

**WHO'S AFRAID OF SECTION 1498? A CASE FOR
GOVERNMENT PATENT USE IN PANDEMICS AND OTHER
NATIONAL CRISES**

Christopher J. Morten & Charles Duan*

COVID-19 has created pressing and widespread needs for vaccines, medical treatments, PPE, and other medical technologies, needs that may conflict—indeed, have already begun to conflict—with the exclusive rights conferred by United States patents. The U.S. government has a legal mechanism to overcome this conflict: government use of patented technologies at the cost of government-paid compensation under 28 U.S.C. § 1498. But while many have recognized the theoretical possibility of government patent use under that statute, there is today a conventional wisdom that § 1498 is too exceptional, unpredictable, and dramatic for practical use, to the point that it ought to be invoked sparingly or not at all, even in extraordinary circumstances such as a pandemic.

Yet that conventional wisdom is a recent one, and it conflicts with both history and theory. This Article considers the role of § 1498 in the context of national crises and emergencies like

* Copyright 2020 Christopher J. Morten and Charles Duan. Morten is the deputy director of the Technology Law and Policy Clinic and a Fellow at the Engelberg Center on Innovation Law & Policy at New York University School of Law. He is also a Visiting Fellow of the Yale Global Health Justice Partnership and an Affiliated Fellow of the Information Society Project at Yale Law School. Duan is a Senior Fellow at the R Street Institute, Washington, D.C. Order of authorship was determined by coin flip. Portions of this Article are based on *Who's Afraid of Section 1498? Government Patent Use as Versatile Policy Tool*, WRITTEN DESCRIPTION (Apr. 24, 2020), <https://writtendescription.blogspot.com/2020/04/whos-afraid-of-section-1498-government.html>. The authors would like to thank Al Engelberg, Daniel Hemel, Amy Kapczynski, Priti Krishtel, Matthew Lane, Lisa Larrimore Ouellette, Zain Rizvi, Bhaven Sampat, Jason Schultz, Ken Shadlen, Kathy Strandburg, Jacob Victor, and the editors of the *Yale Journal of Law and Technology* for their valuable insights and assistance that contributed to this Article. C.J.M. gratefully acknowledges Kara Smith (NYU Law '22) for research support. All errors are the authors' own.

COVID-19, a context so far not addressed substantially in the literature on the statute. We find that government patent use is not nearly as exceptional as it is commonly made out to be, and indeed has been not only used but expanded through statutory amendment over the last century. Review of the development and use of the statute during both world wars and the post–September 11 period reveals widespread acceptance of government patent use as a tool for addressing imminent national problems, and it illuminates particular features of government patent use that become especially pertinent in times of crisis. In the United States, government patent use and national emergencies have a close and special relationship; each has shaped the other.

Drawing from the lessons of history and analysis of the statute, we develop a novel framework for comparing § 1498 to other policy tools, including prizes, research grants, and patent buyouts. Under this framework, four features of § 1498 stand out: speed of invocation, flexibility in the scope of its use, post-crisis determination of compensation, and use of an impartial adjudicator. Whenever these four features are advantageous—which will be true in most national emergency situations, as we demonstrate—the U.S. government should strongly consider government patent use over patent buyouts and other policy tools. We show the advantages of these four features in a case study: government patent use to expand supply and access to the COVID-19 treatment remdesivir. Accordingly, and contrary to the conventional view of § 1498, we conclude that government patent should be an ordinary tool of government policy.

TABLE OF CONTENTS

INTRODUCTION.....	4
I. HISTORICAL ROLE OF GOVERNMENT PATENT USE IN TIMES OF CRISIS	13
A. Origin of the Statute.....	13
B. World War I	15
C. World War II.....	20
D. Bioterrorism Threats After September 11	26
E. Lessons for the COVID-19 Pandemic	33
II. THE GOVERNMENT'S INNOVATION POLICY TOOLBOX	39
A. Grants	39
B. Prizes	40
C. Patent Buyouts.....	41
D. Government Patent Use Under Section 1498	43
III. SECTION 1498 AS POLICY TOOL IN A NATIONAL EMERGENCY	50
A. Four Key Features of Government Patent Use in a National Emergency	51
1. <i>Speed</i>	51
2. <i>Flexibility</i>	54
3. <i>Ex Post Remedy Determination</i>	61
4. <i>Determination of Compensation by an Impartial Adjudicator</i>	66
B. A Case Study for the Use of § 1498: Remdesivir in the COVID-19 Pandemic.....	69
1. <i>Remdesivir: An Experimental Drug That Promises Modest but Important Benefits</i>	71
2. <i>Two Problems: Shortages and Overpricing</i>	74
3. <i>Patents Are the Sole Significant Barrier to Access</i>	78
4. <i>Government Patent Use Offers a Way Forward</i>	85
IV. CONCLUSION.....	91
V. APPENDIX: MEMORANDUM FROM ALFRED B. ENGELBERG TO SENATOR CHARLES E. SCHUMER	92

INTRODUCTION

Among certain patent lawyers, one number generates some awe and trepidation: 1498. It is the section number of a statute in Title 28 of the United States Code, a law that provides the U.S. government with the power to manufacture and use any patented invention at the cost of “reasonable and entire compensation for such use and manufacture.”¹ This seemingly unremarkable statutory language has sat on the books for over a century. Yet 28 U.S.C. § 1498 and government patent use are regularly characterized in the language of extremity. Commentators describe the statute as “breaking” patents,² “seizure” of rights,³ “stealing,”⁴ “expropriating private property,”⁵ “taboo,”⁶ “a radical change,”⁷ a “specter,”⁸ a

¹ 28 U.S.C. § 1498(a). Other current laws, most notably the march-in rights provision of the Bayh–Dole Act, provide alternate pathways for the government to make use of patented inventions. *See* 35 U.S.C. § 203(a); *see also* 16 U.S.C. § 831r (Tennessee Valley Authority power to use patented inventions); 42 U.S.C. § 2183(b)(2) (Atomic Energy Commission power to use and license patents). *See generally* Tejas N. Narechania, *Patent Conflicts*, 103 GEO. L.J. 1483, 1513–16 (2015).

² *E.g.*, Daniel R. Cahoy, *Breaking Patents*, 32 MICH. J. INT’L L. 461, 465 n.15 (2011) (noting use of phrase “for hyperbolic effect”).

³ Michael Lehr, *Federal Seizure of Patented Inventions: A COVID-19 Response*, DUNLAP BENNETT & LUDWIG (Apr. 2, 2020), <https://www.dblawyers.com/federal-seizure-of-patented-inventions-a-covid-19-response>; *see* Chris Katopis, *Recognizing the Limits of Government Procurement in the Pharmaceutical Industries*, CTR. FOR PROTECTION INTELL. PROP. (Dec. 20, 2018), <https://cpip.gmu.edu/2018/12/20/recognizing-the-limits-of-government-procurement-in-the-pharmaceutical-industries>.

⁴ *E.g.*, Elizabeth Wright, *Stealing Patents Won’t Bring Down Drug Costs*, CITIZENS AGAINST GOV’T WASTE (Apr. 3, 2018), <https://www.cagw.org/thewastewatcher/stealing-patents-won%E2%80%99t-bring-down-drug-costs>; Charles Sauer, *Government May Attempt to Steal COVID Vaccine*, REALCLEAR HEALTH (June 17, 2020), https://www.realclearhealth.com/articles/2020/06/17/government_may_attempt_to_steal_covid_vaccine_111060.html.

⁵ James Edwards, *A Protection, Not a Weapon*, CONSERVATIVES FOR PROP. RTS (May 27, 2020), <https://www.property-rts.org/post/a-protection-not-a-weapon>.

⁶ Natalie Shure, *Force Drug Companies to Lower Prices*, AM. PROSPECT (Sept. 26, 2019), <https://prospect.org/day-one-agenda/force-drug-companies-to-lower-prices>.

⁷ Adam Houldsworth, *New York Times’ Seizure Call Shows How Far the Tide Is Turning Against Pharma IP*, IAM (July 13, 2019), <https://www.iam-media.com/law-policy/new-york-times-pharma-patents>.

⁸ Joel Wallace, *Mad Dash to Coronavirus Vaccine May Face Legal Hurdles*,

“nuclear option,”⁹ and equivalent to eminent-domain condemnation.¹⁰ Even supporters of invoking the law sometimes characterize use of § 1498 as exceptional.¹¹ And the COVID-19 pandemic, despite having elicited numerous calls to invoke

IPWATCHDOG (Mar. 12, 2020), <https://www.ipwatchdog.com/2020/03/12/mad-dash-coronavirus-vaccine-may-face-legal-hurdles/id=119790>.

⁹ E.g., Michael Rosen, *Running Roughshod over Intellectual Property Rights Won't Lower Drug Prices*, AEI IDEAS BLOG (July 24, 2018), <https://www.aei.org/technology-and-innovation/intellectual-property/running-roughshod-over-intellectual-property-rights-wont-lower-drug-prices>; Valerie Bauman, *Government May Have Ownership or Rights to Coronavirus Vaccines*, BLOOMBERG L. (Mar. 20, 2020), <https://news.bloomberglaw.com/pharma-and-life-sciences/government-may-have-ownership-or-rights-to-coronavirus-vaccines>.

¹⁰ In addition to the literature that analyzes § 1498 under a takings framework, *see infra* note 20, there is significant commentary that invokes eminent domain largely for rhetorical effect. *See, e.g.*, Adam Mossoff, Sean O'Connor & Evan Moore, *Proposal for Drug Price Controls is Legally Unprecedented and Threatens Medical Innovation*, CTR. FOR PROTECTION INTELL. PROP. (Nov. 5, 2018), <https://cpip.gmu.edu/2018/11/05/proposal-for-drug-price-controls-is-legally-unprecedented-and-threatens-medical-innovation>; Henry Grabowski, *Government Appropriation of Breakthrough Drug Patent Rights Would Deter Biopharmaceutical R&D and Innovation*, HEALTH AFF. BLOG (June 20, 2016), <https://www.healthaffairs.org/doi/10.1377/hblog20160620.055440/full>.

¹¹ *See, e.g.*, Letter from Bernard Sanders, Senator, U.S. Senate, to Robert A. McDonald, Sec'y, U.S. Dep't of Veterans Affairs 1 (May 12, 2015), <https://www.sanders.senate.gov/download/051215-letter> (calling for Department of Veterans Affairs to use § 1498 “to break the patents” on certain drugs); Joel Dodge, *The Government Can Legally Commandeer Drug Patents*, PEOPLE'S POL'Y PROJECT (Oct. 2, 2017), <https://www.peoplespolicyproject.org/2017/10/02/the-government-can-legally-commandeer-drug-patents> (quoting Sen. Bill Cassidy on use of § 1498 to “commandeer” the drug industry); George Abi Younes et al., *COVID-19: Insights from Innovation Economists*, 47 SCI. & PUB. POL'Y 1, 7 (2020) (describing “implementation of compulsory licensing” as “challenging but a real option on the table”); Editorial Bd., *How the Government Can Lower Drug Prices*, N.Y. TIMES (June 20, 2018), <https://www.nytimes.com/2018/06/20/opinion/prescription-drug-costs-naloxone-opioids.html> (describing § 1498 as “a sort of eminent domain”). In their authoritative analysis of § 1498 in the pharmaceutical context, Brennan, Kapczynski, Monahan, and Rizvi advocate use of § 1498 but conclude that the tool should be used relatively sparingly, “suggest[ing] that the government only invoke its § 1498 power where drug pricing has created sizeable deadweight loss.” Hannah Brennan et al., *A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health*, 18 YALE J.L. & TECH. 275, 319 (2016). The authors also argue that, “[a]s with eminent domain, where the government often purchases land on the private market despite having the power to take it, so too should government use of patents be invoked in the exceptional rather than routine case.” *Id.*

§ 1498,¹² has not changed the views of many that government patent use is a destabilizing intervention, tantamount to “throw[ing] our IP system out the window.”¹³

To be sure, § 1498 can be used in bold, interventionist ways. For example, Senators Bernie Sanders and Elizabeth Warren, along with the *New York Times* editorial board, have called for the use of § 1498 to discipline the pricing of certain vital and best-selling prescription drugs.¹⁴ Though the United States has not used § 1498 in this dramatic way, there is much merit to such bold use, which could save billions in public and private drug spending.¹⁵

¹² See, e.g., Michael Liu et al., *March-in Rights and Compulsory Licensing—Safety Nets for Access to a COVID-19 Vaccine*, HEALTH AFF. BLOG (May 6, 2020), <https://www.healthaffairs.org/doi/10.1377/hblog20200501.798711/full>; Amy Kapczynski, Paul Biddinger & Rochelle Walensky, *Remdesivir Could Be in Short Supply. Here’s a Fix*, N.Y. TIMES (July 29, 2020), <https://www.nytimes.com/2020/07/28/opinion/remdesivir-shortage-coronavirus.html>.

¹³ Adam Houldsworth, *IP Is Crucial to Finding Breakthrough Covid-19 Medicines*, Novartis Policy Head States, IAM (Apr. 30, 2020), <https://www.iam-media.com/coronavirus/ip-crucial-finding-breakthrough-covid-19-medicines-novartis-policy-head-states> (quoting Corey Salsberg, Head of IP Affairs at Novartis); see also Tom Giovanetti, *Attempts to Degrade Drug Patents are Counterproductive in This Pandemic*, TOWNHALL (June 1, 2020), <https://townhall.com/columnists/tomgiovanetti/2020/06/01/progressive-activists-want-to-keep-meritless-obama-era-lawsuits-alive-n2569704> (invoking § 1498 during pandemic “is to do away with the IP system for good”); Bauman, *supra* note 9; Matt Rizzolo et al., *What If Gov’t Allows Patent Infringement For COVID-19 Drugs?*, LAW360 (Apr. 1, 2020), <https://www.law360.com/articles/1258739/what-if-gov-t-allows-patent-infringement-for-covid-19-drugs>.

¹⁴ See Sanders, *supra* note 11; Maia Anderson, *EpiPen, Humira Among Drugs Warren Wants to Regulate*, BECKER’S HOSP. REV. (Nov. 19, 2019), <https://www.beckershospitalreview.com/pharmacy/epipen-humira-among-drugs-warren-wants-to-regulate.html>; Editorial Bd., *supra* note 11; see also Letter from Ro Khanna, Member of Cong., House of Representatives, to Alex Azar, Sec’y, U.S. Dep’t of Health & Human Servs. (Feb. 15, 2018), <https://khanna.house.gov/sites/khanna.house.gov/files/Final%20Letter%20-%20signed.pdf>.

¹⁵ See, e.g., Christopher J. Brennan et al., *supra* note 11, at 280–81; Brittany S. Bruns, *The Pharmaceutical Access Act: An Administrative Eminent Domain Solution to High Drug Prices*, 106 CAL. L. REV. 2023, 2047–54 (2018); Amy Kapczynski & Aaron S. Kesselheim, “Government Patent Use”: A Legal Approach to Reducing Drug Spending, 35 HEALTH AFF. 791, 792–93 (2016); Barbara M. McGarey & Annette C. Levey, *Patents, Products, and Public Health: An Analysis of the CellPro March-in Petition*, 14 BERKELEY TECH. L.J. 1095, 1115 (1999) (noting advantages of § 1498 over Bayh–Dole Act march-in rights); Christopher J. Morten & Amy Kapczynski, *Assessing Drug Pricing Reform*

But the statute is not limited to such uses, and our focus in this Article is to show that § 1498 need not be at all extreme in its operation or impact. Under its authority to have patented inventions “used or manufactured by or for the United States” at the cost of “reasonable and entire compensation,” the government can fine-tune the scope and duration of its invocation of § 1498 to make modest interventions in the market, perhaps with only limited disruption to investment-backed expectations. And as a matter of history, § 1498 is not nearly as exceptional as some modern critics make it out to be. The government has long exercised both § 1498 and even stronger government patent-use powers, often with substantial support from the stakeholder community.

To highlight this more modest, ordinary role that § 1498 can play in national policy, we consider a specific class of uses: federal responses to complex large-scale crises, including the COVID-19 pandemic that the world faces today. While the statute’s effectiveness can go well beyond crisis management, a focus on emergency contexts reveals particular aspects and advantages of § 1498 that illuminate its value and carry over into non-emergency contexts as well. To be sure, national emergencies entail some policy considerations different from those of non-emergency times, but nevertheless they helpfully draw focus to latent features of § 1498 that might otherwise escape attention. We find that § 1498 is well suited to a perfectly ordinary role as a crisis management policy tool, on the same plane as other emergency powers such as the Defense Production Act, the invocation of which many have supported to tackle COVID-19.¹⁶

Proposals: The Real Leverage and Benefits of Competitive Licensing, HEALTH AFF. BLOG (Nov. 4, 2019), <https://www.healthaffairs.org/doi/10.1377/hblog20191101.594551/full> (noting unique benefits of compulsory licensing of patents on prescription drugs); 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).

¹⁶ See, e.g., Tim Hains, *Nancy Pelosi: President Trump Must Use Defense Production Act to Build More Ventilators Now*, “Save Lives,” REALCLEAR POL. (Mar. 31, 2020), https://www.realclearpolitics.com/video/2020/03/31/pelosi_trump_must_use_defense_production_act_to_build_more Ventilators_now.html; Caleb Watney & Alec Stapp, *Masks for All: Using Purchase Guarantees and Targeted Deregulation to Boost Production of Essential Medical Equipment*, MERCATUS CTR. 3–5 (Apr. 8, 2020), <https://www.mercatus.org/publications/covid-19-crisis-response/masks-all-using-purchase-guarantees-and-targeted-deregulation>.

This Article is, to our knowledge, the first to consider in detail the special role of government patent use in cases of national emergency in the United States.¹⁷ Past scholarship on the historical development and use of § 1498 has tended to focus on judicial cases where patents were actually used by the U.S. government under the statute or its predecessors,¹⁸ which are useful for explicating the scope and nature of the statute but less helpful for assessing the appropriateness of invoking it in the first place (since, after all, a case about government patent use can only arise after the government has used the patent). A handful discuss its legislative history and note in passing its connection to American involvement in World War I.¹⁹ Turning to normative analyses, substantial

¹⁷ While this Article does not treat international or foreign law extensively, we note that § 1498 is related to and consistent with international treaty provisions and other nations' laws that permit for compulsory licensing "in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use." See Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, art. 31(b), 1869 U.N.T.S. 299; Coenraad Visser, *Patent Exceptions and Limitations in the Health Context*, U.N. Doc. SCP/15/3 (Sept. 2, 2010). For discussion of the international dimensions of government patent use in emergency situations, see Reed Beall & Randall Kuhn, *Trends in Compulsory Licensing of Pharmaceuticals Since the Doha Declaration: A Database Analysis*, PLOS MED., 2012, at 3; Cynthia M. Ho, *Inoculation Inventions: The Interplay of Infringement and Immunity in the Development of Biodefense Vaccines*, 8 J. HEALTH CARE L. & POL'Y 111, 151 (2005); Robert Shapiro, *Patent Infringement During a Time of National Emergency: Are Canadian, American and Mexican Governments Permitted to Do So Under Their Domestic Law, NAFTA and TRIPS? If So at What Cost?*, 18 WINDSOR REV. LEGAL & SOC. ISSUES 37, 44–56 (2004); and Sapna Kumar, *Compulsory Licensing of Patents During the Pandemic* (Dec. 11, 2020) (unpublished manuscript), <https://ssrn.com/abstract=3636456>.

¹⁸ See, e.g., James E. Denny, *Eminent Domain Aspects of 28 USC 1498*, 4 PAT. TRADEMARK & COPYRIGHT J. RES. & EDUC. 257, 257–74 (1960); 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, 408–15 (1995); Richard J. McNeely, *Governmental Indirect Patent Infringement: The Need to Hold Uncle Sam Accountable Under 28 U.S.C. § 1498*, 36 CAP. U. L. REV. 1065, 1100–05, 1112–18 (2007); Blake E. Reese, Note, *Do as I Say, Not as I Do: An International and Comparative Study of Governments' Rights to "Infringe" Patents in Light of the Federal Circuit's Recent Interpretation of 28 U.S.C. § 1498 and a Call for Congress to Modernize the Statute*, 4 BUFF. INTELL. PROP. L.J. 84, 86–102 (2006).

¹⁹ See Colleen V. Chien, *Cheap Drugs at What Price to Innovation: Does the*

literature addresses the question of whether government patent use under § 1498 constitutes a Fifth Amendment taking of property,²⁰ a proposition that the Federal Circuit recently rejected.²¹ That literature does not generally distinguish emergency conditions from other situations.²² Others have considered the role of § 1498 in

Compulsory Licensing of Pharmaceuticals Hurt Innovation?, 18 BERKELEY TECH. L.J. 853, 868 (2003) (“[T]he statute was originally conceived with wartime urgency in mind”); Sean M. O’Connor, *Taking, Tort, or Crown Right? The Confused Early History of Government Patent Policy*, 12 J. MARSHALL REV. INTELL. PROP. L. 145, 188 (2012); William Brownell Humphrey, *A History and Analysis of Section 1498 of Title 28 of the United States Code Dealing with Unlicensed Use of Patents by the United States Government and Its Effect on Procurement* 9–12 (1974) (unpublished thesis), <https://apps.dtic.mil/sti/pdfs/AD0777985.pdf>. Brennan and colleagues give a “brief” history of § 1498’s application that is more extensive than most, though they consider use of the statute broadly rather than its specific application to national emergencies. See Brennan et al., *supra* note 11, at 298–307.

²⁰ For analysis contending that it is, see, for example, Joshua I. Miller, *28 U.S.C. § 1498(a) and the Unconstitutional Taking of Patents*, 13 YALE J.L. & TECH. 1, 5 (2011) (arguing that, being an act of eminent domain, exercise of § 1498 requires compensation for litigation costs); Lavenue, *supra* note 18, at 506 (similar); David R. Lipson, *We’re Not Under Title 35 Anymore: Patent Litigation Against the United States Under 28 U.S.C. § 1498(a)*, 33 PUB. CONT. L.J. 243, 244–45 (2003). For contrary views, see, for example, Denny, *supra* note 18, at 274 (finding eminent-domain treatment of § 1498 to be “unfortunate in the many problems that have arisen” in the case law as a result); Jonathan S. Masur & Adam K. Mortara, *Patents, Property, and Prospectivity*, 71 STAN. L. REV. 963, 991–92 (2019) (observing that government patent use “is described in terms of eminent domain or takings when that characterization is irrelevant to the resolution of the case at hand”). Much of this commentary was prompted by a Federal Circuit panel decision in *Zoltek Corp. v. United States (Zoltek I)* that government patent use was not a Fifth Amendment taking. See 442 F.3d 1345, 1353 (Fed. Cir. 2006) (per curiam), *vacated*, 672 F.3d 1309 (Fed. Cir. 2012) (en banc); Bradley M. Taub, *Why Bother Calling Patents Property—The Government’s Path to License Any Patent and Maybe Pay for It*, 6 J. MARSHALL REV. INTELL. PROP. L. 151, 154 (2006); Justin Torres, *The Government Giveth, and the Government Taketh Away: Patents, Takings, and 28 U.S.C. § 1498*, 63 N.Y.U. ANN. SURV. AM. L. 315, 338–41 (2007); Reese, *supra* note 18, at 117–19. That decision was vacated when an en banc court reversed the panel on different grounds. See *Zoltek Corp. v. United States (Zoltek II)*, 672 F.3d at 1318 (vacating *Zoltek I*); *id.* at 1327 (“[W]e need not and do not reach the issue of the Government’s possible liability under the Constitution for a taking.”).

²¹ See *Golden v. United States*, 955 F.3d 981, 988 (Fed. Cir. 2020); see also *infra* notes 213–212–220.

²² Earlier commentary from about the 1960s, by contrast, does occasionally note

specific fields such as health care,²³ government contracting and procurement,²⁴ and human rights.²⁵

Commentators have, to be sure, considered the applicability of § 1498 to certain specific emergency contexts.²⁶ Several commentators have suggested that § 1498 may be useful in a public health emergency, for example.²⁷ Some have specifically supported government patent use as a relief measure during the COVID-19 pandemic.²⁸ Others have noted the statute's relationship to war, generally in service of concluding its use is inappropriate outside of

this distinction, perhaps because the active area of discussion at that time was the role of § 1498 in government procurement. *See, e.g.,* Humphrey, *supra* note 19, at 21.

²³ *See* references cited *supra* note 15.

²⁴ *See, e.g.,* Humphrey, *supra* note 19, at 14–20; Lavenue, *supra* note 18, at 483–87; Gerald J. Mossinghoff & Robert F. Allnutt, *Patent Infringement in Government Procurement: A Remedy Without a Right*, 42 NOTRE DAME L. REV. 5, 9–14 (1967).

²⁵ *See* Cahoy, *supra* note 2, at 501–07.

²⁶ *See, e.g.,* Daniel R. Cahoy, *Treating the Legal Side Effects of Cipro: A Reevaluation of Compensation Rules for Government Takings of Patent Rights*, 40 AM. BUS. L.J. 125, 136 (2002) (rejecting “blanket arguments” against § 1498); *see also* Grace K. Avedissian, *Global Implications of a Potential U.S. Policy Shift Toward Compulsory Licensing of Medical Inventions in a New Era of “Super-Terrorism,”* 18 AM. U. INT’L L. REV. 237, 291 (2002) (calling for compulsory licensing to respond to “super-terrorism”). Torrance provides a comprehensive review of patent-related options, including § 1498, during a natural disaster, but focuses on a new statutory proposal. *See* Andrew W. Torrance, *Patents to the Rescue—Disasters and Patent Law*, 10 DEPAUL J. HEALTH CARE L. 309, 354 (2007).

²⁷ *See, e.g.,* Dennis D. Crouch, *Nil: The Value of Patents in a Major Crisis Such as an Influenza Pandemic*, 39 SETON HALL L. REV. 1125, 1126 (2009); McGarey & Levey, *supra* note 15, at 1115 (briefly noting speed advantages of § 1498 in cases of “a public health need for the invention, particularly an immediate need”); Neiloy Sircar, *Public Health Emergencies: Reconciling Trips and IHR* (2005), 41 HOUS. J. INT’L L. SIDEBAR 101, 120 (2018); *cf.* Amanda Mitchell, *Tamiflu, the Takings Clause, and Compulsory Licenses: An Exploration of the Government’s Options for Accessing Medical Patents*, 95 CAL. L. REV. 535, 557–58 (2007) (favoring condemnation of patents over § 1498 during an influenza epidemic). One article considers several advantages and drawbacks of government patent use during an emergency, but ultimately reaches no conclusion and recommends that governments “continue to use their negotiating skills in hopes of securing agreements” with patent holders. Shapiro, *supra* note 17, at 62.

²⁸ *See* Kumar, *supra* note 17, at 27–30; sources cited *supra* note 12.

wartime.²⁹ But this research generally stops at observing that § 1498 could remediate (or not remediate) particular situations, without developing a more comprehensive theoretical basis for when and why the government should make use of third-party patents during national emergencies. And some scholars,³⁰ including Hemel and Ouellette,³¹ have advocated for an alternative approach to expanding access to patented anti-COVID-19 technologies—patent buyouts of some sort—without (to our knowledge) weighing the advantages and disadvantages of a buyout against those of government patent use under § 1498.

This Article thus makes several contributions. First, it provides an up-to-date primer on government patent use—what it is, how it works, and how it compares to other policy tools to incentivize new inventions and allocate access to those inventions.³² Second, it makes a novel descriptive contribution by synthesizing the history

²⁹ See, e.g., Taub, *supra* note 20, at 171–72; Humphrey, *supra* note 19, at 21 (quoting speech by Leonard Rawicz, Patent Counsel, Goddard Space Flight Center) (“[S]ome view that the purpose of 28 U.S.C. 1498 was to assure patent litigation free procurement only during a national emergency or war”); Trojan, Inc. v. Shat-R-Shield, Inc., 885 F.2d 854, 858 (Fed. Cir. 1989) (Newman, J., concurring).

³⁰ See, e.g., Anton Howes, *Bringing the Future Forward*, ENTREPRENEURS NETWORK (May 27, 2020), <https://www.tenentrepreneurs.org/blog/bringing-the-future-forward>; Anton Howes, *Innovation: Eyes on the Prize*, ENTREPRENEURS NETWORK (Mar. 26, 2020), <https://www.tenentrepreneurs.org/blog/innovation-eyes-on-the-prize>; Thomas Pogge & Peggy Tse, *Restructuring Pharmaceutical Innovation*, CHINA GLOBAL TELEVISION NETWORK (June 2, 2020), <https://news.cgtn.com/news/2020-06-02/Restructuring-pharmaceutical-innovation-QZq50NZOxi/index.html>.

³¹ See Daniel Hemel & Lisa Ouellette, *Pharmaceutical Profits and Public Health Are Not Incompatible*, N.Y. TIMES (Apr. 8, 2020), <https://www.nytimes.com/2020/04/08/opinion/coronavirus-drug-company-profits.html>.

³² Others have covered large portions of this descriptive terrain before us, though we see value in explaining the basics, particularly as a Cabinet Secretary professed ignorance of § 1498 just last year (despite writing about the law in 2002). See Ari Shapiro & Selena Simmons-Duffin, *How HHS Secretary Reconciles Proposed Medicaid Cuts, Stopping the Spread of HIV*, NPR (Apr. 8, 2019), <https://www.npr.org/sections/health-shots/2019/04/08/711020181/how-trumps-hhs-reconciles-medicaid-cuts-with-stopping-the-spread-of-hiv> (quoting Secretary Alex Azar as stating that “There’s no such thing as a legal right to break patents in the United States.”). But see Alex Azar II, *Cipro: Good Deal, Good Policy*, AM. LAW., Apr. 2002, at 141 (“Section 1498(a) permits the United States to procure items without first obtaining a license, so long as it pays reasonable and entire compensation.”).

of the use of § 1498 and related statutes in times of national emergency. We include numerous early examples of government patent use that have not been explored in the legal academic literature. Even though the law has never been limited to those contexts and has broader application, § 1498 and norms of government patent use were shaped by national emergencies like the two world wars, and government patent use was widely accepted to be a valuable and critical tool during such emergencies. Third, the Article makes a novel, general normative case for government patent use in national emergencies, based on four key features of § 1498: (1) speed, (2) flexibility, (3) ex post determination of the appropriate compensation and (4) determination of that compensation by an impartial adjudicator. Whenever these four features are advantageous—which will be true in most national emergency situations, as we show, but may also apply in peacetime—the U.S. government should strongly consider government patent use over patent buyouts and other policy tools. Government patent use under § 1498 can be used in many ways, big and small, in a national emergency. Fourth, we provide a novel roadmap to government patent use in one particularly practical use case: ensuring adequate and affordable access to remdesivir, an antiviral drug, in the COVID-19 pandemic.

