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Compulsory Licensing of Patents During Pandemics

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Wealthy countries with major pharmaceutical industries have historically supported strong patent rights and opposed temporarily abrogating them—even to save lives. However, as drug shortages have become commonplace due to COVID-19, governments have begun reassessing their views. The European Union and various countries have issued new policies and passed legislation facilitating their ability to provide drugs to their citizens for the duration of the pandemic. They have signaled a willingness to do so through "compulsory licensing," in which the government issues a license to a third party to produce a patented invention without the patent holder's permission and pays the patent holder compensation. By contrast, the United States has opposed compulsory licensing of drugs for several decades. Although the Biden administration supports lower-income countries seeking to license patented drugs, it remains opposed to the practice to provide drugs for its own citizens, even during drug shortages. This Article provides an overview of compulsory licensing and examines the U.S. government's inconsistent views regarding its use. It further discusses how other high-income countries have facilitated compulsory licensing during the pandemic. It then proposes legislative and contractual solutions for addressing future pandemic-related drug shortages in the United States. This includes expanding third-party manufacturers' ability to petition for a compulsory license and requiring companies to provide an adequate supply of patented drugs that were developed with government funds, or else be required to license out their technology and know-how to willing third-party manufacturers.

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Compulsory Licensing of Patents During Pandemics

SAPNA KUMAR [*]

I. INTRODUCTION

In the summer of 2020, an unusual dynamic arose with regard to drug access and public health. The United States faced a critical shortage of Gilead Sciences' drug remdesivir, which led to doctors rationing access for hospitalized patients.[1] Meanwhile, Bangladesh-based Beximco Pharmaceuticals Ltd (Beximco) reverse-engineered remdesivir and, along with other Bangladeshi manufacturers, was able to produce a surplus.[2] Driving this disparity was the fact that remdesivir is subject to patent protection in the United States, but not in Bangladesh.

The COVID-19 pandemic has highlighted an uneasy balancing act between incentivizing new drug development through patent rights and preventing drug shortages. Pharmaceutical research and development is slow and expensive; it is not well-supported by temporary infusions of public money tied to specific outbreaks.[3] But the exclusive rights that incentivize the development of needed drugs simultaneously hinder the public's access to them during emergencies.[4]

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) permits countries to contract with third-party manufacturers to produce patented goods in exchange for the government compensating

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[1] Eric Boodman & Casey Ross, *Doctors Lambaste Federal Process for Distributing Covid-19 Drug Remdesivir*, STAT (May 6, 2020), https://www.statnews.com/2020/05/06/doctors-lambaste-federal-process-for-distributing-covid-19-drug-remdesivir/ (discussing the remdesivir shortage in various states, including Massachusetts and California, in May 2020).

[2] *See* discussion *infra* Part III.B.

[3] *See* Ana Santos Rutschman, *IP Preparedness for Outbreak Diseases*, 65 UCLA L. REV. 1200, 1207 (2018) (discussing how "[t]he lengthy and costly traditional model for developing vaccines and therapies is ill-suited to" outbreaks of diseases).

[4] *See id.* at 1234–35; 1242–43 (providing case studies for the Zika outbreak and discussing how the intellectual property ("IP") rights that promoted vaccine development simultaneously hindered access).

the patent holder—a practice known as "compulsory licensing."[5] Similar rights exist under U.S. patent law.[6] Compulsory licensing can be a useful tool for countries seeking to provide drugs to their citizens during public health emergencies.[7] Admittedly, it is not a complete solution: without "know-how" from the patent holders, complex drugs such as mRNA vaccines may be too difficult or time-consuming for others to reproduce, and shortages in raw materials and manufacturing capacity may also hinder drug supplies.[8] However, for at least some drugs, compulsory licensing can boost supply and increase access.[9]

In light of the pandemic, several high-income countries have shifted their positions on the use of compulsory licensing in the face of scarcity. Various European Union (EU) member states, Canada, and other governments passed pandemic-specific laws that provided their health ministers with greater authority to issue compulsory licenses.[10] Israel, Hungary, and Russia issued pandemic-related compulsory licenses.[11]

The U.S. government's position, however, has been less supportive. Although it provided significant funding to private companies for COVID-19-related drug development under Operation Warp Speed, it failed to secure assurances that resulting drugs would be available to the public in

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[5] Agreement on Trade-Related Aspects of Intellectual Property Rights art. 31(h), Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299 [hereinafter TRIPS]. *See also* discussion *infra* Part II.A.

[6] 28 U.S.C. § 1498(a); 35 U.S.C. § 203(a)(2). *See also* discussion *infra* Part II.B.1.

[7] *See* TRIPS, *supra* note 5, at art. 31(b) (allowing member states to use patents without permission and without attempting to obtain the patent holder's authorization "in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use").

[8] *See* JOSHUA CHOE, MATTHEW CRANE, JEREMY GREENE, JINGMIAO LONG, JOELYNN MWANGA, JOSHUA M. SHARFSTEIN, MARIANA SOCAL & RACHEL STRODEL, JOHNS HOPKINS UNIV., THE PANDEMIC AND THE SUPPLY CHAIN: ADDRESSING GAPS IN PHARMACEUTICAL PRODUCTION AND DISTRIBUTION 1–3 (2020), https://www.jhsph.edu/research/affiliated-programs/johns-hopkins-drug-access-and-affordability-initiative/publications/Pandemic_Supply_Chain.pdf (discussing how shortages of active pharmaceutical ingredients, inadequate supply chain management, and a lack of manufacturing capacity contributed to COVID-19-related drug shortages); Lisa M. Jarvis, *Scaling Up Remdesivir Amid the Coronavirus Crisis*, CHEM. & ENG'G NEWS (Apr. 20, 2020), https://cen.acs.org/biological-chemistry/infectious-disease/Scaling-remdesivir-amid-coronavirus-crisis/98/web/2020/04 (noting that it typically takes nine to twelve months to produce a retroviral and discussing the complexity of drug manufacturing). Note that small-molecule drugs are generally easier to produce compared to biologics. *Small Molecule Versus Biological Drugs*, GENERICS & BIOSIMILAR INITIATIVE (June 29, 2012), http://www.gabionline.net/Biosimilars/Research/Small-molecule-versus-biological-drugs.

[9] *See* discussion *infra* Part III.B.

[10] *See* discussion *infra* Part IV.C.4.

[11] *See* discussion *infra* Part IV.B. *See also* discussion *infra* Part IV.C.3; *Russian Court Rejects U.S. Firm's Lawsuit over COVID-19 Drug Remdesivir*, REUTERS (May 28, 2021, 6:02 AM), https://www.reuters.com/business/healthcare-pharmaceuticals/russian-supreme-court-rejects-gilead-lawsuit-over-covid-19-drug-2021-05-27/ (discussing the Russian Supreme Court's affirmance of the Russian government's issuance of a compulsory licensing for remdesivir).

sufficient quantity.[12] Instead, the government bought priority access to vaccines[13] and prioritized securing raw materials for its needs ahead of other countries.[14] Although the Biden administration supports waiving patent right requirements under TRIPS for COVID-19-related inventions,[15] it has failed to examine how to prevent future domestic drug shortages.

This Article compares the use of compulsory licensing for public health emergencies in the United States versus other high-income countries, and it considers how U.S. law and policy contributed to drug shortages. Part II discusses compulsory licensing under TRIPS. It further explains how the U.S. government and its contractors can produce patented goods without permission under 28 U.S.C. § 1498 and the Bayh-Dole Act. It examines how the United States has punished countries that utilize compulsory licensing and discusses the controversies surrounding its use. Part III then explains how the United States procured COVID-19 drugs and provides a case study of the 2020 remdesivir shortage.

Part IV discusses how other high-income countries facilitated compulsory licensing during the pandemic. Part V then argues that existing U.S. law is inadequate to safeguard public health and urges Congress to pass legislation to make it easier for third parties to petition for licenses during drug shortages. It proposes that U.S. agencies that fund medical research utilize contractual provisions to ensure that a sufficient quantity of any resulting drug be made available to the public. A public health emergency that could impact drug supplies or a manufacturing-related drug shortage would trigger an out-licensing obligation for the relevant patent holder, requiring it to

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[12] *See* Rutschman, *supra* note 3, at 1250–51 (discussing how the U.S. Army granted Sanofi an exclusive license to a Zika vaccine candidate, but failed to secure safeguards to ensure the vaccine would be brought to market).

[13] *See* Keith Collins & Josh Holder, *See How Rich Countries Got to the Front of the Vaccine Line*, N.Y. TIMES (Mar. 31, 2021), https://www.nytimes.com/interactive/2021/03/31/world/global-vaccine-supply-inequity.html (discussing how the United States and other high-income countries pre-purchased an excess of vaccines, while lower-income countries struggled to secure doses).

[14] Under Title 1 of the U.S. Defense Production Act ("DPA"), the President may require businesses to prioritize and accept government contracts for materials and services ahead of everybody else. 50 U.S.C. § 4511 (effective Jan. 1, 2022). The Biden administration used the DPA to obtain needed materials for manufacturing vaccines, including providing Pfizer priority access to raw materials and needed equipment to increase its manufacturing capacity. Shayan Karbassi, *Understanding Biden's Invocation of the Defense Production Act*, LAWFARE (Mar. 4, 2021, 8:01 AM), https://www.lawfareblog.com/understanding-bidens-invocation-defense-production-act. By prioritizing the U.S. vaccine supply chain, President Biden may have harmed other countries' ability to obtain needed supplies. *See* Allison Martell & Euan Rocha, *How the U.S. Locked Up Vaccine Materials Other Nations Urgently Need*, REUTERS (May 7, 2021, 11:15 AM), https://www.reuters.com/business/healthcare-pharmaceuticals/how-us-locked-up-vaccine-materials-other-nations-urgently-need-2021-05-07/ (noting that the U.S. government prioritized its own vaccine manufacturers over foreign ones for vaccine components and equipment).

[15] *See* Ashutosh Pandey, *Access to COVID Vaccine Patents Is Not the Same as Access to Vaccines*, DEUTSCHE WELLE (May 6, 2021), https://www.dw.com/en/access-to-covid-vaccine-patents-is-not-the-same-as-access-to-vaccines/a-57448750 (discussing the Biden Administration's support of a COVID-19 patent waiver and obstacles that remain regarding access to drugs).

license out relevant technology and know-how to third-party manufacturers until the supply is stabilized. Part VI concludes.

II. AN INTRODUCTION TO GOVERNMENT USE AND COMPULSORY LICENSING OF PATENTS

A compulsory license allows the government or a government-authorized third party to use or manufacture a patented good, or practice a patented process, without the patent owner's consent.[16] In exchange, the government pays "adequate remuneration" to the patent holder.[17] The patent remains in effect, and the owner has the right to exclude other parties from using it.[18] TRIPS Article 31(b) expressly permits countries to enact national laws authorizing compulsory licensing.[19]

The United States has two statutes that allow U.S. agencies and their contractors to produce drugs without patent-holder permission: 28 U.S.C. § 1498 and the Bayh-Dole Act. The United States has used patents without permission to obtain cheap drugs, and it regularly uses defense-related patents without permission.[20] Nevertheless, the U.S. government frequently retaliates against low- and middle-income countries that issue compulsory licenses, even during public health crises.[21]

Section A discusses TRIPS provisions regarding compulsory licensing. Section B examines the scope of 28 U.S.C. § 1498 and the Bayh-Dole Act. It discusses instances when the United States has used patents without permission or threatened to do so to obtain a discount. It further examines how the U.S. government has threatened countries that utilized compulsory

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[16] *See Compulsory Licensing of Pharmaceuticals and TRIPS*, WORLD TRADE ORG., https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm (last visited Aug. 9, 2021) (stating "[c]ompulsory licensing is when a government allows someone else to produce a patented product or process without the consent of the patent owner or plans to use the patent-protected invention itself"); CYNTHIA M. HO, ACCESS TO MEDICINE IN THE GLOBAL ECONOMY: INTERNATIONAL AGREEMENTS ON PATENTS AND RELATED RIGHTS 127 (2011) [hereinafter HO, ACCESS TO MEDICINE] (noting "[a] compulsory license permits a nation (or a third party authorized by the nation) to use a patented invention without permission of the patent owner in exchange for payment of a government-determined royalty").

