https://news.abbvie.com/news/abbvie-announces-global-resolution-humira-adalimumab-patent-disputes-with-sandoz.htm (vis-a-vis adalimumab (Humira), explaining that, subsequent to patent litigation, biosimilar makers Amgen, Samsung Bioepis, Mylan, and Sandoz had agreed with originator and patent holder AbbVie not to sell their biosimilar products in the U.S. until 2023); Arlene Weintraub, *Amgen's Enbrel fends off biosimilar threat—and heads toward blockbuster superstardom*, FiercePharma (Jul. 2, 2020), https://www.fiercepharma.com/pharma/amgen-catches-a-break-enbrel-biosimilar-threat-as-federal-court-upholds-patent-win (vis-a-vis etanercept (Enbrel), observing that originator and patent holder's Amgen's U.S. patents on the drug are not due to expire until the late 2020s); Kelly Davio, *FDA Approves Pfizer's Rituximab Biosimilar, Ruxience, AJMC, Center for Biosimilars* (Jul. 23, 2019), https://www.centerforbiosimilars.com/view/fda-approves-pfizers-rituximab-biosimilar-ruxience (vis-a-vis rituximab (Rituxan), explaining that although Pfizer's biosimilar product had received full FDA approval, "no launch date ha[d] been announced" for that product and that "earlier this year, Pfizer reached a settlement with" the patent holder, Roche). For details of Truvada, see the following main text.

[180] Centers for Disease Control and Prevention, *Pre-Exposure Prophylaxis (PrEP)* (May 18, 2020), https://www.cdc.gov/hiv/clinicians/prevention/prep.html.

[181] Jaime Rosenberg, *Reactions Are Mixed as Gilead Announces PrEP Donations, Early Launch of Generic, AJMC* (May 10, 2019), https://www.ajmc.com/view/reactions-are-mixed-as-gilead-announces-prep-donations-early-launch-of-generic.

[182] Liz Highleyman, *First Generic Truvada Now Available in the United States*, POZ (Oct. 2, 2020), https://www.poz.com/article/first-generic-truvada-now-available-united-states.

[183] *Id.*

companies agreed not to enter the U.S. market until 2021 at the earliest.[184] Because these generic companies have full FDA approval, Gilead's patents and the generics' patent settlement agreements with Gilead are the only barriers to their entry into the U.S. market.

HHS could use § 1498 to accelerate the entry of these other generic manufacturers and obtain lower prices on generic versions of Truvada. For example, one major generic, Mylan, sells its generic version of Truvada tablets in Canada for much less—as little as $250 per month.[185] (Because manufacturing costs are low, generic manufacturers elsewhere sell such tablets for even lower prices—e.g., less than $50 per month in Australia.[186]) HHS could contract with one or more of the generic manufacturers already approved by the FDA—Aurobindo, Amneal, and Zydus—to procure a generic Truvada product at much lower cost and then redistribute it to patients and healthcare providers around the United States, as part of HHS's mission to end the U.S. HIV/AIDS epidemic by 2030.[187] Such a contract would constitute "authorization" under § 1498, and Gilead could no longer use its patents to prevent these generics from selling to HHS.[188]

Gilead could then, of course, bring a claim in the Court of Federal Claims against the U.S. government under § 1498 for its "reasonable and entire compensation." See Section 4. The court could then determine if Gilead's patents are valid, enforceable, and infringed and, if so, determine the appropriate compensation. In setting the appropriate compensation, the court would look to the factors presented in Section 4. The court could, for example, consider the significantly lower prices at which Gilead has chosen to sell Truvada in other countries (at a profit). For example, as of 2016, Gilead sold Truvada as PrEP in the U.K. at an average price of £4331 per patient per year, equivalent to about $475 per month.[189]

As explained in Section 4, HHS could conceivably avoid litigation by negotiating with Gilead a settlement agreement that includes a mutually agreeable royalty.