While the focus of this Article is the utility of § 1498 in the context of a national crisis, government patent use does not need to be reserved for extraordinary circumstances. We aim to demonstrate that government patent use is a flexible, highly useful policy tool. As we show below, § 1498 can be used modestly as well as massively to achieve various public benefits—lowering prices, expanding supply, or shielding socially useful activity from the risk of liability or injunction. The four key features of § 1498 that we highlight are permanent features of the section, and their benefits may warrant government patent use in ordinary circumstances as well as extraordinary ones, and not just in times of crisis but in times of relative calm, too. Ultimately, § 1498 is as much a Swiss Army knife as a sledgehammer.

The Article proceeds as follows. Part I reviews the historical development of § 1498 and government patent use, particularly from a legislative and policy perspective, to assess perceptions and legislative expansions of the role of government patent use during times of national emergency. Part II briefly describes the present-day nature of § 1498 and places it in the context of other policy tools

relevant to technological development and national crisis management. Part III then identifies several key advantages of § 1498 that are especially pertinent to large-scale crisis situations. Those advantages can be used as factors to assess the utility of § 1498 in particular situations, which we demonstrate through a case study of government patent use to expand supply and access to the COVID-19 treatment remdesivir. Part IV briefly concludes.

I. HISTORICAL ROLE OF GOVERNMENT PATENT USE IN TIMES OF CRISIS

Throughout history, § 1498 has been closely tied to American responses to national crises. In addition to reviewing the origins of § 1498, the discussion below focuses on three examples: the First World War, the Second World War, and the bioterrorism threat following September 11, 2001.

While the U.S. government used § 1498 extensively at these times and others,³³ the purpose of this Part is not to catalog invocations of § 1498. Instead, to discern the policy considerations that motivate the legislative and executive branches to contemplate government patent use, we focus on the complex and disputed cases, namely situations where policymakers relied on powers broader than § 1498, amended § 1498, or publicly contested the application of that statute. Aside from there being better records of these disputed cases,³⁴ the arguments elicited best highlight lawmakers' interests and motivations in ways that are instructive for future situations of government patent use.

A. Origin of the Statute

Enacted in 1910, the first incarnation of § 1498³⁵ was not born of any national emergency—it was triggered by Congress repaving the Capitol building. In *Schillinger v. United States*, the owner of a patent on a concrete pavement method brought an infringement suit

³³ For articles reviewing cases under and invocations of § 1498, see generally Brennan et al., *supra* note 11, at 302–07; Denny, *supra* note 18, at 258–74; Lavenue, *supra* note 18, at 452–72.

³⁴ Because there is no formal process for invoking § 1498, *see infra* text accompanying note 230, uses of the statute are not catalogued and may even go unrecorded.

³⁵ See Act of June 25, 1910 (1910 Act), ch. 423, 36 STAT. 851. The law was not numbered “§ 1498” at the time, but the government patent use laws described herein share a direct lineage to contemporary § 1498. See § 1498, hist. n. (noting derivation from 35 U.S.C. § 68 (1940)); 35 U.S.C. § 68 (noting derivation from 1910 Act). Accordingly for purposes of simplicity, this Article uses that section number to refer to the statute throughout.

against the government, whose contractor had used the patented method during the Capitol renovation.³⁶ The Supreme Court rejected the suit on grounds of sovereign immunity.³⁷ Despite the Tucker Act having partially waived sovereign immunity for “claims founded upon the Constitution . . . or upon any contract” with the United States,³⁸ the Court found this waiver inapplicable. The contract provision did not apply because the patent infringement action was “one sounding in tort.”³⁹ Nor was the action “founded upon the Constitution” despite the patent holder’s protestations that the government’s infringement was a “taking of private property,” as the Court deemed that reading excessively broad;⁴⁰ instead the Court read the waiver of sovereign immunity for Constitution-founded claims to exclude torts.⁴¹

In response to *Schillinger*, Congress enacted the Act of June 25, 1910 to “provide additional protection for owners of patents” by offering them a cause of action for “reasonable compensation” (but not injunctive relief) for any use of a patented invention “by the United States without license of the owner thereof or lawful right to use the same.”⁴² Contrary to how some have viewed the law, then, the logic of § 1498’s predecessor statute was not that it cut back on patentees’ remedies against the government; the baseline situation was that no remedy was available at all in view of sovereign immunity, and § 1498’s predecessor *expanded* patent protection by offering a new, albeit partial, remedy for government use.⁴³

³⁶ 155 U.S. 163, 171–72 (1894).

³⁷ See *id.* at 167 (“The general principle which we have already stated as applicable to all governments, forbids, on a policy imposed by necessity, that they should hold themselves liable for unauthorized wrongs inflicted by their officers on the citizen, though occurring while engaged in the discharge of official duties.”) (quoting *Gibbons v. United States*, 75 U.S. (8 Wall.) 269, 275 (1869)).

³⁸ Tucker Act, ch. 359, sec. 1, 24 STAT. 505, 505 (1887), *quoted in Schillinger*, 155 U.S. at 167.

³⁹ *Schillinger*, 155 U.S. at 169.

⁴⁰ *Id.* at 168 (“Can it be that Congress intended that every wrongful arrest and detention of an individual, or seizure of his property by an officer of the government, should expose it to an action for damages in the Court of Claims?”).

⁴¹ *Id.* (“[Congress] added, ‘all claims founded upon the Constitution of the United States,’ but that does not include claims founded upon torts . . .”).

⁴² Act of June 25, 1910 (1910 Act), ch. 423, 36 STAT. 851.

⁴³ See Brennan et al., *supra* note 11, at 298–99; see also ADDITIONAL PROTECTION FOR OWNERS OF PATENTS, H.R. REP. NO. 61-1288, at 3 (1910) (“Our only purpose is to extend the jurisdiction of [the Court of Claims] so that it may entertain suits

While national emergencies did not cause § 1498's original enactment, at least some members of Congress recognized the law's close tie to one sort of emergency condition: national security. The House report "conceded that the Government ought to have the right to appropriate any invention necessary or convenient for natural defense or for beneficent public use, and that, too, without previous arrangement or negotiation with the owner."⁴⁴ The congressional debate record also reveals that Congress consulted with the War and Navy Departments on the bill, and Representative Currier, the leading proponent of the 1910 Act in the House, specifically called out during the debate the possibility that "government officers can be restrained in preparing the national defense."⁴⁵ In subsequent debate, Representative Dalzell, another proponent of the bill, was asked what should happen if "one of our officers of the army or the navy, having invented some useful implement of war, should decline to allow the Government to have it." Dalzell's answer was that the invention "ought to be appropriated by the Government by due process of law."⁴⁶ Thus, § 1498 in its origins was plainly envisioned to have applicability outside of national emergencies—repaving the Capitol was rather clearly not one—but the statute's authors recognized its relevance to emergency conditions from the very beginning.

B. World War I

Hypothetical national security and emergency response concerns became reality during the First World War. As a war that heavily exploited science in the service of combat and that arguably invented the military public-private partnership,⁴⁷ World War I set

and award compensation to the owners of patents . . ."). One might wonder whether the statutory language "without . . . lawful right to use" in the 1910 Act undercuts this view of § 1498 as expanding conditions on the patent grant, the argument being that if the government has a preexisting right to use a patent, then the statute could not logically refer to situations where the government is "without . . . lawful right to use" the patent. But the legislative history makes clear that the aforementioned provision was intended to refer to a different form of "lawful right to use," namely shop rights arising from inventions of government employees. See H.R. REP. NO. 61-1288, *supra*, at 3.

⁴⁴ H.R. REP. NO. 61-1288, *supra* note 43, at 2. The term "natural defense" is likely a typographical error; it probably should have been "national defense."

⁴⁵ 45 CONG. REC. 8759 (1910).

⁴⁶ *Id.* at 8781 (1910).

⁴⁷ See M. Anthony Mills & Mark P. Mills, *The Invention of the War Machine*, 42

the stage for clashes between patents and national defense, clashes that would sharpen the role of government patent use in times of crisis. While patent disputes interfered with the war effort with respect to multiple technologies,⁴⁸ the development of aviation technology most clearly characterizes the role of government patent use during war.

The Wright brothers' solution to the lateral-roll problem in 1903 gave birth to a worldwide industry of powered aircraft.⁴⁹ It also gave birth to a massive tangle of patent litigation, as the Wrights' main competitor, airplane manufacturer Glenn Curtiss, sought to avoid the Wrights' patented twisting-wing design through a design-around involving inflexible hinged ailerons.⁵⁰ Across the early 1900s, the brothers waged a forceful campaign of patent lawsuits against not just Curtiss and other manufacturers but also individual aviators at flying exhibitions, reportedly springing service on them immediately after the shows.⁵¹ And both Curtiss and the Wrights engaged in patent licensing at rates that some historians have

NEW ATLANTIS 3, 3 (2014); *see also* KATHERINE C. EPSTEIN, *TORPEDO: INVENTING THE MILITARY-INDUSTRIAL COMPLEX IN THE UNITED STATES AND GREAT BRITAIN* 2–3 (2014) (describing role of torpedoes “in the invention of the military-industrial complex”).

⁴⁸ Disputes over torpedo technology, for example, would drag the government through almost a decade of litigation and arguably stall American torpedo development. *See* E.W. Bliss Co. v. United States, 253 U.S. 187, 188–90 (1920); EPSTEIN, *supra* note 48, at 154; Charles Duan, *Of Monopolies and Monocultures: The Intersection of Patents and National Security*, 36 SANTA CLARA HIGH TECH. L.J. 369, 388–89 (2020). The Chief of the Navy's Bureau of Ordnance wrote that its torpedo contractor, the E.W. Bliss Company, had used its patent-backed “monopoly” to force the government “to accept the terms offered or get no torpedoes,” which ultimately “influenced the E.W. Bliss Company in its prices, deliveries and workmanship.” Letter from N.E. Mason, Chief of Bureau of Ordnance, to Sec'y of the Navy, in *Estimates Submitted by the Secretary of the Navy: Hearing Before the H. Comm. on Naval Affairs*, 59th Cong. 433, 436 (1907), <https://www.loc.gov/item/tmp92007441>.

⁴⁹ *See* U.S. Patent No. 821,393 3 ll. 12–30 (filed Mar. 23, 1903); *see also* Wright Co. v. Herring–Curtiss Co., 177 F. 257, 259 (C.C.W.D.N.Y. 1910) (noting Wrights' successful demonstrations), *rev'd*, 180 F. 110 (C.C.A.2d 1910).

⁵⁰ *See Wright*, 177 F. at 259–60; Herbert A. Johnson, *The Wright Patent Wars and Early American Aviation*, 69 J. AIR L. & COM. 21, 28–30 (2004).

⁵¹ *See* Johnson, *supra* note 50, at 31–33 & note 39 (noting “resentment that the Wright Company allowed flying events to occur, and decided whether to sue after the exhibition had been staged”).

described as “almost confiscatory” and “prohibitive.”⁵²

The Wrights' vigorous patent enforcement is generally considered to have been a key impediment to aviation technology innovation in the United States.⁵³ By 1910, Europe had outstripped the United States in airplane motor design, and had made great strides in fixed single-wing aircraft while American manufacturers remained fixated on the Wrights' flexible two-wing configuration. In 1913, on the eve of World War I, the United States was far behind other nations in military aviation: France held 266 military airplanes while the United States sported just six.⁵⁴

With looming war and an industry impasse, the government's military branches found it necessary to take action. Congress in 1915 had formed a National Advisory Committee on Aeronautics,⁵⁵ and in January 1917, Acting Secretary of the Navy Franklin D. Roosevelt and Acting Secretary of War W.M. Ingraham asked

⁵² LAWRENCE GOLDSTONE, *BIRDMEN: THE WRIGHT BROTHERS, GLENN CURTISS, AND THE BATTLE TO CONTROL THE SKIES* 203 (2014); 1 ALEX ROLAND, *MODEL RESEARCH: THE NATIONAL ADVISORY COMMITTEE FOR AERONAUTICS 1915–1958*, at 38 (1985).

⁵³ There is some debate as to the relationship between the Wrights' patent activity and American innovation lag. The conventional view is that American firms eschewed investment in airplane technology out of fear of lawsuits or excessive royalty demands. *See, e.g.*, ROLAND, *supra* note 52, at 38; Phaedra Hise, *How The Wright Brothers Blew It*, *FORBES* (Nov. 19, 2003), <https://www.forbes.com/2003/11/19/1119aviation.html>; Johnson, *supra* note 50, at 42–43; Scott McCartney, *Wright Brothers' Patent Battle Proved Costly in Aviation Race*, *WALL ST. J.* (Dec. 17, 2003), <https://www.wsj.com/articles/SB107159573141697200>; Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 890–91 (1990). But several dissenting scholars note that there was substantial investment in airplane manufacturing during the pendency of the lawsuits and immediately after. *See* Tom D. Crouch, *Blaming Wilbur and Orville: The Wright Patent Suits and the Growth of American Aeronautics*, in *ATMOSPHERIC FLIGHT IN THE TWENTIETH CENTURY* 290–91 (Peter Galison & Alex Roland eds., 2000); Ron D. Katznelson & John Howells, *The Myth of the Early Aviation Patent Hold-up—How a US Government Monopsony Commandeered Pioneer Airplane Patents*, 24 INDUS. & CORP. CHANGE 1, 11 (2014). A potentially better explanation, as one of us has hypothesized elsewhere, is that the Wrights' litigation campaign, especially against foreign aviators, dampened knowledge crossovers between the United States and Europe. *See* Duan, *supra* note 48, at 391–92.

⁵⁴ *See* TOM D. CROUCH, *WINGS: A HISTORY OF AVIATION FROM KITES TO THE SPACE AGE* 147 (2003).

⁵⁵ *See* ROLAND, *supra* note 52, at 24.

NACA for a solution to the patent dilemma.⁵⁶ In response, the committee's chairman Charles D. Walcott petitioned President Wilson in February to introduce legislation to appropriate \$1 million for acquiring aviation patents "by purchase, condemnation, donation, or otherwise." The legislation was enacted in a naval appropriations bill on March 4, 1917.⁵⁷

The ability to obtain patents by "condemnation"—that is, seizure by eminent domain—was enough to bring the Wright-Martin and Curtiss-Burgess companies into a cross-licensing agreement.⁵⁸ Under the supervision of NACA and military representatives, the aircraft manufacturers formed the Manufacturers' Aircraft Association and agreed to pay the MAA a royalty of \$200 per airplane—substantially less than Wright-Martin's usual \$1000 rate—to be distributed among the patent holders according to set percentages.⁵⁹ Even so, the War and Navy Departments found the \$200 royalty rate infeasible given the government's expected wartime needs for airplane manufacturing, and threatened "to proceed to condemn the necessary patents" unless the MAA reduced the royalty rates to \$100 per plane, with a maximum payment of \$2 million.⁶⁰ The MAA agreed, granting in March 1918 the government the requested royalty "during the period of the present war."⁶¹

To be sure, the aviation patent arrangement is not necessarily a model for future actions: Outright condemnation of patents is far stronger than use under § 1498,⁶² and the MAA, which would outlive World War I by almost a half century, came to be the sort of patent-backed industry cartel that antitrust reformers of the late 1930s would come to criticize strongly.⁶³ But the airplane patent wars show how patents can cause problematic unpreparedness in the face of a national crisis such as war, and the origins of the MAA show the government's once-unhesitating willingness to invoke the

⁵⁶ See *id.* at 38.

⁵⁷ See Naval Service Appropriations Act, ch. 180, 39 STAT. 1168, 1169 (1917); ROLAND, *supra* note 52, at 39.

⁵⁸ See ROLAND, *supra* note 52, at 39–41; Johnson, *supra* note 50, at 57.

⁵⁹ See *Mfrs. Aircraft Ass'n, Inc. v. United States*, 77 Ct. Cl. 481, 487 (1933); Johnson, *supra* note 50, at 57.

⁶⁰ *Mfrs. Aircraft Ass'n*, 77 Ct. Cl. at 491.

⁶¹ *Id.* at 492.

⁶² See discussion *infra* notes 216–218 and accompanying text.

⁶³ See Johnson, *supra* note 50, at 58–61.

power of government patent use to bargain for satisfactory licensing arrangements in times of crisis.

Coming off of its successes dealing with aviation patents, the Navy Department next looked to expand government patent use more broadly. In April 1918, Navy Secretary Roosevelt wrote to Congress proposing an expansion of the government patent use statute then in force.⁶⁴ The occasion for Roosevelt's letter was the Supreme Court's decision in *William Cramp & Sons Ship & Engine Building Co. v. International Curtis Marine Turbine Co.* a month earlier, which held that despite the 1910 Act, a government contractor could be sued and enjoined for patent infringement.⁶⁵ Reasoning that the 1910 Act was intended "not to weaken the rights of patentees, but to further secure them," the Court concluded that the statute could not have acted to eliminate suits against government contractors.⁶⁶ The Navy, according to Roosevelt, had been working on the opposite assumption that contractors were insulated from suit, and the Court's decision apparently was now deterring contractors from working with the government.⁶⁷

Roosevelt's proposed amendment to the 1910 Act was introduced in a Senate amendment to the House naval appropriations bill on May 22, 1918.⁶⁸ The amendment was brought to the House floor by Representative Lemuel P. Padgett, chair of the House Committee on Naval Affairs, on June 18.⁶⁹ Padgett initially expressed "great reluctance" about bringing a patent law

⁶⁴ See Letter from Franklin D. Roosevelt, Acting Sec'y of the Navy, to Benjamin R. Tillman, Chairman, Senate Comm. on Naval Affairs, in *Wood v. Atl. Gulf & Pac. Co.*, 296 F. 718, 720, 720 (S.D. Ala. 1924).

⁶⁵ See 246 U.S. 28, 42 (1918) (finding "want of foundation for the contention that . . . the statute conferred upon all who contracted with the United States for the performance of work a right to disregard and take without compensation the property of patentees").

⁶⁶ *Id.* at 37.

⁶⁷ See Roosevelt, *supra* note 64, at 721. The Navy's justification was that it had relied a prior case, *Crozier v. Fried. Krupp AG*, 224 U.S. 290 (1912), for the proposition that the 1910 Act insulated government contractors from suit. See Roosevelt, *supra* note 64, at 721. While *Crozier* involved infringement by a federal officer, the Court reasoned that the statute applied because "the United States shall be considered as having ratified the act of the officer and be treated as responsible pecuniarily for the consequences." *Crozier*, 224 U.S. at 305. It appears that the Navy assumed (apparently wrongly, in light of *Cramp*) that this ratification logic would apply to contractors as well.

⁶⁸ 56 CONG. REC. 6886 (1918).

⁶⁹ *Id.* at 7960.

amendment to a naval appropriations bill but defended its placement based on the Navy's need for the amendment.⁷⁰ A colleague quickly allayed his concerns:

Mr. [William E.] Cox. Does not the gentleman feel that this is a law that would expedite the manufacture of war material?

Mr. Padgett. That is what I am going to do.

Mr. Cox. I think the gentleman could get it in three minutes.⁷¹

As Cox predicted, the amendment was agreed to, and enacted into law on July 1.⁷²

The 1918 amendment effected a recognition of government patent use not just as a compensatory mechanism for patent holders but also as a shield enabling the government to protect certain patent users from injunctions and liability for patent infringement. That such an amendment could pass “in three minutes” when it would “expedite the manufacture of war material” shows that, at least in emergency circumstances such as war, there was no objection to the government limiting patent liability in the service of the public.

C. World War II

Government patent use would arise forcefully again at the start of the Second World War. Here as well the historical events show the unique relevance that the government use statute can play at a time of national emergency. In particular, the start of American entry into the war highlighted the immediacy and unpredictability of needs with respect to patents—immediacy and unpredictability that made § 1498 especially well-suited.

To see how the national emergency of a world war invited government patent use, we begin with the pre-war conversation over patents, which was closely tied to the conversation over competition policy. Beginning in the late 1930s, concerns arose over dominant firms and the role of antitrust law in policing oligopoly collusion.⁷³

⁷⁰ See *id.* at 7961.

⁷¹ *Id.*

⁷² See *id.*; Naval Service Appropriations Act, ch. 114, 40 STAT. 704, 705 (1918).

⁷³ President Roosevelt's 1938 anti-monopoly speech to Congress is generally considered to signal the opening of this period. See 1938 FRANKLIN D. ROOSEVELT, *Recommendations to the Congress to Curb Monopolies and the Concentration of Economic Power*, in THE PUBLIC PAPERS AND ADDRESSES OF FRANKLIN D. ROOSEVELT 305, 306 (Samuel I. Rosenman ed., 1941), <https://quod>.

The charge was led by Thurman Arnold, President Roosevelt's 1938 appointee to the post of Assistant Attorney General in the Antitrust Division of the Department of Justice.⁷⁴ Arnold, a Yale law professor, vigorously pursued an agenda of breaking up industry cartels.⁷⁵ In his view, monopolistic and oligopolistic industries encouraged higher prices, constrained supply, and slowed innovation; the last point was exemplified by an agreement under which lightbulb manufacturers agreed not to invent low-wattage fluorescent bulbs so as not to cut into the electric utilities' profits.⁷⁶

Patents were seen, at the time, as a primary vehicle for big-business abuse to bolster those cartels. In a 1942 essay in the *Atlantic Monthly*, Arnold described the patent laws as the "principal smoke screens under which domestic and international cartels have cloaked their activities," insofar as arrangements such as patent pools enabled firms to divide up markets, fix prices, and restrict consumer-beneficial innovation.⁷⁷ These views were not unique: Roosevelt himself criticized the use of patents "to create industrial monopolies."⁷⁸ Roosevelt's call to end monopoly abuse led Congress in 1938 to create the Temporary National Economic Committee to "make a full and complete study and investigation . . . on monopoly and the concentration of economic power,"⁷⁹ and it is indicative of the close tie between patents and antitrust that the TNEC's first formal non-introductory proceeding was on "the effect of the use of patents upon industry."⁸⁰ In its final

lib.umich.edu/p/ppotpus; see also Gene M. Gressley, *Thurman Arnold, Antitrust, and the New Deal*, 38 BUS. HIST. REV. 214, 217 (1964).

⁷⁴ See Gressley, *supra* note 73, at 217–18; Spencer Weber Waller, *The Antitrust Legacy of Thurman Arnold*, 76 ST. JOHN'S L. REV. 569, 574–77 (2004).

⁷⁵ See Gressley, *supra* note 73, at 222–25 (describing Arnold's approach to antitrust enforcement); Waller, *supra* note 74, at 588–94 (listing cases brought). In his later years, Arnold co-founded the law firm Arnold & Porter.

⁷⁶ See Thurman W. Arnold, *The Abuse of Patents*, 24 J. PAT. OFF. SOC'Y 531, 539–40 (1942); see also *id.* at 536–38 (industry agreement not to develop synthetic rubber technology); *id.* at 538–39 (agreement not to improve flashlight bulbs in service of battery manufacturers).

⁷⁷ *Id.* at 536.

⁷⁸ Roosevelt, *supra* note 73, at 318.

⁷⁹ Joint Resolution to Create a Temporary National Economic Committee, ch. 456, § 2(a), 52 STAT. 705, 705 (1938).

⁸⁰ *Investigation of Concentration of Economic Power: Hearings Before the Temporary National Economic Comm.*, 75th Cong. 253, 253 (1939–1941). Arnold was a member of the committee and the initial witness at the patent hearing. See *id.* at 254.

report in 1941, the TNEC's lead suggestions for legislative changes focused on patents, with the report finding that "[n]o one can read the testimony developed before this committee on patents without coming to a realization that in many important segments of our economy the privilege accorded by the patent monopoly has been shamefully abused."⁸¹

While these concerns about patents arose independently from the war, Arnold and others drew an immediate connection: Patents enabled cartels, cartels enjoyed benefits from constraining supply and limiting certain forms of technological advancement, and limits on supply and innovation hampered the war effort.⁸² In March 1941 the House Committee on Patents held a hearing to consider a bill that would enable the Commissioner of Patents to declare certain patents "necessary to the national defense" and thereby restrict injunctive relief on those patents "during the continuance of the national emergency" that the president had declared as of September 1939.⁸³ There, Arnold testified on how patent arrangements constrained military supply, describing in particular how a deal between the dominant optical glass manufacturers, Bausch & Lomb in America and Zeiss in Germany, was creating a shortage of military-grade optical lenses: "our production goes down . . . and German production goes shooting up."⁸⁴

At a time when American entry into the war was still speculative, the Patents Committee found the war–patent connection too speculative as well. Committee Chair Charles Kramer harshly

⁸¹ INVESTIGATION OF CONCENTRATION OF ECONOMIC POWER: FINAL REPORT AND RECOMMENDATIONS OF THE TEMPORARY NATIONAL ECONOMIC COMMITTEE, S. DOC. NO. 77-35, at 36 (1941), <https://catalog.hathitrust.org/Record/001430359>. The report specifically recommended compulsory licensing of patents, prohibition on use-restricted licenses, recordation of assignments, limitations on infringement actions, and forfeiture of patents for licensing violations. *Id.* at 36–37. Well ahead of its time, the report also called for creation of a single patent appeals court and a patent term of twenty years from filing rather than seventeen years from issuance. *Id.* at 37.

⁸² See, e.g., Arnold, *supra* note 76, at 536–37.

⁸³ H.R. 3360, 77th Cong. § 1 (1941), reprinted in *Preventing Publication of Inventions and Prohibiting Injunctions on Patents: Hearings on H.R. 3359 and H.R. 3360 Before the H. Comm. on Patents*, 77th Cong. 55 (1941), <https://catalog.hathitrust.org/Record/002009460>.

⁸⁴ *Preventing Publication of Inventions and Prohibiting Injunctions on Patents*, *supra* note 83, at 119; see also *id.* at 148 (statement of Francis M. Shea, Assistant Att'y Gen.) ("Bausch & Lomb and Zeiss have unlawfully combined and conspired to suppress and limit competition in military optical instruments . . .").

criticized Arnold, questioning the accusations against Bausch & Lomb⁸⁵ and later flatly accusing Arnold of “attacking” the patent system.⁸⁶ More importantly, the Committee asked military representatives to assess the need for the bill; the representatives could not identify any. Major Francis H. Vanderwerker, representing the War Department, supported the patent bill based on the possibility that “in some of the other Government departments there may be a need for this type of legislation,” but testified that “the War Department has no present need for a bill of this character.”⁸⁷ Lieutenant Commander K.C. Caldwell noted that the Navy Department was conducting an investigation for problematic patents, and knew of “instances” where patents had hampered the Navy, but did not identify any specifically.⁸⁸

Skepticism about the effect of patents on national preparedness would quickly change once the threat of war became real on December 7, 1941. Just months after the attack on Pearl Harbor, the Senate Committee on Patents took up a wartime measure that went further than the House bill, giving the president power to mandate compulsory licensing of any patent “upon such terms and for such period of time as the President may prescribe,” and further power “to acquire patents, applications therefor, inventions, or licenses under any of the foregoing, by donation, purchase, taking or otherwise.”⁸⁹ Across April–August 1942, the Committee held thirty-three days of hearings on that bill and the patent system generally.⁹⁰ The chair of the Committee, Senator Homer T. Bone, opened the hearings with a strong statement on the role of government patent use:

No right fashioned by law is superior to the public welfare or national interest. The very fact that men are to die to preserve our system and our way of life leaves only one conclusion; that is, that patent rights and every other form of property right must be subordinated to the all-out effort confronting us. It is

⁸⁵ *See id.* at 119–20.

⁸⁶ *Id.* at 131.

⁸⁷ *See id.* at 107.

⁸⁸ *Id.* at 109.

⁸⁹ S. 2303, 77th Cong. §§ 1(a), 2 (1942), reprinted in 1 *Hearings on S. 2303 Before the S. Comm. on Patents*, 77th Cong. 1 (1942), <https://catalog.hathitrust.org/Record/001511288>.

⁹⁰ *See* 1 *Hearing on S. 2303*, *supra* note 89.

crystal clear that in this hour of trial the profit motive cannot be accented without inviting the destruction of morale. . . .

The American patent system enters the trenches and goes along on the battlefield with our boys. To the extent that they achieve victory, to the same extent do we achieve safety and security for our social and economic system.⁹¹

The House Patents Committee, for its part, also revisited patents during the exigencies of war in October 1942, as it considered an emergency legislative proposal from the War and Navy Departments.⁹² The statutory proposal, subsequently enacted into law, was intended “to aid in the successful prosecution of the War”⁹³ and had two primary effects. First, the statute cleared up an ambiguity as to whether subcontractors were covered under § 1498, making explicit that “a contractor, a subcontractor, or any person, firm, or corporation” could enjoy immunity to a patent infringement suit based on government use.⁹⁴ Second, the statute enabled a government department to identify patent royalties “which are believed to be unreasonable or excessive” and to terminate payment of such royalties, fixing an alternate rate that the department head determined to be “fair and just, taking into account the conditions of wartime production.”⁹⁵ The patentee in that situation was not stuck with the department-authorized royalty, but could bring suit in federal court to recover any deficiency from “fair and just compensation.”⁹⁶ This provision responded to an observed situation in which the government already had a licensing arrangement in place with a patent holder, but the royalty rates, though reasonable

⁹¹ *Id.* at 3–4.

⁹² *See Adjusting Royalties for the Use of Inventions for the Benefit of the United States: Hearing on H.R. 7620 Before the H. Comm. on Patents, 77th Cong.* 1-4, 31-32 (Oct. 13–15, 1942) [hereinafter *Royalty Adjustment Act Hearing*], <https://catalog.hathitrust.org/Record/100669202>.

⁹³ *Royalty Adjustment Act*, ch. 634, § 1, 56 STAT. 1013, 1013 (Oct. 31, 1942).

⁹⁴ *Id.* § 6, 56 STAT. at 1014. This defect in the statute had been identified in the 1941 House hearing, for example by Commissioner of Patents Conway Coe, who testified that it was “open to doubt, I should say, as to whether or not a subcontractor falls under the provisions” of the 1910 Act. *See Preventing Publication of Inventions and Prohibiting Injunctions on Patents*, *supra* note 83, at 56; *see also id.* at 57 (testimony of Major Vanderwerker).

⁹⁵ *Royalty Adjustment Act* § 1, 56 STAT. at 1013.

⁹⁶ *Id.* § 2, 56 STAT. at 1013.

in peacetime conditions, proved excessive in view of massively increased wartime demands;⁹⁷ in *Newport News Shipbuilding & Dry Dock Co. v. Isherwood* a court had held that § 1498 was inapplicable where the government already had a license in place.⁹⁸ The new royalty-termination provision was carefully limited: The statute repeatedly called on agencies and courts to consider “the conditions of wartime production,”⁹⁹ and included a sunset of the provision six months after termination of the war.¹⁰⁰

In stark contrast to the 1941 House committee hearing, by 1942 the military had found numerous instances of patents interfering with wartime production. The Secretaries of War and the Navy wrote of “a number of instances” of existing patent royalty arrangements that “when applied to the enormous quantities needed for the prosecution of the war such royalty rates are regarded in some cases as exorbitant, excessive, and unfair.”¹⁰¹ Colonel Earl S. Patterson offered more detail on behalf of the War Department, testifying as to the government’s difficulties with patents on airplane parts, recoil springs, steel milling, and radio technology.¹⁰² The Senate report on the legislation acknowledges the “cost of patents in war procurement” as the driving force behind the law.¹⁰³ With this evidence and general consensus in favor, the bill swiftly passed Congress and was enacted into law.