[17] *Compulsory Licensing of Pharmaceuticals and TRIPS*, *supra* note 16.

[18] *Id.*

[19] TRIPS, *supra* note 5, art. 31.

[20] *See infra* Part II.C.

[21] The U.S. government's approach could be due to the significant influence the pharmaceutical industry wields—pharmaceuticals and health products are the top lobbying forces in the United States. *See Leading Lobbying Industries in the United States in 2020, by Total Lobbying Spending*, STATISTA (Jan. 2021), https://www.statista.com/statistics/257364/top-lobbying-industries-in-the-us/ (showing that the pharmaceutical and health product industry spent $306.23 million in 2020, as compared to $156.9 million spent by the electronics manufacturing and equipment industry). This high level of spending dates back decades. Olivier J. Wouters, *Lobbying Expenditures and Campaign Contributions by the Pharmaceutical and Health Product Industry in the United States, 1999-2018*, 180 J. AM. MED. ASS'N INTERNAL MED. 688 (2020).

licensing for public health purposes. Section C then considers why compulsory licensing is viewed as controversial by some scholars.

A. *Government Use and Compulsory Licensing Under TRIPS*

TRIPS is a multilateral agreement that came into force in 1995, binding 164 member states including the United States.[22] It provides minimum standards for patent protection and is enforceable through the World Trade Organization's (WTO's) dispute process.[23] Because TRIPS links patent and other intellectual property (IP) protection to trade,[24] countries that fail to adopt its minimal standards risk being shut out of lucrative markets, such as that of the United States. Consequently, countries that once provided little or no patent protection for drugs were forced to expand patent rights.[25]

TRIPS Article 31(b) provides members with a right to invoke national laws permitting the government to use patented inventions without permission and to issue a compulsory license authorizing a third party to practice the patented invention.[26] Such use must relate to a public interest, counter anticompetitive conduct, or be for noncommercial government use.[27] Generally, a member must first attempt to obtain an agreement from

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[22] *Frequently Asked Questions About TRIPS [Trade-Related Aspects of Intellectual Property Rights] in the WTO*, WORLD TRADE ORG., https://www.wto.org/english/tratop_e/trips_e/tripfq_e.htm (last visited Aug. 9, 2021); *Members and Observers*, WORLD TRADE ORG., https://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm (last visited Aug. 9, 2021).

[23] *See* Ruth L. Okediji, *Legal Innovation in International Intellectual Property Relations: Revisiting Twenty-One Years of the TRIPS Agreement*, 36 U. PA. J. INT'L L. 191, 202–03, 206 (2014) (noting that TRIPS raised minimum standards of IP protection, including making broad changes in international patent law, and provided a means for resolving disputes); Cynthia M. Ho, *Patent Breaking or Balancing?: Separating Strands of Fact from Fiction Under TRIPS*, 34 N.C. J. INT'L L. & COM. REG. 371, 384 n.45 (2009) [hereinafter Ho, *Breaking or Balancing*] (discussing the WTO dispute resolution process); Rochelle Cooper Dreyfuss & Andreas F. Lowenfeld, *Two Achievements of the Uruguay Round: Putting TRIPS and Dispute Settlement Together*, 37 VA. J. INT'L L. 275, 277 (1997) (discussing the significance of TRIPS creating a mechanism for enforcing IP disputes among nations).

[24] *See* Srividhya Ragavan, PATENT AND TRADE DISPARITIES IN DEVELOPING COUNTRIES 63–64 (2012) (noting how TRIPS linked IP to trade for the first time). Note that forty-six Least-Developed Countries are currently exempt from the drug patent requirements under TRIPS. *Least Developed Countries (LDCs)*, UNITED NATIONS, https://www.un.org/development/desa/dpad/least-developed-country-category.html (last visited Oct. 20, 2021); *WTO Members Agree to Extend Drug Patent Exemption for Poorest Member*s, WORLD TRADE ORG. (Nov. 6, 2015), https://www.wto.org/english/news_e/news15_e/trip_06nov15_e.htm.

[25] *See* Okediji, *supra* note 23, at 227–30 (discussing how Brazil and India strengthened patent protection for pharmaceuticals because of TRIPS).

[26] *See* TRIPS, *supra* note 5, art. 31 (providing conditions for permitting the unauthorized use of patents "by the government or third parties authorized by the government"). *See also* Ho, *Breaking or Balancing*, *supra* note 23, at 395 (observing that the preamble of Article 31 "permits nations to issue compulsory licenses not only for governmental manufacture of patented inventions, but also for a government authorized third party").

[27] TRIPS, *supra* note 5, art. 31(b); Jerome H. Reichman, *Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options*, 37 J.L. MED. & ETHICS 247, 248 (2009) (discussing

the patent holder "on reasonable commercial terms."[28] However, during "a national emergency or other circumstances of extreme urgency," the member need only notify the patent holder "as soon as reasonably practicable."[29] TRIPS places no restrictions on the types of inventions that can be subject to a compulsory license.[30]

Article 31(f) states that any use of a patent without permission "shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use."[31] This provision originally prohibited countries from using compulsory licenses to produce medicines for export, which disadvantaged countries that lacked the means for producing needed drugs domestically.[32] The WTO subsequently adopted the 2001 Doha Declaration on the TRIPS Agreement and Public Health, which emphasized that TRIPS supports "WTO members' right to protect public health" and "promote access to medicines for all."[33] The Doha Declaration reiterated that members have a broad right to determine the grounds upon which a compulsory license is granted and clarified that "public health crises . . . can represent a national emergency or other circumstances of extreme urgency."[34] It further directed the TRIPS Council to find a solution for low-income members that lacked the resources to produce their own drugs under license.[35]

Two years later, the WTO created a waiver to Article 31(f) that permitted members to issue compulsory licenses to export drugs to countries that asked for permission; the waiver was subsequently codified under TRIPS Article 31*bis*.[36] However, the United States, EU member states, and many others opted out of the ability to import drugs

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how governments may "grant compulsory licenses on virtually any ground—including public interest, abuse or anti-competitive conduct, or for noncommercial government use").

[28] TRIPS, *supra* note 5, art. 31(b).

[29] *Id.*

[30] *Id.*

[31] TRIPS, *supra* note 5, art. 31(f).

[32] *See* Reichman, *supra* note 27, at 248 (noting that, although Article 31 allowed developing countries to issue compulsory licenses, "most of these countries lacked the capacity to manufacture the drugs in question, or otherwise to obtain the key active ingredients," making Article 31 "an empty gesture").

[33] World Trade Organization, Ministerial Declaration of 14 November 2001, WTO Doc. WT/MIN(01)/DEC/1, 41 ILM 746 (2002).

[34] *Id.*

[35] *Id.*

[36] TRIPS, *supra* note 5, art. 31*bis*.

manufactured in other countries under a compulsory license.[37] These countries would need to take steps to opt back in.[38]

When compulsory licensing safeguards were incorporated into TRIPS, the goal was to lessen the negative impact of patent rights on public health in low- and middle-income countries. However, since that time, there has been growing awareness that compulsory licensing can be a valuable tool for wealthy countries with mature patent systems.[39] Moreover, if high-income countries were to purchase drugs that were produced under licenses from these countries, it would improve economies of scale and could lead to lower drug costs for everyone.[40]

B. *The U.S. Approach to Compulsory Licenses for Safeguarding Public Health*

The U.S. government once ignored patent rights when entering into drug-procurement contracts. However, as the pharmaceutical industry grew and became more influential, federal agencies stopped manufacturing and importing drugs without permission. Instead, the United States began punishing countries that lawfully used compulsory licensing under TRIPS. Although the Biden administration has signaled support for compulsory licensing in the context of the COVID-19 pandemic, it is unclear whether future administrations will be as supportive.

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[37] Ed Silverman, *Wealthy Nations Urged to Embrace WTO Deal and Import Meds Made Under Compulsory Licenses*, STAT (Apr. 7, 2020), https://www.statnews.com/pharmalot/2020/04/07/wto-compulsory-licensing-covid19-coronavirus-patents/. *See also* Frederick M. Abbott & Jerome H. Reichman, *Facilitating Access to Cross-Border Supplies of Patented Pharmaceuticals: The Case of the COVID-19 Pandemic*, 23 J. INT'L ECON. L. 535, 558–60 (2020) (describing the opt out by high-income countries as "a misguided effort to protect the commercial interests of their pharmaceutical companies notwithstanding the most severe public health emergencies"). Note that the EU Commissioner for Trade, Phil Hogan, has stated that the EU is open to changing its status to allow it to import drugs under compulsory license. *See* Letter from Phil Hogan, Member of the Eur. Trade Comm'n, to Bernd Lange, Chairman of the Comm. on Int'l Trade for the Eur. Parliament (May 26, 2020), https://www.politico.eu/wp-content/uploads/2020/06/Van-Brempt-2.pdf.

[38] *See* Abbott & Reichman, *supra* note 37, 559–60 (2020) (discussing the different ways that countries could opt back in to being able to import drugs made under compulsory license); *see also* James Love, *Open Letter Asking 37 WTO Members to Declare Themselves Eligible to Import Medicines Manufactured Under Compulsory License in Another Country, Under 31bis of TRIPS Agreement*, KNOWLEDGE ECOLOGY INT'L (Apr. 7, 2020), https://www.keionline.org/32707 (urging countries that opted out of importing drugs manufactured under compulsory license to reverse their positions).

[39] *See* Kyung-Bok Son, *Importance of the Intellectual Property System in Attempting Compulsory Licensing of Pharmaceuticals: A Cross-Sectional Analysis*, 15 GLOBALIZATION & HEALTH 42, 43–44 (2019) (discussing the positive role that compulsory licensing can play in developed countries with established patent systems).

[40] *See* Carlos M. Correa, *TRIPS Agreement and Access to Drugs in Developing Countries*, 2 SUR INT'L J. HUM. RTS. 25, 35 (2005) (noting the problem that small, poor countries face in producing drugs under compulsory license with economies of scale).

1. *U.S. Legal Landscape for Third-Party Patent Use*

The United States has two major statutes that address government and third-party use of patented inventions without patent-holder permission. First, 28 U.S.C. § 1498 provides "reasonable and entire compensation" to patent holders whose inventions are used by the government or its contractors.[41] Second, the Bayh-Dole Act provides agencies that fund research resulting in patents with "march-in rights," and it theoretically permits third parties to apply for a compulsory license.[42] The government may also facilitate drug production by utilizing the Defense Production Act (DPA) to acquire raw materials and obtain access to manufacturing facilities.[43]

a. 28 U.S.C. § 1498

Until the early twentieth century, no statute permitted patent holders to sue the United States for patent infringement.[44] The government enjoys sovereign immunity under the U.S. Constitution and cannot be sued without its "unequivocally expressed" consent.[45] In 1894, the Supreme Court held that because the government had not waived its immunity for tort actions, it could not be sued for patent infringement.[46] Between 1910 and 1918, Congress passed legislation consenting to suit for direct,[47] and later indirect, patent infringement.[48] The early legislation was shaped by World War I, with a 1918 Act extending immunity to third-party contractors to ensure that the government could procure needed equipment.[49]

In 1948, Congress passed 28 U.S.C. § 1498, which remains in effect today.[50] This statute grants patent holders a limited right to sue the U.S. government for patent infringement for "reasonable and entire compensation

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[41] 28 U.S.C. § 1498.

[42] An Act to Amend the Patent and Trademark Laws (Bayh-Dole Act), Pub. L. No. 96-517, 94 Stat. 3015 (1980) (codified as amended at 35 U.S.C. §§ 200–211, 301–307).

[43] 50 U.S.C. § 4511 (effective Jan. 1, 2022).