SCENARIO B

In Scenario B, a generic or biosimilar manufacturer has filed an application with the FDA and has received "tentative" rather than full FDA approval.[190]

What is tentative approval? The FDA grants tentative approval when the generic or biosimilar application is fully "approvable"—the product meets FDA standards for safety, efficacy, and so on— but the FDA is aware of some exclusivity (patent or regulatory) held by the brand-name drug company that remains in effect; this ongoing exclusivity prevents the FDA from granting full approval.[191] The FDA will not convert the tentative approval to a full approval until it is assured that the relevant exclusivity no longer stands in the generic or biosimilar competitor's way.

In some cases, the exclusivities holding up full approval are not patents, or patent-based, and consequently are not "patent problems" solvable through the use of § 1498. The relevant exclusivity preventing full approval may be non-patent, FDA-granted "data exclusivity" or "market exclusivity."[192] So long as these non-patent exclusivities are in effect, § 1498 alone may not suffice to enable entry of a generic, because § 1498 is limited to government patent use and cannot authorize a generic company to bypass non-patent exclusivity.

However, in other cases the relevant exclusivity preventing the FDA from converting a tentative

[185] *Frequently Asked Questions*, Davie Buyers Club (undated), https://daviebuyersclub.wordpress.com/home/frequently-asked-questions/.

[186] *PrEP For HIV Prevention*, EndingHIV.org/ACON Health Limited, (undated), https://endinghiv.org.au/stay-safe/prep/.

[187] *About Ending the HIV Epidemic Initiative*, Centers for Disease Control and Prevention (Jul. 30, 2020), https://www.cdc.gov/endhiv/about.html; Alex M. Azar, *Ending the HIV Epidemic: A Plan for America* (Feb. 5, 2019) https://www.hhs.gov/blog/2019/02/05/ending-the-hiv-epidemic-a-plan-for-america.html.

[188] In this hypothetical, patent settlement agreements between these generic manufacturers and Gilead might impose separate contractual penalties in the event that the generic manufacturers begin to sell their generic products prior to the contractually agreed-upon date. The generic manufacturers might nonetheless accept HHS's order if their expected profits from selling to the U.S. government outweigh the contractual penalties.

[189] Valentina Cambiano et al., *Cost-effectiveness of pre-exposure prophylaxis for HIV prevention in men who have sex with men in the UK: a modelling study and health economic evaluation*, 18 The Lancet 85, 88 (2018).

[190] Scenario B is specific to generic small molecule drugs rather than biologic biosimilar drugs because the FDA grants tentative approval status only to small molecule drugs.

[191] *How FDA Approves Drugs and Regulates Their Safety and Effectiveness*, Congressional Research Service (May 8, 2018), https://crsreports.congress.gov/product/pdf/R/R41983.

[192] The FDA-granted 5-year New Chemical Entity exclusivity and the 7-year Orphan Drug exclusivity are examples of non-patent-related exclusivities. Non-patent data and market exclusivities are complex, and a detailed overview is beyond the scope of this guide. Readers should consult other sources, such as Yaniv Heled, *Patents v. Statutory Exclusivities in Biological Pharmaceuticals - Do We Really Need Both*, 18 Mich. Telecomm. & Tech. L. Rev. 419 (2012), https://repository.law.umich.edu/mttlr/vol18/iss2/2/; and *Drug Pricing and the Law: Regulatory Exclusivities*, Congressional Research Service (May 17, 2019), https://fas.org/sgp/crs/misc/IF11217.pdf, for detailed explanation of these exclusivities.

approval to a full approval is squarely patent-related, and these "patent problems" can be addressed through § 1498. For example, the 30-month stay triggered by ANDA litigation and described above may be in effect. While the 30-month stay is in effect, the FDA will not grant full approval, only tentative.[193] In this situation, § 1498 may be able to clear the way for a generic to enter the market. Upon appropriate "authorization" by the government under § 1498, a generic manufacturer can obtain a court order dismissing the lawsuit from the same district court that instituted the 30-month stay (because its use of the patents is authorized by the U.S. government under § 1498). Once the district court dismisses the patent infringement suit, the 30-month stay would be lifted.[194] Once the stay is lifted, the FDA can quickly convert its tentative approval to full approval, and the generic manufacturer can begin selling its product to the U.S. government.