⁹⁷ See Royalty Adjustment Act Hearing, *supra* note 92, at 17.

⁹⁸ See 5 F.2d 924, 934 (1925) (government use statute inapplicable where “[t]here was no use of a patent by the United States, without license of the owner”).

⁹⁹ Royalty Adjustment Act §§ 1–2, 56 STAT. at 1013–14.

¹⁰⁰ See *id.* § 7, 56 STAT. at 1014.

¹⁰¹ Letter from Henry L. Stimson, Sec’y of War, to Speaker, House of Representatives, in Royalty Adjustment Act Hearing, *supra* note 92, at 3, 3; accord Letter from James Forrestal, Acting Sec’y of the Navy, to Charles Kramer, House of Representatives, in Royalty Adjustment Act Hearing, *supra* note 92, at 31, 32.

¹⁰² See Royalty Adjustment Act Hearing, *supra* note 92, at 18–19, 22. The Navy’s representative similarly identified examples of problematic patent licensing arrangements, though he did not identify specific technologies, perhaps out of secrecy concerns. See *id.* at 42–44.

¹⁰³ See ADJUSTMENT OF ROYALTIES FOR THE USE OF INVENTIONS FOR THE BENEFIT OF THE UNITED STATES, S. REP. NO. 77-1640, at 2 (1942), <https://books.google.com/books?id=FNx8zn1cIfgC&pg=RA14-PA1&lpg=RA14-PA1>.

D. Bioterrorism Threats After September 11

Government patent use and § 1498 again took center stage amidst an immediate national threat following the terrorist attacks on the United States on September 11, 2001.¹⁰⁴ This historical episode confirmed the nondisruptive and beneficial role that § 1498 can play and indeed suggests broad acceptance of use of § 1498 in times of need.

In the two months following the September 11 attacks, Congress, the Bush Administration, and the public became aware of a likely possibility of bioterrorism, specifically in the form of anthrax spores being blanketed over a large population.¹⁰⁵ At the time, the only approved antibiotic for treating anthrax was ciprofloxacin, sold under the brand name Cipro. The drug quickly became a household name after news anchor Tom Brokaw, himself the recipient of an anthrax-laden letter, ran a television segment ending with the line, “in Cipro we trust.”¹⁰⁶ Calls for a federal

¹⁰⁴ The episode described here has been covered generally a number of times. *See, e.g.,* Cahoy, *supra* note 26, at 126–27, 171–73 (focusing on monetary compensation to patent holder); Duan, *supra* note 48, at 392–94 (national security implications); Erika Mullenbach, *The Influence of Disease on the Evolution of U.S. Patent Law and Policy Towards Foreign Patent Laws in the Late Twentieth to Early Twenty-First Century*, 7 TUL. J. TECH. & INTELL. PROP. 227, 239–42 (2005) (impact on access to AIDS treatments in Africa); Shapiro, *supra* note 17, at 39–41, 59–61 (pharmaceutical industry impact). One particularly interesting source describes the situation from the perspective of Bayer’s marketing and brand management campaign, concluding that “Bayer AG was able to be a good and ethical corporate citizen, placate the regulatory environment, impede entry for competitors, and enable the US government to provide the public with life-saving medicines.” Hagai Gringarten, *Bayer, Ethics, and the Anthrax Scare: Leveraging National Crisis for a Public Relations Bonanza*, in *ETHICAL BRANDING AND MARKETING: CASES AND LESSONS* 69, 76 (Hagai Gringarten & Raúl Fernández-Calienes eds., 2019).

¹⁰⁵ *See, e.g.,* *Effective Responses to the Threat of Bioterrorism: Hearing Before the Subcomm. on Public Health of the S. Comm. on Health, Education, Labor, and Pensions*, 107th Cong. 5 (Oct. 9, 2001) (statement of Sen. Bill Frist).

¹⁰⁶ Howard Kurtz, *Tom Brokaw, Putting a Familiar Face on the Anthrax Story*, WASH. POST (Oct. 18, 2001), <https://www.washingtonpost.com/archive/lifestyle/2001/10/18/tom-brokaw-putting-a-familiar-face-on-the-anthrax-story/d3b2c39b-74b3-4e66-8357-291a3f55f4c5/>; *see* Donald G. McNeil Jr., *A Rush for Cipro, and the Global Ripples*, N.Y. TIMES (Oct. 17, 2001), <https://www.nytimes.com/2001/10/17/world/a-nation-challenged-the-drug-a-rush-for-cipro-and-the-global-ripples.html>. Other treatments may have been equally effective or possibly superior; the national focus on ciprofloxacin may have been a failure of messaging

stockpile of the drug, however, met a roadblock: the German firm Bayer AG held a patent on ciprofloxacin, but was unable to meet the government's requisition amount for a sufficient stockpile; the company reported that it would require almost two years to manufacture enough.¹⁰⁷ While generic manufacturers estimated that they could fulfill the requisition in three months, Bayer refused to license the patent.¹⁰⁸

Bayer's patent standoff led to numerous calls to invoke § 1498 to enable generic manufacturing of the drug. Alfred Engelberg, a "smart and tough-as-nails attorney" known for his role in the Hatch-Waxman Act governing pharmaceuticals,¹⁰⁹ authored a memorandum to Senator Chuck Schumer, laying out the case for invoking the law and a procedure for doing so. Engelberg proposed that the Department of Health and Human Services provide a blanket government authorization for generic firms to submit federal

consistency from federal health experts. See Elin Gursky et al., *Anthrax 2001: Observations on the Medical and Public Health Response*, 1 BIOSECURITY & BIOTERRORISM: BIODEFENSE STRATEGY PRAC. & SCI. 97, 105 (2003) (noting CDC's recommendation of doxycycline rather than ciprofloxacin); UPMC CTR. FOR HEALTH SEC., HOW TO STEWARD MEDICAL COUNTERMEASURES AND PUBLIC TRUST IN AN EMERGENCY: A COMMUNICATION CASEBOOK FOR FDA AND ITS PUBLIC HEALTH PARTNERS 111–12 (2016), <https://www.centerforhealthsecurity.org/our-work/events/2016%20FDA%20MCM/Summary>. Some have used the availability of alternatives to suggest that the anthrax scare was not an actual emergency, see, e.g., Azar, *supra* note 32, but that would appear to be hindsight reasoning.

¹⁰⁷ See Elisabeth Bumiller, *Administration Won't Allow Generic Versions of Drug*, N.Y. TIMES (Oct. 18, 2001), <https://www.nytimes.com/2001/10/18/us/nation-challenged-response-administration-won-t-allow-generic-versions-drug.html>.

¹⁰⁸ See *id.* For its part, Bayer thought that its production capacity was sufficient for U.S. demand and questioned whether generic manufacturers could ramp up production so quickly, see Vanessa Fuhrmans & Ron Winslow, *Bayer Works to Meet Soaring Cipro Demand as It Starts Campaign to Keep Patent in U.S.*, WALL ST. J. (Oct. 22, 2001), <https://www.wsj.com/articles/SB1003698325298160000>, despite simultaneously "exploring whether to ask some rival drug companies to produce some of its antibiotic Cipro to make certain an adequate supply of the drug is available," see Vanessa Fuhrmans, *Bayer May Ask Its Rivals for Help Producing Anthrax Antibiotic Cipro*, WALL ST. J. (Oct. 18, 2001), <https://www.wsj.com/articles/SB100334769597877200>.

¹⁰⁹ 148 CONG. REC. 15,356 (2002) (statement of Sen. Hatch); *Competition in the Pharmaceutical Marketplace: Antitrust Implications of Patent Settlements: Hearing Before the S. Comm. on the Judiciary*, 117th Cong. 32 (2001).

bids for procurement.¹¹⁰ Just days later, the senator called for invocation of the law in a press conference,¹¹¹ leading to national interest in the possibility of invoking government use of Bayer's patent.¹¹²

Engelberg's memorandum is succinct in its analysis of § 1498. It simply observes "ample authority" and "overwhelming precedents" supporting the use of § 1498 to procure a stockpile of ciprofloxacin,¹¹³ quotes a few cases, and moves on to more detailed analysis of practical questions of regulatory approval and dismissal of ongoing patent infringement litigation. The memorandum does not discuss effects on incentives to innovate or other policy implications of invoking government patent use at all.

One can imagine a variety of reasons for this summary treatment of § 1498, but the likeliest is the prior context. In the decades prior to 2001, the appropriateness of § 1498 in the context of federal procurement—in both emergency and non-emergency situations—was settled. A 1958 decision of the Comptroller General addressed the question of whether procurement officers should consider patent or patent license holdings in the course of choosing among bids.¹¹⁴ The Comptroller General's answer was no, based on an understanding that any standard procurement invitation automatically provided the requisite authorization and consent under § 1498.¹¹⁵ The U.S. government was, and still is, free to procure whatever it needs from whomever it wants without permission from patent holders. The Comptroller General's decision

¹¹⁰ Because the memorandum does not appear to be otherwise available in any permanent form, it is reprinted as an appendix to this Article with permission from Mr. Engelberg. *See infra* Part V.

¹¹¹ *See Senator Seeks Generic Cipro*, CNN MONEY (Oct. 16, 2001), https://money.cnn.com/2001/10/16/news/generic_cipro.

¹¹² *See Shankar Vedantam & Terence Chea, Drug Firm Plays Defense in Anthrax Scare*, WASH. POST (Oct. 20, 2001), <https://www.washingtonpost.com/archive/politics/2001/10/20/drug-firm-plays-defense-in-anthrax-scare/aa3b0b39-2cb3-4264-a360-aed1babbe8f8>. A bill was introduced a few weeks later to enable the HHS Secretary to authorize compulsory licensing of patents during a public health emergency. *See* H.R. 3235, 107th Cong. § 2(a) (Nov. 6, 2001); *see also* Avedissian, *supra* note 26, at 261–62.

¹¹³ In a contemporaneous interview, Engelberg remarked, "[i]t boils down to something very simple. . . . The government has the right to procure whatever it needs for government purposes." Bumiller, *supra* note 107.

¹¹⁴ *See* Herbert Cooper Co., 38 Comp. Gen. 276, 277 (1958), <https://catalog.hathitrust.org/Record/003100408>.

¹¹⁵ *Id.* at 279.

sparked a wave of patentee-friendly legislative proposals across the 1960s to restrict the U.S. government's patent-blind procurement practice; none of the bills succeeded.¹¹⁶ As government procurement officers purchased patented technologies again and again in subsequent decades, case law confirmed repeatedly that § 1498 is automatically invoked and “the patentees’ sole remedy [is] a suit against the United States in the Court of Claims.”¹¹⁷ Given this long-settled federal policy of using § 1498 as a routine part of government contracting, there was no need to treat in depth the question of using § 1498 for procuring ciprofloxacin.

In the wake of Senator Schumer's call, Bayer rapidly moved to oppose any invocation of § 1498. Bayer immediately launched a comprehensive branding campaign (including a \$3 million buy for full page advertising in all the major papers) promising that the company would “stand ready to support the United States government providing Cipro to meet emergency needs.”¹¹⁸ Bayer and other pharmaceutical industry representatives also lobbied Congress and the administration heavily “to provide reassurance of Bayer's commitment.”¹¹⁹ Bayer also attempted to paint government patent use as misguided, even illegitimate, “emphasiz[ing] the importance of patents for research and investment.”¹²⁰ Remarkably, the Bush Administration initially sided with Bayer on the aptness of § 1498. Likely concerned about contradicting its international opposition to compulsory patent licensing—having rejected calls to invoke compulsory licensing on HIV/AIDS drug patents in the Global South as the landmark 2001 Doha Declaration was being

¹¹⁶ See Mossinghoff & Allnutt, *supra* note 24, at 16–27 (describing legislative reform proposals).

¹¹⁷ TVI Energy Corp. v. Blane, 806 F.2d 1057, 1060 (Fed. Cir. 1986); *see also* Trojan, Inc. v. Shat-R-Shield, Inc., 885 F.2d 854, 857 (Fed. Cir. 1989); W.L. Gore & Assocs., Inc. v. Garlock, Inc., 842 F.2d 1275, 1282 (Fed. Cir. 1988); Motorola, Inc. v. United States, 729 F.2d 765, 771–72 (Fed. Cir. 1984); Decca Ltd. v. United States, 640 F.2d 1156, 1166–67 (Ct. Cl. 1980); Rel-Reeves, Inc. v. United States, 534 F.2d 274, 298 (Ct. Cl. 1976); Roberts v. Herbert Cooper Co., 236 F. Supp. 428, 430 (M.D. Pa. 1959) (“No extended discussion is required on the question whether this action falls within the provisions of 28 U.S.C. § 1498.”).

¹¹⁸ Paul Holmes, *Bayer Responds to Cipro Crisis*, PROVOKE (Nov. 19, 2001), <https://www.provokemedia.com/latest/article/bayer-responds-to-cipro-crisis>.

¹¹⁹ See Paul Holmes, *In Cipro We Trust*, PROVOKE (Oct. 22, 2002), <https://www.provokemedia.com/latest/article/in-cipro-we-trust>.

¹²⁰ *Id.*; *see also* Fuhrmans & Winslow, *supra* note 108; Gringarten, *supra* note 104, at 77–79.

negotiated¹²¹—the Bush administration publicly rebuked calls to invoke the statute. A spokesman for HHS said that “[w]e don’t feel there’s a need to lift the patent at this time,”¹²² and HHS Secretary Tommy Thompson more bluntly rejected calls to “break” Bayer’s patent: “No. 1, it’s illegal,” the *Wall Street Journal* quoted him as saying.¹²³

As pressure mounted, though, the government appeared to change course: Secretary Thompson “threatened to bypass Bayer’s patent” and was “ready to ask Congress for special legislation that would make the government exempt from paying any damages to Bayer for breaking the patent.”¹²⁴ Ultimately, Bayer agreed to make substantial concessions in negotiations with the government, including massive increases in manufacturing and a price cut on ciprofloxacin to \$0.95 or less per pill, compared to \$1.83 that the government had been paying previously and the wholesale price of \$4.67.¹²⁵

What role § 1498 played in that ultimate deal is a *Rashomon* question with at least three possible answers. The majority view, as reported by almost all commentators at the time and subsequently, was that Thompson did indeed threaten to invoke § 1498, which “provide[d] the government with the necessary leverage” to force Bayer into a concession.¹²⁶ Indeed, Bayer’s financial statements

¹²¹ See Divya Murthy, *The Future of Compulsory Licensing: Deciphering the Doha Declaration on the TRIPs Agreement and Public Health*, 17 AM. U. INT’L L. REV. 1299, 1313–16 (2002).

¹²² Amy Harmon & Robert Pear, *Canada Overrides Patent for Cipro to Treat Anthrax*, N.Y. TIMES (Oct. 19, 2001) <https://www.nytimes.com/2001/10/19/business/nation-challenged-treatment-canada-overrides-patent-for-cipro-treat-anthrax.html>.

¹²³ Fuhrmans, *supra* note 108; *see also* Bumiller, *supra* note 107.

¹²⁴ Keith Bradsher, *Bayer Agrees to Charge Government a Lower Price for Anthrax Medicine*, N.Y. TIMES (Oct. 25, 2001), <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”).

¹²⁵ *See* Bradsher, *supra* note 124.

¹²⁶ Brennan et al., *supra* note 11, at 303; *see, e.g.*, Jennifer R. Andrew, *Swine Flu, Bird Flu, Sars, Oh My—Applying the Precautionary Principle to Compulsory Licensing of Pharmaceuticals Under Article 31 of Trips*, 2011 MICH. ST. L. REV.

noted that “in response to anthrax bioterror attacks in the United States in 2001, the U.S. and Canadian governments contemplated compulsory licensing of our ciprofloxacin antibiotic,” which seems to confirm that § 1498 did come up in Bayer’s negotiations.¹²⁷ Thompson’s general counsel Alex Azar, on the other hand, contended that Thompson “never threatened to break Bayer’s patent,” though Thompson did advise Bayer that he was willing to ask Congress for “authority to procure generics” in a manner that was “hardly the same thing as threatening a company.” Azar repeated that statement at his 2018 nomination for HHS Secretary.¹²⁸ Bayer’s CEO Helge Wehmeier advanced a third view and claimed that Thompson had not even gone that far—according to Wehmeier, the negotiation over Cipro took “less than ten minutes” with no invocation of leverage, from § 1498 or Congress.¹²⁹

The Wehmeier and Azar views that § 1498 played no role in the negotiations have found little traction among historians. Even those critical of § 1498 generally accept that HHS invoked it or some other threat of government patent use en route to negotiating a favorable

405, 411 (2011); *Bayer’s Reasons for Not Giving Cipro Away; USA Slammed for “Double Standards,”* PHARMA LETTER (Nov. 7, 2001), <https://www.thepharmalletter.com/article/bayer-s-reasons-for-not-giving-cipro-away-usa-slammed-for-double> (noting “USA’s threat to override Bayer’s patent”); Jill Carroll & Ron Winslow, *Bayer Agrees to Slash Price for Cipro Drug*, WALL ST. J. (Oct. 25, 2001), <https://www.wsj.com/articles/SB1003966074330899280> (describing “high-stakes threat by Tommy Thompson . . . to break Bayer’s patent”); Matt Fleischer-Black, *The Cipro Dilemma*, AM. LAW., Jan. 2002, at 53; Aaron S. Kesselheim & Jerry Avorn, *Biomedical Patents and the Public’s Health: Is There a Role for Eminent Domain?*, 205 J. AM. MED. ASS’N 434, 435 (2006); Mullenbach, *supra* note 104, at 227; Ho, *supra* note 17, at 113–14; Jennifer Penman & Fran Quigley, *Better Late than Never: How the U.S. Government Can and Should Use Bayh-Dole March-in Rights to Respond to the Medicines Access Crisis*, 54 WILLAMETTE L. REV. 171, 187–88 (2017).

¹²⁷ See Bayer AG, Registration Statement (Form 20-F), at 10 (June 24, 2002), <https://www.sec.gov/Archives/edgar/data/1144145/000115697302000306/f00360e20vf.txt>; James Love, *Secretary Alex Azar’s Comment on 28 USC 1498 Submitted for the Record of the 2018 Confirmation Hearings*, KNOWLEDGE ECOLOGY INT’L (Aug. 1, 2018), <https://www.keionline.org/28631>.

¹²⁸ Azar, *supra* note 32; *accord Nomination of Alex Michael Azar II: Hearing Before the S. Comm. on Finance*, 115th Cong. 119–20 (Jan. 9, 2018), <https://www.govinfo.gov/content/pkg/CHRG-115shrg34341/pdf/CHRG-115shrg34341.pdf> (“Bayer was never threatened with the use of section 1498 . . .”).

¹²⁹ Holmes, *supra* note 118; see also Carroll & Winslow, *supra* note 126.

deal for the government,¹³⁰ and Azar's letter appears to not to have been cited in any subsequent literature.¹³¹

But Bayer's massive public relations push, coupled with the Bush Administration's initial vocal disavowal of the appropriateness of § 1498, seems to have had an important (and underacknowledged) legacy, shifting views of § 1498 from a routine, beneficial government power commonplace in federal procurement to a dramatic incursion too extreme for use even in the face of a credible terrorist threat—or even “illegal.” Legal observers at the time were left “scratching their heads” over this change.¹³² This history suggests that contemporary views of § 1498 are of relatively recent vintage, rather than being any long-held understanding about the statute. The now widespread “conventional wisdom” that § 1498 is an “exceptional” remedy to be used only in a vanishingly small set of circumstances¹³³ seems to be a product of just the last two out of the eleven decades the statute has been on the

¹³⁰ See F. Scott Kieff, *Removing Property from Intellectual Property and (Intended) Pernicious Impacts on Innovation and Competition*, 19 SUP. CT. ECON. REV. 25, 35 (2011) (discussing the “infamous” Cipro case in which “the Government’s threat . . . was enough to get Bayer, the patentee, to drop its price”); Natalie Goldberg, *The Bayh-Dole Act: Is It the Proper Treatment for the Big Pharma Price-Gouging Epidemic?*, 29 FED. CIR. B.J. 387, 414 (2020) (discussing arguments against compulsory licensing but observing that “the Government has also taken or threatened to utilize compulsory licensing . . . to address anthrax with Cipro”); Eileen M. Kane, *Achieving Clinical Equality in an Influenza Pandemic: Patent Realities*, 39 SETON HALL L. REV. 1137, 1164 (2009) (“The possibility that the U.S. government might issue a compulsory license under 28 U.S.C. § 1498 . . . was very real and represented a significant departure from existing reluctance to exercise such power.”); see also Kirby W. Lee, *Permitted Use of Patented Inventions in the United States: Why Prescription Drugs Do Not Merit Compulsory Licensing*, 36 IND. L. REV. 175, 175–76, 196 (2003) (noting calls to “override Bayer’s patent rights” but not indicating a view as to whether § 1498 was used); Jason D. Ferrone, Note, *Compulsory Licensing during Public Health Crises: Bioterrorism’s Mark on Global Pharmaceutical Patent Protection*, 26 SUFFOLK TRANSNAT’L L. REV. 385, 409–10 (2002) (criticizing the “contemplation of compulsory licensing of ciproflaxin [*sic*]” as rendering “the U.S.-championed TRIPS Agreement less effective”).

¹³¹ A search of the HeinOnline Law Journal Library for “Azar w/50 cipro*” and JSTOR for “(Azar cipro* ~50) AND patent” produced no relevant results other than one of our own articles.

¹³² Fleischer-Black, *supra* note 126 (quoting a “former Reagan administration health official” saying, “They can’t seriously be suggesting that [the government] can’t buy generic Cipro”).

¹³³ See sources cited *supra* notes 2–13.

books. For much more of our nation's history, § 1498 was used routinely, especially in times of national emergency.

At the same time, if Engelberg and Schumer had not put § 1498 on the table, Bayer may not have made that massive public relations push or been as conciliatory to the federal government as it eventually was. Bayer's efforts were described as "[u]ncertain" and "detached" in the days before Schumer proposed invoking § 1498, and Canada not only threatened but actually ordered a compulsory license.¹³⁴ The company's media and lobbying salvo focused not just on reassuring the public of Bayer's manufacturing capacities, but also on "the importance of the patent issue,"¹³⁵ suggesting that Bayer's public response was likely triggered by an expectation that § 1498 might actually be used. If that was so, then the Cipro crisis both confirmed the statute's vitality and simultaneously marginalized it in the years to come.

E. Lessons for the COVID-19 Pandemic

The foregoing history shows that for most of the last century, § 1498 and government patent use more generally have been viewed as ordinary and integral policy tools with which the U.S. government can face emergencies of national dimension, including public health crises. The COVID-19 pandemic is not a war or a threat of terrorism, but it presents exigencies of the same ilk. Millions of human lives are at stake. Success depends on rapid, collaborative technological developments.¹³⁶ A patent system that favors single-firm control over a technological field clashes with that demand. The promise of pecuniary gain from patent protection is of course a strong motivator for innovation in emergencies as in ordinary times. But this pandemic, like all other crises, may demand that holders of patents, as with any other roadblocks to fast deployment of technology, temporarily cede some pecuniary gain to limit a crisis of national, existential dimensions.

In addition to this overarching point, several other lessons may

¹³⁴ Edmund L. Andrews, *Drug Maker Seems Uncertain in Response to Cipro Frenzy*, N.Y. TIMES (Oct. 20, 2001) <https://www.nytimes.com/2001/10/20/business/nation-challenged-drug-maker-drug-maker-seems-uncertain-response-cipro-frenzy.html>; see Gringarten, *supra* note 104, at 75 (noting "two weeks of no decisive response to the crisis").

¹³⁵ Holmes, *supra* note 118.

¹³⁶ See Matt Apuzzo & David D. Kirkpatrick, *Covid-19 Changed How the World Does Science, Together*, N.Y. TIMES (Apr. 1, 2020), <https://www.nytimes.com/2020/04/01/world/europe/coronavirus-science-research-cooperation.html>.

be drawn about the role of government patent use in national crises. First, there is consistent general recognition that emergency conditions demand greater government involvement in directing use of patents. The U.S. government's creation of the Manufacturers' Aircraft Association after a threat of condemnation of patents exemplifies this,¹³⁷ as does the Royalty Adjustment Act, when Senator Bone proclaimed that the "patent system enters the trenches and goes along on the battlefield with our boys."¹³⁸

In the past, even the patent holders and lawyers who typically opposed government patent use quickly came around to accepting it in emergencies. Patent attorney Lawrence Langner offered a nearly line-by-line rebuttal to Thurman Arnold's 1942 patents-and-cartels article in the *Atlantic Monthly*, but Langner nevertheless agreed that "the grant of compulsory licenses under all patents during the war period . . . can be accepted in principle if it is surrounded by the proper safeguards and the license is limited to the war period."¹³⁹ Similarly, at the 1942 House hearing, the American Patent Law Association "approve[d] Government regulation of royalties to be paid by the Government under patents during the emergency of war conditions,"¹⁴⁰ and the American Bar Association approved in principle the "compulsory granting of licenses under patents in furtherance of the war effort."¹⁴¹ In the 2001 anthrax scare, a representative for the pharmaceutical industry agreed with "[p]utting aside personal and company considerations in a time of crisis," which included "making some compromises,"¹⁴² and another industry executive found the Cipro negotiations to be "completely legitimate" and even would have accepted "abrogation of patents in the time of a true national emergency."¹⁴³ Despite the

¹³⁷ See *supra* notes 55–61 and accompanying text.

¹³⁸ 1 *Hearing on S. 2303*, *supra* note 89, at 4.

¹³⁹ Lawrence Langner, *We Depend on Invention: An Answer to Thurman Arnold*, *Atlantic Monthly*, July 1942, reprinted in 24 J. PAT. OFF. SOC'Y 545, 561 (1942).

¹⁴⁰ Royalty Adjustment Act Hearing, *supra* note 92, at 52 (statement of Karl Fenning, American Patent Law Association).

¹⁴¹ Letter from Chester L. Davis, Am. Bar Ass'n, to Charles Kramer, House of Representatives, in Royalty Adjustment Act Hearing, *supra* note 92, at 51.

¹⁴² Gardiner Harris, *Bayer's Cipro Will Be Profitable, Even on Discount Deal With U.S.*, WALL ST. J. (Oct. 26, 2001), <https://www.wsj.com/articles/SB1004048954559116840> (quoting Jeff Trehwitt on behalf of the Pharmaceutical Research and Manufacturers of America).

¹⁴³ Carroll & Winslow, *supra* note 126 (quoting Henry McKinnell, chairman and chief executive of Pfizer Inc.) (internal quotation marks omitted).

post-2001 conventional wisdom that rejects use of § 1498 even in moments of national emergency, history demonstrates near-universal acceptance of government patent use in furtherance of the national interest in times of emergency.

Second, the driving motivation behind government patent use was often not lowering costs but increasing supply and accelerating technological development, a finding that is especially important in response to the dominant criticism that use of § 1498 will be deleterious to future innovation.¹⁴⁴ Patent squabbles were a key cause of the lack of American aviation technology (and plain lack of airplanes) prior to World War I,¹⁴⁵ and in the 1930s and '40s they contributed to the supply constraints that Arnold criticized.¹⁴⁶ The impasse over steel milling patents, as noted in the 1942 House hearing, acutely affected wartime supply, since the War Department reported that “all mills of the noninfringing type are already loaded to capacity.”¹⁴⁷ And the threat to invoke § 1498 on Bayer's ciprofloxacin patent stemmed largely from fears that Bayer could not manufacture enough antibiotic to counter a terrorist attack. To be sure, cost was often significant: The very purpose of the Royalty Adjustment Act was to adjust royalties to save the government money,¹⁴⁸ and Cipro tablet prices were central to the HHS negotiation.¹⁴⁹ But the possibility that a patent could cause the government simply to run out of materials during a crisis has consistently been a focus of the conversation over government patent use. The notion that government patent use will decrease innovation, then, must be tempered by historical cases of government patent use increasing both production and innovation by overcoming patent impasses.

Third, national need for patented technologies may turn out to be highly unpredictable in an emergency situation. Just months before the United States entered World War II, neither Congress nor the military departments could predict what patents would pose

¹⁴⁴ Nearly all of the criticisms of § 1498 described *supra* notes 2–13 rely on this proposition in some form.

¹⁴⁵ See *supra* note 53.

¹⁴⁶ See *supra* text accompanying notes 77–84.

¹⁴⁷ See Royalty Adjustment Act Hearing, *supra* note 92, at 19.

¹⁴⁸ See *id.* at 21 (“The War Department is today fully cognizant of the fact that patent cost in war procurement is a vital problem.”).

¹⁴⁹ See Bradsher, *supra* note 124.

issues or if patents would indeed pose issues at all.¹⁵⁰ As late as August 1942, Arnold and his Department of Justice colleague Francis M. Shea hypothesized that the superiority of magnesium over steel would render the former metal of greater importance to the war effort.¹⁵¹ By October 1942, though, the military had identified specific patents of concern and identified patents on steel as the actual holdup.¹⁵² Pre-war hypothesizing over government patent use in the abstract was no substitute for wartime knowledge of concrete public needs. Once those exact needs were identified, expediency was of the greatest concern: Between introduction of the Royalty Adjustment Act in Congress and its enactment into law, a single month elapsed.¹⁵³

Fourth, in times of crisis the U.S. government and the public have historically been willing to go far beyond § 1498 with respect to government patent use. Under § 1498, the government effectively receives a nonexclusive license to use a patented invention on its own behalf at a judicially-set compensation rate; the patentee's other rights and exclusivities are unaffected.¹⁵⁴ Contrast this with the World War I authorization to condemn aviation patents,¹⁵⁵ the World War II bill authorizing compulsory licensing at a presidentially set royalty rate,¹⁵⁶ the Royalty Adjustment Act that undid existing government patent licenses, and Secretary Thompson's threat that he would go to Congress to "make the government exempt from paying any damages to Bayer."¹⁵⁷ Compared to these far more dramatic actions and threats, § 1498 is relatively tame, suggesting a normative reason in favor of applying the statute more often. To the extent that § 1498 is off the table in the run-up to an emergency, as many critics of the statute would like it to be, lawmakers may be pressured or compelled during the emergency to act more

¹⁵⁰ See *supra* text accompanying notes 82–88.

¹⁵¹ See *Preventing Publication of Inventions and Prohibiting Injunctions on Patents*, *supra* note 83, at 140–41; Arnold, *supra* note 76, at 542–43.

¹⁵² See Royalty Adjustment Act Hearing, *supra* note 92, at 19.

¹⁵³ H.R. 7620 was introduced on September 30, 1942, and enacted on October 31. See 88 CONG. REC. 7661 (1942); Royalty Adjustment Act, ch. 634, 56 STAT. 1013, 1015 (Oct. 31, 1942).