[44] *See* Gerald J. Mossinghoff & Robert F. Allnutt, *Patent Infringement in Government Procurement: A Remedy Without a Right?*, 42 NOTRE DAME LAW. 5, 6–7 (1966) (noting that, prior to 1910, no suit could be brought for patent infringement by the United States due to its failure to consent to being sued for patent infringement). For a detailed history of the government use of patented inventions under 28 U.S.C. § 1498, see Christopher J. Morten & Charles Duan, *Who's Afraid of Section 1498? A Case for Government Patent Use in Pandemics and Other National Crises*, 23 YALE J.L. & TECH. 1, 4–13 (2020).

[45] United States v. Nordic Vill., Inc., 503 U.S. 30, 33 (1992).

[46] Schillinger v. United States, 155 U.S. 163, 169 (1894).

[47] Act of June 25, 1910, ch. 423, 36 Stat. 851 (current version at 28 U.S.C. § 1498). *See also* Crozier v. Fried. Krupp Aktiengesellschaft, 224 U.S. 290, 304–05 (1912) (discussing the scope of the Act of June 25, 1910).

[48] Act of July 1, 1918, ch. 114, 40 Stat. 705 (current version at 28 U.S.C. § 1498). *See also* Richmond Screw Anchor Co. v. United States, 275 U.S. 331, 343–44 (1928) (noting the statute was amended to shield government contractors from patent infringement liability).

[49] *Richmond Screw Anchor Co.*, 275 U.S. at 345.

[50] 28 U.S.C. § 1498.

for such use and manufacture" of the patented invention.[51] The government may therefore procure goods of any sort at a lower price, regardless of whether there is an emergency.[52] All § 1498 cases must be filed in the United States Court of Federal Claims, which does not offer jury trials.[53] Patent owners cannot obtain prospective relief,[54] so contractors are free to continue using the patent on the government's behalf, so long as the government pays compensation.

The United States Court of Appeals for the Federal Circuit (Federal Circuit) and the precursor of the Court of Federal Claims both cautioned that § 1498's remedy is "not completely analogous" to those under the Patent Act.[55] Nevertheless, courts rely on case law from the Patent Act, applying the *Georgia-Pacific* factors for assessing a reasonable royalty.[56] The Federal Circuit further maintains that "lost profits should be recoverable in at least some infringement actions against the government,"[57] though such awards appear to be uncommon.[58] The amount of compensation that the patent

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[51] *Id.* This right extends to assignees and exclusive licensees. *See* Lionel Marks 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, 420 n.166 (1995) (discussing relevant cases).

[52] *See* W.L. Gore & Assocs., Inc. v. Garlock, Inc., 842 F.2d 1275, 1282 (Fed. Cir. 1988) (quoting TVI Energy Corp. v. Blane, 806 F.2d 1057, 1060 (Fed. Cir. 1986)) (noting § 1498 remains broad enough "so as not to limit the Government's freedom in procurement by considerations of private patent infringement").

[53] Suits against the U.S. government must be brought in the United States Court of Federal Claims, which does not offer jury trials. 28 U.S.C. § 1498. *See also* Mark A. Lemley, *Why Do Juries Decide If Patents Are Valid?*, 99 VA. L. REV. 1673, 1717 (2013) (noting that "trials in the Court of Claims are to judges, not juries, even though [under 28 U.S.C. § 1498] damages are the only remedy available").

[54] *See* Coakwell v. United States, 372 F.2d 508, 511 (Ct. Cl. 1967) (noting § 1498 was enacted "for the purpose of enabling the Government to purchase goods for the performance of its functions without the threat of having the supplier enjoined from selling patented goods to the Government"); *TVI Energy*, 806 F.2d at 1059–60 (observing that legislative history supports that the purpose of § 1498 "was to relieve private Government contractors from expensive litigation with patentees, possible injunctions, payment of royalties, and punitive damages," and holding that § 1498 immunity extends to a competitor for a government contract). *See also* LiLan Ren, Comment, *A Comparison of 28 U.S.C. § 1498(A) and Foreign Statutes and an Analysis of § 1498(A)'s Compliance with TRIPS*, 41 HOUS. L. REV. 1659, 1665 (2005) (discussing the broad reach of § 1498); Paul Janicke, *Current State of U.S. Patent Law Regarding Infringement of Drug Patents by the Government*, UNIV. HOUS. L. CTR. (Dec. 7, 2001), https://www.law.uh.edu/healthlaw/perspectives/Food/011207Current.html (noting the provision's "requirements for 'authorization or consent' by the government are quick and virtually automatic in practice" and do not entail any formalities).

[55] Gargoyles, Inc. v. United States, 113 F.3d 1572, 1576 (Fed. Cir. 1997) (quoting Leesona Corp. v. United States, 599 F.2d 958, 968 (Ct. Cl. 1979)).

[56] *Id.* at 1580 (applying Georgia-Pacific Corp. v. U.S. Plywood Corp., 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970), *modified and aff'd*, 446 F.2d 295, 302 (2d Cir. 1971)). In *Georgia-Pacific*, the district court created fifteen factors to guide the court in computing reasonable royalty damages for patent infringement. *Georgia-Pacific Corp.*, 318 F. Supp. at 1120.

[57] *Gargoyles, Inc.*, 113 F.3d at 1576. *Panduit Corp. v. Stahlin Bros. Fibre Works, Inc.*, 575 F.2d 1152 (6th Cir. 1978), established four factors that a patent holder must prove for the court to award lost profits under 35 U.S.C. § 284 on sales that the patent holder would have made but for the infringement. The factors include: "(1) demand for the patented product, (2) absence of acceptable noninfringing substitutes, (3) his manufacturing and marketing capability to exploit the demand, and (4) the amount of the profit he would have made." *Id.* at 1156.

[58] *See* Morten & Duan, *supra* note 44, at 44 (discussing the availability of lost profits).

holder receives through this process is generally less than what the Patent Act allows.[59]

The attitude of the U.S. government towards using patents without permission has varied dramatically over the years. In the 1930s and 1940s, the government sometimes considered whether a bidder for a government contract had permission to use patented technology.[60] From the late 1950s through at least the 1960s, however, some U.S. agencies did not consider patent rights in evaluating bids for goods or services,[61] leading the government to import patented drugs like tetracycline merely to reduce costs.[62]

In the early 2000s, after several people received anthrax in the mail, the government sought to procure a supply of Bayer's ciprofloxacin antibiotic.[63] The drug cost $4.67 per tablet wholesale and $5 to $7 per tablet retail, although Bayer offered to sell it to the government for $1.75 to $1.83 per tablet.[64] People began pressuring the U.S. government to utilize § 1498, including Senator Chuck Schumer.[65] During this time, Canada licensed a domestic company to manufacture the drug without Bayer's permission[66]

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[59] Under the Patent Act, someone who willfully infringes a patent may be forced to pay up to treble damages and attorney fees. 35 U.S.C. §§ 284–285 (noting in § 284 that "the court may increase the damages up to three times the amount found or assessed," and authorizing in § 285 that "[t]he court in exceptional cases may award reasonable attorney fees to the prevailing party"). That is not available under 28 U.S.C. § 1498.

[60] *See* Comptroller Gen. McCarl to the Sec'y of Com., 13 Comp. Gen. 173 (1933) (noting that, if the use of a valid patent is required to manufacture supplies for the U.S. government, "bidders properly may be required to show legal right to use the patents"); Mossinghoff & Allnut, *supra* note 44, at 761 (discussing statements by the Comptroller General in 1933 and 1944 regarding patent rights).

[61] *See* Mossinghoff & Allnutt, *supra* note 44, at 762 (writing in 1966 that a then-present policy of agencies not considering patent infringement liability in evaluating contract bids or proposals was first established in 1958); Hannah Brennan, Amy Kapczynski, Christine H. Monahan & Zain Rizvi, *A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health*, 18 YALE J.L. & TECH. 275, 304 (2016) (discussing how there were "multiple federal agencies deliberately 'purchas[ing] certain drug products covered by U.S. product and process patents, from unlicensed sources for use in the United States in deliberate violation of these patents'") (quoting *Patent Infringement: Hearing on S. 1047 Before the Subcomm. on Patents, Trademarks, & Copyrights of the S. Comm. on the Judiciary*, 89th Cong. 15 (1965)).

[62] In the late 1950s, the U.S. Military Medical Supply Agency ("MMSA") concluded that the price of tetracycline was too high at $17.25 per bottle and entered into an agreement with an Italian firm to produce it for $8.50 per bottle. MILTON M. SILVERMAN & PHILIP R. LEE, PILLS, PROFITS, AND POLITICS 187 (1974). The authors note that, in about three years, MMSA utilized § 1498 "for approximately fifty drug purchases, saving American taxpayers roughly $21 million." *Id.* Note that, at the time, Italy did not offer patents for drugs. Brennan et al., *supra* note 61, at 304–05.

[63] *See* Lody Petersen & Robert Pear, *A Nation Challenged: CIPRO; Anthrax Fears Send Demand for a Drug Far Beyond Output*, N.Y. TIMES, Oct. 16, 2001, at A1.

[64] *See* Keith Bradsher & Edmund L. Andrews, *A Nation Challenged: CIPRO; U.S. Says Bayer Will Cut Cost of Its Anthrax Drug*, N.Y. TIMES, Oct. 24, 2001, at B7 (discussing how the United States' successful negotiation with Bayer came immediately after Canada issued a compulsory license and used it as leverage).

[65] Morten & Duan, *supra* note 44, at 27.

[66] *Patent Protection Versus Public Health*, 358 LANCET 1563, 1563 (2001).

and subsequently negotiated with Bayer a price of $1.30 per tablet.[67] Meanwhile, Health and Human Services Secretary Tommy Thompson initially refused to "break" Bayer's patent, claiming that it was not legal.[68] But he later reversed course, threatening to buy generic ciprofloxacin and maintaining that he would ask Congress to legislatively deny Bayer any compensation.[69] Consequently, the day after the Canadian arrangement was made, the U.S. government succeeded in negotiating a price of $0.95 per tablet for an order of 100 million tablets.[70] Although § 1498 was not used in the end, Bayer admitted that the threat of compulsory licensing motivated it to reach a voluntary agreement.[71]

During the Avian Flu outbreak of 2005, some members of Congress, including Senator Schumer, called for the government to utilize § 1498 to alleviate a shortage of Roche's Tamiflu.[72] The Congressional Research Service reported that "[t]he threat of compulsory licensing (or imposing other legal limitations on Roche's patent rights) may have played a role in persuading Roche" to license Tamiflu to nineteen generic manufacturers to increase the supply.[73]

Although the government has not licensed drug patents without permission for several decades, it frequently does so for defense technology. In *FastShip, LLC v. United States*, the Court of Federal Claims awarded approximately $7.8 million in attorneys' fees, following a $12.36 million damages award, for the U.S. Navy's infringement of the company's ship patents.[74] In *Hitkansut LLC v. United States*, the Federal Circuit affirmed

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[67] *See id.* (noting Bayer responded to Canada overriding its patent "by donating a large amount of Cipro to Canada, and promising more in the event of an emergency, which led the Canadian government to agree to acquire ciprofloxacin exclusively from Bayer for the duration of the patent agreement").

[68] Morten & Duan, *supra* note 44, at 30.

[69] Bradsher & Andrews, *supra* note 64.

[70] *See id.* (noting that the day after Canada secured a $1.30 per tablet price, the U.S. government succeeded in negotiating a $0.95 per tablet price); Fred Charatan, *Bayer Cuts Price of Ciprofloxacin After Bush Threatens to Buy Generics*, 323 BMJ 1023, 1023 (2001) (discussing Bayer's agreement "to sell 100 million tablets of ciprofloxacin to the government at [$0.95]" per tablet).

[71] *See* Bayer Aktiengesellschaft, Registration Statement Pursuant to Section 12(b) or 12(g) of the Securities Exchange Act of 1934 (Form 20FR12B/A) (Jan. 14, 2002) (discussing how Canada and the United States contemplated using compulsory licensing, leading to Bayer reaching an agreement to provide ciprofloxacin "while preserving our existing patent rights").