SCENARIO C

In Scenario C, an application for approval of a generic or biosimilar product has been filed with the FDA but has not yet received any kind of FDA approval, either full or tentative. In this scenario, the FDA may still be reviewing the ANDA or ABLA to confirm that the generic or biosimilar drug is safe and effective.

As of writing, this scenario applies to the important HIV treatment and HIV PrEP drug emtricitabine/tenofovir alafenamide, sold under the brand name Descovy. In late 2019, no fewer than nine separate generic drug manufacturers filed ANDAs with the FDA for approval of generic versions of Descovy.[195] To our knowledge, these applications remain pending at the FDA as of writing, and the generic manufacturers remain embroiled in patent infringement litigation with the patent-holding manufacturer of Descovy, Gilead.[196]

In this scenario, patents are not the only barrier to generics entering the market. The need for FDA approval creates a separate barrier; unless and until it is FDA-approved, a drug cannot legally be distributed within the US. Exercise of § 1498 will not thus permit HHS to procure the drug immediately.

However, if HHS is interested in procuring a particular generic or biosimilar drug, it can begin discussions and negotiations with the generic or biosimilar manufacturer even before full or tentative approval is granted. During this time, HHS may learn from the generic or biosimilar manufacturer the expected timing of the FDA approval process[197] and can begin to negotiate an appropriate price. HHS can reach an agreement with the generic or biosimilar manufacturer to begin procurement of a drug under § 1498 on the same day the FDA grants approval. In addition, as is true with all four Scenarios A-D, HHS could also use the prospect of authorized generic competition under § 1498 to bring the patent holder to the negotiating table and attempt to negotiate lower prices and/or expanded supply.

SCENARIO D

In Scenario D, makers of generic or biosimilar drugs have not yet filed an application with the FDA for approval of their product. The drug maker may not have filed an application because the product is not yet fully developed, or the drug maker may have a fully developed product but may not have filed an application for other reasons.

For example, in November 2020, the FDA granted emergency use authorizations to two biologic drugs useful in treating COVID-19: therapeutic monoclonal antibody products developed and manufactured by the originator drug companies Eli Lilly[198] and Regeneron.[199] To our knowledge, no biosimilar drug makers have yet developed follow-on products for these antibodies, let alone filed applications for their authorization or approval. As such, these drugs fit Scenario D.

[193] 21 CFR 314.107.

[194] 21 CFR 314.107(b)(3)(viii).

[195] *See* Complaint in *Gilead Sciences, Inc. v. Apotex, Inc.*, Case No. 1:20-cv-00189-UNA (D. Del. Feb. 7, 2020), at ¶¶ 1-2 (alleging that nine generic drug manufacturers "seek approval to market generic versions of Gilead's products containing tenofovir alafenamide ("TAF"), including ... DESCOVY®," prior to the expiration of the patents covering Descovy).

[196] See Case No. 1:20-cv-00189-UNA (D. Del.).

[197] In 2017, the median total time from filing to approval for an ANDA was about 37 months, see *FDA Approves More Generic Drugs, but Competition Still Lags, Pew Charitable Trust* (Feb 2019), https://www.pewtrusts.org/-/media/assets/2019/02/fda_approves_more_generic_drugs_but_competition_still_lags.pdf, but some ANDAs are approved in 10 months or less, *see GENERIC DRUG APPLICATIONS FDA Should Take Additional Steps to Address Factors That May Affect Approval Rates in the First Review Cycle*, U.S. Government Accounting Office (Aug. 2019), https://www.gao.gov/assets/710/700779.pdf.