¹⁵⁴ See § 1498(a); see also *infra* Part II.D.

¹⁵⁵ See Naval Service Appropriations Act, ch. 180, 39 STAT. 1168, 1169 (1917).

¹⁵⁶ See H.R. 3360, 77th Cong. § 1 (Feb. 17, 1941), reprinted in *Preventing Publication of Inventions and Prohibiting Injunctions on Patents*, *supra* note 83, at 55.

¹⁵⁷ Bradsher, *supra* note 124.

aggressively toward patents than § 1498 permits.

Finally, § 1498 enhances the government's bargaining power; where it is absent patentees have proven willing to hold out even in times of crisis.¹⁵⁸ Even after the airplane manufacturers had formed the Manufacturers' Aircraft Association to head off condemnation of their patents, they still demanded a royalty in excess of what the government found feasible.¹⁵⁹ In view of the *Newport News* decision that § 1498 could not affect preexisting government patent licenses even to adjust for increased wartime production needs,¹⁶⁰ the Navy Department testified to Congress that most patent owners had "patriotically agreed to take a greatly reduced royalty," but at least some "owners of inventions have insisted on receiving the full royalty even though unreasonable."¹⁶¹ In other words, where government patent use is not available as a backstop, patent owners may not act in the nation's best interests. By contrast, after Senator Schumer and (probably) HHS proposed use of § 1498 in 2001, Bayer ceded some profits and negotiated a deal with the U.S. government. Indeed, starting in 2005, Roche, Inc. agreed to sublicense the patent on Tamiflu to at least nineteen contractors and made numerous pricing concessions to alleviate potential shortages of the influenza treatment in preparation for a possible avian flu pandemic; while not loudly proclaimed, § 1498 "may have played a role in persuading Roche to enter the sublicensing agreements."¹⁶²

This quiet role of § 1498 as a motivator for negotiation and "corporate patriotism" is frequently missed. Epstein suggested in the wake of the Cipro deal that the government's monopsony buyer status was leverage enough to procure a price cut without resorting

¹⁵⁸ See also Brennan et al., *supra* note 11, at 303 (§ 1498 "provides the government with the necessary leverage to obtain major price reductions"). This is consistent with Lemley's finding that most government patent use cases are settled in the shadow of § 1498 rather than resolved judicially. See Mark A. Lemley, *Contracting Around Liability Rules*, 10 CAL. L. REV. 463, 473 (2012).

¹⁵⁹ See *supra* text accompanying notes 55–61.

¹⁶⁰ See *Newport News Shipbuilding & Dry Dock Co. v. Isherwood*, 5 F.2d 924, 934 (4th Cir. 1925).

¹⁶¹ Royalty Adjustment Act Hearing, *supra* note 92, at 41 (statement of Ralph L. Chappell).

¹⁶² CONG. RESEARCH SERV., REPORT NO. RL33159, INFLUENZA ANTIVIRAL DRUGS AND PATENT LAW ISSUES 9 (2007), <https://www.everycrsreport.com/reports/RL33159.html>.

to § 1498,¹⁶³ but neither the airplane manufacturing firms in the 1910s nor the patent licensor holdouts in 1942 were swayed by that status alone—nor was Bayer, until the prospect of § 1498 was concrete. Others have suggested that some drug companies’ professed willingness to negotiate with the United States and other governments during the COVID-19 pandemic refutes the need to use § 1498.¹⁶⁴ But this view ignores the fact that such willingness to negotiate is likely a response to the possibility of § 1498 being used otherwise. The oft-repeated sentiment that patents have not been a barrier to the COVID-19 response¹⁶⁵ may be not so much an

¹⁶³ See Richard A. Epstein, *Respect Bayer’s Patent*, WALL ST. J. (Oct. 25, 2001), <https://www.wsj.com/articles/SB122660341966225183> (“It is equally clear that wholly without resorting to this threat he had powerful leverage in price negotiations with Bayer, just as any other volume purchaser whom a monopolist can cheaply provide.”).

¹⁶⁴ See, e.g., Valerie Bauman, *States Demanding Gilead Drug Seizure Misread Law, Attorneys Say*, BLOOMBERG L. (Aug. 6, 2020), <https://news.bloomberglaw.com/health-law-and-business/states-demanding-gilead-drug-seizure-misread-law-attorneys-say> (disputing call for compulsory patent licensing on remdesivir because its manufacturer “Gilead has already voluntarily licensed the drug to generic drugmakers in Egypt, India, and Pakistan to boost global supply”). Gilead and other firms have indeed made various pledges of reduced or free patent licensing. See, e.g., Darrell Etherington, *Medtronic Is Sharing Its Portable Ventilator Design Specifications and Code for Free to All*, TECHCRUNCH (Mar. 30, 2020), <https://techcrunch.com/2020/03/30/medtronic-is-sharing-its-portable-ventilator-design-specifications-and-code-for-free-to-all>; Diane Peters & Eric Steuer, *Tech Giants Join the CC-Supported Open COVID Pledge*, CREATIVE COMMONS (Apr. 20, 2020), <https://creativecommons.org/2020/04/20/tech-giants-join-the-cc-supported-open-covid-pledge>.

¹⁶⁵ See, e.g., Richard Lloyd, *No Evidence That Patents Are Acting as a Barrier to Covid Research, Says Bristol Myers IP Head*, IAM (Aug. 4, 2020), <https://www.iam-media.com/coronavirus/bristol-myers-squibbs-henry-hadad-no-evidence-patents-are-acting-barrier-covid-research> (interviewing Henry Hadad, deputy general counsel of Bristol Myers Squibb) (“I have yet to hear one example of a patent being enforced or litigation being threatened in a way that has been a barrier to research with respect to covid.”); Nicholson Price et al., *Are COVID-19 Vaccine Advance Purchases a Form of Vaccine Nationalism, an Effective Spur to Innovation, or Something in Between?*, WRITTEN DESCRIPTION (Aug. 5, 2020), <https://writtendescription.blogspot.com/2020/08/are-covid-19-vaccine-advance-purchases.html> (“[T]here’s no evidence that IP is being used to frustrate competition or keep early-stage [COVID-19 vaccines] developers off the market. Nor would patents likely be used to restrict the supply of any successful vaccine.”). This view is questionable, given that at least one patent has already been asserted against a COVID-19 testing service. See Mike Masnick, *SoftBank*

argument against § 1498 as exemplification of the statute's long shadow.

II. THE GOVERNMENT'S INNOVATION POLICY TOOLBOX

As seen above, government patent use has evolved across history, as reflected in the legislative expansions of § 1498 and policy debates in times of national emergency. That history brings us to the law of government patent use in place today. This Part describes § 1498 in its current formulation, and in particular places the statute in the context of related innovation policy tools that have featured prominently in the COVID-19 dialogue: research grants, prizes, and patent buyouts.¹⁶⁶ All of these policy tools variously incentivize the invention and development of new innovations or allocate existing and prospective innovations to those who need or want them,¹⁶⁷ so the overview presented in this Part tees up a comparison of their relative merits in Part III.

A. Grants

One straightforward and hugely important means of incentivizing innovation is directly funding innovators' research and development work. The U.S. government provides over \$100 billion

Owned Patent Troll, Using Monkey Selfie Law Firm, Sues to Block Covid-19 Testing, Using Theranos Patents, TECHDIRT (Mar. 16, 2020), <https://www.techdirt.com/articles/20200316/14584244111/softbank-owned-patent-troll-using-monkey-selfie-law-firm-sues-to-block-covid-19-testing-using-theranos-patents.shtml>.

¹⁶⁶ See generally Joseph E. Stiglitz, *Economic Foundations of Intellectual Property Rights*, 57 DUKE L.J. 1693, 1719–24 (2008). Many other policy tools can incentivize new innovations and allocate existing ones; these include tax incentives for R&D and outright government seizure of patents, patented products, and the manufacturers themselves. See Daniel J. Hemel & Lisa Larrimore Ouellette, *Beyond the Patents–Prizes Debate*, 92 TEX. L. REV. 303, 321 (2013), <http://texaslawreview.org/wp-content/uploads/2015/08/HemelOuellette.pdf> (explaining U.S. government tax incentives, such as tax credits and deductions); discussion of patent condemnation *infra* notes 216–218 and accompanying text.

¹⁶⁷ For more on the dual roles of intellectual property as innovation incentive and allocation mechanism, see Daniel J. Hemel & Lisa Larrimore Ouellette, *Innovation Policy Pluralism*, 128 YALE L.J. 544, 547 (2019), <https://digitalcommons.law.yale.edu/ylj/vol128/iss3/1>. See also James Love & Tim Hubbard, *Prizes for Innovation of New Medicines and Vaccines*, 18 ANNALS HEALTH L. 155 (2009) (exploring the possibility of a hybrid patent-and-prize system that would “de-link” the innovation incentives and allocation mechanisms of the patent system); Aidan Hollis, *An Efficient Reward System for Pharmaceutical Innovation* (Jan. 17, 2005) (unpublished working paper), <http://www.keionline.org/misc-docs/drugprizes.pdf> (same).

per year in direct grants to federal laboratories, private and public universities, private companies, and other entities.¹⁶⁸ Grantmaking is not monolithic; grants to recipients outside the government can, for example, be conditioned on commitments to study a particular research problem or to price affordably any inventions that result from government-funded research. As Price has shown, the grant system provides U.S. government policymakers with rich and flexible tools to incentivize and disseminate innovation.¹⁶⁹

Grant-making has been a primary—perhaps *the* primary—innovation policy tool used by the U.S. government in its COVID-19 response. For example, a single COVID-19 bill, the Coronavirus Aid, Relief and Economic Security (CARES) Act, allocated over \$3 billion to the Biomedical Advanced Research and Development Authority (BARDA) and over \$700 million to the National Institute of Allergy and Infectious Diseases (NIAID) to be spent on research and development of COVID-19 vaccines, treatments, and diagnostics, mostly through grants to entities outside the U.S. government.¹⁷⁰ As of writing, Congress has allocated the Department of Health and Human Services’ “Operation Warp Speed” a staggering total of almost \$10 billion in funding for grantmaking for and procurement of a COVID-19 vaccine.¹⁷¹

B. Prizes

Innovation prizes are an alternative policy tool that the U.S. government could use—and already does use, to a limited

¹⁶⁸ See Hemel & Ouellette, *supra* note 166, at 320 (overview of grants); MATT HOURIHAN & DAVID PARKES, AM. ASS’N FOR THE ADVANCEMENT OF SCI., FEDERAL R&D BUDGET TRENDS: A SHORT SUMMARY 4 (2019), <https://www.aaas.org/sites/default/files/2019-01/AAAS%20R%26D%20Primer%202019.pdf> (showing U.S. government spending on R&D in excess of \$100 billion every year since the early 1980s).

¹⁶⁹ W. Nicholson Price II, *Grants*, 34 BERKELEY TECH. L.J. 1, 31 (2019); see also Danielle Conway-Jones, *Research and Development Deliverables Under Government Contracts, Grants, Cooperative Agreements and CRADAs: University Roles, Government Responsibilities and Contractor Rights*, 9 COMPUTER L. REV. & TECH. J. 181 (2004).

¹⁷⁰ Kellie Moss et al., *The Coronavirus Aid, Relief, and Economic Security Act: Summary of Key Health Provisions*, KAISER FAM. FOUND. (Apr. 9, 2020), <https://www.kff.org/coronavirus-covid-19/issue-brief/the-coronavirus-aid-relief-and-economic-security-act-summary-of-key-health-provisions>.

¹⁷¹ Press Release, U.S. Dep’t of Health & Human Servs., *Fact Sheet: Explaining Operation Warp Speed* (June 15, 2020), <https://www.hhs.gov/about/news/2020/06/16/fact-sheet-explaining-operation-warp-speed.html>.

extent¹⁷²—to incentivize the creation of new technologies while simultaneously ensuring widespread access to those technologies. In a classic prize system, the government promises payment of some set amount of money—\$1 billion, say—to the first entity to create some desired innovation, such as a cold fusion reactor or a rechargeable battery manufactured without heavy metals. As a condition of claiming the prize, the winner's innovation is placed in the public domain, permitting many competing manufacturers to make and sell the innovation at near marginal cost and thereby ensuring widespread access. Some notable legal scholars and economists have endorsed prizes as a useful complement or alternative to patents, including Abramowicz¹⁷³ and Stiglitz.¹⁷⁴

In the COVID-19 pandemic, several scholars and other experts have suggested that the U.S. government use prizes to incentivize development of the most critically needed technologies, first and foremost a vaccine.¹⁷⁵ In March of 2020, Hemel and Ouellette notably proposed a prize for a working COVID-19 vaccine of \$500 per person—approximately \$165 billion, assuming all Americans receive it—to “ensure that a vaccine would be cheap—or even free” to patients “while giving the private sector powerful incentives to pour resources into vaccine research.”¹⁷⁶

C. Patent Buyouts

Patent buyouts enable expanded access to already-patented technologies. In a classic patent buyout—as in Kremer's proposal—a government purchases a patent from a private patent holder and

¹⁷² Hemel & Ouellette, *supra* note 166, at 317 (describing the U.S. government's limited use of innovation prizes); MARCY E. GALLO, CONG. RESEARCH SERV., REPORT NO. R45271, FEDERAL PRIZE COMPETITIONS (2020), <https://fas.org/sgp/crs/misc/R45271.pdf> (same).

¹⁷³ Michael B. Abramowicz, *Perfecting Patent Prizes*, 56 VAND. L. REV. 114 (2003).

¹⁷⁴ Joseph Stiglitz, *Prizes, Not Patents*, PROJECT SYNDICATE (Mar. 6, 2007), <https://www.project-syndicate.org/commentary/prizes--not-patents>.

¹⁷⁵ See, e.g., Charles Duan, *Coronavirus Reveals Holes in American Innovation Policy—and How to Fix Them*, WASH. EXAMINER (Apr. 9, 2020), <https://www.washingtonexaminer.com/opinion/coronavirus-reveals-holes-in-american-innovation-policy-and-how-to-fix-them>; Simon Lester & Bryan Mercurio, *We Need a Coronavirus Vaccine. Patents Might Slow the Process*, NAT'L INT. (Apr. 7, 2020), <https://nationalinterest.org/blog/buzz/we-need-coronavirus-vaccine-patents-might-slow-process-141627>.

¹⁷⁶ Daniel Hemel & Lisa Ouellette, *Want a Coronavirus Vaccine, Fast? Here's a Solution*, TIME (Mar. 4, 2020), <https://time.com/5795013/coronavirus-vaccine-prize-challenge>.

then commits to license the patent non-exclusively for little or nothing, or disclaims the patent altogether and thereby places the patented invention in the public domain.¹⁷⁷ In so doing, the government opens the floodgates for all to make, use, and sell the patented invention, thereby driving down its cost to near marginal cost. In order for the patent holder to consent to the buyout, the purchase price of the buyout must be at or above the patent holder's expected profits from the patent.¹⁷⁸

Despite their conceptual appeal and perennial attention in the scholarly literature, true patent buyouts seem rare, or perhaps altogether extinct. The U.S. government does not appear to have purchased and taken title to any privately held patent in the last sixty years.¹⁷⁹

Nevertheless, some commentators have proposed patent buyouts as a COVID-19 response to ensure widespread access to therapeutics while preserving traditional patent incentives. Hemel

¹⁷⁷ Michael R. Kremer, *Patent Buyouts: A Mechanism for Encouraging Innovation*, 113 Q.J. ECON. 1137, 1138 (1998) (explaining how the government of France purchased the patent for Daguerreotype photography in 1839 and then placed it in the public domain).

¹⁷⁸ See *id.* (proposing that the government “buy out patents at [their] private value times a fixed markup that would roughly cover the difference between the social and private values of inventions”).

¹⁷⁹ Michael Kremer's influential 1998 paper discusses nineteenth century patent buyouts in France, England, and several U.S. states, but it provides no modern example of a U.S. government patent buyout. *Id.* at 1144. Kremer points out that “[t]he United States Patent Compensation Board compensates developers of innovations of military value relating to atomic energy,” but does not provide examples. *Id.* at 1145. The most recent example we have been able to find of the U.S. government purchasing or otherwise compensating an inventor for an atomic energy patent is in 1953, when the Atomic Energy Commission purchased U.S. Patent No. 2,206,634, entitled “Process for the production of radioactive substances,” from a group of inventors that included Enrico Fermi. See Simon Turchetti, “*For Slow Neutrons, Slow Pay*”: *Enrico Fermi's Patent and the U.S. Atomic Energy Program, 1938–1953*, 97 ISIS 1, 2 (2006). Hemel and Ouellette describe the U.S. government's Medicaid program as “[t]he closest thing to a large-scale patent buyout scheme in the United States.” Hemel & Ouellette, *supra* note 167, at 594. But Medicaid and other federal programs under which the U.S. government purchases authorized copies of prescription drugs and medical devices at full or near-full price differ significantly from true patent buyouts, not least because the government's purchases of patented products under Medicaid transfer no patent rights to the government and do not empower the government to manufacture those products itself, nor to authorize competitor manufacturers to do so.

and Ouellette suggest that the United States and others could “offer strong incentives to drugmakers while ensuring affordability by committing to patent buyouts for effective treatments.”¹⁸⁰ Kominers has similarly proposed that the U.S. government “could purchase medical-device patents and then place them in the public domain,” which would “free manufacturers—with coordination from government—to produce those devices and meet soaring demand” during the COVID-19 crisis.¹⁸¹

D. Government Patent Use Under Section 1498

Today’s government patent use statute, codified at 28 U.S.C. § 1498(a), opens as follows:

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.¹⁸²

The statute goes on to make clear, based on the World War II amendments noted earlier,¹⁸³ that federal contractors, subcontractors, and other authorized agents are immune to infringement liability where they have “authorization and consent of the Government.”¹⁸⁴

The nature of “reasonable and entire compensation” under the statute is worth some discussion.¹⁸⁵ The Supreme Court has historically emphasized the “comprehensive character of the remedy provided” under the law.¹⁸⁶ Courts have interpreted the statute

¹⁸⁰ Hemel & Ouellette, *supra* note 31.

¹⁸¹ Scott Duke Kominers, *Patent Protection Should Take a Backseat in a Crisis*, BLOOMBERG (Mar. 26, 2020), <https://www.bloomberg.com/opinion/articles/2020-03-26/patent-protection-should-take-backseat-in-coronavirus-crisis>.

¹⁸² § 1498(a).

¹⁸³ *See supra* note 94.

¹⁸⁴ *See* 28 U.S.C. § 1498(a); *Madey v. Duke Univ.*, 307 F.3d 1351, 1359 (Fed. Cir. 2002).

¹⁸⁵ For more comprehensive discussions of compensation under § 1498, see generally Brennan et al., *supra* note 11, at 310; Cahoy 2011, *supra* note 2; Cahoy 2002, *supra* note 26.

¹⁸⁶ *Richmond Screw Anchor Co. v. United States*, 275 U.S. 331, 343 (1928).

generally to call for a reasonable royalty rather than other remedies.¹⁸⁷ Lost profits may be available “only after the strictest proof that the patentee would actually have earned and retained those sums in its sales to the Government”;¹⁸⁸ value to the government is rarely the standard.¹⁸⁹ Any royalty is premised upon a *nonexclusive* license adequate to cover the goods and services procured or authorized by the government, rather than the value of an exclusive license or total appropriation of the patent.¹⁹⁰

Belying the perception that government patent use is “stealing,” “expropriation,” a “nuclear option,” or the like,¹⁹¹ surveys of past § 1498 cases confirm that reasonable royalty awards under § 1498 are “generally provided at a market rate,”¹⁹² such that the reasonable royalty paid for government patent use is similar to compensation for private infringement calculated using the standard factors of *Georgia-Pacific Corp. v. U.S. Plywood Corp.*¹⁹³ Royalty awards under § 1498 may, and often do, account for a patent holder’s risk-

¹⁸⁷ See *Hughes Aircraft Co. v. United States*, 86 F.3d 1566, 1573 (Fed. Cir. 1996); *Decca Ltd. v. United States*, 640 F.2d 1156, 1169 & n.22 (Ct. Cl. 1980) (citing *Tektronix, Inc. v. United States*, 552 F.2d 343, 349 (Ct. Cl. 1977)); Brennan et al., *supra* note 11, at 313; Cahoy, *supra* note 26, at 156–57; Mitchell, *supra* note 27, at 542–43.

¹⁸⁸ *Tektronix*, 552 F.2d at 349; *accord* *Leesona Corp. v. United States*, 599 F.2d 958, 970–71 (Ct. Cl. 1979); *see also* Brennan et al., *supra* note 11, at 311 (“‘[L]ost profits’ are strongly disfavored, and perhaps entirely unavailable, under § 1498.”); Cahoy, *supra* note 26, at 155 (“[L]ost profits have apparently been out of reach to plaintiffs in § 1498 actions since the mid-1930s.”).

¹⁸⁹ See *Leesona*, 599 F.2d at 971; *Decca*, 640 F.2d at 1167 n.20.

¹⁹⁰ See *Motorola, Inc. v. United States*, 729 F.2d 765, 768 n.3 (Fed. Cir. 1984) (describing government as “a compulsory, nonexclusive licensee”).

¹⁹¹ See *supra* notes 2–13.

¹⁹² Cahoy, *supra* note 2, at 491; *see also* *Bendix Corp. v. United States*, 676 F.2d 606, 609 (Ct. Cl. 1982) (Federal Circuit’s predecessor court describing “awards against the private infringer, and against the government taker,” as “similar”); 7 DONALD S. CHISUM, CHISUM ON PATENTS § 20.03 (2020) (describing § 1498 compensation as “construed and applied in a fashion similar to the measure of compensatory damages in suits against infringers other than the United States”); Laura Burson et al., *Suing for Patent Infringement if the Government Takes Your Intellectual Property During the COVID-19 Pandemic*, IPWATCHDOG (Apr. 24, 2020), <https://www.ipwatchdog.com/2020/04/24/suing-patent-infringement-government-takes-intellectual-property-covid-19-pandemic/id=120922> (noting the use of “hypothetical negotiation” under *Georgia-Pacific Corp. v. U.S. Plywood Corp.* to assess § 1498 damages).

¹⁹³ 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970), *rev’d on other grounds*, 446 F.2d 295 (2d Cir. 1971).

adjusted investments in research and development.¹⁹⁴ In other words, government patent use will generally not “represent a discount from the market price of the licensed good” unless the patentee’s expectations are excessive;¹⁹⁵ the public value of § 1498 may instead be accuracy and objectivity of compensation. As a result, Cahoy observes that, rather than being “disruptive,” government patent use and § 1498 “can fit within the broader goals of the intellectual property system, encouraging fair and intelligent pricing, and supporting access.”¹⁹⁶ Government patent use does not dramatically undercompensate patent holders and, as such, need not upset patent holders’ investments or incentives to innovate (although the *timing* of compensation under § 1498 is delayed, as we discuss below¹⁹⁷).

One way of understanding the operation of § 1498 is through the distinction between “property rules,” where the price of an entitlement is subjectively set by the holder, and “liability rules,” where the price is set by an independent adjudicator.¹⁹⁸ Patents are

¹⁹⁴ See *Tektronix, Inc. v. United States*, 552 F.2d 343, 350 (Ct. Cl. 1977) (noting relevance of patentee “which took the risks and bore the expense of developing the [invention] and creating a market for them”); Brennan et al., *supra* note 11, at 314. Numerous scholars have suggested that royalties of 10% or less of the infringers’ sales are common in § 1498 cases, and that royalties of over 10% are rare. See Brennan et al., *supra* note 11, at 310; Kapczynski & Kesselheim, *supra* note 15, at 793 (“Royalties are commonly set at 10 percent of sales or less” in § 1498 cases involving the Department of Defense); 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%.”); see also JAMES LOVE, WHO, REMUNERATION GUIDELINES FOR NON-VOLUNTARY USE OF A PATENT ON MEDICAL TECHNOLOGIES 18 (2005), <https://apps.who.int/iris/handle/10665/69199> (same). While we are not aware of a court-ordered royalty under § 1498 of more than 10% of the revenues associated with the government’s use—e.g., the sales revenues of a contractor authorized under § 1498—reasonable royalties calculated under the *Georgia-Pacific* factors in routine patent infringement suits under 35 U.S.C. § 271 sometimes exceed 10%. See 4 ROBERT A. MATTHEWS, JR., ANNOTATED PATENT DIGEST §§ 30:107–30:110 (2019) (documenting reasonable royalties in recent § 271 cases of greater than 10% of the infringers’ sales revenues, e.g., 14.5%, 17.5%, and 32%). It seems to us that the same may be true in future litigation under § 1498.

¹⁹⁵ Cahoy, *supra* note 2, at 494.

¹⁹⁶ *Id.*

¹⁹⁷ See *infra* Part III.A.3.

¹⁹⁸ See Guido Calabresi & A. Douglas Melamed, *Property Rules, Liability Rules*,

ordinarily treated under a property rule, insofar as courts and administrative tribunals may issue injunctions that prevent would-be infringers from using a patented invention without the voluntary consent of the patent holder.¹⁹⁹ While the desirability of applying a property rule to patents is a topic of much debate,²⁰⁰ it has been long recognized that injunctive relief is inappropriate where access to a patented invention is necessary for public health or safety.²⁰¹ Section 1498 can thus be understood to give the U.S. government discretion to waive the property rule remedy of patent injunctions in appropriate situations.

Government patent use under § 1498 should be distinguished from several other forms of public and private ordering of patent interests. First, it is entirely distinct from arrangements involving so-called “FRAND” licenses. The latter concept relates to patent-holder obligations to license certain patents on “Fair, Reasonable, and Non-Discriminatory” terms, arising either out of a private commitment to do so²⁰² or to satisfy a government regulation or

and Inalienability: *One View of the Cathedral*, 85 HARV. L. REV. 1089, 1092 (1972).

¹⁹⁹ See Tariff Act of 1930 § 337(d)(1), 19 U.S.C. § 1337 (as amended); 35 U.S.C. § 283. In private patent infringement disputes, liability rather than property rules often prevail, as courts frequently decline to order injunctive relief under the Supreme Court’s test in *eBay Inc. v. MercExchange, LLC*. See 547 U.S. 388, 391 (2006). See Christopher B. Seaman, *Permanent Injunctions in Patent Litigation After eBay: An Empirical Study*, 101 IOWA L. REV. 1949, 1984 (2016). Such circumstances are somewhat less common with respect to pharmaceutical patents, because courts tend to award injunctions to bona fide operating manufacturers. See *id.* at 1988–90.

²⁰⁰ See Colleen V. Chien & Mark A. Lemley, *Patent Holdup, the ITC, and the Public Interest*, 98 CORNELL L. REV. 1 (2012); Daniel A. Crane, *Intellectual Liability*, 88 TEX. L. REV. 253, 255–56 (2009); Mark A. Lemley & Philip J. Weiser, *Should Property or Liability Rules Govern Information?*, 85 TEX. L. REV. 783, 784 (2007); Doug Lichtman, *Patient Patents: Can Certain Types of Patent Litigation Be Beneficially Delayed?*, 46 J. LEGAL STUD. 427 (2017); Carl Shapiro, *Injunctions, Hold-Up, and Patent Royalties*, 12 AM. L. & ECON. REV. 280, 308 (2010); Katherine J. Strandburg, *Patent Fair Use 2.0*, 1 U.C. IRVINE L. REV. 265, 278 (2011). See generally Seaman, *supra* note 199, at 1956–58 & nn.33–49 (citing sources and reviewing arguments).

²⁰¹ See, e.g., *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1547–48 (Fed. Cir. 1995) (citing examples); Seaman, *supra* note 199, at 1962, 1991.

²⁰² Patent owners may commit to FRAND licensing in order to have their technologies adopted into privately developed technical standards such as Wi-Fi or mobile communications systems. See generally Jorge L. Contreras, *A Brief*

benefit condition.²⁰³ While FRAND arrangements also overcome the property rule of patent remedies and indeed often enlist a court to do so, the computation of such royalties is idiosyncratic and subject to rules different from the traditional *Georgia-Pacific* factors.²⁰⁴

Additionally, government patent use under § 1498 is distinct from the Defense Production Act (DPA).²⁰⁵ The DPA, enacted at the start of the Korean War²⁰⁶ and since expanded,²⁰⁷ permits the U.S. government to take effective control of manufacturing when doing so is “necessary or appropriate to promote the national defense,”²⁰⁸ broadly defined.²⁰⁹ The DPA also includes a variety of powers “to help ensure that the nation has an adequate supply of, or the ability to produce, essential materials and goods necessary for the national defense.”²¹⁰ This makes the DPA complementary to § 1498, in that

History of FRAND: Analyzing Current Debates in Standard Setting and Antitrust Through a Historical Lens, 80 ANTITRUST L.J. 39, 42 (2015); Herbert Hovenkamp, *FRAND and Antitrust*, 105 CORNELL L. REV. 1683 (2020); Mark A. Lemley & Timothy Simcoe, *How Essential Are Standard-Essential Patents?*, 104 CORNELL L. REV. 607, 610 (2019).

²⁰³ See, e.g., 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program, 85 Fed. Reg. 25642, 25960–61 (May 1, 2020) (to be codified at 45 C.F.R. § 171.303) (requiring licensing of certain electronic health record technology on “reasonable” and “non-discriminatory” terms); AT&T Commc’ns of Va., Inc. v. Bell Atl.-Va., Inc., 197 F.3d 663, 670–71 (4th Cir. 1999) (holding telecommunications statute requiring “access to network elements” on terms that are “reasonable and nondiscriminatory,” 47 U.S.C. § 251, to require provider “to renegotiate its existing intellectual property licenses”); Narechania, *supra* note 1, at 1517–23.

²⁰⁴ See *Microsoft Corp. v. Motorola, Inc.*, 795 F.3d 1024, 1041–42 (9th Cir. 2015); *Ericsson, Inc. v. D-Link Sys., Inc.*, 773 F.3d 1201, 1230–32 (Fed. Cir. 2014).

²⁰⁵ Defense Production Act of 1950, 50 U.S.C. §§ 4501–4568.

²⁰⁶ Defense Production Act of 1950, Pub. L. No. 81-774, 64 STAT. 798.

²⁰⁷ See J. Michael Littlejohn, *Using All the King's Horses for Homeland Security: Implementing the Defense Production Act for Disaster Relief and Critical Infrastructure Protection*, 36 PUB. CONT. L.J. 1, 3-4 (2006) (tracing gradual expansion of the DPA).

²⁰⁸ 50 U.S.C. § 4511(a).

²⁰⁹ § 4552(14) (defining “national defense” to encompass “programs for military and energy production or construction, military or critical infrastructure assistance to any foreign nation, homeland security, stockpiling, space, and any directly related activity”).