[72] Press Release, Charles E. Schumer, U.S. Senator for New York, As Avian Flu Closes In on U.S., Schumer Calls for Immediate Action: Demands Suspension of Tamiflu Patent so Vaccine Can Be Mass-Produced, Dramatically Increasing Supply (Aug. 1, 2006), https://www.schumer.senate.gov/newsroom/press-releases/as-avian-flu-closes-in-on-us-schumer-calls-for-immediate-action-demands-suspension-of-tamiflu-patent-so-vaccine-can-be-mass-produced-dramatically-increasing-supply. *See* CONG. RSCH. SERV., RL33159, INFLUENZA ANTIVIRAL DRUGS AND PATENT LAW ISSUES (2007) (noting that, "[i]n response to the heightened demand for the drug, as well as faced with threatened abrogation of its patent rights by U.S. politicians and government officials in other countries," Roche voluntarily licensed its Tamiflu patents).

[73] CONG. RSCH. SERV., *supra* note 72, at 9.

[74] 153 Fed. Cl. 215, 219–20 (2021).

approximately $4.4 million in attorneys' fees, following a $200,000 damages award, for Oak Ridge National Laboratory's unauthorized use of Hitkansut's patented method.[75] Because the government need not notify patent holders when it uses patents without permission, patent holders may not realize when their patents are being infringed. Consequently, one can only guess how widespread the government's practice of licensing defense-related inventions without permission is. Moreover, defense contractors that frequently do business with the U.S. government may be reluctant to sue for compensation.

In recent years, scholars and elected officials have proposed utilizing § 1498 to lower U.S. drug prices. Amy Kapczynski and Aaron S. Kesselheim proposed that the government authorize hepatitis C antiviral drugs for Medicaid patients.[76] In 2018, Representative Lloyd Doggett and Senator Sherrod Brown introduced legislation that would permit the government to negotiate with pharmaceutical companies for drugs covered under Medicare and issue compulsory licenses when voluntary agreements could not be reached.[77] Although the legislation had support from 104 House Democrats,[78] it failed to gain traction among House Republicans, and conservative commentators denounced it.[79] Indeed, during a Senate committee hearing, the United States Department of Health and Human Services (HHS) Secretary Alex Azar referred to the practice as "socialist compulsory licensing,"[80] notwithstanding the U.S. government's regular use of it for defense purposes.

b. The Bayh-Dole Act

Prior to 1980, government agencies lacked a consistent position on whether to allow federal grant recipients to patent their resulting

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[75] 958 F.3d 1162, 1170 (Fed. Cir. 2020); Hitkansut LLC v. United States, 130 Fed. Cl. 353, 394 (2017), *aff'd without opinion*, 721 F. App'x 992, 993 (Fed. Cir. 2018) (per curiam).

[76] Amy Kapczynski & Aaron S. Kesselheim, *'Government Patent Use': A Legal Approach to Reducing Drug Spending*, 35 HEALTH AFFS. 791, 792 (2016) (noting that the government could utilize § 1498 to lower the price of hepatitis C drugs for Medicaid patients).

[77] *See* Rena M. Conti & Paul Kleutghen, *Is 'Competitive Licensing' Proposed in HR 1046 Practical for Lowering Drug Prices?*, HEALTH AFFS. BLOG (July 29, 2019), https://www.healthaffairs.org/do/10.1377/hblog20190724.85223/ (discussing HR 1046).

[78] Medicare Negotiation and Competitive Licensing Act of 2018, H.R. 6505, 115th Cong. (2018).

[79] *See*, *e.g.*, Elizabeth Wright, *Compulsory Pharmaceutical Licensing Is Little More Than Government Theft*, HILL (Aug. 4, 2018, 7:05 PM), https://thehill.com/opinion/healthcare/400415-compulsory-pharmaceutical-licensing-is-little-more-than-government-theft (characterizing compulsory licensing as "government theft"); Peter J. Pitts, *Doggett-Brown Bill Destroys Drug Innovation*, INSIDESOURCES (Apr. 23, 2019), https://www.insidesources.com/doggett-brown-bill-destroys-drug-innovation/ (maintaining, as FDA Associate Commissioner for External Relations under President George W. Bush, that HR 1046 would harm innovation).

[80] James Love, *Hits and Misses from the Senate HELP Committee Hearing on the President's Blueprint for Lower Drug Prices*, BILL OF HEALTH (June 14, 2018), https://blog.petrieflom.law.harvard.edu/2018/06/14/hits-and-misses-from-the-senate-help-committee-hearing-on-the-presidents-blueprint-for-lower-drug-prices/.

inventions.[81] The Bayh-Dole Act authorized the commercialization and patenting of such inventions.[82] Funding recipients must comply with various requirements, such as providing a detailed disclosure of the invention to the funding agency and notifying the agency if it plans to seek a patent.[83] This allows the agency to determine whether "exceptional circumstances" exist, meriting government use of the patent.[84] If proper disclosures are not made, the agency can obtain title to the invention.[85]

The funding agency retains "march-in rights" for resulting patented inventions, which allows it to license the invention "upon terms that are reasonable under the circumstances" in several situations.[86] For example, it may grant a license if the patent holder "has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application,"[87] with "practical application" requiring that the invention's "benefits are . . . available to the public on reasonable terms."[88] It may also grant a license if "necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees."[89]

The funding agency's right is a "nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world."[90] Consequently, the government and its contractors need not pay the patent holder royalties.[91] This is different from § 1498, which allows the patent

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[81] *See* Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 VA. L. REV. 1663, 1671–91 (1996) (reviewing the history of patenting government-sponsored research).

[82] An Act to Amend the Patent and Trademark Laws (Bayh-Dole Act), Pub. L. No. 96-517, 94 Stat. 3015, 3019 (1980). Note that, although the Bayh-Dole Act initially permitted only small businesses and nonprofit organizations to commercialize inventions resulting from government-funded research, such permission later expanded to all businesses by executive order. Eisenberg, *supra* note 81, at 1665.

[83] 35 U.S.C. § 202(c)(1); 37 C.F.R. § 401.14(c)(1)–(2) (2021).

[84] 35 U.S.C. § 202(a).

[85] 37 C.F.R. § 401.14(d)(1) (2021).

[86] 35 U.S.C. § 203(a).

[87] *Id.* § 203(a)(1).

[88] *Id.* § 201(f). Some commentators have argued that this section allows the government to march in if the subject invention is offered to the public at an unreasonable price. *See* Gerald Barnett, *Bayh-Dole Basics, 8: Reasonable Terms*, RSCH. ENTER. (May 29, 2019), https://researchenterprise.org/2019/05/29/bayh-dole-basics-8-reasonable-terms/ (noting "the terms on which the public has access to benefits *necessarily must include price*—arguably non-discriminatory and non-exploitative pricing"); Peter S. Arno & Michael H. Davis, *Why Don't We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed upon Patents Deriving in Whole or in Part from Federally Funded Research*, 75 TULANE L. REV. 631, 650–53 (2001) (maintaining that "reasonable terms" in the Bayh-Dole Act includes price).

[89] 35 U.S.C. § 203(a)(2).

[90] *Id.* § 202(c)(4).

[91] *See id.* (noting that the government's nonexclusive license is "paid-up"); WENDY H. SCHACHT, CONG. RSCH. SERV., RL32076, THE BAYH-DOLE ACT: SELECTED ISSUES IN PATENT POLICY AND THE COMMERCIALIZATION OF TECHNOLOGY 16 (2012) (noting that 35 U.S.C. § 202(c)(4) provides the government with a royalty-free license).

owner to sue for compensation. However, the royalty-free license only applies to inventions that the government helped fund; it does not automatically attach to other related patents.[92] Furthermore, a third party that petitions an agency for march-in rights would still be obligated to pay compensation "upon terms that are reasonable under the circumstances."[93]

The Bayh-Dole Act was supposed to strike a balance—"promot[ing] the utilization of inventions arising from federally supported research or development" while "protect[ing] the public against nonuse or unreasonable use of inventions."[94] By permitting universities to partner with private biotechnology companies, Congress may have helped bring more new drugs to market.[95] However, the Bayh-Dole Act has contributed to "[t]he blurring of the boundary between commercial and noncommercial research."[96] It has forced the public to pay for inventions twice: first by funding government research grants through taxation and then by purchasing the resulting inventions at inflated prices because of patent protection and the domestic manufacturing requirement.[97] If patents are supposed to incentivize research, it is unclear why the public should fund the underlying research and absorb the risk.[98]

March-in rights are generally unsuitable for public-health emergencies. To date, no agency has been willing to exercise them, even during drug shortages.[99] The petitioning process is too cumbersome for agencies and

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[92] SCHACHT, *supra* note 91, at 16.

[93] 35 U.S.C. § 203(a). *See* JOHN R. THOMAS, CONG. RSCH. SERV., R44597, MARCH-IN RIGHTS UNDER THE BAYH-DOLE ACT 8 (2016), https://sgp.fas.org/crs/misc/R44597.pdf (noting that march-in rights recipients "would presumably pay royalties to the patent proprietor").

[94] 35 U.S.C. § 200.

[95] *See* Daniel J. Hemel & Lisa Larrimore Ouellette, *Bayh-Dole Beyond Borders*, 4 J.L. & BIOSCIENCES 282, 288–89 (2017) (discussing the commercialization theory supporting Bayh-Dole).

[96] Katherine J. Strandburg, *What Does the Public Get? Experimental Use and the Patent Bargain*, 2004 WIS. L. REV. 81, 86.

[97] *See* Bd. of Trs. of Leland Stanford Junior Univ. v. Roche Molecular Sys., Inc., 563 U.S. 776, 796 (2011) (Breyer, J., dissenting) (maintaining that legal rules must produce some community benefit under Bayh-Dole because, otherwise, "[w]hy should the public have to pay twice for the same invention?"); Rochelle Cooper Dreyfuss, *Collaborative Research: Conflicts on Authorship, Ownership, and Accountability*, 53 VAND. L. REV. 1161, 1194 (2000) (discussing how the public pays twice under Bayh-Dole); *see also* Okediji, *supra* note 23, at 211 n.81 (maintaining that Bayh-Dole is "arguably . . . an impermissible subsidy under the GATT rules").

[98] *See* Eisenberg, *supra* note 81, at 1668–69 (suggesting that because the public has paid for the underlying research and absorbed the risk, perhaps the resulting inventions should pass into the public domain).

[99] *See* THOMAS, *supra* note 93, at 8–10 (discussing six unsuccessful march-in rights petitions from third parties). There are some reports of the government threatening to use march-in rights to obtain a license for a third party. *See* JAMES PACKARD LOVE, KNOWLEDGE ECOLOGY INT'L, RECENT EXAMPLES OF THE USE OF COMPULSORY LICENSES ON PATENTS (2007); *Memorandum of Understanding*, UNIV. OF WIS. (Sept. 5, 2001), https://news.wisc.edu/memorandum-of-understanding/ (claiming that HSS used the threat of using march-in rights to get the University of Wisconsin to license out patents on stem-cell lines).

involves a detailed hearing for the patent holder.[100] Moreover, if the license-seeker were to prevail, the agency's determination would not take effect until the contractor exhausted all appeals,[101] which could take years.

2. *U.S. Reaction to Foreign Compulsory Licensing of Pharmaceutical Patents*

For years, the U.S. government strongly opposed the compulsory licensing of pharmaceuticals. Republican and Democratic administrations threatened countries seeking to use them with trade sanctions and maintained that it undermines TRIPS's minimum protections.[102] U.S. pharmaceutical companies have also retaliated against countries that license their drugs.[103]

For example, South Africa passed the Medicines and Related Substances Control Amendment Act of 1997 to improve access to essential medicines through methods including compulsory licensing and parallel importation.[104] At the time, a three-drug cocktail for treating HIV patients cost between $10,000 and $15,000 a year, but Indian generic manufacturer Cipla produced it for substantially less.[105] The Pharmaceutical Manufacturers' Association of South Africa and forty-one pharmaceutical companies sued, claiming that South Africa was violating TRIPS,[106] notwithstanding the permissibility of compulsory

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[100] *See* 37 C.F.R. § 401.6(e) (2021) (providing the procedural requirements for utilizing march-in rights, including a factfinding hearing that "should afford the contractor the opportunity to appear with counsel, submit documentary evidence, present witnesses and confront such persons as the agency may present").