[198] FDA, *Letter from U.S. Food and Drug Administration to Eli Lilly Corporation re: Emergency Use Authorization for bamlanivimab* (Nov. 10, 2020), https://www.fda.gov/media/143602/download.

[199] FDA, *Letter from U.S. Food and Drug Administration to Regeneron Pharmaceuticals, Inc. re: Emergency Use Authorization for emergency use of casirivimab and imdevimab, administered together* (Nov. 21, 2020) https://www.fda.gov/media/143891/download.

In this scenario, HHS will not be able to rely on § 1498 alone for quick procurement of generic or biosimilar drugs. However, HHS may be able to collaborate with a generic or biosimilar manufacturer to submit an application, work through the FDA review process, and obtain FDA approval. In the event that non-patent, FDA-granted data exclusivity prohibits the filing of an abbreviated application, HHS may be able to work with a determined generic or biosimilar applicant to generate or obtain the requisite clinical trial data and submit a full application, and thereby circumvent the prohibition.[200]

[200] Rebecca S. Eisenberg, *Data Secrecy in the Age of Regulatory Exclusivity*, in THE LAW AND THEORY OF TRADE SECRECY 467, 488 (Rochelle C. Dreyfuss & Katherine J. Strandburg eds., 2011) ("[R]egulatory exclusivity defers the filing and approval of ANDAs, but not of NDAs. An applicant who is able to submit 'full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use' need not wait until the end of the exclusivity period, when the statute permits the use of an ANDA, but could instead file an NDA. . . . [I]f the data were publicly available, the competitor could file its own NDA at reasonable cost."). Morten & Duan describe in some detail how HHS could authorize a generic manufacturer to use the patents covering the COVID-19 drug remdesivir and assist the generic manufacturer with obtaining the necessary clinical trial data to submit a full (rather than an abbreviated) application. See Morten & Duan at 69.

SECTION 6

ABOUT THE CLINIC, ACKNOWLEDGMENTS & COPYRIGHT NOTICE

ABOUT THE TECHNOLOGY LAW & POLICY CLINIC AT NYU LAW

With technological advances driving greater social, economic, and political change—from access to information, healthcare, and entertainment to impacts on the environment, education, and commerce to increased surveillance by law-enforcement agencies—issues related to privacy, consumer rights, algorithmic accountability, free speech, and intellectual property are becoming increasingly critical and complex. The Technology Law & Policy Clinic at NYU Law focuses on the representation of individuals, nonprofits, and consumer groups who are engaged with these questions from a public interest point-of-view. The clinic involves a mixture of fieldwork and seminar discussion ranging from technology law and policy to the ethical challenges of representing public interest organizations. The clinic is taught by Professors Jason Schultz and Brett Max Kaufman and Deputy Director Chris Morten. The clinic's website is **https://www.law.nyu.edu/academics/clinics/tech-law-policy**.

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APPENDIX

COURT OF CLAIMS DECISIONS ADJUDICATING "REASONABLE AND ENTIRE" COMPENSATION

The following is a chronological list of Court of Claims decisions that adjudicate "reasonable and entire" compensation under 28 U.S.C. § 1498.[202]