²¹⁰ MICHAEL H. CECIRE & HEIDI M. PETERS, CONG. RESEARCH SERV., REPORT NO. R43767, THE DEFENSE PRODUCTION ACT OF 1950: HISTORY, AUTHORITIES, AND CONSIDERATIONS FOR CONGRESS 9, <https://fas.org/sgp/crs/natsec/R43767.pdf>;

the former can force a firm to engage in certain manufacturing, while the latter removes patent-infringement barriers to that manufacturing.²¹¹ But the U.S. government can use patents under § 1498 without invoking the DPA, and government patent use is, in many ways, a milder intervention than coordinated production under the DPA. For example, if a manufacturer refuses to sell a particular patented product to the U.S. government, the government might choose to procure the product from a competitor authorized under § 1498, or it might instead choose to invoke the DPA and compel the manufacturer's own factories to supply the government. The government patent use option would protect the manufacturer's existing contracts and business relationships; the DPA option would upend them.

Finally, § 1498 must be distinguished from eminent domain, or takings, under the Fifth Amendment. The Federal Circuit recently reaffirmed this distinction in *Golden v. United States*, holding that “a patent owner may not pursue an infringement action as a taking under the Fifth Amendment,” because patent infringement actions against the U.S. government “sound in tort and are to be pursued exclusively under 28 U.S.C. § 1498.”²¹² The court deemed this

see also James A. Durham, *The Present Status of Price Control Authority*, 52 COLUM. L. REV. 868 (1952); Littlejohn, *supra* note 207; Note, *The Defense Production Act: Choice as to Allocations*, 51 COLUM. L. REV. 350 (1951).

²¹¹ See Rick Longton et al., *Intellectual Property Considerations for Manufacturers Contracted Under the Defense Production Act*, COVINGTON & BURLING LLP 2 (Apr. 2, 2020), <https://www.cov.com/en/news-and-insights/insights/2020/04/intellectual-property-considerations-for-manufacturers-contracted-under-the-defense-production-act>. The DPA alone likely cannot affect patents. See *Defense Production Act of 1950: Hearing on H.R. 9176 Before the H. Comm. on Banking and Currency*, 81st Cong. 35 (July 24–25, 1950), <https://catalog.hathitrust.org/Record/102432877> (testimony of Mr. Kendall, National Security Resources Board).

²¹² 955 F.3d 981, 987-88 (Fed. Cir. 2020). While *Golden* did not answer the question of whether application of § 1498 itself is an eminent domain action, the opinion is irreconcilable with that view in describing government patent use as sounding in tort. *Golden* further repeatedly approves of *Zoltek I*, which squarely rejected § 1498 being an eminent domain statute. See *Zoltek I*, 442 F.3d 1345, 1352 (Fed. Cir. 2006) (per curiam) (“Had Congress intended to clarify the dimensions of the patent rights as property interests under the Fifth Amendment, there would have been no need for the new and limited sovereign immunity waiver [of the 1910 Act].”), *vacated*, 672 F.3d 1309 (Fed. Cir. 2012) (en banc), *cited with approval in Golden*, 955 F.3d at 987-88. The Supreme Court denied certiorari in *Golden* in December 2020. *Golden v. United States*, No. 20-5532, 2020 WL 7132384 (U.S. Dec. 7, 2020).

holding “mandate[d]” by the Supreme Court’s decision in *Schillinger* that patent infringement could not be remedied as a taking.²¹³ Eminent domain may serve as a helpful analogy for government patent use, but it is a distinct act.²¹⁴ Indeed, outright government condemnation of patents was historically contemplated with regard to aviation technology²¹⁵ and commentators have called for the government to invoke eminent domain on patents,²¹⁶ but condemnation has distinctly different consequences from government patent use: In the former case but not the latter, the owner of the condemned patent loses the ability to license the patent to third parties and indeed may lose the ability to practice the invention at all.²¹⁷ To be sure, a substantial line of Supreme Court and other cases describe § 1498 in terms of eminent domain,²¹⁸ as do multiple commentators.²¹⁹ But, as Masur and Mortara observe from review of those § 1498 cases, those judicial statements have consistently been in dicta with “no effect whatsoever on the success or failure of the claims”; in other words, government patent use “is described in terms of eminent domain or takings when that characterization is irrelevant to the resolution of the case at hand.”²²⁰

²¹³ *Golden*, 955 F.3d at 988.

²¹⁴ *See, e.g., Brennan et al., supra* note 11, at 307–09.

²¹⁵ *See supra* notes 55–61.

²¹⁶ *See, e.g., Kesselheim & Avorn, supra* note 126, at 435; Mitchell, *supra* note 27, at 548–49 (distinguishing takings of patents from § 1498); *cf. Fran Quigley, Tell Me How It Ends: The Path to Nationalizing the U.S. Pharmaceutical Industry*, 53 U. MICH. J.L. REFORM 755, 804–05 (2020) (suggesting that seizure of patents may not require significant Fifth Amendment compensation).

²¹⁷ As one of us has noted, the government could use intellectual property condemnation as a mechanism for suppressing information, with obvious and troubling consequences for speech interests. *See* Charles Duan, *Copyright Law Could Stop 3-D Printed Guns. Should It?*, LAWFARE (Aug. 31, 2018), <https://www.lawfareblog.com/copyright-law-could-stop-3-d-printed-guns-should-it>.

Government patent use cannot effect this result.

²¹⁸ *See, e.g., James v. Campbell*, 104 U.S. 356, 358 (1882); *Leesona Corp. v. United States*, 599 F.2d 958, 964–65 (Ct. Cl. 1979). *Contra De Graffenried v. United States*, 29 Fed. Cl. 384, 387 (1993) (“[T]he far more compelling argument is that Section 1498(a) actions are not ‘eminent domain proceedings’”); *Charles Pfizer & Co., 39 Comp. Gen. 760, 763* (1960) (“Clearly, [the 1910] act is an amendment to the patent laws and restricts the rights of a patentee by providing for government use of patents”).

²¹⁹ *See* sources cited *supra* note 20.

²²⁰ Masur & Mortara, *supra* note 20, at 990–92. *James* provides a striking example: The Court digresses for a page and a half on the takings nature of

III. SECTION 1498 AS POLICY TOOL IN A NATIONAL EMERGENCY

The history and nature of § 1498 suggest a useful framework for weighing the role of government patent use, in national emergencies and otherwise. In particular, we discern four generally underappreciated features of § 1498: (1) speed, (2) flexibility, (3) ex post determination of the appropriate compensation (occurring not only after not only invention but after the government's use), and (4) determination of that compensation by an impartial adjudicator. The salience of these four factors to any particular situation, in our view, is indicative of whether § 1498 will likely be advantageous in that situation over other tools such as patent buyouts for ensuring access to critical technologies. That is not to say that § 1498 is always preferable to, or should be used to the exclusion of other innovation policy tools; it is instead a *complement* that can be freely mixed and matched with the others when appropriate.²²¹

These features of § 1498 do not depend on the presence of a national emergency, and we do not find the existence of emergency conditions to be a prerequisite to use of § 1498. Besides the obvious difficulties in defining national emergencies,²²² the identified advantages of § 1498 can be relevant to plainly non-emergency situations. The flexibility of government patent use, for example, can be highly relevant to the operations of financial markets.²²³ Furthermore, we intend this analysis to be one of sufficiency rather than necessity: Where none of these advantages is especially salient, use of § 1498 may still be warranted, but that use could be justified on other factors outside of the scope of the present analysis, such as deadweight loss from monopoly pricing²²⁴ or human rights.²²⁵

government patent use, only to then flatly note that “the conclusion which we have reached in this case does not render it necessary to decide this question.” 104 U.S. at 357–59.

²²¹ For an analysis of intellectual property's two distinct elements—innovation incentive and allocation mechanism—and the ways in which patent-based innovation incentives and allocation mechanisms can be mixed and matched with other incentives and mechanisms, such as tax credits and prizes, see Hemel & Ouellette 2019, *supra* note 167, at 563–74.

²²² Cf. *Youngstown Sheet & Tube Co. v. Sawyer*, 343 U.S. 579, 646–47 (1952) (Jackson, J., concurring) (describing “[l]oose and irresponsible use of adjectives” such as “emergency,” “without fixed or ascertainable meanings”).

²²³ See *infra* note 232 (describing use of § 1498 for check clearing transactions).

²²⁴ See Brennan et al., *supra* note 11, at 317–18.

²²⁵ See Cahoy, *supra* note 2, at 500–07.

That these features have indeed been salient in past national crises shows that § 1498 will continue to be an advantageous and sometimes indispensable policy tool. Indeed, as we describe below, the advantages of § 1498 are highly relevant to COVID-19 technologies, including diagnostic tests, ventilators, and medical treatments.²²⁶ To highlight these advantages and their relevance, we develop a roadmap for one use case today: ensuring adequate and affordable access to remdesivir, an antiviral drug that has shown promise as a treatment for COVID-19. Our roadmap illuminates the four underappreciated features of § 1498 and highlights how government patent use can protect public health, patent holders, and the public purse.

A. Four Key Features of Government Patent Use in a National Emergency

1. Speed

Government patent use is quick—a feature particularly valuable in a national emergency. The U.S. government can exercise its powers under § 1498 instantly, without any procedure—not even notice to the holder of patent rights in the product being used or manufactured by the government.²²⁷ (In this regard, “election” or “invocation” of government patent use are perhaps the wrong terms to use—the U.S. government’s power to use privately held patents is always on, by default.²²⁸)

²²⁶ A comment that applies to all of Section IV: this Article was researched and written in the spring and summer of 2020 and edited in the fall of 2020. The COVID-19 pandemic is fast-changing, but we have done our best to ensure that the facts herein were accurate as of mid-September 2020.

²²⁷ According to the 1995 Resource Book published by the United Nations Conference on Trade and Development (UNCTAD) and International Centre on Trade and Sustainable Development (ICTSD) on the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), “under U.S. law, the government may use any patented invention (or authorize its contractor to use such invention) without providing prior notification to the patent holder, subject only to the patent holder’s right to initiate a proceeding before the Court of Claims for compensation.” UNITED NATIONS CONFERENCE ON TRADE & DEV. & INT’L CTR. FOR TRADE & SUSTAINABLE DEV., RESOURCE BOOK ON TRIPS AND DEVELOPMENT 468 (2005); *see also* Cahoy, *supra* note 2, at 494 (observing that “the U.S. essentially engages in” “compulsory licensing without negotiation”).

²²⁸ In this respect, the U.S. government’s patent rights under § 1498 differ from—and are more powerful and versatile than—its march-in rights under the Bayh–Dole Act. *See* 35 U.S.C. § 203(a). To exercise march-in rights and issue a compulsory license on a Bayh–Dole patent, a federal agency must first make a

Indeed, the U.S. government can exercise its rights under § 1498 unwittingly—for example, if it unknowingly purchases products from a supplier that turn out to be covered by another party’s patents.²²⁹ Section 1498 even arguably enables the government to absolve third parties of their liability for *past* acts of infringement: § 1498 applies to acts performed (1) “by or for” the government and (2) with the government’s “authorization or consent.”²³⁰ In *Advanced Software Design Corp. v. Federal Reserve Bank of St. Louis*, the Federal Circuit recognized that private activity that confers “significant benefits to the United States” satisfies the “by and for” the government prong of the test, and “post hoc” consent by the government can constitute the requisite “authorization or consent.”²³¹ This absolution can be achieved quickly—in the same case, a Treasury official simply sent a letter to the infringer, confirming that the U.S. government condoned the infringer’s use of the patented technology.²³²

Government patent use’s instantaneity is particularly valuable

determination that certain statutory conditions have been met, such as a determination that public “health or safety needs . . . are not reasonably satisfied by the [patent rights-holding] contractor, assignee, or their licensees.” § 203(a)(2). No such determination is necessary under § 1498.

²²⁹ See *supra* notes 114–117 and accompanying text. A 1958 opinion of the United States Comptroller General acknowledged as much, and seems indeed to actively encourage a kind of willful blindness on the part of U.S. government procurement officers: “[Section 1498] is not consistent with any duty on the part of a contracting agency of the Government to protect the interests of patentees or licensees with respect to articles which it proposes to purchase, since the statute itself defines and provides an exclusive remedy for enforcement of the patentee’s rights as to the Government.” *Herbert Cooper*, 38 Comp. Gen. 276, 278 (1958). This opinion appears to remain in effect and govern U.S. government procurement even today, despite substantial efforts to undo the decision legislatively across the 1960s. See *Motorola, Inc. v. United States*, 729 F.2d 765, 771 (Fed. Cir. 1984); Brennan et al., *supra* note 11, at 305; Mossinghoff & Allnutt, *supra* note 24, at 16–27 (describing legislative reform proposals).

²³⁰ § 1498(a).

²³¹ 583 F.3d 1371, 1376–79 (Fed. Cir. 2009). In *Advanced Software*, the patented technology was a method of detecting fraudulent bank checks, and the “significant benefits” to the United States that met the “by and for” the government prong of the test was reduced fraud and financial benefits to the Federal Reserve Banks, as well as to private banks. *Id.* at 1373, 1378; see also Brennan et al., *supra* note 11, at 332–33 (reviewing case law on “authorization and consent”).

²³² See *Advanced Software*, 583 F.3d at 1377; see also *Madey v. Duke Univ.*, 413 F. Supp. 2d 601, 608 (M.D.N.C. 2006) (“§ 1498 does not require the authorization to take any specific form.”).

when the government must move quickly to disseminate patented products needed to combat a national crisis. By contrast, a patent buyout with even a willing, good faith patent holder could take weeks to negotiate—weeks the government and the American public may not have to spare.²³³ Moreover, the government may not know all the patents that cover a particular product, and thus it may not know which patents it needs to buy, and from whom. For example, as of writing, many different firms are now developing—and likely patenting—new ventilator designs designed to protect the lungs of COVID-19 patients. In April 2020, CNET reported that “newly designed, cutting-edge ventilators may be on the way from the likes of tech giant Dyson, General Motors, MIT and a British consortium led by Airbus.”²³⁴ In situations like this, a wide-ranging search of active patents and full-fledged “clearance” study (also known as a “freedom to operate” study) by the government would be necessary to identify all relevant patents and their owners before the government could confidently undertake buyout negotiations. Even a single study on a single product can be “time-consuming and costly.”²³⁵

In practice, the government may choose to try to negotiate a buyout or other deal first, in the same way that the government negotiated royalty rates with the Manufacturers' Aircraft Association in 1918 and HHS negotiated the Cipro deal in 2001. Section 1498 nevertheless serves as an important backstop: it prevents “hold-up” or “hold-out” situations where a single patent holder demands a buyout far in excess of the investment costs for developing the invention and a “reasonable” profit.²³⁶ Hold-ups can occur even in times of national emergency, as occurred in 2001's anthrax scare, when Bayer initially refused to budge on the price of

²³³ The same defect seems true of auctions, which Kremer proposes as a mechanism to elicit the market value of patents purchased by the government in patent buyouts. See Kremer, *supra* note 177, at 1146-48.

²³⁴ Jackson Ryan, *In the War Against Coronavirus, One Device Can Be the Difference Between Life and Death*, CNET (Apr. 3, 2020), <https://www.cnet.com/features/coronavirus-ventilators-why-one-machine-is-pivotal-in-the-battle-against-covid-19>.

²³⁵ See Linda J. Thayer, *When is a Freedom to Operate Opinion Cost-Effective?*, FINNEGAN (March 2013), <https://www.finnegan.com/en/insights/articles/when-is-a-freedom-to-operate-opinion-cost-effective.html>.

²³⁶ See Brennan et al., *supra* note 11, at 309.

ciprofloxacin until HHS threatened to use § 1498.²³⁷ Hold-ups are socially harmful, as they cause delay and inefficient public overspending on the patented technology.²³⁸ Indeed, there may be hold-up situations that delay, even derail, dissemination of needed patented products to the public that arise not from any intentional gamesmanship on the part of the patent holder but simply from the patent holder's genuine overvaluation of its own patent. If there is no zone of agreement between the patent holder and the government—if the patent holder's reserve price exceeds the government's willingness or ability to pay—then no buyout deal will ever be reached.

2. Flexibility

Government patent use under § 1498 can be used flexibly, in numerous ways. We highlight two here.

(a) “Surgical strikes” to expand supply and relieve shortages. Section 1498 is particularly well-suited to relieve limits on production and supply created by patents, especially in times of national emergency. In past emergencies of infectious disease, for example, suppliers that hold patents on important technologies have been unable to keep up with demand, even while they have declined to license their patents to competitor manufacturers. The story of Bayer and ciprofloxacin (Cipro), told above, is one vivid instance.²³⁹ Roche and oseltamivir (Tamiflu) is another; in 2005, a global outbreak of avian flu led to a spike of demand in the United States and around the world.²⁴⁰ Roche's own manufacturing capacity was

²³⁷ See *supra* Part I.D; see also Leslie Wayne & Melody Petersen, *A Muscular Lobby Rolls Up Its Sleeves*, N.Y. TIMES (Nov. 4, 2001), <https://www.nytimes.com/2001/11/04/business/a-muscular-lobby-rolls-up-its-sleeves.html> (reporting that, to the pharmaceutical industry, “any threats to [patent] protection, even at a time of national crisis, is a clarion call to action” and that Bayer initially refused to give the U.S. government any discount on large-scale purchases of ciprofloxacin).

²³⁸ See Brennan et al., *supra* note 11, at 309-10.

²³⁹ See *supra* Part I.D.

²⁴⁰ See CONG. RESEARCH SERV., *supra* note 162, at 2-3. Somewhat ironically, independent researchers later uncovered clinical trial data (which Roche had withheld from the medical literature) revealing that the billions of dollars spent on oseltamivir by governments around the world were largely wasted: oseltamivir failed to prevent the spread of the flu, reduce hospital admissions, or minimize complications significantly. See Richard Van Noorden, *Report Disputes Benefit of Stockpiling Tamiflu*, NATURE NEWS & COMMENT (Apr. 10, 2014), <http://www.nature.com/news/report-disputes-benefit-of-stockpiling-tamiflu-1.15022> (citing

unable to meet demand, but Roche declined to license its patents to Cipla, saying it “fully intend[ed] to remain the sole manufacturer of Tamiflu.”²⁴¹ This led to shortages, to several senators calling for invocation of § 1498, and ultimately to Roche making an “about-face” and agreeing to multiple licenses.²⁴²

The same phenomenon—a patent-holding manufacturer apparently unable to meet demand and yet unwilling to voluntarily license its patents—has already occurred in the COVID-19 pandemic. One significant example is the field of anti-COVID-19 therapeutic drugs: Gilead, which holds patents on the COVID-19 treatment drug remdesivir, was unable to meet demand (both within the United States and overseas) and yet (to date) is largely unwilling to license its patents to other manufacturers. We tell the story of remdesivir in detail below and make a case for use of § 1498 to expand supply.²⁴³

Another example of the phenomenon seems to have occurred in diagnostic testing. The molecular diagnostics company Cepheid has drawn praise for developing what is, as of writing, among the most reliable, sensitive point-of-care diagnostic tests for COVID-19, sold under the Xpert Xpress SARS CoV-2 brand name.²⁴⁴ These tests

Tom Jefferson et al., *Neuraminidase Inhibitors for Preventing and Treating Influenza in Adults and Children*, in 2014 COCHRANE DATABASE SYSTEMATIC REVIEWS, <https://doi.org/10.1002/14651858.CD008965.pub4>). Oseltamivir does appear, however, to shorten some symptoms. See *What You Should Know About Flu Antiviral Drugs*, CTRS. FOR DISEASE CONTROL & PREVENTION (last visited Nov. 13, 2020), <https://www.cdc.gov/flu/treatment/whatyoushould.htm>.

²⁴¹ See Donald G. McNeil Jr., *Indian Company to Make Generic Version of Flu Drug Tamiflu*, N.Y. TIMES (Oct. 14, 2005), <https://www.nytimes.com/2005/10/14/health/indian-company-to-make-generic-version-of-flu-drug-tamiflu.html>.

²⁴² Sabin Russell, *About-Face on Influenza Drug / Manufacturer Says It Will Consider Licensing Tamiflu*, S.F. CHRON. (Oct. 19, 2005), <https://www.sfgate.com/health/article/About-face-on-influenza-drug-Manufacturer-says-2575819.php>; see CONG. RESEARCH SERV., *supra* note 162, at 13–14.

²⁴³ See *infra* Part III.B.

²⁴⁴ See Bruce Japsen, *FDA Approves More “Rapid” COVID-19 Coronavirus Tests for Use on Frontlines*, FORBES (Mar. 24, 2020), <https://www.forbes.com/sites/brucejapsen/2020/03/24/us-approves-more-rapid-covid-19-tests-for-use-on-frontlines/> (describing FDA’s emergency use authorization for the Xpert Xpress SARS CoV-2); Giorgia Guglielmi, *The Explosion of New Coronavirus Tests That Could Help to End the Pandemic*, NATURE (July 17, 2020), <https://www.nature.com/articles/d41586-020-02140-8> (explaining that Cepheid’s test “take[s] less than one hour to perform”); Rachana Pradhan, *As Problems Grow with Abbott’s*

provide results in less than hour, making them particularly useful in hospitals and other “point-of-care” locations where rapid results are needed to provide appropriate medical care. HHS has spent millions in public money to purchase Cepheid’s test machines through the Strategic National Stockpile for public health emergencies²⁴⁵ and distribute them to hospitals in need.²⁴⁶ Each Xpert Xpress SARS CoV-2 test uses a single disposable plastic cartridge, pre-filled with the appropriate chemicals to run the test.²⁴⁷ Cepheid has struggled to manufacture and distribute enough of the disposable cartridges tests to meet demand through the summer of 2020.²⁴⁸

A third example of shortages of (presumably) patented anti-COVID technologies has occurred with personal protective equipment (PPE). In the spring of 2020, 3M’s patented N95 respirators were widely demanded by health care providers across

Fast COVID Test, FDA Standards Are Under Fire, KAISER HEALTH NEWS (June 22, 2020), <https://khn.org/news/abbott-rapid-test-problems-grow-fda-standards-on-covid-tests-under-fire/> (describing Cepheid’s test as more accurate than a competitor’s point-of-care test). Cepheid has also drawn some criticism for its pricing. See Press Release, Médecins Sans Frontières Int’l, *Cepheid Charging Four Times More than It Should for Coronavirus COVID-19 Tests* (July 28, 2020), <https://www.msf.org/diagnostic-company-cepheid-charging-more-it-should-covid-19-tests>.

²⁴⁵ See *FDA standards under fire as problems grow with fast COVID-19 tests*, HEALTHCARE PURCHASING NEWS (Jun. 24, 2020), <https://www.hpnonline.com/sourcing-logistics/lab-pharmacy-supply-management/article/21143494/fda-standards-under-fire-as-problems-grow-with-fast-covid19-tests>.

²⁴⁶ See Pradhan, *supra* note 244; *Contracts for April 10, 2020*, U.S. DEP’T DEF. (Apr. 10, 2020), <https://www.defense.gov/Newsroom/Contracts/Contract/Article/2146301/> (“Cepheid, Sunnyvale, California, was awarded a \$32,788,420 firm-fixed-price contract for the purchase of up to 137 Cepheid GeneXpert instruments, 105 GeneXpert 16s instruments, and up to 472,000 emergency-use-only assays to detect novel coronavirus disease in human clinical samples.”).

²⁴⁷ See Michael J. Loeffelholz et al., *Multicenter Evaluation of the Cepheid Xpert Xpress SARS-CoV-2 Test*, 58 J. CLINICAL MICROBIOLOGY 1, 2 (2020), <https://jcm.asm.org/content/58/8/e00926-20>.

²⁴⁸ See Lauren Dunn, *COVID-19 Tests: There’s an Insurmountable Backlog of Virus Tests. A Rapid Test Could Help*, NBC NEWS (July 23, 2020), <https://www.nbcnews.com/health/health-news/covid-19-tests-there-s-insurmountable-backlog-virus-tests-rapid-n1234622>; Craig LeMoult, *Hospitals Can’t Get Enough COVID-19 Tests*, WGBH NEWS (Jun. 29, 2020), <https://www.wgbh.org/news/local-news/2020/06/29/hospitals-cant-get-enough-covid-19-tests>; see also Joel Rose, *Coronavirus Testing Machines Are Latest Bottleneck in Troubled Supply Chain*, NPR (May 28, 2020), <https://www.npr.org/2020/05/28/863558750/coronavirus-testing-machines-are-latest-bottleneck-in-troubled-supply-chain> (describing shortages of other COVID-19 tests).

the United States, but the company proved unable to meet demand, leading Governor Beshear of Kentucky to call on 3M to voluntarily license its patents to competitor manufacturers to increase supply.²⁴⁹

Shortages of drugs, diagnostic tests, and PPE in the COVID-19 pandemic suggest a valuable use of § 1498: to break logjams like these and increase supply, and quickly.²⁵⁰ Government patent use can be used to make focused “surgical strikes” in places where there is a need to move quickly to expand supply of patented products—e.g., supplying COVID-19 diagnostic tests to emerging rural virus hotspots where there is little existing testing capacity.²⁵¹ HHS could, for example, continue to purchase and distribute as many Xpert Xpress SARS CoV-2 cartridges and test machines from Cepheid as the company can manufacture while simultaneously soliciting bids for further supply of diagnostic tests that mimic Cepheid’s. Assume that Cepheid holds one or more patents on its tests and can manufacture up to about 500,000 Xpert Xpress test cartridges per week.²⁵² Assume further that Cepheid declines to license its patents

²⁴⁹ 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-3m-release-patent-n-95-respirator-amid-pandemic/5112729002>.

²⁵⁰ We do not mean to suggest here that patents or other intellectual property protection are the sole source of shortages of goods used against COVID-19. Shortages are caused by a large number of factors—scarcity of raw materials, breakdown in supply chains or distribution systems, customs and regulatory rules, etc. See, e.g., Erin R. Fox et al., *Drug Shortages: A Complex Health Care Crisis*, 89 MAYO CLINIC PROC. 361 (2014), <https://doi.org/10.1016/j.mayocp.2013.11.014>. Shortages of simple, presumably off-patent commodities like nasal swabs have also plagued the United States’s COVID-19 response. See, e.g., David Lim & Brianna Ehley, *Inside America’s Unending Testing Snafu*, POLITICO (Apr. 22, 2020), <https://www.politico.com/news/2020/04/22/coronavirus-testing-problem-america-201372>. Our point is simply that whenever a shortage arises from, or is aggravated by, a patent holder’s reluctance to voluntarily license its patents and inability to manufacture enough of its patent products to meet demand, government patent use offers a straightforward solution.

²⁵¹ Reis Thebault & Abigail Hauslohner, *A Deadly “Checkerboard”: Covid-19’s New Surge Across Rural America*, WASH. POST (May 24, 2020), <https://www.washingtonpost.com/nation/2020/05/24/coronavirus-rural-america-outbreaks>.

²⁵² This was, roughly speaking, the case as of June 2020, when Cepheid anticipated its cartridge manufacturing capacity over the summer of 2020 would be approximately 2 million tests per month (6 million tests per quarter). See Susan Kelly, *Cepheid Developing Test to Distinguish COVID-19 from Flu*, MEDTECHDRIVE (June 10, 2020), <https://www.medtechdrive.com/news/cepheid-developing-test-to-distinguish-covid-19-from-flu/579524>.

voluntarily to competitor manufacturers (as, so far, it seems to have). National demand for reliable point-of-care COVID-19 tests is, as of writing, running much higher than 500,000 tests per week; some public health experts estimate that the United States must administer millions of tests per *day* to contain future outbreaks.²⁵³ Under these circumstances, Cepheid might ordinarily sell its Xpert Xpress test cartridges at a high price to the highest-bidding users as it gradually ramps up its manufacturing capacity, leaving everyone else without access to Cepheid's testing technology, which is purportedly best-in-class. HHS could expand supply more quickly—and deal with the COVID-19 testing crisis plaguing the United States as we write—by invoking § 1498 to enable generic manufacturing even as it continues to buy tests at Cepheid's monopoly price.

The above hypothetical “surgical strike” to increase supply of and expand access to Cepheid's point-of-care diagnostic test for COVID-19 illustrates how the U.S. government can tailor its use of § 1498 to make relatively small interventions in the marketplace and the “normal” operation of patents and patent incentives. Such use of § 1498 would protect Cepheid's investments and expectations, as Cepheid would receive compensation under § 1498 for the government-authorized generic manufacturing in addition to its profits on all of the tests it is able to manufacture and sell at full price. In specific circumstances—even in whole fields of technology—where the U.S. government is particularly concerned about patent holders' investment expectations and incentives for future innovation, such modest interventions with § 1498 may be most appropriate.²⁵⁴ The possibility of using § 1498 in this flexible, modest way belies the conventional wisdom²⁵⁵ that government patent use is necessarily disruptive.

(b) Shielding beneficial activity from infringement liability.

Section 1498 could also be used to shield specific socially useful activities from the threat of unexpected patent infringement liability.

²⁵³ See Alexis C. Madrigal & Robinson Meyer, *A Dire Warning From COVID-19 Test Providers*, ATLANTIC (June 30, 2020), <https://www.theatlantic.com/science/archive/2020/06/us-coronavirus-testing-could-fail-again/613675>. This number includes both rapid point-of-care testing and slower laboratory testing.

²⁵⁴ See, e.g., Rizzolo et al., *supra* note 13 (expressing concern over the possibility that exercise of § 1498 on patented anti-COVID-19 drugs could “have a chilling effect on biopharmaceutical research and drug development”).

²⁵⁵ See *supra* notes 3–13.

For example, in March 2020, a non-practicing entity, Labrador Diagnostics LLC, filed a patent infringement suit seeking injunctive relief against a company whose equipment is used in some COVID-19 diagnostic testing, raising concern over the (admittedly remote) possibility that the lawsuit would reduce or delay testing.²⁵⁶ As Moss and Harmon of the Electronic Frontier Foundation have argued, HHS could conceivably intervene in situations like this, providing post hoc authorization for the allegedly infringing activity under § 1498 and shifting onto the government any liability for patent infringement, thereby ensuring the activity continues.²⁵⁷ Such intervention occurred in *Advanced Software*, where the Treasury Department retroactively authorized patent-infringing activity.²⁵⁸ (This diagnostic testing scenario would satisfy the first prong of *Advanced Software*'s test: a use of patented technology that confers "significant benefits to the United States" constitutes use "by and for" the government, as required by the text of § 1498.²⁵⁹ "When the government requires private parties to perform quasi-governmental functions, . . . there can be no question that those actions are undertaken 'for the benefit of the government.'"²⁶⁰)

Recall that Congress revised § 1498's predecessor statute in 1918 and again in 1942 to permit precisely this type of government patent use: protecting and encouraging socially useful third-party activity that is, or might be, patent infringing from the risk of an injunction and monetary liability.²⁶¹ As an appellate panel of the Court of Claims held in 1967 (in a case concerning the Department of Defense's purchase of third-party anti-G suits and valves to prevent military pilots from blacking out in flight), "[i]t is clear that [§ 1498] was enacted for the purpose of enabling the Government to

²⁵⁶ See Masnick, *supra* note 165.