[101] 35 U.S.C. § 203(b); *see also* Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 LAW & CONTEMP. PROBS. 289, 294 (2003) (noting that "the Bayh-Dole Act seriously limits the value of march-in rights as a mechanism for achieving prompt dissemination by deferring such rights from taking effect pending elaborate administrative proceedings and exhaustion of court appeals").

[102] *See, e.g.*, HO, ACCESS TO MEDICINE, *supra* note 16, at 151 (discussing how the United States retaliated against Thailand's use of compulsory licenses under both the W. Bush and Obama administrations).

[103] *See id.* at 149–50 (discussing how Abbott retaliated against Thailand after it issued a compulsory license on Kaletra); WILLIAM W. FISHER III & TALHA SYED, *Chapter 6: Sticks*, *in* INFECTION: THE HEALTH CRISIS IN THE DEVELOPING WORLD AND WHAT WE SHOULD DO ABOUT IT 8 (Jan. 18, 2020) (available at http://ccb.ff6.mwp.accessdomain.com/P/Infection.htm) (observing that "the pharmaceutical firms disadvantaged by compulsory licenses and the governments of the countries in which those firms are based sometimes retaliate (or threaten to retaliate) against the countries that use them").

[104] *See* Heinz Klug, *Access to Medicines and the Transformation of the South African State: Exploring the Interactions of Legal and Policy Changes in Health, Intellectual Property, Trade, and Competition Law in the Context of South Africa's HIV/AIDS Pandemic*, 37 LAW & SOC. INQUIRY 297, 314 (2012) (discussing the legislation); *see also The Price of Africa's Cheap Drugs*, ECONOMIST (Apr. 19, 2001), http://www.economist.com/node/578891 (noting that South Africa was negotiating with Indian generic manufacturer Cipla to cheaply obtain AIDS drugs).

[105] *See* Katherine Eban, *How an Indian Tycoon Fought Big Pharma to Sell AIDS Drugs for $1 a Day*, QUARTZ INDIA (July 15, 2019), https://qz.com/india/1666032/how-indian-pharma-giant-cipla-made-aids-drugs-affordable/ (discussing how Cipla is able to sell generic AIDS drugs for significantly less than the name-brand versions).

[106] Notice of Motion, *Pharm. Mrfs.' Ass'n of S. Afr. v. President of the Republic of S. Afr.* 1998, Case Number 4183/98 (S. Afr.), http://www.cptech.org/ip/health/sa/pharmasuit.html.

licensing under Article 31(b). Three U.S. companies—Bristol-Myers Squibb; Merck & Co., Inc.; and Eli Lilly and Company—participated in the litigation.[107]

The Pharmaceutical Research and Manufacturers of America (PhRMA) asked the U.S. trade representative to place South Africa under the Special 301 Review, characterizing South Africa as "a 'test case' for those who oppose the U.S. government's long-standing commitment to improve the terms of protection for all forms of American intellectual property, including pharmaceutical patents."[108] The Clinton administration's U.S. trade representative subsequently placed South Africa on the Special 301 Report's Watch List for two years in a row, putting its request for preferential tariff treatment on hold and later subjecting it to an out-of-cycle review.[109] Remarkably, the 1999 Report singled out South Africa for choosing to organize with other countries to support the use of compulsory licensing of pharmaceuticals under TRIPS.[110]

The U.S. government and other high-income countries' actions sparked public backlash. Thousands protested in support of South Africa, and both the EU and the World Health Organization expressed support.[111] The pharmaceutical companies involved in the lawsuit subsequently conceded that South Africa's law complied with TRIPS and eventually dropped suit.[112] President Clinton subsequently issued an executive order stating that the U.S. government would not seek the revocation of any law or policy of a sub-Saharan African country that was attempting to expand access to HIV/AIDS drugs for impacted areas.[113]

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[107] *Id.* at para. 2.4.

[108] *What Is the U.S. Role in Combating the Global HIV/AIDS Epidemic?: Hearing Before the Subcomm. on Crim. Just., Drug Pol'y, & Hum. Res. of the Comm. on Gov't Reform*, 106th Cong. 106–26 (1999); *id.* app. B at 163 (providing, according to its title, a "Timeline of Disputes over Compulsory Licensing and Parallel Importation in South Africa").

[109] OFF. OF THE U.S. TRADE REPRESENTATIVE, EXEC. OFF. OF THE PRESIDENT, 1998 SPECIAL 301 REPORT 1, 15, 21 (1998); OFF. OF THE U.S. TRADE REPRESENTATIVE, EXEC. OFF. OF THE PRESIDENT, 1999 SPECIAL 301 REPORT 1–2, 14, 22 (1999) [hereinafter 1999 SPECIAL 301 REPORT]; *see also* William W. Fisher III & Cyrill P. Rigamonti, *The South Africa AIDS Controversy: A Case Study in Patent Law and Policy*, LAW & BUS. OF PATENTS 1, 7 (2005), https://cyber.harvard.edu/people/tfisher/South%20Africa.pdf (discussing the United States' use of the Special 301 Watch List to pressure South Africa, and noting that this move brought South Africa "one step closer to the imposition of unilateral trade sanctions"); Sapna Kumar, *Innovation Nationalism*, 51 CONN. L. REV. 205, 240 (2019) (discussing the Clinton administration's actions against South Africa).

[110] *See* 1999 SPECIAL 301 REPORT, *supra* note 109, at 22 (maintaining that "South African representatives have led a faction" of countries "in calling for a reduction in the level of protection provided for pharmaceuticals in TRIPS"); *see also* Klug, *supra* note 104, at 315 (observing that the USTR had a problem with the patent protection in South Africa, as well as with the position it took in the global debate regarding the scope of TRIPS).

[111] Rachel L. Swarns, *Drug Makers Drop South Africa Suit over AIDS Medicine*, N.Y. TIMES, Apr. 20, 2001, at A6.

[112] *Id.* As the then-CEO of GlaxoSmithKlein noted, "We're a very major corporation. We're not insensitive to public opinion. That is a factor in our decision-making." *Id.*

[113] Exec. Order No. 13,155, 3 C.F.R. 13,155 (2001).

Although pharmaceutical interest groups such as PhRMA and the Biotechnology Innovation Organization (BIO) continue to characterize compulsory licensing as harmful,[114] the United States has begun to shift its position. In a surprising move, the Biden administration announced support for a TRIPS waiver of COVID-19-related patents for the duration of the pandemic.[115] Although such a waiver is far from certain, the support signifies that the Biden administration might be willing to tolerate compulsory licensing in the future when it is used by lower-income countries to produce lifesaving drugs.

C. *The Debate over Compulsory Licensing During Public Health Emergencies*

There is an ongoing debate regarding whether compulsory licensing should be utilized during public health emergencies. Points of disagreement include what the scope of TRIPS Article 31 is, whether compulsory licensing is helpful to low-income countries, and whether the practice is ethical.

1. *What Is the Scope of TRIPS Article 31?*

One point of disagreement is how broadly TRIPS Article 31 protects compulsory licensing. Some low-income countries use compulsory licensing to offset high drug prices,[116] and others claim that TRIPS permits working requirements that require patent holders to domestically produce patented goods.[117] Pharmaceutical industry groups, however, seek sanctions against countries that use compulsory licensing to deal with drug prices.[118] They also maintain that Article 27(1) prohibits working requirements and observe that the practice increases the cost of producing patented products.[119]

2. *Does Compulsory Licensing Help Low-Income Countries?*

Some groups argue that compulsory licensing does not help low-income countries. Conservative commentators and pharmaceutical lobby groups

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[114] *See* BIOTECHNOLOGY INNOVATION ORG., SPECIAL 301 SUBMISSION 9 (2021) (criticizing various governments' use and support of compulsory licensing); PHARM. RSCH. & MFRS. OF AM., SPECIAL 301 SUBMISSION 2 (2020) [hereinafter PHRMA SPECIAL 301 SUBMISSION] (characterizing compulsory licensing as a "harmful practice[]").

[115] Amy Maxmen, *In Shock Move, US Backs Waiving Patents on COVID Vaccines*, NATURE (May 6, 2021), https://www.nature.com/articles/d41586-021-01224-3.

[116] RAGAVAN, *supra* note 24, at 72.

[117] *See* HO, ACCESS TO MEDICINE, *supra* note 16, at 130–31 (discussing the United States' suit against Brazil for its working requirement).

[118] *See supra* notes 102–103 and accompanying text (discussing Thailand's use of compulsory licensing due to price).

[119] *See* HO, ACCESS TO MEDICINE, *supra* note 16, at 130–31 (observing that commentators are divided on the issue of whether working requirements violate TRIPS); Jay Taylor, *Compulsory Licensing: A Misused and Abused International Trade Law*, PHARM. RSCH. & MFRS. OF AM. (May 16, 2017), https://catalyst.phrma.org/compulsory-licensing-a-misused-and-abused-international-trade-law (asserting that working requirements violate TRIPS in his role as the Vice President of International Advocacy at PhRMA).

frequently cite to a single study by Reed Beall, Randall Kuhn, and Amir Attaran, which claims that international procurement markets yield better prices for low-income countries compared to compulsory licensing.[120] The study compared drug prices in similarly situated countries, some of which used compulsory licensing.[121] The researchers considered "the possibility that compulsory licensing activity in a given calendar year drove down contemporaneous international procurement prices," which, when factored, led to the international procurement price matching the compulsory licensing price.[122]

However, the study had a major limitation: the mere threat of compulsory licensing can impact drug prices,[123] as it did for Canada and the United States with ciprofloxacin. The authors conceded that their study "does not preclude the possibility that compulsory licenses can be advantageous under certain circumstances."[124] They further admitted the possibility that "these licenses have indirectly contributed to lowering international prices" and noted that "[t]he existence of compulsory licensing as a legal right *likely exerts a generalized downward pressure on global medicine prices*."[125]

3. *Is Compulsory Licensing Immoral or Unethical?*

Some commentators treat patents as a privileged type of property right[126] and characterize the use of compulsory licensing to control drug prices as theft or stealing.[127] Others maintain that compulsory licensing disrupts investment-backed expectations, which may reduce foreign direct investment.[128]

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[120] *See, e.g.*, PHRMA SPECIAL 301 SUBMISSION, *supra* note 114, at 23 n.90 (citing Reed F. Beall, Randall Kuhn & Amir Attaran, *Compulsory Licensing Often Did Not Produce Lower Prices for Antiretrovirals Compared to International Procurement*, 34 HEALTH AFFS. 493 (2015)); Christopher Holt & Will Rinehart, *The Folly of Compulsory Licensing*, AM. ACTION F. (Aug. 10, 2018), https://www.americanactionforum.org/weekly-checkup/the-folly-of-compulsory-licensing/ (citing the same); Wright, *supra* note 79 (citing the same).

[121] Beall, Kuhn & Attaran, *supra* note 120, at 494–98.

[122] *Id.* at 497.

[123] *See* Gorik Ooms & Johanna Hanefeld, *Threat of Compulsory Licenses Could Increase Access to Essential Medicines*, BMJ (May 28, 2019), https://www.bmj.com/content/365/bmj.l2098 (observing that "compulsory licenses also have power when governments warn patent owners that they will use them if necessary").

[124] Beall, Kuh & Attaran, *supra* note 120, at 498.

[125] *Id.* (emphasis added).

[126] Cynthia M. Ho, *Unveiling Competing Patent Perspectives*, 46 HOUS. L. REV. 1047, 1057–58 (2009) (discussing how some view patents "as a *privileged* property right").