NAME	INVENTION	AMOUNT
Waite v. United States, 69 Ct. Cl. 153, 4 USPQ 387 (1930), *modified on other grounds*, 282 U.S. 508, 51 S. Ct. 227, 75 L. Ed. 494, 8 USPQ 121 (1931)	X-ray transformer	$6001.42 ($59.42 profit lost on sales of transformers but not related equipment; plaintiff was former supplier)
Imperial Mach. &Foundry Corp. v. United States, 69 Ct. Cl. 667, 5 USPQ 332 (1930)	Abradant disk for potato-peeling machine	$48,333.83 (lost profits of $67.91 per machine with disk and $11.25 per disk; plaintiff was former supplier)
Carley Life Float Co. v. United States, 74 Ct. Cl. 682, 13 USPQ 112 (1932)	Life float	$176,518.44 (10.86% of infringing sales; average royalty under exclusive license)
Meurer Steel Barrel Co. v. United States, 85 Ct. Cl. 554, 34 USPQ 123 (1937), *cert. denied*, 302 U.S. 754 (1937)	Clamping ring for steel drums	$21,724.85 ($.35 per barrel; "narrow" patent; prior settlements of $.25 adjusted upward)
Barlow v. United States, 87 Ct. Cl. 287, 34 USPQ 127 (1937)	Bomb detonator	10% (prior license between plaintiff and government)
Olsson v. United States, 87 Ct. Cl. 642, 25 F. Supp. 495, 37 USPQ 767 (1938)	Recoil mechanism for howitzer	$72,499 (25% of manufacturing cost savings; U.S. incurred design expense; plaintiff lacked manufacturing capacity)

[202] The list is sourced from 7 Chisum on Patents § 20.03.

NAME	INVENTION	AMOUNT
Marconi Wireless Telegraph Co. of America v. United States, 99 Ct. Cl. 1, 53 USPQ 246 (1942), *aff'd and modified*, 320 U.S. 1, 87 L. Ed. 1731, 63 S. Ct. 1393, 57 USPQ 471 (1943)	(1) Lodge patent on selective tuning of radio transmitting station; (2) Marconi patent on adjustable condenser addition to radio receiver antenna	(1) $34,607.70 (10% of whole sets bought but not spare parts; prior licenses of 2 patents at 20% with reduction to 10% on expiration of one (2) $42,984.93 (65% of cost saving over alternative—-remanded so as to exclude value of improvements added by defendant)
Shearer v. United States, 101 Ct. Cl. 196, 60 USPQ 414 (1944)	Concrete revetment construction	$319,673.16 (20% of portion of average cost saving attributable to patented method)
Fauber v. United States, 112 Ct. Cl. 302, 81 F. Supp. 218, 79 USPQ 410 (1948)	Hydroplane boat hull	$88,686 (1 1/2% of cost; other licenses of 5%; defendant did development work and bought large quantities)
Breese Burners, Inc. v. United States, 140 Ct. Cl. 9, 115 USPQ 179 (1957)	Oil burner	$146,580.50 ($.25 per unit; licenses on related patents averaged $.17, adjusted upward as patent in suit was valuable improvement)
Badowski v. United States, 150 Ct. Cl. 482, 278 F.2d 934, 125 USPQ 656 (1960)	Parachute release	3% on first $1 million in cost, 2% on excess (government was large purchaser; other licenses at 5% of higher cost)
Saulnier v. United States, 161 Ct. Cl. 223, 314 F.2d 950, 137 USPQ 222 (1963)	Airplane canopy assembly	$250,000 (3% on first $5 million, 2% on excess; settlement with British government)
Ushakoff v. United States, 179 Ct. Cl. 780, 375 F.2d 822, 150 USPQ 810, 153 USPQ 410 (1967)	Inflatable solar still for converting salt water to drinking water	$125,000 (about 5% plus interest at 4%; parties far apart—plaintiff at $1,062,749 based on 25% of cost savings; defendant at $54,808 based on 2-3% of procurement cost)