²⁵⁷ See Elliot Harmon, *How Patent Abuse Could Hurt the Fight Against the Pandemic*, SLATE (Apr. 27, 2020), <https://slate.com/technology/2020/04/patent-abuse-government-research-coronavirus.html>; Alex Moss & Elliot Harmon, *The Feds Can Stop Patent Trolls from Endangering COVID-19 Testing and Treatment*, ELECTRONIC FRONTIER FOUND. (Mar. 25, 2020), <https://www.eff.org/deeplinks/2020/03/feds-can-stop-patent-trolls-endangering-covid-19-testing-and-treatment>.

²⁵⁸ See *supra* text accompanying note 232.

²⁵⁹ *Advanced Software Design Corp. v. Fed. Reserve Bank of St. Louis*, 583 F.3d 1371, 1378 (Fed. Cir. 2009).

²⁶⁰ *Iris Corp. v. Japan Airlines Corp.*, 769 F.3d 1359, 1362 (Fed. Cir. 2014). In *Iris*, the quasi-governmental function was detection of fraudulent passports.

²⁶¹ *Supra* text accompanying notes 47–103.

purchase goods for the performance of its functions without the threat of having the supplier enjoined”²⁶²

Government patent use to protect, even encourage, socially beneficial but patent-infringing activity may have wider import and application than generally appreciated. We are not aware of other scholars who have drawn the connection, but it seems to us that such use of § 1498 could even serve a fair use-like function within patent law, in emergency and normal periods alike. Prominent scholars have proposed that patent law should, through statutory reform or perhaps through judicial intervention, develop a fair use doctrine comparable to copyright law’s.²⁶³ Strandburg, for example, has observed that “there are situations in which the social costs of exclusivity in a particular context simply outweigh the social benefits of the additional patent incentive provided by infringement liability in that context, such that use in that context should be permitted without conditions.”²⁶⁴ Government patent use allows the U.S. government to do just that, making government authorization under § 1498 a rough surrogate for a judicial determination that fair use applies.²⁶⁵

In addition, though we are not aware of a historical example or proposal, it seems clear to us that government patent use under § 1498 could be deployed as a shield in connection with a non-patent innovation incentive: innovation prizes set by the U.S. government.²⁶⁶ Prizes as an innovation incentive encourage many competitors to race all at once to solve a problem, but if one competitor obtains and enforces patents on a technology needed to reach or commercialize the prize goal, then they may be able to extract royalties or even enjoin the prizewinner, reducing the value of the innovation incentive. A straightforward way to avoid this problem would be for the government to guarantee § 1498 as a shield: it could authorize the use of any patents needed to develop,

²⁶² *Coakwell v. United States*, 372 F.2d 508, 511 (1967).

²⁶³ See Maureen A. O’Rourke, *Toward a Doctrine of Fair Use in Patent Law*, 100 COLUM. L. REV. 1177 (2000); Strandburg, *supra* note 200.

²⁶⁴ Strandburg, *supra* note 200, at 278.

²⁶⁵ Jacob Victor has argued, in the copyright context, that compulsory licensing and fair use provisions of the Copyright Act ultimately similarly serve the same ends of maximizing social utility. See Jacob Victor, *Reconceptualizing Compulsory Copyright Licenses*, 72 STAN. L. REV. 915 (2020); Jacob Victor, *Utility-Expanding Fair Use*, 105 MINN. L. REV. (forthcoming 2021).

²⁶⁶ *Supra* Part II.B.

test, or commercialize the prizewinning innovation. This would enable those vying for the prize to use any and all existing technology freely in solving the prize problem, increasing the effectiveness of the prize.

Like government patent use, a patent buyout could also shield socially beneficial third-party activity, but a buyout will often be inferior to government patent use. When the government knows precisely which patents stand in the way of that activity—as when the company that makes COVID-19 testing equipment was sued for infringement—it could purchase or license them from the patent holders and then extend the necessary licenses to the third-party infringer. In this situation, the benefits of a buyout would be comparable to those of § 1498. However, when the relevant patents have not been identified in advance of the infringing activity—as in the prize-setting scenario—buyouts will generally be more difficult than government patent use, as they will require the government to undertake a lengthy and expensive search to find those patents before it can begin the buyout negotiation. Separately, when a patent holder has already brought suit against an alleged third-party infringer—or is negotiating a buyout with the U.S. government to immunize that infringer—the hold-up or nuisance value of the suit may lead the patent holder to demand a price higher than the value of the patented technology, making a buyout more expensive for the government than use of § 1498.²⁶⁷

3. Ex Post Remedy Determination

Under § 1498, the appropriate compensation due to the patent owner is determined ex post, when the injured patent holder brings a claim for compensation in the Court of Federal Claims. In this regard, the remedy is determined not just ex post but “extra” ex post—that is, not merely after the invented technology is successfully reduced to practice and becomes worthy of a patent,²⁶⁸ but after, and often long after, the government and the public at large actually make use of the patented invention. Given the typical

²⁶⁷ See, e.g., John R. Allison, Mark A. Lemley & David L. Schwartz, *How Often Do Non-Practicing Entities Win Patent Suits?*, 32 BERKELEY TECH. L.J. 237, 242, 255 & nn.22 & 80 (2017) (describing “nuisance-value settlements” in patent infringement cases); Megan M. La Belle, *Against Settlement of (Some) Patent Cases*, 67 VAND. L. REV. 375, 403 (2014).

²⁶⁸ It is in this sense that Hemel and Ouellette use the phrase “ex post.” See Hemel & Ouellette, *supra* note 167, at 544.

pendency of a lawsuit under § 1498,²⁶⁹ this could mean several years elapse between the government's first use of a patent and the determination of appropriate compensation. Sufficient time passes that when the Court of Federal Claims awards the "reasonable and entire compensation" owed under § 1498, it often adds interest on the reasonable royalty, to make the patent holder whole for the time passed since government patent use began.²⁷⁰ This patience is a feature, not a bug, of government patent use.

In our view, patience in determining compensation has numerous benefits in a fast-moving national crisis like COVID-19. Sober patent valuation is hard amidst a pandemic or other national emergency.²⁷¹ For example, estimates of the value of a vaccine or treatment may be wildly variable until its therapeutic properties—e.g., its side effects, its efficacy, and, in the case of a vaccine, its duration of effect—are fully established, years after first approval and the first purchases. (As the FDA has stated, "the true picture of a product's safety actually evolves over the months and even years that make up a product's lifetime in the marketplace."²⁷²) In that sense, § 1498 may actually end up offering the patent holder a better deal, in the end, than a buyout: if the emergency takes a turn substantially for the worse or the invention turns out to be especially useful, the compensation paid under § 1498 would be greater than a one-time ex ante payment.

A separate benefit of patience is that it avoids any potential problems with "royalty stacking": the situation where a single

²⁶⁹ See Michael J. Schaengold & Robert S. Brams, *Choice of Forum for Government Contract Claims: Court of Federal Claims vs. Board of Contract Appeals*, 17 FED. CIR. B.J. 279, 321 (2008) (suggesting that across all cases in the Court of Federal Claims, "[b]arring extensive filing of pretrial motions, it will take approximately two years for a case to progress from the filing of the complaint to the issuance of a decision").

²⁷⁰ See *Decca Ltd. v. United States*, 640 F.2d 1156, 1168 (Ct. Cl. 1980) ("The other component of 'reasonable and entire' compensation for a patent license taken by the Government is delay compensation. Delay compensation is recompense for the Government's delay in paying for the license."); 7 CHISUM, *supra* note 192, § 20.03 ("[A] patent owner may recover prejudgment interest as delay compensation")

²⁷¹ For a broader analysis of how delaying the calculation of damages in patent infringement cases can improve courts' analysis and accuracy, see Lichtman, *supra* note 200.

²⁷² *Step 5: FDA Post-Market Drug Safety Monitoring*, U.S. FOOD & DRUG ADMIN. (Jan. 4, 2018), <https://www.fda.gov/patients/drug-development-process/step-5-fda-post-market-drug-safety-monitoring>.

product infringes multiple patents held by multiple patent owners, increasing the risk of hold-up by one or more of those patent holders, as well as the risk of overcompensation of patent holders whose technology contributes only a small portion of the product's value.²⁷³ Given the flurry of inventive activity directed to COVID-19, it is very possible that we will see overlapping patent rights on important technologies like ventilator designs (as noted above) and research tools for vaccine development. (While less common in pharma, royalty stacking problems sometimes emerge there, too,²⁷⁴ especially with biologic drugs, whose manufacture may be more complex than that of small molecules drugs.) If there are multiple patent holders with patents infringed by products used by the government under § 1498, they can all bring claims to the CFC, and (in a consolidated case) the judge could apportion the value of each patent holders' contribution to the product and allocate compensation accordingly. By contrast, in a buyout situation, the government risks overpaying if it negotiates a buyout with one patent holder without recognizing that other patent holders hold additional relevant patents. (The government could undertake a comprehensive search of others' patents and buy those out, too, but this would impose unnecessary search costs on the government and slow it down unnecessarily, as noted above.)

Of course, if a patent holder in fact thinks it would get a better deal from determination of the value of the patent *after* the government uses it, it could achieve the same result—or any of a flexible array of outcomes—through a patent buyout. For example, the patent holder for an effective COVID-19 treatment could offer rights to its drug for \$X upfront plus \$Y per use plus \$Z on the basis of patient outcomes (as determined through, say, an arbitration process). But such a negotiation would take time—and could thus cost additional lives—to produce an effective ex post evaluation system comparable to what already exists under § 1498.

Indeed, these same problems—uncertainty and time wasted in attempting to predict the value of the government's use before it has

²⁷³ See Mark A. Lemley & Carl Shapiro, *Patent Holdup and Royalty Stacking*, 85 TEX. L. REV. 1991, 1993 (2007); Benjamin C. Li, *The Global Convergence of FRAND Licensing Practices: Towards "Interoperable" Legal Standards*, 31 BERKELEY TECH. L.J. 429, 432 (2016).

²⁷⁴ See, e.g., Leila Abboud, *Abbott's Bid to Squeeze Royalties May Carry Wider Impact*, WALL ST. J., Nov. 22, 2004, <https://www.wsj.com/articles/SB110108567498880474>.

occurred—afflict not only patent buyouts but government-funded direct grants and prizes, too. Government grants are disbursed to innovators before their inventions are complete and are therefore an example of what Hemel and Ouellette term *ex ante* incentives—monetary incentives whose incentive value is set before results are achieved.²⁷⁵ Prizes are “*ex post*” incentives in the Hemel and Ouellette sense—they are disbursed only after an invention proves successful. Yet prizes turn out to share a common Achilles heel with grants: they require the government to set the value of the incentive long *prior* to the government’s use, and typically before inventions have been reduced to practice. For a prize to have any utility in incentivizing innovation, the government must set and announce the prize, and commit itself to a payout, *before* innovators have begun experimenting. It is true that the incentive size of a prize, like that a patent buyout, is flexible and can be conditioned on the value of the patented technology and the government’s use thereof—e.g., \$X upon proof of a functional prototype plus \$Y per government use plus \$Z on the basis of patient outcomes. Such conditions can limit the government’s risk of overpaying for an invention that proves only marginally useful. But these conditions only reduce risk; they cannot eliminate it. When setting the size of a prize, the government must always hazard some estimates about the costs of developing an invention and its social utility. In a fast-moving emergency, this is a serious drawback. The government needs time and resources to gather information to make those estimates—time and resources it may not have. Use of § 1498 eliminates this uncertainty inherent in prizes, since the court-ordered reasonable and entire compensation always coincides with the precise extent of the government’s use.²⁷⁶

The fact that compensation under § 1498 coincides with the precise scope of the government’s use produces another advantage of government patent use as compared to buying a patent outright: by choosing government patent use, the government will likely spend less of the public’s money. Any time the government uses a patent under § 1498, the patent holder retains substantial rights in the patent: a right to continue practicing the patent, a right to license it to third parties, a right to enforce it against third parties not

²⁷⁵ Hemel & Ouellette, *supra* note 167, at 556.

²⁷⁶ Indeed, one might consider compensation under § 1498 “to effectively set an *ex post* prize” with the advantage that the adjudicator may “examine evidence of market share” before setting it. Brennan et al., *supra* note 11, at 317.

authorized by the government, and so on. And government patent use is typically time-limited. As soon as the government ceases using the patent, the patent holder's ability to exploit the patent is restored in full. As such, even expansive government patent use necessarily leaves a significant fraction of the total value of the patent in the hands of the patent holder, and the reasonable and entire compensation the government pays under § 1498 should always be less than the price the government would pay in an outright buyout of the patent.²⁷⁷

To be sure, ex post determination of the appropriate compensation can have drawbacks, too, in some contexts. Small innovative companies may rely primarily or entirely on revenues from their patents to raise capital and sustain themselves, and they may not be able to wait years for compensation. In such circumstances, the U.S. government might voluntarily choose to pay compensation for government patent use sooner to keep the companies afloat, or it might decide to use another policy tool (such as a buyout) instead. The government should weigh potential impacts on the patent holder, its investors, and broader incentives in the sector before deciding to use § 1498, and whether to make a large intervention or a small one.²⁷⁸

If HHS does elect to use § 1498 to procure drugs, tests, ventilators, and other technologies necessary to navigate the COVID-19 crisis, it could take steps from the start to ensure a deep evidentiary record to support the determination of appropriate compensation when the day comes. For example, HHS could ask that the recipients of products procured through § 1498 document who uses these products and how well these products work. HHS could also put known patent holders on notice as to its exercise of § 1498 and encourage them to collect and keep data that will be useful if the CFC must later determine the appropriate level of compensation under § 1498, such as data on the patent holder's R&D costs and the patent holder's perception of the value of its invention. Asking patent holders to collect and retain such data is efficient—the patent holder is likely best positioned to generate useful evidence about the value of the invention—and patent holders

²⁷⁷ See Mitchell, *supra* note 27, at 553 (“The fair market value indicates what a willing buyer would pay for ownership, while a reasonable royalty is simply what a licensee would pay for ongoing use of the patent as a licensee.”).

²⁷⁸ See *supra* Part III.A.2.

have good incentives to collect reliable evidence that will hold up to court scrutiny, as we discuss in the next subpart.

4. Determination of Compensation by an Impartial Adjudicator

Finally, a fourth key feature of government patent use under § 1498 is the adjudicator of the remedy: when the U.S. government uses patents, the appropriate compensation is decided not by the government or the patent holder but by impartial judges. As noted above, this makes § 1498 a liability rule: the value of the patent is objectively determined (by a court) rather than subjectively determined by the patent holder and the government's negotiator.

Placing the question of patent valuation in the hands of an independent arbiter has numerous benefits. First, many of the entities likely to hold important patents on COVID-19 technologies are the same set of pharmaceutical, medical device, and biotechnology companies who wield some of the most powerful lobbies in the United States²⁷⁹ and who have been accused for decades of government and media capture,²⁸⁰ price-gouging,²⁸¹ strategic gamesmanship of the patent and data exclusivity

²⁷⁹ Karl Evers-Hillstrom, *Big Pharma Continues to Top Lobbying Spending*, OPENSECRETS (Oct. 25, 2019), <https://www.opensecrets.org/news/2019/10/big-pharma-continues-to-top-lobbying-spending/>; see also Wayne & Petersen, *supra* note 237 (observing that, as of 2001, the pharmaceutical industry's lobby had "managed to stave off many actions that would harm them, like violating patents or forcing them to supply free drugs").

²⁸⁰ See, e.g., JULIE MARGETTA MORGAN & DEVIN DUFFY, THE COST OF CAPTURE: HOW THE PHARMACEUTICAL INDUSTRY HAS CORRUPTED POLICYMAKERS AND HARMED PATIENTS, ROOSEVELT INSTITUTE ISSUE BRIEF 2019 (May 2019), https://rooseveltinstitute.org/wp-content/uploads/2019/05/RI_Pharma_Cost-of-Capture_brief_201905.pdf; Gringarten, *supra* note 104, at 74–76 (describing Bayer's "crisis management" lobbying efforts to shape media coverage and the U.S. government's response to the anthrax crisis); Alexander Zaitchik, *How Big Pharma Was Captured by the One Percent*, NEW REPUBLIC (June 28, 2018), <https://newrepublic.com/article/149438/big-pharma-captured-one-percent>.

²⁸¹ See, e.g., KEVIN T. RICHARDS ET AL., CONG. RESEARCH SERV., REPORT NO. R46221, DRUG PRICING AND PHARMACEUTICAL PATENTING PRACTICES 2 (2020) ("critics argue that these patenting practices are used to keep drug prices high, without any benefit for consumers or innovation"); MÉDECINS SANS FRONTIÈRES, LIVES ON THE EDGE: TIME TO ALIGN MEDICAL RESEARCH AND DEVELOPMENT WITH PEOPLE'S HEALTH NEEDS 17 (2016) (collecting examples of alleged pharmaceutical industry price-gouging and profiteering).

systems,²⁸² and antitrust violations.²⁸³ (And others may be non-practicing patent assertion entities like Labrador Diagnostics, noted above.²⁸⁴) As noted earlier, there is a real risk of gamesmanship and hold-up by this set of patent holders in the event of a rushed buyout precipitated by an ongoing public health crisis.²⁸⁵ Hold-up in patent buyouts can lead not only to harmful delay but also to the government overpaying.

In a patent buyout, patent holders are not the only worry. As noted above,²⁸⁶ the U.S. government does not appear to have negotiated a patent buyout in over 60 years. As such, the government's own negotiators are likely inexperienced and ill prepared to enter a high-stakes buyout negotiation, whether in a time of emergency or not. Indeed, the government's IP negotiators may not even have deep expertise in other types of IP valuation, such as licensing the government's own patent portfolio. For example, the Department of Defense's intellectual property negotiators were, as of 2018, sufficiently inexperienced that Congress demanded formation of a "cadre of IP experts" to help.²⁸⁷

By contrast, the judges of Court of Federal Claims have deeper and recent experience in valuing patents in § 1498 cases, as

²⁸² See generally Robin Feldman, *May Your Drug Price Be Evergreen*, 5 J.L. & BIOSCIENCE 590 (2018); RICHARDS ET AL., *supra* note 281. For specific examples of alleged gamesmanship and misuse of patent and data exclusivity, see *Allergan, Inc. v. Teva Pharm. USA, Inc.*, No. 2:15-cv-1455, 2017 WL 4619790, at *2 (Oct. 16, 2017) (court expressing "serious concerns about the legitimacy of" Allergan's efforts to immunize its patents from challenge by transferring ownership to a Native American tribe); Michael Daniel et al., *The Orphan Drug Act: Restoring the Mission to Rare Diseases*, 39 AM. J. CLINICAL ONCOLOGY 210 (2016).

²⁸³ See, e.g., Michael A. Carrier, *Higher Drug Prices from Anticompetitive Conduct: Three Case Studies*, 39 J. LEGAL MED. 151 (2019) (documenting examples of anticompetitive conduct by pharmaceutical companies); C. Scott Hemphill, *Paying For Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1568 (2006) (describing widespread anticompetitive "pay-for-delay" tactics by pharmaceutical companies).

²⁸⁴ *Supra* notes 256–260.

²⁸⁵ *Supra* notes 236–238 and accompanying text.

²⁸⁶ See *supra* note 179.

²⁸⁷ See National Defense Authorization Act for Fiscal Year 2018 § 802(b), 10 U.S.C. § 2322; see also Adam Bartolanzo & Keith Szeliga, *Contractors Beware: The 2018 NDAA Ushers In New Changes Affecting IP Rights*, GOV'T CONT. & INVESTIGATIONS BLOG (Jan. 30, 2018), <https://www.governmentcontractslaw.com/2018/01/articles/departments-of-defense/ndaa-ip-rights>.

numerous cases are brought every year.²⁸⁸ This experience means there is a body of law on the reasonable and entire compensation under § 1498 that helps to anchor the calculation and provide some consistency and predictability—something missing in a patent buyout. While we are not aware of a recent, in-depth empirical review of the consistency and predictability of damages awards in § 1498 cases decided by the Court of Federal Claims, some anecdotal evidence suggests that they are at least on par with those in the federal district courts.²⁸⁹ While calculation of damages in patent cases is inherently complex and somewhat unpredictable—reasonable royalties very much included—the expertise and experience of the judges of the Court of Federal Claims should allay concerns somewhat.

Other benefits flow from § 1498's use of the Court of Federal Claims as impartial adjudicator to determine compensation.²⁹⁰

²⁸⁸ A Westlaw search for Court of Federal Claims cases returned 134 decisions decided between January 1, 2010 and December 31, 2019 that reference “28 U.S.C. § 1498” and “patent.” 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, *supra* note 18, at 496.

²⁸⁹ In an empirical study published 2001, Chu concluded that judgments of the Court of Federal Claims in patent cases are affirmed by the Federal Circuit at a higher rate (and reversed at a lower rate) than is true for any district court in the nation. See Christian A. Chu, *Empirical Analysis of the Federal Circuit's Claim Construction Trends*, 16 BERKELEY TECH. L.J. 1075, 1124–25 (2001). In *Return Mail, Inc. v. United States Postal Service*, the Supreme Court suggested that remedies in § 1498 cases are at least as predictable as remedies in 35 U.S.C. § 271 cases brought in district court, though the Court's analysis focused on the simple fact that injunctions are not available in § 1498 cases but are in 35 U.S.C. § 271 cases. See 139 S. Ct. 1853, 1867 (2019) (“[A]lthough federal agencies remain subject to damages for impermissible uses, they do not face the threat of preliminary injunctive relief that could suddenly halt their use of a patented invention, and they enjoy a degree of certainty about the extent of their potential liability that ordinary accused infringers do not.”).

²⁹⁰ One significant cost flows from § 1498's use of a court to determine compensation: the costs of litigation. We are not aware of specific estimates of the costs of litigation under § 1498, but district court patent infringement suits and Section 337 investigations at the International Trade Commission cost a median of \$700,000 to \$4 million in 2019. See Scott McBride, *Strategies For Controlling Costs in Patent Litigation*, LAW360 (Sept. 12, 2019), <https://www.law360.com/articles/1198463/strategies-for-controlling-costs-in-patent-litigation>. These costs are real, but we think them acceptable, for four reasons. First, small patent holders'

Federal judges of the CFC appointed to 15-year terms²⁹¹ are also insulated from the pernicious influence of industry lobbying in a way that the U.S. government's negotiators may not be. Discovery in litigation will disgorge otherwise secret information relevant to the calculation of compensation—on the patent holder's R&D costs, on others' (including the government's) contributions to that R&D, on the value of the patented invention (e.g., a drug's safety and efficacy), and so on.²⁹² And the critical issues of patent validity, enforceability, and infringement can be properly ventilated and decided. (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.) Patent holders may benefit from this independent adjudicator, too, insofar as the government cannot use its vast media and regulatory powers, or its sometime monopsony purchaser status, to strong-arm an unduly cheap deal.

B. A Case Study for the Use of § 1498: Remdesivir in the COVID-19 Pandemic

To exemplify how policymakers can weigh these four advantages of § 1498 to assess its applicability, this Part considers how these advantages apply to the COVID-19 pandemic and the experimental drug remdesivir, one of the few treatments for

costs are typically paid by the government in a successful § 1498 action. *See* § 1498(a) ("Reasonable and entire compensation shall include the owner's reasonable costs, including reasonable fees for expert witnesses and attorneys, in pursuing the action if the owner is an independent inventor, a nonprofit organization, or an entity that had no more than 500 employees at any time during the 5-year period preceding the use or manufacture of the patented invention by or for the United States."). Second, from the public's perspective, even paying both a successful patent holder's costs and the government's will be cost-effective in situations where the value of the patented technology used—potentially worth hundreds of millions or billions of dollars—will dwarf those costs. Third, the costs of litigation are, to some extent, simply the unavoidable costs of gathering (through discovery and judicial fact-finding) useful information on the value of the patent; collecting the same information prior to a patent buyout, for example, would also incur costs. Fourth, like any litigants, the patentee plaintiff and the U.S. government can settle at point prior to or during litigation and thereby avert further litigation costs. *See* Lemley, *supra* note 158, at 473.

²⁹¹ *See* 28 U.S.C. § 172.

²⁹² *See* Brennan et al., *supra* note 11, at 316 (discussing the value of discovery and expert testimony in actions brought under § 1498 to determine "R&D outlays and the risk of failure at each stage of investment" in the patented invention).

COVID-19 currently available.²⁹³ Remdesivir is also economically significant—the potential U.S. market for the drug has been estimated in the billions of dollars per year for years to come.²⁹⁴ We trace below how the U.S. government could use § 1498 to expand supplies of the drug while simultaneously spending less (and produce savings for private payers, too).

We select remdesivir largely because it is a “ripe” example: a fully developed anti-COVID-19 technology about which we now have meaningful information on manufacturing costs, supply limitations, retail pricing, patent protection, and so on.²⁹⁵ But the logic of government patent use to expand supply and lower prices could apply equally to other currently experimental and patented technologies useful against COVID-19, such as monoclonal antibodies,²⁹⁶ new diagnostics, and, perhaps most important, a vaccine. The United States and other countries have invested unprecedented sums to accelerate vaccine development,²⁹⁷ but there currently are profound concerns that the public may not get access

²⁹³ See, e.g., Matthew Herper, *Covid-19 Study Details Benefits of Treatment with Remdesivir, and Also Its Limitations*, STAT (May 22, 2020), <https://www.statnews.com/2020/05/22/covid-19-study-details-benefits-of-treatment-with-remdesivir-and-also-its-limitations>.

²⁹⁴ Cristin Flanagan, *Gilead Upgraded With Covid Sales Seen Reaching \$7.7 Billion*, BLOOMBERG (June 3, 2020), <https://www.bloomberg.com/news/articles/2020-06-03/gilead-loses-a-skeptic-with-remdesivir-sales-seen-at-7-billion>.

²⁹⁵ One of us (C.J.M.) published earlier, briefer analyses of potential exercise of government patent use to expand access to and lower prices on remdesivir. See Christopher Morten, Christian Urrutia & James Krellenstein, *A Powerful Law Gives HHS the Right to Take Control of Remdesivir Manufacturing and Distribution*, STAT (July 2, 2020), <https://www.statnews.com/2020/07/02/powerful-law-gives-hhs-right-to-control-remdesivir-manufacturing-distribution>; James Krellenstein & Christopher J. Morten, *U.S. Government's Apparent Co-Ownership of Patents Protecting Remdesivir*, PREP4ALL (May 20, 2020), <https://www.prep4all.org/news/remdesivir>.

²⁹⁶ Janet Woodcock, the Director of the Center for Drug Evaluation and Research at the FDA, has publicly expressed concern about inadequate supplies of anti-COVID-19 monoclonal antibodies and the possible need to draw on global monoclonal antibody manufacturing capacity. See Carolyn Y. Johnson, *Operation Warp Speed Is Pushing for Covid-19 Therapeutics by Early Fall*, WASH. POST (July 13, 2020), <https://www.washingtonpost.com/health/2020/07/13/operation-warp-speed-is-pushing-covid-19-therapeutics-by-early-fall>.

²⁹⁷ See *Mapping of Global Public Funding for Covid-19*, UNIVS. ALLIED FOR ESSENTIAL MEDS. (2020), <https://www.publicmeds4covid.org>.

to a vaccine despite this public funding,²⁹⁸ should global demand overwhelm the manufacturing and distribution capabilities of patent holders.²⁹⁹ Our analysis of § 1498 and remdesivir would likely apply with equal force to a hypothetical vaccine patent, but vaccines exhibit additional considerations that we discuss briefly in this Part.³⁰⁰

1. Remdesivir: An Experimental Drug That Promises Modest but Important Benefits

What is remdesivir? It is a small molecule experimental antiviral drug manufactured by Gilead Sciences, Inc. (“Gilead”), under the brand name Veklury.³⁰¹ Gilead holds patents on remdesivir and is the sole supplier in the United States. Remdesivir was originally developed through a collaboration by Gilead, the Centers for Disease Control and Prevention (CDC), and U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) and was tested against numerous viruses, including Ebola, but proved ineffective against them.³⁰²

²⁹⁸ See, e.g., Will Feuer & Noah Higgins-Dunn, *WHO Warns Against Coronavirus “Vaccine Nationalism and Risk of Price Gouging”*, CNBC (Aug. 13, 2020), <https://www.cnbc.com/2020/08/13/who-warns-against-coronavirus-vaccine-nationalism-and-risk-of-price-gouging.html>; Elisabeth Rosenthal, *How a Covid-19 Vaccine Could Cost Americans Dearly*, N.Y. TIMES (July 6, 2020), <https://www.nytimes.com/2020/07/06/opinion/coronavirus-vaccine-cost.html>.

²⁹⁹ See, e.g., Damien Garde & Helen Branswell, *6 Burning Questions Congress Could Push Covid-19 Vaccine Makers to Answer Today*, STAT (July 20, 2020), <https://www.statnews.com/2020/07/20/covid19-vaccines-merck-moderna-congress>; Christopher Rowland et al., *Even Finding a Covid-19 Vaccine Won't Be Enough to End the Pandemic*, WASH. POST (May 11, 2020), <https://www.washingtonpost.com/business/2020/05/11/coronavirus-vaccine-global-supply>; Julie Steenhuysen & Kate Kelland, *Vaccine Makers Face Biggest Medical Manufacturing Challenge in History*, REUTERS (June 25, 2020), <https://www.reuters.com/article/us-health-coronavirus-vaccines-manufacture-idUSKBN23W1ND>.

³⁰⁰ See *infra* text accompanying notes 359–366. See generally Ana Santos Rutschman, *The COVID-19 Vaccine Race: Intellectual Property, Collaboration(s), Nationalism and Misinformation*, 64 WASH. U. J.L. & POL'Y (forthcoming 2021), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3656929.

³⁰¹ Gilead Scis., *Fact Sheet for Health Care Providers: Emergency Use Authorization (EUA) of Veklury (remdesivir)* (July 2020), <https://www.gilead.com/-/media/files/pdfs/remdesivir/eua-fact-sheet-for-hcps.pdf>.