[127] *See, e.g.*, Wright, *supra* note 79; Ronald A. Cass, *Patent Remedy*, WALL ST. J. (Aug. 28, 2007, 12:01 AM), https://www.wsj.com/articles/SB118824874547610202 (characterizing Thailand's use of a compulsory licensing as "effective theft of pharmaceutical companies' intellectual property").

[128] *See* Robert Bird & Daniel R. Cahoy, *The Impact of Compulsory Licensing on Foreign Direct Investment: A Collective Bargaining Approach*, 45 AM. BUS. L.J. 283, 284 (2008) (noting that

The analogy between patents and traditional property is somewhat strained.[129] Under U.S. law, patent infringement is a tort, and it is not covered under the Fifth Amendment's Takings Clause.[130] Patents are non-rivalrous goods that lack clear boundaries and provide only the right to exclude—rather than the right to use—an invention.[131] Patents also have at least some attributes of being a public right,[132] and their "boundaries" are heavily shaped by the U.S. Patent & Trademark Office.[133] In addition, the U.S. government can abolish the patent system at any time, which it cannot do for real property ownership.[134] There are, furthermore, no criminal penalties for patent infringement as there are for tangible property theft.[135]

Any moral judgments against compulsory licensing must be weighed against the death and disability resulting from limited drug access. As Margo Bagley noted, "[m]aking sure the poor have access to the drugs they need in order to live, in a way that does not harm the patent holder, should be viewed as part of the social bargain inherent in the patent system and deemed morally right, not morally wrong."[136] Examining the broader moral perspective, Bagley suggests that it might be more appropriate to view "the pharmaceutical companies trying to keep needed drugs from the poor as thieves."[137]

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compulsory licensing comes at the cost of "disrupt[ing] the investment-backed expectation of the property right").

[129] *See* Margo A. Bagley, *The Morality of Compulsory Licensing as an Access to Medicines Tool*, 102 MINN. L. REV. 2463, 2465 (2018) (questioning the analogy between patents and property).

[130] *See* Golden v. United States, 955 F.3d 981, 987 (Fed. Cir. 2020) (observing that "a cause of action under the Fifth Amendment is unavailable to patent owners alleging infringement by the government") (citing Schillinger v. United States, 155 U.S. 163, 168–69 (1894)).

[131] Bagley, *supra* note 129, at 2465.

[132] *See* Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC, 138 S. Ct. 1365, 1373 (2018) (holding that "[i]nter partes review falls squarely within the public-rights doctrine").

[133] *See* Bagley, *supra* note 129, at 2479 (observing that "patent rights are limited property rights at best" and noting "that their contours and scope are constantly being adjusted through judicial, legislative, and administrative action"); Sapna Kumar, *Life, Liberty, and the Pursuit of Genetic Information*, 65 ALA. L. REV. 625, 638–40 (2014) (noting that "unlike with real property, a government agency is involved in shaping the scope of the patent right at the outset").

[134] Article I, Section 8, Clause 8 of the Constitution grants Congress the power to create a patent system, but it does not require Congress to do so. U.S. CONST. art. I, § 8, cl. 8. *See also* Bagley, *supra* note 129, at 2479. By contrast, under the Fifth Amendment, the government cannot take property "without due process of law." U.S. CONST. amend. V. Note, however, that patent protection is required under Articles 27 and 28 of TRIPS. TRIPS, *supra* note 5, arts. 27–28.

[135] *See* Dowling v. United States, 473 U.S. 207, 227 (1985) (noting that, "[d]espite its undoubted power to do so, . . . Congress has not provided criminal penalties for distribution of goods infringing valid patents"). *See also* Irina D. Manta, *The Puzzle of Criminal Sanctions for Intellectual Property Infringement,* 24 HARV. J.L. & TECH. 469, 488 (2011) (noting that the only criminal provisions relating to U.S. patents are for forging a patent and falsely marking an invention as being patented).

[136] Bagley, *supra* note 129, at 2480–81 (footnotes omitted).

[137] *Id.* at 2493.

4. *Does Compulsory Licensing Harm Innovation?*

The most difficult question to answer is whether compulsory licensing harms innovation and future drug development.[138] Some suggest that the only way to promote innovation is to have "undiluted" patent rights.[139] There are concerns that utilizing the Bayh-Dole Act's march-in rights will "undermine America's innovation ecosystem" and threaten future drug development, thereby causing long-term harm.[140] Others claim that the government can rely on pharmaceutical companies to make new treatments affordable or available to U.S. consumers.[141]

However, counterarguments can be made. Any gain in innovation must be weighed against the economic harm caused by an increased mortality and disability rate during a pandemic.[142] There is also a lack of firm empirical evidence to support the claim that compulsory licensing hurts innovation.[143] Furthermore, it is unclear why investors would have strong investment-backed

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[138] *See, e.g.*, Wright, *supra* note 79 (claiming that, if the United States utilizes compulsory licensing to control drug prices, then there would be "fewer miracle drugs being researched and developed").

[139] *See, e.g.*, Maureen K. Ohlhausen, *Patent Rights in a Climate of Intellectual Property Rights Skepticism*, 30 HARV. J.L. & TECH. 103, 108–109 (2016) (maintaining that "the collective legal environment has been hostile to U.S. patent owners" and that "calls for diluted patent rights often go beyond incremental adjustment and threaten to weaken patents systemically, which could compromise R&D investment").

[140] *See* Fred Reinhart, *Exercising Bayh-Dole March-In Rights Would Handicap COVID-19 Innovation*, STAT (May 4, 2020), https://www.statnews.com/2020/05/04/bayh-dole-march-in-rights-handicap-covid-19-innovation/ (maintaining that march-in rights would lead to a decrease in investment in new medicines); *see also* Joseph Allen, *Stand Up to the Anti-Patent COVID-19 Narrative*, IP WATCHDOG (Apr. 30, 2020), https://www.ipwatchdog.com/2020/04/30/stand-anti-patent-covid-19-narrative/id=121197/ (claiming any use of march-in rights for COVID-19 treatments will hinder the development of new treatments); BIOTECHNOLOGY INNOVATION ORG., *supra* note 114, at 9–10 (arguing pandemic-related compulsory licensing harms innovation).

[141] *See* Reinhart, *supra* note 140 (noting that "[s]everal firms have already pledged to make coronavirus treatments widely accessible"); Allen, *supra* note 140 (quoting the Managing Director for University Technology Commercialization and Faculty Innovation at Yale University as stating that "[w]e have academia, industry, government and venture capital all working on a common purpose" and "that companies like Gilead are pledging to make their drug, Remdesivir, available at cost").

[142] *See* Maria Polyakova, Geoffrey Kocks, Victoria Udalova & Amy Finkelstein, *Initial Economic Damage from the COVID-19 Pandemic in the United States Is More Widespread Across Ages and Geographies than Initial Mortality Impacts*, 117 PROC. NAT'L ACAD. SCIS. 27,934, 27,937 (2020) (finding "a significant positive relationship between excess all-cause mortality and economic damages across states" and noting negative spill-over effects). *See also* David E. Bloom, Daniel Cadarette & JP Sevilla, *New and Resurgent Infectious Diseases Can Have Far-Reaching Economic Repercussions*, 55 FIN. & DEV., June 2018, at 46, 46, 49 (discussing how epidemics cause economic harm); WORLD HEALTH ORG., WHO GUIDE TO IDENTIFYING THE ECONOMIC CONSEQUENCES OF DISEASE AND INJURY 2, 27 (2009), https://www.who.int/choice/publications/d_economic_impact_guide.pdf (discussing the macroeconomic impact of disease).

[143] *See* Colleen Chien, *Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation?*, 18 BERKELEY TECH. L.J. 853, 891 (2003) (analyzing data and concluding that compulsory licenses for drugs "that issue predictably in significant markets" are likely to impact innovation).

expectations for drugs that are developed with significant public funding.[144] One may also argue that any good-will gestures from pharmaceutical companies during the pandemic are merely calculated attempts to forestall compulsory licensing, such as Bayer's "voluntary" price-reduction of ciprofloxacin in 2001.[145]

It is important to note how uncontroversial compulsory licensing is in other areas of technology. As noted earlier, the U.S. government regularly ignores patent rights in an effort to cut costs for defense-related patents.[146] Furthermore, it subjects more than five thousand patent applications a year to secrecy orders under § 181 of the Patent Act.[147] Inventors whose inventions are subject to such an order can only receive damages under § 183 of the Patent Act,[148] and they lose the ability to file for patents in other countries for the order's duration.[149] These heavy restrictions likely impact innovation in a variety of technological areas, but are tolerated for aiding national defense. This raises the question of why similar restrictions are not accepted to promote public health.

III. THE U.S. APPROACH TO DEVELOPING AND OBTAINING COVID-19 DRUGS

During the COVID-19 pandemic, the U.S. government attempted to secure needed medicines by outspending other countries and by prioritizing its raw material orders ahead of others. But this did not prevent drug shortages in the United States. Section A discusses the U.S. government's funding contracts with vaccine manufacturers and argues that they were

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[144] *See* Abbott & Reichman, *supra* note 37, at 539–40 (noting that, given that the government has provided a substantial amount of funding for COVID-19 drugs and vaccines, investors should have modest expectations with regard to profitability).

[145] It is unclear whether AbbVie would have refrained from enforcing its Kaletra patents had Israel not issued a compulsory license. Likewise, Gilead Science's move to allow generic companies to manufacture remdesivir for low- to middle-income countries is arguably motivated by Gilead Science trying to forestall compulsory licenses from issuing. A similar phenomenon was seen with HIV/AIDS drugs. *See* Jennifer Hillman, *Drugs and Vaccines Are Coming—But to Whom?*, FOREIGN AFFS. (May 19, 2020), https://www.foreignaffairs.com/articles/world/2020-05-19/drugs-and-vaccines-are-coming-whom (discussing how, during the AIDS epidemic, pharmaceutical companies voluntarily adopted better licensing terms, hoping "to avoid the stigma and financial pain of compulsory licensing").

[146] *See supra* notes 74–75 and accompanying text.

[147] *See* Erin Duffin, *Number of Patent Applications Stifled by U.S. Government Secrecy Orders 2000-2020*, STATISTA (Mar. 3, 2021), https://www.statista.com/statistics/257098/number-of-patent-applications-stifled-by-us-government-secrecy-orders/ (noting that at the end of the 2020 fiscal year, 5915 patent applications secrecy orders were in effect); Steven Aftergood, *Invention Secrecy Hits Recent High*, FED'N OF AM. SCIENTISTS (Oct. 31, 2018), https://fas.org/blogs/secrecy/2018/10/invention-secrecy-2018 (discussing U.S. Patent & Trademark Office data showing the number of secrecy orders has been increasing); Steven Aftergood, *Invention Secrecy Activity*, PROJECT ON GOV'T SECRECY https://sgp.fas.org/othergov/invention/stats.html (last visited Nov. 26, 2021) (showing an increase of secrecy orders from the 2017 to 2021 fiscal years).

[148] For a discussion of this process, see Scott D. Locke, *The Invention Secrecy Act: The USPTO as a Gatekeeper of National Security*, 8 IP THEORY 71, 81–86 (2019).

[149] 35 U.S.C. § 184(a).

overly protective of the pharmaceutical companies' patent rights. Section B discusses the U.S. shortage of remdesivir in 2020 and explains why compulsory licensing could have helped alleviate it.

A. *Government-Funded Drug Development and Procurement*

While high-income countries were pooling resources,[150] the Trump administration embraced "vaccine nationalism"—prioritizing obtaining vaccines ahead of others.[151] Under Operation Warp Speed, it established a public-private partnership to develop, manufacture, and distribute COVID-19-related drugs,[152] with $18 billion in funding coming from a variety of sources.[153] The Biomedical Advanced Research and Development Authority (BARDA)[154] and other federal agencies funded vaccine development by seven manufacturers, including Moderna, Johnson & Johnson (J&J), Sanofi, and Merck.[155] The government also pre-purchased 100 to 300 million vaccine doses from Moderna, J&J, Sanofi, Pfizer, AstraZeneca, and Novavax.[156]

There are problems regarding how BARDA's funding agreements addressed patent rights. As discussed earlier, when a government agency

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[150] *See* Press Release, World Health Org., Global Leaders Unite to Ensure Everyone Everywhere Can Access New Vaccines, Tests and Treatments for COVID-19 (Apr. 24, 2020), https://www.who.int/news-room/detail/24-04-2020-global-leaders-unite-to-ensure-everyone-everywhere-can-access-new-vaccines-tests-and-treatments-for-covid-19.