NAME	INVENTION	AMOUNT
Van Veen v. United States, 181 Ct. Cl. 884, 386 F.2d 462, 156 USPQ 403 (1967)	Survival sleeping bag	5% of cost (Canadian plaintiff's settlement with his own government at 4%; low level of procurement)
Amerace Esna Corp. v. United States, 199 Ct. Cl. 175, 462 F.2d 1377, 172 USPQ 305, 174 USPQ 517 (1972)	Process for removing marine growth from ballast tanks	$25,000 (5% of cost of compound bought for use in process; hypothetical negotiation for license)
Calhoun v. United States, 197 Ct. Cl. 41, 453 F.2d 1385, 172 USPQ 438 (1972)	O-ring sealing element for pistons	$60,554.36 ($.25 per unit rate set by licenses to commercial users; no increase for litigation expense)
Pitcairn v. United States, 212 Ct. Cl. 168, 547 F.2d 1106, 192 USPQ 612 (1976), *cert. denied*, 434 U.S. 1051 (1978)	Helicopter	2% of procurement cost (patent holder's general offer to commercial users)
Tektronix, Inc. v. United States, 213 Ct. Cl. 257, 552 F.2d 343, 193 USPQ 385 (1977), *modified*, 213 Ct. Cl. 307, 557 F.2d 265 (Ct. Cl. 1977)	Electronic circuitry of oscilloscope	10% of procurement cost of patented scopes plus necessary plug-ins (plaintiff made 25% profit)
Leesona Corp. v. United States, 220 Ct. Cl. 234, 599 F.2d 958, 202 USPQ 424 (1979), *cert. denied*, 444 U.S. 991 (1979)	Mechanically rechargeable metal-air batteries	10% of procurement cost of original package, including extra anodes (defendant's savings; plaintiff's development costs; hypothetical negotiation)
Decca Ltd. v. United States, 640 F.2d 1156, 209 USPQ 52 (Ct. Cl. 1980), cert. denied, 454 U.S. 819 (1981)	Hyperbolic radio navigation system	$2,043,425 basic compensation; $1,131,033 delay compensation (7.5% of adjusted cost of patented system; prior private commercial license rate)
Jamesbury Corp. v. United States, 207 USPQ 131 (Trial Div. 1980)	Floating ball valve for pipelines	6 1/2% of procurement (settlement agreement; large procurement—$87,300,000)

NAME	INVENTION	AMOUNT
Kornylak Corp. v. United States, 207 USPQ 145 (Trial Div. 1980) (alternative holding)	Motor vehicle with laterally adjustable cab	$1000 per vehicle (3 1/4% of cost)
Dynamics Corp. of America v. United States, 5 Cl. Ct. 591, 223 USPQ 1308 (Claims Court 1984), *aff'd and remanded*, 766 F.2d 518, 226 USPQ 622 (Fed. Cir. 1985).	General purpose analog computer for checking operations	6% (importance of invention, volume)
ITT Corp. v. U.S., 17 Cl. Ct. 199, 11 USPQ2d 1657 (Cl. Ct. 1989)	Fiber optic connector (axial tolerance relief, strain relief	3.5% for 1st patent; 3% for 2d patent; 4% when both patents used; rate doubled when devices sold as components (prior license rate negotiated upward by 1% because patent was weak at time of license; *Georgia-Pacific* factors; expert testimony)
de Graffenried v. United States, 25 Cl. Ct. 209, 24 USPQ2d 1594 (Cl. Ct. 1992)	Large gun barrel bore guiding controller system	$50,000 up-front royalty plus 5% of equipment cost (patentee's license offer, industry practice not to use per-use royalties)
Hughes Aircraft Co. v. United States, 35 USPQ2d 1243 (Fed. Cl. Ct. 1994), *aff'd*, 86 F.3d 1566, 39 USPQ2d 1065 (Fed. Cir. 1996), *vacated and remanded,* 520 U.S. 1183 (1997), *aff'd*, 140 F.3d 1470, 46 USPQ2d 1285 (Fed. Cir. 1998), *reh'g denied, suggestion for reh'g in banc declined*, 148 F.3d 1384, 47 USPQ2d 1542 (Fed. Cir. 1998), *cert. denied*, 119 S. Ct. 1112 (1999)	Spin-stabilized spacecraft	1% (patentee's prior license offers; large size of compensation base; potential competitive alternatives; lack of development)
Gargoyles, Inc. v. United States, 113 F.3d 1572, 42 USPQ2d 1760 (Fed. Cir. 1997)	Protective eyewear	10% (*Georgia–Pacific* factors; profitability of invention to patentee; expert testimony; case precedents)