³⁰² See Dustin Siegel et al., *Discovery and Synthesis of a Phosphoramidate Prodrug of a Pyrrolo[2,1-f][triazin-4-amino] Adenine C-Nucleoside (GS-5734)*

Remdesivir's safety and therapeutic benefits in COVID-19 patients are still being investigated,³⁰³ but as of writing, those benefits appear both modest and significant. One clinical trial sponsored by the National Institute of Allergy and Infectious Diseases (NIAID) has shown that remdesivir helps hospitalized patients with severe COVID-19 recover and leave the hospital more quickly than a placebo—a median of 4 days more quickly.³⁰⁴ Another trial showed some statistically significant benefit in recovery time in patients whose COVID-19 symptoms were moderate (rather than severe) and who received 5 days of treatment with the drug.³⁰⁵ A third trial that terminated early due to under-enrollment showed no statistically significant improvement in COVID-19 patients treated with remdesivir compared to placebo.³⁰⁶ Remdesivir has not been shown in any rigorous clinical trial to reduce mortality in COVID-19 patients—that is, to save lives.³⁰⁷

Although the clinical trial data supporting remdesivir's use in COVID-19 patients is limited, doctors have few good alternatives.³⁰⁸ Based on the NIH trial, FDA granted an emergency

for the Treatment of Ebola and Emerging Viruses, 60 J. MEDICINAL CHEMISTRY 1648 (2017); Travis K. Warren et al., *Therapeutic Efficacy of the Small Molecule GS-5734 Against Ebola Virus in Rhesus Monkeys*, 530 NATURE 381 (2016). For remdesivir's failure as a treatment for Ebola, see Helen Branswell, *Two Ebola Treatments Yield "Substantial Decrease" in Mortality, Landmark Trial Shows*, STAT (Nov. 27, 2019), <https://www.statnews.com/2019/11/27/two-ebola-treatments-mortality-decrease/>; Gina Kolata, *How Remdesivir, New Hope for Covid-19 Patients, Was Resurrected*, N.Y. TIMES (May 1, 2020), <https://www.nytimes.com/2020/05/01/health/coronavirus-remdesivir.html>.

³⁰³ See Ameet Sarpatwari et al., *Missed Opportunities on Emergency Remdesivir Use*, 324 J. AM. MED. ASS'N 331 (2020).

³⁰⁴ See John H. Beigel et al., *Remdesivir for the Treatment of Covid-19—Preliminary Report*, 383 NEW ENG. J. MED. 1813 (2020).

³⁰⁵ See Christoph D. Spinner et al., *Effect of Remdesivir vs Standard Care on Clinical Status at 11 Days in Patients with Moderate COVID-19: A Randomized Clinical Trial*, 324 J. AM. MED. ASS'N 1048 (2020).

³⁰⁶ See Yeming Wang et al., *Remdesivir in Adults with Severe COVID-19: A Randomised, Double-Blind, Placebo-Controlled, Multicentre Trial*, 395 LANCET 1569 (2020), [https://doi.org/10.1016/s0140-6736\(20\)31022-9](https://doi.org/10.1016/s0140-6736(20)31022-9).

³⁰⁷ Matthew Herper, *Major Study Finds Common Steroid Reduces Deaths Among Patients with Severe Covid-19*, STAT (June 16, 2020), <https://www.statnews.com/2020/06/16/major-study-finds-common-steroid-reduces-deaths-among-patients-with-severe-covid-19>.

³⁰⁸ See Denise Grady, *Malaria Drug Promoted by Trump Did Not Prevent Covid Infections, Study Finds*, N.Y. TIMES (June 3, 2020), <https://www.nytimes.com/>

use authorization (EUA) to the drug on May 1, 2020.³⁰⁹ Remdesivir has been described by Dr. Anthony Fauci, an infectious disease expert and one of the leaders of the White House Coronavirus Task Force, as the current “standard of care” for COVID-19,³¹⁰ and the drug has already been used in thousands of patients.³¹¹

Should further clinical trial data prove that remdesivir is indeed safe and effective at reducing COVID-19 mortality, it will be an indispensable tool in the COVID-19 response in the United States and around the world. Even if the drug saves no lives but merely accelerates recovery in patients with severe disease, it will nonetheless be valuable, considering the enormous social benefits of keeping people out of the hospital. A single day in an American intensive care unit (ICU) costs thousands of dollars,³¹² so accelerating recovery by even a day has significant economic

2020/06/03/health/hydroxychloroquine-coronavirus-trump.html. In June and July 2020, a group at the University of Oxford reported clinical trial results suggesting that the widely available steroid dexamethasone successfully reduced mortality in patients with moderate or advanced COVID-19 disease who were receiving mechanical ventilation or oxygen. See Nancy Lapid, *Steroid's COVID-19 Benefits Confirmed; Spotlight on Immune Cells*, REUTERS (July 18, 2020), <https://www.reuters.com/article/us-health-coronavirus-science-idUSKCN24I2SY>.

³⁰⁹ See Press Release, U.S. Food & Drug Admin., Coronavirus (COVID-19) Update: FDA Issues Emergency Use Authorization for Potential COVID-19 Treatment (May 1, 2020), <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-emergency-use-authorization-potential-covid-19-treatment>. In August 2020, the FDA expanded the EUA to cover hospitalized COVID-19 patients with more moderate disease. See Press Release, U.S. Food & Drug Admin., *COVID-19 Update: FDA Broadens Emergency Use Authorization for Veklury (Remdesivir) to Include All Hospitalized Patients for Treatment of COVID-19* (Aug. 28, 2020), <https://www.fda.gov/news-events/press-announcements/covid-19-update-fda-broadens-emergency-use-authorization-veklury-remdesivir-include-all-hospitalized>.

³¹⁰ Sue Hughes, *Remdesivir Now “Standard of Care” for COVID-19, Fauci Says*, HOSPITALIST (Apr. 30, 2020), <https://www.the-hospitalist.org/hospitalist/article/221518/coronavirus-updates/remdesivir-now-standard-care-covid-19-fauci-says>.

³¹¹ See Laurie McGinley & Christopher Rowland, *FDA Authorizes Use of Gilead Sciences' Remdesivir for Patients Severely Ill with Covid-19*, WASH. POST (May 1, 2020), <https://www.washingtonpost.com/health/2020/05/01/fda-authorizes-use-gilead-sciences-remdesivir-severely-ill-patients-with-covid-19>.

³¹² See Joseph S. Dasta et al., *Daily Cost of an Intensive Care Unit Day: The Contribution of Mechanical Ventilation*, 33(6) CRITICAL CARE MED. 1266 (2005), https://journals.lww.com/ccmjjournal/Abstract/2005/06000/Daily_cost_of_an_intensive_care_unit_day__The.13.aspx.

benefits on that basis alone³¹³—not to mention the benefits of allowing people to return to their jobs, homes, and loved ones. Accelerating recovery also frees ICU beds, equipment, and personnel to treat more patients. ICU shortages have plagued many countries' early COVID-19 responses, exacerbating mortality,³¹⁴ and experts suggested in spring and summer 2020 that the United States risks a new wave of ICU bed shortages in late 2020.³¹⁵

2. Two Problems: Shortages and Overpricing

The United States's COVID-19 response faces two problems vis-à-vis remdesivir: the problem of shortage and the problem of overpricing.

The United States faced deep shortages of remdesivir through the spring and summer of 2020, causing physicians to ration the drug and patients to go without—shortages apparently caused at least in part by Gilead's inability to manufacture enough.³¹⁶ Gilead has,

³¹³ Gilead's CEO, Daniel O'Day, justified the price Gilead intends to charge for remdesivir on this basis. See Press Release, An Open Letter from Daniel O'Day, Chairman & CEO, Gilead Sciences (June 29, 2020), <https://www.gilead.com/news-and-press/press-room/press-releases/2020/6/an-open-letter-from-daniel-oday-chairman--ceo-gilead-sciences> (“Taking the example of the United States, earlier hospital discharge would result in hospital savings of approximately \$12,000 per patient. Even just considering these immediate savings to the healthcare system alone, we can see the potential value that remdesivir provides.”). There is some irony in a pharmaceutical company—a member of one oft-criticized sector of America's oft-criticized health care system—using high prices of hospital care—another oft-criticized sector of the same—to justify its own high prices.

³¹⁴ See Shadman Aziz et al., *Managing ICU Surge During the COVID-19 Crisis: Rapid Guidelines*, 46 INTENSIVE CARE MED. 1303 (June 8, 2020); Alberto Zangrillo & Luciano Gattinoni, *Learning from Mistakes During the Pandemic: The Lombardy Lesson*, INTENSIVE CARE MED. (June 5, 2020).

³¹⁵ See Will Feuer, *CDC Says U.S. Has “Way Too Much Virus” to Control Pandemic as Cases Surge Across Country*, CNBC (June 29, 2020), <https://www.cnbc.com/2020/06/29/cdc-says-us-has-way-too-much-virus-to-control-pandemic-as-cases-surge-across-country.html>; Nolan D. McCaskill, *Rising ICU Bed Use “a Big Red Flag”*, POLITICO (May 28, 2020), <https://www.politico.com/news/2020/05/28/rising-icu-bed-use-red-flag-287552>.

³¹⁶ See Elizabeth Cohen, *Covid-19 Drug Rationed in the US Is Plentiful in Developing Countries*, CNN (Sept. 9, 2020), <https://www.cnn.com/2020/09/09/health/covid-remdesivir-us-vs-other-countries/index.html>; Cristin Flanagan, *Gilead's Virus Drug Seen in Short Supply for Americans*, BLOOMBERG (May 11, 2020), <https://www.bloomberg.com/news/articles/2020-05-11/gilead-s-covid-19-drug-seen-in-short-supply-for-americans>; Berkeley Lovelace Jr., *Gilead Says It*

rather gradually, voluntarily licensed its patents to competitor drug manufacturers in the United States and overseas,³¹⁷ which expanded its supplies, but not quickly enough.³¹⁸

As the federal department ultimately responsible for navigating the country through the COVID-19 crisis, HHS has taken on itself the job of distributing of remdesivir to the hospitals in greatest need throughout the United States.³¹⁹ But despite purported “coordination,” HHS proved consistently unable throughout the spring and summer of 2020 to allocate the nation’s (short) supplies efficiently or effectively.³²⁰ In an effort to address ongoing shortages, in June of 2020, HHS announced that it had contracted with Gilead to dedicate over 90% of Gilead’s supply of remdesivir from July through September 2020 to the United States alone—about 500,000 treatment courses.³²¹ The deal was striking in its

Will Be Able to Make Enough Remdesivir to Meet Global Coronavirus Demand in October, CNBC (Aug. 6, 2020), <https://www.cnbc.com/2020/08/06/gilead-says-it-will-be-able-to-make-enough-remdesivir-to-meet-global-coronavirus-demand-in-october.html>; Sydney Lupkin, *How Feds Decide on Remdesivir Shipments to States Remains Mysterious*, NPR (Aug. 19, 2020), <https://www.npr.org/sections/health-shots/2020/08/19/903946857/how-feds-decide-on-remdesivir-shipments-to-states-remains-mysterious>.

³¹⁷ See Valerie Bauman, *Gilead Gives Royalty-Free Remdesivir Licenses to Five Drugmakers*, BLOOMBERG L. (May 12, 2020), <https://news.bloomberglaw.com/pharma-and-life-sciences/gilead-gives-royalty-free-remdesivir-licenses-to-five-drugmakers>; Peter Maybarduk, *Remdesivir Should Be in the Public Domain; Gilead’s Licensing Deal Picks Winners and Losers*, PUB. CITIZEN (May 12, 2020), <https://www.citizen.org/news/remdesivir-should-be-in-the-public-domain-gileads-licensing-deal-picks-winners-and-losers/>.

³¹⁸ After shortages were reported in the summer of 2020, Reuters reported in mid-September 2020 that U.S. hospitals were turning away new shipments of remdesivir, suggesting that they had ample supplies and that shortages and rationing had ended. See Deena Beasley, *Exclusive: U.S. Hospitals Turn Down Remdesivir; Limit Use to Sickest COVID-19 Patients*, REUTERS (Sept. 11, 2020), <https://www.reuters.com/article/us-health-coronavirus-remdesivir-exclusive/idUKKBN2622UM>.

³¹⁹ Press Release, U.S. Dep’t of Health & Human Servs., HHS Announces Shipments of Donated Remdesivir for Hospitalized Patients with COVID-19 (May 9, 2020), <https://www.hhs.gov/about/news/2020/05/09/hhs-ships-first-doses-of-donated-remdesivir-for-hospitalized-patients-with-covid-19.html>.

³²⁰ See Kapczynski, Biddinger & Walensky, *supra* note 12 (describing HHS’s distribution as “uneven and opaque,” and leading to shortages); *see also* Lupkin, *supra* note 316.

³²¹ Press Release, U.S. Dep’t of Health & Human Servs., Trump Administration Secures New Supplies of Remdesivir for the United States (June 29, 2020)

nationalism and disregard of COVID-19 patients outside the United States—billions of people sick and at risk in countries outside Gilead’s network of authorized generic suppliers³²² may have no access to remdesivir.³²³ (And even those 500,000 doses proved insufficient to meet demand within the United States.³²⁴) In August 2020, Gilead announced that it expects, finally, to be able to manufacture enough remdesivir to meet global demand by early October,³²⁵ but despite projecting manufacture of two million doses this year, Gilead acknowledged to investors that “there is no assurance that we will be able to meet global supply needs for remdesivir.”³²⁶ Some experts, including former FDA Commissioner Gottlieb, have predicted new peaks of infections and hospitalizations in the fall of 2020 and winter of 2021;³²⁷ if their fears come to pass, then shortages of remdesivir may continue.

Besides shortages, the other problem is price. On June 29, 2020, Gilead announced what it plans to charge for remdesivir once donated doses run out in July 2020: \$3,120 for a typical course of treatment for patients with private insurance as well as those covered by Medicare and Medicaid, and \$2,340 for a smaller number of patients covered by certain other U.S. government insurance programs.³²⁸ The \$3,120 price tag is over ten times what an expert independent organization (the Institute for Clinical and Economic Review (ICER)) deems to be remdesivir’s cost-effective value

[hereinafter HHS Press Release], <https://www.hhs.gov/about/news/2020/06/29/trump-administration-secures-new-supplies-remdesivir-united-states.html>.

³²² See Ed Silverman, *Gilead Signs Deals for Generic Companies to Make and Sell Remdesivir*, STAT (May 12, 2020), <https://www.statnews.com/pharmalot/2020/05/12/gilead-generics-remdesivir-covid19-coronavirus-licenses>.

³²³ Sarah Boseley, *US Secures World Stock of Key Covid-19 Drug Remdesivir*, GUARDIAN (June 30, 2020), <https://www.theguardian.com/us-news/2020/jun/30/us-buys-up-world-stock-of-key-covid-19-drug>.

³²⁴ See Cohen, *supra* note 316; Lovelace, *supra* note 316; Lupkin, *supra* note 316.

³²⁵ See Lovelace, *supra* note 316.

³²⁶ Gilead Scis., Inc., Quarterly Report (Form 10-Q), at 30, 44 (Aug. 6, 2020), <http://investors.gilead.com/static-files/5648e7dd-c981-4d5b-8c8f-22342d60a946>.

³²⁷ See Joseph Guzman, *America Could Have a Third Act of Coronavirus and It Will Likely Be “More Pervasive,” Says Top Health Expert*, HILL (Aug. 21, 2020), <https://thehill.com/changing-america/well-being/longevity/513125-america-could-have-a-third-act-of-coronavirus-and-it>; see also Feuer, *supra* note 315.

³²⁸ See Matthew Herper, *Gilead Announces Long-Awaited Price for Covid-19 Drug Remdesivir*, STAT (June 29, 2020), <https://www.statnews.com/2020/06/29/gilead-announces-remdesivir-price-covid-19>.

(\$310)³²⁹ and perhaps over three hundred times its manufacturing cost (which has been estimated at less than \$10³³⁰). The \$3,120 price tag that most Americans will pay is the highest in the world (despite U.S. taxpayers' contributions to the drug); other wealthy countries will pay \$2,340.³³¹ Experts corroborate the view that the \$3,120 Gilead will charge most American patients is unfairly high, given the drug's moderate therapeutic value, its low manufacturing costs, and the American public's substantial contributions—at least \$70,500,000—to its discovery and development.³³² Gilead's prices for remdesivir will likely generate enormous revenue for the company³³³ but strain the budgets of federal and state public health

³²⁹ See Melanie D. Whittington & Jonathan D. Campbell, *Alternative Pricing Models for Remdesivir and Other Potential Treatments for COVID-19*, 2020 INST. FOR CLINICAL AND ECON. REV. 1, 6 (June 24, 2020), https://icer-review.org/wp-content/uploads/2020/06/ICER-COVID_Revised_Report_20200624.pdf (concluding that \$310 is the appropriate cost-effectiveness price for remdesivir, given that it speeds recovery but has not been proven to reduce mortality).

³³⁰ Andrew Hill et al., *Minimum Costs to Manufacture New Treatments for COVID-19*, 6 J. VIRUS ERADICATION 61 (Apr. 2020).

³³¹ See Michael Erman et al., *Gilead Prices COVID-19 Drug Remdesivir at \$2,340 per Patient in Developed Nations*, REUTERS (June 29, 2020), <https://www.reuters.com/article/us-health-coronavirus-gilead-sciences-idUSKBN2401C8>.

³³² See, e.g., Damian Garde & Ed Silverman, *Less than a Movie Ticket or "Impossible to Overpay"? Experts Name Their Price for Remdesivir*, STAT (May 15, 2020), <https://www.statnews.com/2020/05/15/gilead-remdesivir-pricing-coronavirus> (quoting expert Peter Bach, director of Memorial Sloan Kettering's Center for Health Policy and Outcomes, as suggesting a price of about \$1,000 per patient as fair); Angus Liu, *New Fair Price for Gilead's Remdesivir? Below \$2,800 if Dexamethasone Lives up to Its COVID-19 Promise*, FIERCE PHARMA (June 24, 2020), <https://www.fiercepharma.com/pharma/new-fair-price-for-gilead-s-remdesivir-below-2-800-if-dexamethasone-lives-up-to-its-covid-19>; Jing Luo et al., *Treatments Don't Work If We Can't Afford Them: The Global Need for Open and Equitable Access to Remdesivir*, BMJ OPINION (June 3, 2020), <https://blogs.bmj.com/bmj/2020/06/03/treatments-dont-work-if-we-cant-afford-them-the-global-need-for-open-and-equitable-access-to-remdesivir> ("In higher-income countries, until more robust mortality data becomes available, existing evidence suggests that a price between 'at cost' (\$10) and the lower of ICER's cost-effective estimates (\$390) is appropriate."). Public Citizen has documented that the United States and other governments have contributed at least \$70,500,000 to the development of remdesivir. See *The Real Story of Remdesivir*, PUB. CITIZEN (May 7, 2020), <https://www.citizen.org/article/the-real-story-of-remdesivir/?eType=EmailBlastContent&eId=9bdafb07-71bb-41dc-8726-f80183f3f648>.

³³³ See Ed Silverman, *Gilead's Pricing for Remdesivir Raises Questions About the*

agencies, insurers, and individual patients.³³⁴ HHS's plan to distribute 500,000 doses of remdesivir between July and September 2020 committed parts of the U.S. government and all private payers to paying full price.³³⁵

3. Patents Are the Sole Significant Barrier to Access

Government patent use can be effective in solving shortages and overpricing, but only if there are no other insurmountable barriers to competition. We consider three candidates for non-patent barriers to remdesivir manufacturing and distribution and find that none of them will likely be impassable.

First, although § 1498 is limited to government patent use rather than generalized compulsory licensing, § 1498 would still suffice to expand public access to remdesivir because the government could distribute the drug broadly. HHS's distribution of remdesivir (or any therapeutic or vaccine used against COVID-19) would satisfy the statute's requirement that authorization under § 1498 be limited to products "used or manufactured by or for the United States."³³⁶ Accelerating the recovery of people sick with COVID-19 and safeguarding hospital bed capacity clearly provides "significant benefits to the United States" and therefore meets the standard set out in *Advanced Software*.³³⁷ As of writing, HHS is already coordinating distribution of remdesivir throughout the United States and has been since the earliest days of the COVID-19 pandemic.³³⁸ HHS could, if it desired, purchase and distribute remdesivir through

Drug's Long-Term Prospects, STAT (June 29, 2020), <https://www.statnews.com/pharmalot/2020/06/29/gilead-remdesivir-covid19-coronavirus-drug-prices> (quoting a Wall Street prediction that Gilead could earn \$2.3B from remdesivir in 2020 alone).

³³⁴ Garde & Silverman, *supra* note 332.

³³⁵ Libby Watson, *Big Pharma's Got a Brand New Coronavirus Grift*, NEW REPUBLIC (June 30, 2020), <https://newrepublic.com/article/158337/big-pharma-coronavirus-grift>; see also Peter B. Bach, *Remdesivir Less Expensive for 'Government Programs.'* Not So Fast, Drug Pricing Lab (2020), <https://drugpricinglab.org/wp-content/uploads/2020/07/Remdesivir-Paper-1.pdf> (alleging that most U.S. government programs will pay full price for remdesivir).

³³⁶ 28 U.S.C. § 1498(a).

³³⁷ *Advanced Software Design Corp. v. Fed. Reserve Bank of St. Louis*, 583 F.3d 1371, 1378 (Fed. Cir. 2009).

³³⁸ See, e.g., HHS Press Release, *supra* note 321 (Announcing that remdesivir "will be allocated [in July, August, and September 2020] in the same way that Gilead's donation of approximately 120,000 treatment courses of remdesivir were allocated: HHS allocates product to state and territorial health departments based on COVID-19 hospital burden, and health departments allocate it to hospitals.").

the Strategic National Stockpile for public health emergencies, which would qualify as “use[] or manufacture[] by or for the United States,” as Wang and Kesselheim have noted.³³⁹

Second, trade secrets and internal know-how will pose minimal barriers to generic manufacturing. Remdesivir is a small molecule drug with a relatively simple formulation: the active ingredient is combined with an excipient that improves its stability and solubility to form a powder and then dissolved in water to form an injectable solution.³⁴⁰ Making remdesivir is nontrivial in practice: the active ingredient is somewhat complex to synthesize, as small molecules go, and formulation involves a days-long step—lyophilization—that requires specialized equipment.³⁴¹ Yet the drug can be reverse engineered, and generic manufacturers overseas have already been able to develop formulations bioequivalent to Gilead's, quickly.³⁴² For example, as of July 2020, one generic company in Bangladesh (Beximco) had scaled up its manufacturing of remdesivir from zero to 80,000 vials per month in less than three months, without authorization or assistance from Gilead.³⁴³ The same company

³³⁹ Wang & Kesselheim, *supra* note 15, at 478.

³⁴⁰ Gilead Scis., *supra* note 301.

³⁴¹ See Himani Chandna, *Govt Steps up Pressure on Remdesivir-Makers to Increase Output, Crack down on Black Marketing*, THEPRINT (July 23, 2020), <https://theprint.in/health/govt-steps-up-pressure-on-remdesivir-makers-to-increase-output-crack-down-on-black-marketing/466887>; Lisa M. Jarvis, *Scaling up Remdesivir Amid the Coronavirus Crisis*, CHEMICAL & ENGINEERING NEWS (Apr. 20, 2020), <https://cen.acs.org/biological-chemistry/infectious-disease/Scaling-remdesivir-amid-coronavirus-crisis/98/web/2020/04>.

³⁴² See *India's CDSCO Approves Generics of Favipiravir and Remdesivir for Covid-19 Treatment*, PHARMACEUTICAL BUS. REV. (June 22, 2020), <https://www.pharmaceutical-business-review.com/news/covid-19-india-favipiravir-remdesivir/> (describing two generic formulations of remdesivir approved for sale in India); Zeba Siddiqui, *Bangladesh's Beximco to Begin Producing COVID-19 Drug Remdesivir*, REUTERS (May 5, 2020), <https://www.reuters.com/article/us-health-coronavirus-bangladesh-remdesi/exclusive-bangladeshs-beximco-to-begin-producing-covid-19-drug-remdesivir-coo-idUSKBN22H1DD> (describing approval of generic remdesivir in Bangladesh, developed without Gilead's authorization or assistance); Ed Silverman, *First Generic Version of Gilead's Remdesivir Will Be Sold by a Bangladesh Drug Maker*, STAT (May 22, 2020), <https://www.statnews.com/pharmalot/2020/05/22/gilead-remdesivir-covid19-coronavirus-beximco-patent/> (same).

³⁴³ See A.Z.M. Anas, *Bangladesh's Beximco Thrives on Coronavirus Challenges*, NIKKEI ASIAN REV. (July 26, 2020), <https://asia.nikkei.com/Business/Pharmaceuticals/Bangladesh-s-Beximco-thrives-on-coronavirus-challenges>.

stated that it intends to expand production further, to 160,000 vials per month by the end of August 2020, and that it has already exported the drug outside of Bangladesh to five other countries.³⁴⁴ Another Bangladeshi generic company, Eskayef, has also developed a generic formulation of remdesivir without authorization or assistance from Gilead and has likewise exported the drug outside of Bangladesh.³⁴⁵ Numerous brand-name, generic, and contract drug manufacturers within the United States have the expertise and equipment necessary to manufacture remdesivir. For example, Pfizer announced in August 2020 that it would begin manufacturing remdesivir at a McPherson, Kansas factory that specializes in injectable medicines, under a contract with Gilead, as Gilead gradually (too gradually) responded to shortages.³⁴⁶

Third, manufacturers other than Gilead will likely be able to obtain the regulatory permission they need to distribute and sell remdesivir within the United States.³⁴⁷ Generic firms may not be

Perhaps counterintuitively, generic drug companies are often more, not less, innovative and successful than “innovator” brand-name drug companies at improving drug manufacturing processes, eliminating inefficiencies, and driving down the costs of production. Generics earn much smaller profit margins than brand-name drug companies and often compete fiercely with one another on price, sparking innovation in manufacturing processes that drives costs down. *See* Martha M. Rumore, *The Hatch-Waxman Act—25 Years Later: Keeping the Pharmaceutical Scales Balanced*, PHARMACY TIMES (Aug. 15, 2009), <https://www.pharmacytimes.com/publications/supplement/2009/genericsupplement0809/generic-hatchwaxman-0809> (“[G]enerics innovate, often obtaining ‘design-around’ patents or a more efficient manufacturing process, new formulations, or new forms of the active ingredient”). For example, it was Cipla, a low-margin generic manufacturer, that figured out how to manufacture and sell HIV drugs for \$1 a day, a fraction of the manufacturing costs brand-name companies had incurred. *See* Sarah Boseley, *Yusuf Hamied, Generic Drugs Boss*, GUARDIAN (Feb. 18, 2003), <https://www.theguardian.com/world/2003/feb/18/aids.sarahboseley13>.

³⁴⁴ *See* Anas, *supra* note 343.

³⁴⁵ *Eskayef Pharma’s Remdesivir Is a Headache for Indian Drugmakers*, BUS. STANDARD (June 9, 2020), <https://tbsnews.net/coronavirus-chronicle/eskayef-pharmas-remdesivir-headache-indian-drugmakers-90691>.

³⁴⁶ Press Release, Pfizer Inc., Pfizer Announces Agreement with Gilead to Manufacture Remdesivir for Treatment of COVID-19 (Aug. 7, 2020), <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-announces-agreement-gilead-manufacture-remdesivir>.

³⁴⁷ Regulatory questions are admittedly complex and especially unpredictable in this moment of declared public health emergency. *See* G. Caleb Alexander, Aaron

able to use the normal Abbreviated New Drug Application pathway for FDA approval based on any New Drug Application approval that Gilead receives, because Gilead is likely to receive, upon approval, some data exclusivity that will preclude such abbreviated applications.³⁴⁸ Instead, we see two distinct alternative paths for a competitor manufacturer to obtain permission. The first is an Emergency Use Authorization (EUA). At least as of writing, the FDA has not actually approved Gilead's remdesivir product; instead, the FDA has provided an EUA, which enables the HHS secretary to "authorize the introduction . . . of a drug, device, or biological product intended for use in an actual or potential emergency," even when that product "is not approved, licensed, or cleared for commercial distribution."³⁴⁹ Gilead's EUA was authorized by the FDA on the basis of two trials,³⁵⁰ one of which was the earlier-

S. Kesselheim & Thomas J. Moore, *Searching for an Effective Covid-19 Treatment: Promise and Peril*, STAT (Apr. 10, 2020), <https://www.statnews.com/2020/04/10/searching-for-an-effective-covid-19-treatment-promise-and-peril/>; Reynald Castaneda, *FDA May Be Risk-Averse to Grant Emergency Use for Covid-19 Vaccines*, CLINICAL TRIALS ARENA (July 2, 2020), <https://www.clinicaltrialsarena.com/comment/fda-covid-19-vaccines/>; Leigh Turner, *Could Pressure for COVID-19 Drugs Lead the FDA to Lower Its Standards?*, CONVERSATION (June 10, 2020), <https://theconversation.com/could-pressure-for-covid-19-drugs-lead-the-fda-to-lower-its-standards-139013>.

³⁴⁸ Gilead announced in August 2020 that it is seeking full FDA approval of remdesivir, based on the same trials that supported its EUA. See Press Release, Gilead Scis., Inc., *Gilead Submits New Drug Application to U.S. Food and Drug Administration for Veklury (Remdesivir) for the Treatment of COVID-19* (Aug. 10, 2020), <https://www.gilead.com/news-and-press/press-room/press-releases/2020/8/gilead-submits-new-drug-application-to-us-food-and-drug-administration-for-veklury-remdesivir-for-the-treatment-of-covid19>. In the event that Gilead's application is approved, the FDA will grant Gilead a period of so-called "data exclusivity" that prohibits the filing of "abbreviated" applications on remdesivir for several years. See *Frequently Asked Questions on Patents and Exclusivity*, U.S. FOOD & DRUG ADMIN. (May 2, 2020), <https://www.fda.gov/drugs/development-approval-process-drugs/frequently-asked-questions-patents-and-exclusivity>.

³⁴⁹ Federal Food, Drug, and Cosmetic Act § 564(a)(1)–(a)(2)(A), 21 U.S.C. §§ 360bbb–3; see OFFICE OF COUNTERTERRORISM & EMERGING THREATS, U.S. DEP'T OF HEALTH & HUMAN SERVS., *EMERGENCY USE AUTHORIZATION OF MEDICAL PRODUCTS AND RELATED AUTHORITIES: GUIDANCE FOR INDUSTRY AND OTHER STAKEHOLDERS* 4 (2017), <https://www.fda.gov/media/97321/download>.

³⁵⁰ See Letter from Denise M. Hinton, U.S. Food & Drug Admin., to Ashley Rhoades, Gilead Scis., Inc. (May 1, 2020), <https://www.fda.gov/media/137564/download>; see also Gilead Scis., *supra* note 301, at 33 (summarizing data from NIAID trial).

mentioned clinical trial conducted (and paid for) by NIAID, which showed that remdesivir helps hospitalized patients with severe COVID-19 recover and leave the hospital more quickly than a placebo.³⁵¹ According to news reports, this trial was apparently the more important of the two trials that supported the authorization,³⁵² and it recently formed the sole basis of conditional approval by Canada's drug regulator.³⁵³ NIAID has committed to sharing the "[c]omplete de-identified patient data set" from its trial with any who ask for it, once the clinical study report has been finalized.³⁵⁴ As such, it seems likely to us that a generic manufacturer seeking an EUA from the FDA for its own remdesivir product will be able to obtain one by obtaining and submitting the complete data set from the NIAID trial along with proof that its product is bioequivalent to Gilead's.³⁵⁵ Generic manufacturers may also be able to submit, and rely on, clinical trial data from other publicly funded trials of remdesivir.³⁵⁶ A second path would be for a generic to file a full New Drug Application. Any FDA-granted data exclusivity for Gilead would not prevent a competitor manufacturer from submitting a *complete* (rather than an abbreviated) application for full FDA approval of its own, based on the NIAID trial and other publicly

³⁵¹ See *supra* notes 303–307.