[151] *See* Rebecca Weintraub, Asaf Bitton & Mark L. Rosenberg, *The Danger of Vaccine Nationalism*, HARV. BUS. REV. (May 22, 2020), https://hbr.org/2020/05/the-danger-of-vaccine-nationalism (using "vaccine nationalism" to describe a trend in which, instead of working together, countries take " a 'my nation first' approach to developing and distributing potential vaccines or other pharmaceutical treatments"); Nahal Toosi & Natasha Bertrand, *Fears Rise That Trump Will Incite a Global Vaccine Brawl*, POLITICO, https://www.politico.com/news/2020/05/03/coronavirus-vaccine-trump-world-brawl-230142 (May 3, 2020, 3:58 PM) (discussing how the United States cut funding to the World Health Organization and declined to join the EU in pledging funding for COVID-19 vaccines and treatments).

[152] Press Release, U.S. Dep't of Health & Hum. Servs., Trump Admin. Announces Framework & Leadership for 'Operation Warp Speed' (May 15, 2020), https://www.hhs.gov/about/news/2020/05/15/trump-administration-announces-framework-and-leadership-for-operation-warp-speed.html.

[153] The Trump administration shifted $10 billion meant for hospitals and health care workers and $6 billion that was intended for personal protective equipment, ventilators, and COVID-19 tests. *See* Rachel Cohrs, *The Trump Administration Quietly Spent Billions in Hospital Funds on Operation Warp Speed*, STAT (March 2, 2021), https://www.statnews.com/2021/03/02/trump-administration-quietly-spent-billions-in-hospital-funds-on-operation-warp-speed (discussing the $10 billion reallocated from hospitals); U.S. GOV'T ACCOUNTABILITY OFF., GAO-20-701, COVID-19: FEDERAL EFFORTS COULD BE STRENGTHENED BY TIMELY AND CONCERTED ACTIONS 135 n.283 (2020), https://www.gao.gov/assets/gao-20-701.pdf (discussing $6 billion that was reallocated from the U.S. Strategic National Stockpile).

[154] BARDA was created within the Department of Health and Human Services in 2006 to prepare for biological attacks and pandemics. *See* 42 U.S.C. § 247d(c) (establishing BARDA).

[155] Simi V. Siddalingaiah, CONG. RSCH. SERV., IN11560, OPERATION WARP SPEED CONTRACTS FOR COVID-19 VACCINES AND ANCILLARY VACCINATION MATERIALS 2 (2021), https://crsreports.congress.gov/product/pdf/IN/IN11560. The Biden administration later increased support for ancillary supplies for vaccine development, including needles, syringes, and vaccine dose containers. *Id*.

[156] *Id.*

provides research funds, it retains a paid-up license under the Bayh-Dole Act.[157] Related regulations state that, absent exceptional circumstances, "[e]ach funding agreement awarded to a contractor" is supposed to contain a "standard patent rights clause"[158] that requires resulting inventions to be made "available to the public on reasonable terms."[159] The clause includes the right for the government to use march-in rights if the funding recipient fails to take "effective steps to achieve practical application of the subject invention,"[160] with "practical application" requiring that the resulting invention be "available to the public on reasonable terms."[161] It also provides the government with the right to march-in "to alleviate health or safety needs."[162]

Yet, some COVID-19-related BARDA contracts do not conform to these requirements.[163] For example, the government's contract with J&J subsidiary Janssen Pharmaceuticals, Inc. narrows the use of march-in rights to alleviate "*urgent* health or safety needs" and requires a governmental declaration of a Public Health Emergency, a significant potential for such an emergency, or the "declaration by WHO Director General of a public health emergency of international concern."[164] This would exclude the situation in which COVID-19 becomes endemic.[165]

The Pfizer pre-purchase contract grants the company even stronger protection, likely because Pfizer did not accept vaccine development funds.[166] It states that "all inventions conceived or first actually reduced to practice" in the performance of the contract "shall be owned by Pfizer" and

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[157] 35 U.S.C. § 202(c)(4).

[158] 37 C.F.R. § 401.14, .3 (2021).

[159] *Id.* § 401.14(a)(3).

[160] *Id.* § 401.14(j).

[161] *Id.* § 401.14(a), (j).

[162] *Id.* § 401.14(j)(2).

[163] *See* Sydney Lupkin, *HHS Released More Coronavirus Vaccine Contracts as Election Results Unfolded*, NPR (Nov. 8, 2020, 2:16 PM), https://www.npr.org/sections/health-shots/2020/11/08/932793698/hhs-released-more-coronavirus-vaccine-contracts-as-election-results-unfolded (discussing how some of the BARDA contracts with drug producers lack march-in rights); Bob Herman, *Federal Government Weakened Its March-In Rights for Coronavirus Drugs*, AXIOS (July 1, 2020), https://www.axios.com/federal-government-barda-contracts-moderna-regeneron-aaf9fde2-2ee1-46fb-8465-0d573e6af1ed.html (observing how several of the BARDA contracts with drug producers lack the "on reasonable terms" language required under the Bayh-Dole Act).

[164] Amend. of Solicitation/Modification of Cont. Between Janssen Pharms., Inc. & U.S. Army Contracting Command & Med. Def. CBRN Def. Consortium § IX.8 at 34–35 (Aug. 5, 2020), https://www.hhs.gov/sites/default/files/janssen-corp-covid-vaccine-rapid-ard-to-large-scale-manufacturing.pdf (emphasis added).

[165] *See* Lupkin, *supra* note 163 (discussing march-in rights under the Janssen Pharmaceuticals, Inc. and United States Department of Defense agreement).

[166] Note that Pfizer's vaccine partner BioNTech accepted €100 million from the EU's European Investment Bank and €375 million from the German Federal Ministry of Education and Research. Francesco Guarascio, *Exclusive: Europe to Pay Less than U.S. for Pfizer Vaccine Under Initial Deal—Source*, REUTERS (Nov. 11, 2020, 7:03 AM), https://in.reuters.com/article/us-health-coronavirus-eu-pfizer/eu-seals-deal-with-pfizer-biontech-for-supply-of-300-million-doses-of-covid-vaccine-idINKBN27R1F5.

allows Pfizer to decide "whether to hold Subject Inventions as trade secrets."[167] It furthermore states that the Bayh-Dole Act does not apply and grants Pfizer ownership over all data generated.[168] A Trump-administration HHS spokesperson claimed that the government was "not entitled to any rights" because it did not fund the vaccine's development.[169] However, some scholars argue that guaranteeing $1.95 billion upon the successful invention of a drug merits stronger rights for the government.[170]

B. *Case Study: The U.S. Remdesivir Shortage of 2020*

The 2020 shortage of Gilead Sciences' remdesivir drug illustrates how patent rights can contribute to drug scarcity. Remdesivir was originally investigated as an Ebola treatment,[171] and it was later found effective against some coronaviruses.[172] The U.S. government provided $37.5 million in funding for its development[173] and contributed significantly to the underlying research.[174] Indeed, Justin Hughes and Arti Rai argued that "one

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[167] Letter from the U.S. Army Contracting Command, U.S. Dep't of Def., to Pfizer, Inc. 17 (July 21, 2020), https://www.hhs.gov/sites/default/files/pfizer-tdl.pdf.

[168] *Id.* The government's project agreement with Regeneron Pharmaceuticals, Inc. for antibodies similarly states that "the Bayh-Dole statute does not apply." Project Agreement between Advanced Tech. Int'l & Regeneron Pharms., Inc. § 7.2(a), https://www.sec.gov/Archives/edgar/data/872589/000180422020000030/regn-ex102x09302020x10q.htm.

[169] Sydney Lupkin, *Pfizer's Coronavirus Vaccine Supply Contract Excludes Many Taxpayer Protections*, NPR (Nov. 24, 2020, 4:46 PM), https://www.npr.org/sections/health-shots/2020/11/24/938591815/pfizers-coronavirus-vaccine-supply-contract-excludes-many-taxpayer-protections (quoting Natalie Baldassarre, a spokesperson for the Department of Health and Human Services).

[170] *See id.* (quoting Robin Feldman, a professor at the University of California Hastings College of the Law, as stating that "[t]he government . . . is giving away the store—meeting critical short-term goals but ignoring long-term serious costs" and noting that this could lead to unreasonable prices).

[171] *See generally* Travis K. Warren et al., *Therapeutic Efficacy of the Small Molecule GS-5734 Against Ebola Virus in Rhesus Monkeys*, 531 NATURE 381 (2016) (discussing remdesivir's efficacy in treating Ebola in rhesus monkeys).

[172] *See generally* Timothy P. Sheahan et al., *Broad-Spectrum Antiviral GS-5734 Inhibits Both Epidemic and Zoonotic Coronaviruses*, 9 SCI. TRANSLATIONAL MED. 396 (2017) (discussing how remdesivir "can inhibit SARS-CoV and MERS-CoV replication in multiple in vitro systems").

[173] *See* Varoon Mathur, *Invoking Bayh-Dole May Be Needed to Get Affordable Covid-19 Treatments*, STAT (Apr. 2, 2020), https://www.statnews.com/2020/04/02/invoking-bayh-dole-may-be-needed-to-get-affordable-covid-19-treatments (noting the University of Alabama at Birmingham, which developed remdesivir, received $37.5 million from the National Institute for Health) (citing Savannah Koplon, *$37.5 Million Grant Will Address Research of High-Priority Infections*, UNIV. OF ALA. AT BIRMINGHAM (Mar. 20, 2019), https://www.uab.edu/news/health/item/10307-37-5-million-grant-will-address-research-of-high-priority-infections).

[174] Ed Silverman, *The U.S. Government Contributed Research to a Gilead Remdesivir Patent—But Didn't Get Credit*, STAT (May 8, 2020), https://www.statnews.com/pharmalot/2020/05/08/gilead-remdesivir-covid19-coronavirus-patents. Indeed, in February 2020, the FDA issued Remdesivir orphan drug status—a move that would provide Gilead with an additional seven-year exclusivity. Jonathan Gardner, *In Rare Move, Gilead Gives Up 'Orphan' Status for Experimental Coronavirus Drug*, BIOPHARMA DIVE (Mar. 25, 2020), https://www.biopharmadive.com/news/coronavirus-gilead-remdesivir-orphan-drug/574882. The public backlash was so severe that Gilead asked the FDA to rescind this status. *Id.*

or more government researchers should probably have been listed as inventors on key patents for remdesivir."[175]

On January 31, 2020, HHS Secretary Azar declared a public health emergency due to COVID-19.[176] This enabled the FDA to issue an Emergency Use Authorization on May 1 for remdesivir, which was not FDA-approved at the time.[177] The decision was based on a clinical trial that showed remdesivir shortened the recovery time for sick patients.[178]

Remdesivir shortages in the United States and elsewhere quickly arose. Gilead Sciences blamed the shortage on a "resource- and time-intensive" production process with sequential and specialized steps that required "novel substances with limited global availability."[179] It maintained that production required "sterile drug product manufacturing capabilities," which limited the number of capable manufacturers.[180] It further claimed that the complex manufacturing process hindered scaling up production.[181] Gilead Sciences did utilize some out-licensing by granting a royalty-free license to five generic manufacturers in other countries,[182] which was later expanded to other manufacturers.[183] However, it waited until mid-May to do so, and it excluded the United States and most other highly-developed countries from buying drugs produced under license.[184]

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[175] Justin Hughes & Arti K. Rai, *Acknowledging the Public Role in Private Drug Development: Lessons from Remdesivir*, STAT (May 8, 2020), https://www.statnews.com/2020/05/08/acknowledging-public-role-drug-development-lessons-remdesivir.