³⁵² See, e.g., Maggie Fox et al., *FDA Will Reportedly Authorize Use of Remdesivir for Covid-19 After Trial Shows "Positive Effect" on Recovery Time*, CNN (Apr. 30, 2020), <https://www.cnn.com/2020/04/29/health/gilead-sciences-remdesivir-covid-19-treatment/index.html>.

³⁵³ See *Health Canada Authorises Remdesivir as First Covid-19 Treatment*, PHARMACEUTICAL TECH. (July 29, 2020), <https://www.pharmaceutical-technology.com/news/canada-approval-remdesivir-covid/> (describing conditional approval); Gilead Sciences Canada, Inc., *Product Monograph Including Patient Medication Information: Veklury*, VEKLURY 1, 13 (July 27, 2020), https://pdf.hres.ca/dpd_pm/00057134.PDF (referring to the NIAID trial, and only the NIAID trial).

³⁵⁴ See *Data Sharing Statement*, https://www.nejm.org/doi/suppl/10.1056/NEJMoa2007764/suppl_file/nejmoa2007764_data-sharing.pdf, in Beigel et al., *supra* note 304.

³⁵⁵ See 21 C.F.R. §§ 320.21–.63.

³⁵⁶ See, e.g., "Solidarity" *Clinical Trial for COVID-19 Treatments*, WORLD HEALTH ORG. (last updated July 6, 2020), <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/solidarity-clinical-trial-for-covid-19-treatments>; *Trial of Treatments for COVID-19 in Hospitalized Adults (DisCoVeRy)*, U.S. NAT'L LIBR. MED. (last updated July 22, 2020), <https://clinicaltrials.gov/ct2/show/NCT04315948>.

available data.³⁵⁷

That legal, logistical, and regulatory barriers are traversable makes remdesivir perhaps unlike some other anti-COVID medical products. In particular, with respect to vaccines, several scholars have focused on trade secret knowledge of manufacturing processes, observing that “the more significant impediments to producing a successful coronavirus vaccine lie on the manufacturing side” and are not patents themselves.³⁵⁸ (Vaccines and other biological drug products are often more difficult for competitors to reverse engineer than small molecule drugs.³⁵⁹) As a result, these scholars contend that use of § 1498 could be counterproductive; it could, they argue, erode a patent holder’s financial incentives to scale up manufacturing and distribution of the patented vaccine without concomitantly empowering competitors to make it, leaving the

³⁵⁷ See 21 U.S.C. § 355(b)(1) (permitting filing of applications based on “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”); Rebecca S. Eisenberg, *Data Secrecy in the Age of Regulatory Exclusivity*, in *THE LAW AND THEORY OF TRADE SECRECY: A HANDBOOK OF CONTEMPORARY RESEARCH* 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.”); Erika Lietzan, *A New Framework for Assessing Clinical Data Transparency Initiatives*, 18 MARQ. INTELL. PROP. L. REV. 33, 67 (2014) (“[W]here the [clinical trial] data is released and available, an abbreviated application may not be required by the regulator. A full application can be submitted. This effects an end run around regulatory exclusivity, which prohibits only approval, or sometimes submission, of abbreviated applications.”).

³⁵⁸ Nicholson Price et al., *Are COVID-19 Vaccine Advance Purchases a Form of Vaccine Nationalism, an Effective Spur to Innovation, or Something in Between?*, WRITTEN DESCRIPTION (Aug. 5, 2020), <https://writtendescription.blogspot.com/2020/08/are-covid-19-vaccine-advance-purchases.html>; accord Ken Shadlen, *Speeding up the Development and Distribution of COVID-19 Vaccines*, ISSUES SCI. & TECH. (Aug. 11, 2020), <https://issues.org/covid-vaccines-development-distribution-patenting-shadlen/> (“For some COVID products (vaccines in particular), the [principal] barriers to access will be related to their production . . .”).

³⁵⁹ See Sara Eve Crager, *Improving Global Access to New Vaccines: Intellectual Property, Technology Transfer, and Regulatory Pathways*, 108 AM. J. PUB. HEALTH S414, S415 (2018), <https://ajph.aphapublications.org/doi/pdfplus/10.2105/AJPH.2014.302236r>.

world with less supply than ever.³⁶⁰ These scholars specifically contend that use of § 1498 and other compulsory patent licensing could impede transfer from the patent holder to those competitors of the vital knowledge those competitors need.³⁶¹

There are several reasons to think that knowledge transfer will not be as much a problem in the context of COVID-19 vaccines as these commentators suggest, even if § 1498 is on the table. The premise is that government patent use will lead patent holders to refuse knowledge transfer, but in fact history repeatedly shows that government patent use leads patent owners to be more conciliatory in negotiations; *lack* of government power has tended to give rise to patentee recalcitrance.³⁶² In our view it is more likely that exercise of § 1498 or the threat of its exercise would encourage patent holders to make deals with the government that include elements of knowledge transfer. Furthermore, in cases of extreme impasse, the government may be able to compel technology transfer—including transfer of trade secret manufacturing information—via authority to “allocate materials” under the Defense Production Act.³⁶³

In a larger sense, the fact that § 1498 cannot overcome trade secrets, regulatory exclusivities, and other barriers to emergency response reflects an ongoing failure to consider how these non-patent forms of intellectual property intersect with crises. Even § 1498 itself was not the product of thinking about patents in national emergencies; it arose out of a very non-emergency Capitol renovation.³⁶⁴ That § 1498 has ended up playing a role in past national emergencies suggests a need for Congress to consider § 1498-like statutory authority on trade secrets, regulatory exclusivities, and other competition barriers, as some scholars have argued it should,³⁶⁵ so that the U.S. government can better accelerate competition in the event of shortages, price-gouging, or other

³⁶⁰ See Shadlen, *supra* note 358; Price et al., *supra* note 358.

³⁶¹ See Shadlen, *supra* note 358; Price et al., *supra* note 358.

³⁶² See *supra* notes 158–165 and accompanying text.

³⁶³ 50 U.S.C. §§ 4511(a)(2) & 4552(13) (defining “materials” to include “technical information”); Quigley, *supra* note 216. Of course, the government would need to weigh the costs and benefits before exercising the DPA, just as it should with exercise of § 1498.

³⁶⁴ See *supra* Part I.A.

³⁶⁵ See, e.g., Yaniv Heled, *The Case for Disclosure of Biologics Manufacturing Information*, 47 JOURNAL OF LAW, MEDICINE & ETHICS 54 (2019); Ameet Sarpatwari et al., *The US Biosimilar Market: Stunted Growth and Possible Reforms*, 105 CLINICAL PHARMACOLOGY & THERAPEUTICS 92 (2018).

problems.

4. Government Patent Use Offers a Way Forward

Patents, then, are the major barrier to competitive manufacturing of remdesivir, and there is a straightforward solution to overcoming shortages and excessive pricing: The U.S. government, and HHS specifically, could use government patent use under § 1498 to permit other manufacturers to make and sell remdesivir in the United States. HHS can and should publicly commit now to using § 1498, so that the United States' supply of affordable remdesivir is assured.³⁶⁶

The normative case for the U.S. government use of § 1498 to procure remdesivir is based on our framework. All four advantages of government patent use are highly salient in the case of remdesivir and COVID-19. Government patent use is clearly preferable to a U.S. government buyout of Gilead's patents, which other scholars have proposed.³⁶⁷

First, speed is critical. As noted above, as of writing, the United States and other countries have already faced shortages of remdesivir that hinder doctors' ability to treat their patients, and these shortages could continue into the fall and beyond.³⁶⁸ HHS must do whatever it can to get additional supply of remdesivir into the marketplace as quickly as possible. To this end, HHS can and should announce its intent now to authorize other manufacturers (besides Gilead) under § 1498 to manufacture, import, export, distribute, and sell remdesivir. HHS can do this instantly. By contrast, negotiating a patent buyout or licensing deal with Gilead could take many months. Some delay in getting alternative manufacturers to market is inevitable; Gilead's competitors will need to scale up manufacturing and clear the regulatory hurdles

³⁶⁶ One of us (C.J.M.) has previously advocated in shorter pieces for government patent use to expand access to remdesivir. *See supra* note 295. In July 2020, the legal scholar Amy Kapczynski and the medical researchers and practicing physicians Paul Biddinger and Rochelle Walensky published an op-ed advocating the same. Kapczynski, Biddinger & Walensky, *supra* note 12. To be clear, committing to use § 1498 does not require actually using it if the patent holder puts an appropriate deal on the table, in the same way that the threat of invoking § 1498 prodded Bayer to negotiate on Cipro. *See supra* notes 124–125. But without a clear commitment, patent holders may not feel the same need to negotiate in good faith or with expediency. *See supra* notes 158–165.

³⁶⁷ Hemel & Ouellette 2020b, *supra* note 31 (proposing that HHS buy the patent rights to remdesivir from Gilead).

³⁶⁸ *See supra* notes 316–327 and accompanying text.

noted above. But these practical hurdles will arise regardless of whether a buyout or government patent use is used. A buyout simply introduces extra delay.

Second, the flexibility of government patent use is advantageous here. We trace here two options for HHS—an ambitious intervention, under which *all* of the government's need for remdesivir is met through government patent use, and a modest one, under which the government would authorize generic manufacturing under § 1498 and stockpile a smaller supply of doses, to keep on hand in case of shortages.

Under the more ambitious option, HHS could bypass Gilead altogether and contract with one or more generic drug companies who are able to supply the drug cheaply, much closer to manufacturing cost than the thousands of dollars per course of treatment that Gilead is charging. To bypass Gilead altogether would mimic what the U.S. government threatened to do when Bayer refused to reduce the price or increase supply of ciprofloxacin in the 2001 anthrax crisis.³⁶⁹ It would also mimic the proposals of Brennan et al.,³⁷⁰ Senators Bernie Sanders³⁷¹ and Elizabeth Warren,³⁷² and the editorial board of *The New York Times*,³⁷³ all of whom have called on the U.S. government to use § 1498 to move its spending from expensive brand-name to cheap generic versions of certain drugs. A generic manufacturer in Bangladesh is manufacturing and selling a generic version of remdesivir at a cost of between \$295 and \$781 (USD) per course of treatment,³⁷⁴ and generics in India are selling remdesivir at a similar price.³⁷⁵ (The marginal cost is surely

³⁶⁹ *Supra* Part I.D.

³⁷⁰ Brennan et al., *supra* note 11, at 346 (calling on government procurement officers to contract directly with generic companies to purchase hepatitis C drugs instead of purchasing any such drugs from Gilead).

³⁷¹ Sanders, *supra* note 11.

³⁷² Anderson, *supra* note 14.

³⁷³ Editorial Bd., *supra* note 11.

³⁷⁴ See Silverman, *supra* note 342; Siddiqui, *supra* note 342.

³⁷⁵ See Sohini Das & Vinay Umarji, *Covid-19: At Rs 2,800 per Dose, Zydus Launches Cheapest Remdesivir Brand*, BUS. STANDARD (Aug. 13, 2020), https://www.business-standard.com/article/current-affairs/zydus-cadila-s-cheapest-remdesivir-brand-to-disrupt-indian-market-120081301528_1.html; Angus Liu, *WuXi NextCODE Rebrand; Remdesivir Generic Prices; Sinopharm COVID-19 Vax Phase 3*, FIERCEPHARMA (June 26, 2020), <https://www.fiercepharma.com/pharma-asia/fiercepharmaasia-wuxi-nextcode-rebrand-remdesivir-generic->

even lower, and costs of manufacturing may decline further as generics grow more experienced.) Should these generic manufacturers supply the United States at similar prices to those in South Asia, then payers would reap enormous savings compared to Gilead's current prices of \$2,340 to \$3,120. (Even HHS and the U.S. government, which would be required to pay Gilead "reasonable and entire compensation" for use of its patents, would come out far ahead, as we show below.)

Alternatively, HHS could make a more modest intervention under § 1498, one that would trouble Gilead's business expectations only minimally while simultaneously protecting the American public from a shortage of remdesivir. Under this proposal, HHS could continue to purchase remdesivir from Gilead at Gilead's full price, at whatever rate Gilead is able to supply and sell, while simultaneously contracting with a generic manufacturer to build a stockpile. The stockpile could be reserved to ameliorate shortages and deployed (and replenished) only as needed. HHS would provide compensation to Gilead for its purchases of the generic. And Gilead's existing business—selling remdesivir to HHS and other buyers around the world—would continue.

Third, ex post determination of the appropriate compensation is highly beneficial in the case of remdesivir. Because of skimpy clinical trials and only a few months of real-world evidence, remdesivir's value is currently highly uncertain.³⁷⁶ Remdesivir could prove our best therapeutic weapon against COVID-19, or it could be supplanted by drugs that are more effective or cheaper—or by a vaccine.³⁷⁷ That makes a patent buyout particularly difficult from both Gilead's and the government's perspective: how to factor all that uncertainty? Use of § 1498 would helpfully defer the question of patent valuation and compensation until after more evidence of remdesivir's therapeutic properties and sales has been

prices-sinopharm-covid-vax, (explaining that generic remdesivir in India will cost "around \$350 to \$700 per treatment course, depending on which doses a patient needs"); Anuron Kumar Mitra & Siddharth Cavale, *India's Cipla Prices Its Generic Remdesivir at \$53.34 per Vial, Below Rivals*, REUTERS (July 8, 2020), <https://www.reuters.com/article/us-health-coronavirus-cipla-idUSKBN2492Q3>.

³⁷⁶ See Garde & Silverman, *supra* note 332; Sarpawari et al., *supra* note 303. Perhaps the most critical currently unanswered question is whether remdesivir reduces mortality—i.e., saves lives—or merely accelerates recovery in patients who would survive even without the drug.

³⁷⁷ See Silverman, *Gilead's Pricing*, *supra* note 333.

gathered. Indeed, to ensure a solid evidence base, HHS could concomitantly work with the FDA (a constituent agency) to create a patient registry that collects information on patient outcomes from doctors who prescribe the drug, as Sarpatwari, Kaltenboeck, and Kesselheim have suggested.³⁷⁸ HHS could also sponsor new clinical trials through the National Institutes of Health (another constituent agency) to generate better evidence of remdesivir's therapeutic properties.

Finally, the fourth key feature of § 1498, determination of that compensation by an impartial adjudicator, is likely to be advantageous as well. Placing the question of compensation in the hands of an objective judge rather than Gilead's negotiators is likely preferable from the government's (and public's) perspective, as Gilead has a reputation for price gouging and bad faith, even in its dealings with the U.S. government.³⁷⁹ Given Gilead's track record, a patent buyout raises the prospect of hold-up and worse.

What compensation would HHS pay if chose to use § 1498 to authorize generic manufacturers to make and sell remdesivir?

³⁷⁸ See Sarpatwari et al., *supra* note 303; see also Peter B. Bach, *U.S. Hospitals Need to Study How Well Remdesivir Really Works*, BLOOMBERG L. (July 13, 2020), <https://www.bloomberg.com/opinion/articles/2020-07-13/u-s-hospitals-need-to-study-how-well-remdesivir-really-works>.

³⁷⁹ In 2015, a bipartisan investigation of Gilead's Hepatitis C drug portfolio by Senators Wyden (D-OR) and Grassley (R-IA) concluded that "Gilead's marketing, pricing, and contracting strategies were focused on maximizing revenue—even as the company's analysis showed a lower price would allow more people to be treated—not only for [its first FDA-approved Hepatitis C product], but more importantly for its follow-on . . . product pipeline." STAFFS OF RANKING MEMBER RON WYDEN & COMM. MEMBER CHARLES E. GRASSLEY, 114TH CONG., THE PRICE OF SOVALDI AND ITS IMPACT ON THE U.S. HEALTH CARE SYSTEM 117 (Comm. Print 2015), <https://www.finance.senate.gov/download/the-price-of-sovaldi-and-its-impact-on-the-us-health-care-system-full-report>. The same report criticized Gilead's lack of candor, observing that "despite the company's assurances of cooperation, Gilead failed to produce all relevant documents and supporting materials." *Id.* Gilead is also currently embroiled in a patent infringement lawsuit filed by the U.S. Department of Justice and Department of Health and Human Services (HHS), which alleges that Gilead acted in bad faith in negotiating a patent license to government-held patents with HHS and one of its constituent agencies, the Centers for Disease Control and Prevention. See Complaint at 1–4, *United States v. Gilead Scis., Inc.*, No. 1:19-cv-2103 (D. Del. Nov. 6, 2019) ("Gilead's conduct was malicious, wanton, deliberate, consciously wrongful, flagrant, and in bad faith. This is especially true because . . . the Government has attempted to negotiate [a patent license] in good faith . . ."); *id.* at 69.

Assuming conservatively that HHS pays a sale price of \$800 to the generic for a standard course of treatment (higher than the highest generic prices currently charged overseas) and pays to Gilead a very generous court-set royalty of 50% of that sale price³⁸⁰ HHS would still spend a total of only \$1,200 per course of treatment—far less than Gilead currently charges. HHS, and American taxpayers, would come out ahead.

And Gilead itself would fare well at the Court of Federal Claims; despite “breaking” Gilead’s patent, this scenario is no “nuclear option.” After going to court to claim its compensation from the U.S. government, Gilead would collect a royalty that could run to the hundreds of millions,³⁸¹ even billions,³⁸² of dollars, all while foregoing the manufacturing and distribution costs it would incur if it made the infringing doses itself—while simultaneously selling remdesivir at whatever price it pleases to payers in other countries around the world, *and* perhaps to private payers in the United States not supplied by HHS. Between royalties and its own sales, Gilead should quickly recoup the “up to \$1 billion or more” it has contended (without documentation) that it ultimately plans to invest in remdesivir.³⁸³

Determination of compensation at the Court of Federal Claims has another interesting advantage in the case of remdesivir: the court can adjudicate not only compensation but also ownership of the patents that cover remdesivir. A report recently co-authored by Krellenstein and one of the authors concluded that the U.S. government likely co-owns (with Gilead) the patents on remdesivir itself as well as the method of treating COVID-19 with

³⁸⁰ A 50% royalty would be extraordinarily high, making our estimates conservative (from the government’s perspective). *See supra* note 194 (observing that royalties of over 10% are rare in § 1498 cases).

³⁸¹ Assuming a royalty of \$400 on 500,000 doses, Gilead would receive \$200,000,000.

³⁸² Assuming a royalty of \$400 of 5,000,000 doses, Gilead would receive \$2,000,000,000.

³⁸³ Sydney Lupkin, *Putting a Price on COVID-19 Treatment Remdesivir*, NPR (May 8, 2020), <https://www.npr.org/sections/health-shots/2020/05/08/851632704/putting-a-price-on-covid-19-treatment-remdesivir>. HHS’s contract with Gilead to distribute 500,000 doses of remdesivir at Gilead’s full monopoly price between July and September 2020 may alone suffice to guarantee Gilead a payout of over \$1B, likely sufficient to cover all of Gilead’s purported costs. *See* Bach, *supra* note 335.

remdesivir.³⁸⁴ This rather unusual feature of remdesivir arises from the fact that it was co-developed by Gilead and U.S. government scientists rather than by Gilead alone. This feature makes government patent use particularly appealing from the government's (and public's) perspective: for any patents that the U.S. government is able to prove it co-owns, the "reasonable and entire compensation" the government will owe under § 1498 for use of these patents will be zero.³⁸⁵ HHS would owe compensation only for use of any patents that Gilead owns outright, without co-ownership by the U.S. government.³⁸⁶ Under U.S. patent law, HHS would owe no compensation to Gilead for use of any patent of which the U.S. government turns out to be rightful co-owner.³⁸⁷ The consequent savings to HHS would represent a kind of compensation for the U.S. government's investment in that patent—and, more broadly, compensation for the more than \$70,000,000 that the American public invested in the early, riskiest days of remdesivir's development.³⁸⁸

All four of the key beneficial features of government patent use under § 1498 thus weigh in favor of its use on remdesivir. The end result of government patent use on remdesivir would be increased competition, greater supply, and lower prices—much lower for patients and private payers, who would pay only the price that generic makers charge, and substantially lower even for the U.S. government, who would pay that price plus court-set compensation to Gilead. Given the unique circumstances around remdesivir—not

³⁸⁴ Krellenstein & Morten, *supra* note 295; see also Dani Kass, *Activists Say Gov't Should Have Rights to Remdesivir Patents*, LAW360 (May 27, 2020), <https://www.law360.com/ip/articles/1277114/activists-say-gov-t-should-have-rights-to-remdesivir-patents>.

³⁸⁵ If the U.S. government co-owns these patents, it has a legal right to license them as it pleases, including to generic pharmaceutical companies, without permission from or payment to Gilead. See 35 U.S.C. § 262 ("In the absence of any agreement to the contrary, each of the joint owners of a patent may make, use, offer to sell, or sell the patented invention within the United States, or import the patented invention into the United States, without the consent of and without accounting to the other owners.").

³⁸⁶ Krellenstein & Morten, *supra* note 295, at 15.

³⁸⁷ See 35 U.S.C. § 262 ("In the absence of any agreement to the contrary, each of the joint owners of a patent may make, use, offer to sell, or sell the patented invention within the United States, or import the patented invention into the United States, without the consent of and without accounting to the other owners.").

³⁸⁸ See *supra* note 332.

least the scale of the public health crisis posed by COVID-19 and the deep involvement of HHS scientists in remdesivir's invention and clinical development—HHS should commit now to using this policy tool to protect public health.

IV. CONCLUSION

Section 1498 has long played and ought to continue playing its part in U.S. patent policy. In emergencies past, it has resolved wide-scale tragedies, and it has clear applications, large and small, in the COVID-19 crisis. Section 1498's long pedigree and theoretical advantages dispel the notion that it is antithetical to the modern patent system. It is part and parcel of our patent system, and its advantageous features recommend its use alongside other policy tools for driving innovation and expanding access to patented technologies.

While we conclude that § 1498 has an important role in patent policy and thus reject the view that invocation of the statute is exceptional, impractical, or extreme, we have not established a specific test for when § 1498 should or should not be used, and we do not purport to. Instead, we have identified neglected features of § 1498 that make it a valuable policy tool that could be applied more widely than it has been in recent decades and yield significant social and economic benefits in a wide set of situations, especially—but not only—in times of national emergency. An important area of further research will be the development of more detailed and specific guidance on when invocation of § 1498 is wise as a matter of policy, in view of those advantages and disadvantages that we and others have identified.

That the role of § 1498 in the context of national emergencies has not been explored in depth to date suggests a larger need for research on the relationship of the patent system generally with imminent conditions that require federal response. As one of us has observed in a study of patents and national security,³⁸⁹ traditional narratives of patent policy, though applicable in usual circumstances, do not necessarily hold up when there are national-scale interests at stake. It is our hope that the calamitous circumstances that we face today with COVID-19 will encourage further research into how a system as complex and broad-reaching as U.S. patent law can accommodate the challenges—emergency and routine—that may lie ahead.

³⁸⁹ See Duan, *supra* note 48.

**V. APPENDIX: MEMORANDUM FROM ALFRED B. ENGELBERG
TO SENATOR CHARLES E. SCHUMER**

Alfred B. Engelberg

INCREASING ACCESS TO CIPRO

A Strategy for Rapid Creation of a Government Stockpile

October 13, 2001

1. Background Facts

Panic buying of CIPRO in response to recent threats of bioterrorism involving Anthrax has caused massive shortages of this antibiotic. The ability to create new supplies is limited by the fact that the drug is patented until at least December 2003 and is only available from a single source. A challenge to the validity of the patent which might have resulted in the widespread availability of a low cost generic alternative was settled when the patent owner, Bayer Corporation, reportedly paid Barr Laboratories and others in excess of \$200 million to drop the challenge. The FTC is investigating this settlement as a possible anti-trust violation and several class action antitrust cases have been commenced on behalf of consumers. At the present time at least five generic drug manufacturers have been tentatively approved to manufacture ciprofloxacin, the generic version of CIPRO but, due to the existence of the Bayer patent, they cannot begin the commercial manufacture and sale of generic product until the Bayer patent expires more than 2 years from now.

**2. Current Law Permits the United States to Purchase
Generic Ciprofloxacin Now**

The United States government and its suppliers are immune from suits for patent infringement in the Federal District Courts. The sole and exclusive remedy for an act of infringement by or for the government is a suit against the United States in the Court of Claims pursuant to 28 U.S.C. § 1498 (a). The statute reads as follows:

(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 Claims Court for the recovery of his reasonable and entire compensation for such use and manufacture.

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.

No injunction is available under § 1498 and the only remedy is reasonable compensation for the unauthorized use of an invention. But the government has the right to assert any defense to compensation that a private party could assert, namely that the patent is invalid, not infringed or unenforceable. Under federal procurement regulations, the government is often (although not always) indemnified against claims for compensation by its suppliers and the suppliers assist in asserting these defenses. Accordingly, the government may assert the same challenges to the CIPRO patent that have been asserted by Barr and are now being asserted by others.³⁹⁰

There is ample authority for the proposition that 28 U.S.C. § 1498(a) prevents a Federal District court from issuing an injunction against a government supplier that would interfere with the right of that supplier to bid on and participate in the sale of products to the government. *Gore v. Garlock*, 842 F.2d 1275, 1282 (Fed. Cir. 1988). In fact, that principle has been applied by the courts even in cases where the same supplier was actually enjoined from making commercial sales of the same product. As stated by the Federal Circuit Court of Appeals in *Garlock*:

The patentee takes his patent from the United States subject to the government's eminent domain rights to obtain what it needs from manufacturers and to use the same. The government has graciously consented in the same statute, to be sued in the claims court for reasonable and entire compensation, for what would be an infringement by a private person. The same principles apply to injunctions which are nothing more than the giving of aid of the courts to the enforcement of the patentees right to exclude. Though injunctions may seem to say that making for and selling to the

³⁹⁰ It is noteworthy that the U.S. government has actually used its authority under 28 U.S.C. § 1498 to procure a less expensive generic version of a patented drug (Miltown) from abroad. *See Carter Wallace v. United States*, 449 F.2d 1374 (U.S. Ct. Clms. 1972).

government is forbidden, injunctions based on patent rights cannot in reality do that because of §1498(a).

Quoting the foregoing paragraph in *Trojan v. Shat-R-Shield*, 885 F.2d 854 (Fed. Cir. 1989), the Federal Circuit further stated:

In short, a patent owner may not use its patent to cut the government off from sources of supply, either at the bid stage or during performance of a government contract.

In the face of these overwhelming precedents, Bayer is likely to argue that § 1498 is not applicable to generic drug purchases because a mere applicant for approval of an ANDA is not yet a legitimate competitor for a government contract and, therefore, the act of filing and seeking approval for an ANDA does not have the “authorization and consent” from the government that is a prerequisite to invoking 28 U.S.C. § 1498. The Federal Circuit Court of Appeals rejected a similar argument in *TVI Energy Corp. v. Blane*, 806 F.2d 1057 (Fed. Cir. 1986). As the Federal Circuit noted, § 1498 protects government procurement activities, including acts required to satisfy government procurement requirements and that authorization and consent can be implied and need not be expressly stated by the government.

Despite the foregoing precedents, the government could easily moot any possibility of protracted litigation by issuing a blanket “authorization and consent” for generic manufacturers holding tentative ANDA approvals to submit bids to the appropriate agencies. Such an authorization, which could be issued by OMB, HHS or some other agency with responsibility for drug procurement, would eliminate any basis for litigation. At least five companies now have tentative approvals to manufacture ciprofloxacin and are prevented from full approval solely because of the Bayer patents.

3. Generic Versions of Licensed Drugs Can Be Approved By the FDA Notwithstanding the Patent Certification Procedures Required Under Current Law

Under current law, the FDA will not approve a generic version of a drug for which unexpired patents are listed in the Orange Book unless the applicant makes a Paragraph IV certification alleging that a patent is invalid, unenforceable or will not be infringed. When such a certification is made the FDA is prohibited from approving

the generic drug for 30 months unless a court issues a judgment in a shorter time. An applicant seeking approval for the purpose of marketing a drug solely to the United States government can file a paragraph IV certification and state “Applicant will not infringe U.S. Patent No. ____ because the product of this application will only be sold to the United States.” If a supply agreement has already been authorized by a government agency, documentation of the authorization and consent should accompany the certification.

In all likelihood, the patent owner will sue the first generic applicant that seeks an approval for the exclusive purpose of making sales to the government. Any competent Federal District Court will be compelled to summarily dismiss any such lawsuit on the basis of the precedents cited in this memo. Indeed, it would be appropriate for the ANDA applicant to specifically request and for the court to grant, an immediate final judgment compelling the FDA to grant approval of any ANDA for the purpose of allowing the applicant to sell product to the United States government. At least two generic manufacturers with tentatively approved ANDAs for ciprofloxacin are already engaged in litigation with respect to the Bayer patents. Those parties are in a position to file immediate motions for summary judgment of non-infringement based on the legal theory outlined herein and to by-pass the loss of time that would occur before litigation begins if the normal patent certification process is followed.

4. Timetable & Risk

Assuming that one of the two generic companies now involved in litigation with Bayer is willing to proceed, a motion for summary judgment of non-infringement could be filed, on an expedited or emergency basis, in a Federal District Court in a matter of a couple of days simply by relying on the legal arguments in this memo. There would, however, be no point in doing so without a firm commitment of the US government to make a substantial purchase at a pre-negotiated price. Obviously that price would be heavily discounted as compared to the current wholesale price of the patented product. The contract commitment is essential from both an incentive standpoint and to eliminate any possibility of a legal skirmish on the issue of authorization and consent.

One significant stumbling block could be the issue of who assumes the risk of paying “reasonable compensation” in the event Bayer sues the U.S. for patent infringement and the patent is upheld.

The generic manufacturers will be highly reluctant to assume any portion of that risk since a large award could destroy their business. Moreover, the risk may be real. On February 9, 2001, the U.S. District Court for the District of New Jersey denied a motion for Summary Judgment by Mylan and Schein to declare the basic Bayer patent to be invalid and specifically held the patent valid over the challenge asserted in that motion. At this time, it is unknown whether there are other grounds for challenging the patent or whether the summary judgment decision would be affirmed on appeal. Moreover, there is a substantial question as to whether the patent will ultimately be enforceable in view of the antitrust issues surrounding the settlement with Barr Laboratories. Given the significant benefit to the government of assuring the existence of an adequate supply of ciprofloxacin and the ability to procure that supply at a relatively low cost, the government may wish to consider waiving or limiting the usual indemnification provisions in federal procurement contracts.

Preliminary investigation reveals that a supply of bulk active ingredient is available from reputable FDA-approved sources abroad and that delivery of significant quantities of finished product could commence within 60–90 days assuming the legal obstacles have been cleared away and FDA approval is in hand.