[176] Press Release, U.S. Dep't of Health & Hum. Servs., Sec'y Azar Declares Pub. Health Emergency for U.S. for 2019 Novel Coronavirus (Jan. 31, 2020), https://www.hhs.gov/about/news/2020/01/31/secretary-azar-declares-public-health-emergency-us-2019-novel-coronavirus.html. *See also* Determination of Pub. Health Emergency, 85 Fed. Reg. 7,316 (Feb. 7, 2020) (issuing notice of a public health emergency pursuant to the Federal Food, Drug, and Cosmetic Act, effective February 4, 2020).

[177] Letter from U.S. Food & Drug Admin. to Ashley Rhoades, Manager, Regul. Affs., Gilead Scis., Inc. (Oct. 22, 2020), https://www.fda.gov/media/137564/download. Full FDA approval was granted on October 22, 2020. Press Release, U.S. Food & Drug Admin., FDA Approves First Treatment for COVID-19 (Oct. 22, 2020), https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-covid-19.

[178] Adam Feuerstein & Matthew Herper, *FDA to Allow Emergency Use of Gilead's COVID-19 Drug*, STAT (May 1, 2020), https://www.statnews.com/2020/05/01/fda-to-allow-emergency-use-of-gileads-covid-19-drug.

[179] *Working to Supply Veklury® for COVID-19*, GILEAD, https://www.gilead.com/purpose/advancing-global-health/covid-19/working-to-supply-remdesivir-for-covid-19 (Oct. 22, 2020).

[180] *Id.*

[181] *Id.*

[182] Valerie Bauman, *Gilead Gives Royalty-Free Remdesivir Licenses to Five Drugmakers (1)*, BLOOMBERG L., https://news.bloomberglaw.com/pharma-and-life-sciences/gilead-gives-royalty-free-remdesivir-licenses-to-five-drugmakers (May 12, 2020, 5:12 PM) (discussing a royalty-free license granted to five Indian and Pakistani drug manufacturers).

[183] *Voluntary Licensing Agreements for Remdesivir*, GILEAD, https://www.gilead.com/purpose/advancing-global-health/covid-19/voluntary-licensing-agreements-for-remdesivir (last visited July 31, 2021).

[184] *See* Berkeley Lovelace Jr., *Gilead Strikes Deal to Make Remdesivir Coronavirus Treatment for 127 Countries*, CNBC, https://www.cnbc.com/2020/05/12/remdesivir-coronavirus-treatment-gilead-strikes

During this time, Bangladesh-based companies began working on replicating remdesivir. Bangladesh is classified as a WTO Least-Developed Country, meaning that it is not required to offer patents on pharmaceutical products.[185] In May 2020, Bangladeshi company Beximco achieved the seemingly impossible: it independently recreated remdesivir[186] and began selling it[187] one month before any Gilead Sciences-authorized partners began production.[188] In contrast to the $3,120 per treatment cost that the United States paid,[189] Beximco's drug cost only $336 per treatment.[190] Other Bangladeshi companies soon began producing the generic, leading to a growing surplus that allowed Bangladesh to export fifty-thousand vials to six other countries by late July[191] and to twenty-one countries by late August.[192]

-deal-to-make-drug-in-127-countries.html (May 13, 2020, 9:28 AM) (discussing Gilead's license with Mylan, Cipla, Ferozsons Laboratories, Hetero Labs, and Jubilant Lifesciences).

[185] *See WTO Drugs Patent Waiver for LDCs Extended Until 2033*, UNITED NATIONS, https://www.un.org/ldcportal/wto-drugs-patent-waiver-for-ldcs-extended-until-2033 (last visited July 31, 2021) (discussing that the waiver "exempts LDCs from obligations under the TRIPS agreement related to patents or other intellectual property rights on pharmaceutical products and clinical data"); *Least-Developed Countries*, WORLD TRADE ORG., https://www.wto.org/english/thewto_e/whatis_e/tif_e/org7_e.htm (last visited Oct. 26, 2021) (listing Bangladesh as an LDC).

[186] *See* A.Z.M. Anas, *Bangladesh's Beximco Thrives on Coronavirus Challenges*, NIKKEI ASIA (July 26, 2020, 2:36 AM), https://asia.nikkei.com/Business/Pharmaceuticals/Bangladesh-s-Beximco-thrives-on-coronavirus-challenges (noting Beximco and other Bangladeshi drug manufacturers had no license from Gilead and relied on Bangladesh's Least-Developed Country status); Christopher Garrison, *Price, Profit and the Covid-19 Health Technology Pool: The Example of Remdesivir*, MEDS. L. & POL'Y (May 28, 2020), https://medicineslawandpolicy.org/2020/05/price-profit-and-the-covid-19-health-technology-pool-the-example-of-remdesivir (noting Beximco's generic of remdesivir was independently developed).

[187] *Beximco Pharma Launches First Generic Remdesivir for Covid-19*, PHARM. TECH., https://www.pharmaceutical-technology.com/news/beximco-pharmaceuticals-remdesivir-generic (Sept. 7, 2020, 10:10 AM).

[188] *See* Cheena Kapoor, *India Starts Producing Generic Remdesivir amid Pandemic*, ANADOLU AGENCY (June 22, 2020), https://www.aa.com.tr/en/asia-pacific/india-starts-producing-generic-remdesivir-amid-pandemic/1885845 (noting Cipla and Hetero Pharma began production on June 21, 2020); Sohini Das, *Pharma Firms Commit 815,000 Doses of Remdesivir Supply in August*, BUS. STANDARD, https://www.business-standard.com/article/companies/pharma-firms-commit-815-000-doses-of-remdesivir-supply-in-august-120073000477_1.html (July 30, 2020, 11:07 AM) (noting that only Hetero, Mylan, and Cipla had launched their generics by July 30, 2020); Kaleem Naqvi, *CEO Ferozsons Highlights Agreement Details with Gilead for Manufacturing of Covid-19 Treatment Drug, Remdesivir, in Pakistan*, TECH. TIMES (July 10, 2020), https://www.technologytimes.pk/2020/07/10/ceo-ferozsons-highlights-agreement-details-with-gilead-for-manufacturing-of-covid-19-treatment-drug-remdesivir-in-pakistan (noting Ferozsons gained manufacturing permission from the Drug Regulatory Authority of Pakistan ("DRAP") on June 22, 2020).

[189] 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 (discussing remdesivir pricing).

[190] *See* Anas, *supra* note 186 (discussing Beximco's development of a remdesivir generic and its supply agreements with other countries).

[191] Sajjadur Rahman, *Remdesivir Saved the Day for Pharma Industry*, BUS. STANDARD, https://tbsnews.net/companies/pharma/bangladesh-made-remdesivir-high-export-demand-112387 (July 28, 2020, 11:13 AM).

[192] Jagaran Chakma, *Remdesivir Can Rake in Tk 700cr*, DAILY STAR, https://www.thedailystar.net/business/news/remdesivir-can-rake-tk-700cr-1950581 (Aug. 25, 2020, 2:01 AM).

Beginning in May 2020, the U.S. government was forced to ration remdesivir,[193] as states began reporting shortages.[194] In late June, HHS Secretary Azar bragged that President Trump "struck an amazing deal to ensure Americans have access" to remdesivir and claimed that, "[t]o the extent possible, we want to ensure that any American patient who needs remdesivir can get it."[195] However, shortages in the United States persisted. By mid-July, Texas, Florida, and Arizona were all experiencing remdesivir shortages, and doctors were forced to ration it.[196] Given that several states experienced widespread hospital bed shortages during this time,[197] the shortage likely led to additional patient deaths, either from COVID-19 or from other conditions requiring timely emergency care.

Admittedly, remdesivir shortages were likely exacerbated by the government's failure to fairly distribute its supply.[198] Doctors criticized the lack of transparency in the distribution process, which led to lower-priority hospitals gaining access to drugs before areas in crisis.[199] But notwithstanding the fact that some states had greater access to remdesivir than others, these problems were ultimately a result of the inadequate supply from Gilead Sciences.[200] During this time period, such a shortage did not

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[193] *See* Joseph Walker, *All Remdesivir Supplies to Be Distributed in U.S. by Maker Gilead Sciences*, WALL ST. J., https://www.wsj.com/articles/all-remdesivir-supplies-to-be-distributed-in-u-s-by-maker-gilead-sciences-11601575201 (Oct. 1, 2020, 4:13 PM) (noting how, as of October 2020, remdesivir had been in short supply since it became authorized for emergency use, with the shortage dissipating only in late September 2020).

[194] Boodman & Ross, *supra* note 1 (discussing the remdesivir shortage in various states including Massachusetts and California in May 2020).

[195] Press Release, U.S. Dep't of Health & Hum. Servs., Trump Admin. Secures New Supplies of Remdesivir for the U.S. (June 29, 2020), https://www.hhs.gov/about/news/2020/06/29/trump-administration-secures-new-supplies-remdesivir-united-states.html.

[196] *See* Elizabeth Cohen, *Covid-19 Drug Rationed in the US is Plentiful in Developing Countries*, CNN, https://www.cnn.com/2020/09/09/health/covid-remdesivir-us-vs-other-countries/index.html (Sept. 9, 2020, 9:17 AM) (discussing how doctors in Texas were forced to choose which patients would receive remdesivir); Eric Boodman, *From Houston to Miami, Hospitals Running Short of Remdesivir for Covid-19 Patients*, STAT (July 10, 2020), https://www.statnews.com/2020/07/10/hospitals-running-short-of-remdesivir-for-covid19-patients (discussing remdesivir shortages in Texas, Florida, and Arizona in July 2020).

[197] *See* Edgar Walters, Shannon Najmabadi & Emma Platoff, *Texas Hospitals Are Running Out of Drugs, Beds, Ventilators and Even Staff*, TEX. TRIB. (July 14, 2020, 6:00 AM), https://www.texastribune.org/2020/07/14/texas-hospitals-coronavirus; Eliza Barclay & Dylan Scott, *Hospitals Are Running Out of Staff, Supplies, and Beds for Covid-19 Patients — And This Time Could Be Worse*, VOX, https://www.vox.com/2020/7/15/21317776/covid-19-coronavirus-florida-arizona-texas-california-hospitals (July 16, 2020, 9:19 AM).

[198] *See* Boodman & Ross, *supra* note 1 (noting widespread criticism of the government's "uneven and opaque" remdesivir distribution system).

[199] *Id.*

[200] *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 (noting that, because Gilead failed to meet demand, the U.S. medical system experienced "severe shortages" of remdesivir); Walker, *supra* note 193 (noting, in October 2020, that remdesivir had been in short supply since it became authorized for emergency use).

exist in countries that had access to generics, including Bangladesh, Pakistan, and the Philippines.[201]

Beximco's ability to reverse-engineer and produce remdesivir shows that the United States could have also produced it. Indeed, researchers and private companies in Taiwan were also able to independently replicate remdesivir in a short period of time.[202] Consequently, the six-month U.S. shortage was exacerbated by Gilead Sciences' refusal to license its patents more broadly.[203]

Other countries dealing with COVID-19 outbreaks have chosen to use compulsory licensing for remdesivir, including India and Russia. In the spring of 2021, India faced a shortage, notwithstanding having Gilead Sciences-licensed domestic producers.[204] Although India did not go through the formal compulsory licensing process, it accepted ten thousand doses of Beximco-produced remdesivir.[205] In May 2021, Russia's Supreme Court rejected a lawsuit from Gilead Sciences and affirmed the Russian government's decision to issue a compulsory license to Russian drug manufacturer Pharmasyntez for remdesivir.[206]

IV. HIGH-INCOME COUNTRIES FACILITATING COMPULSORY LICENSING DURING THE PANDEMIC

During the pandemic, several high-income countries have shifted their views regarding compulsory licensing. Canada and several EU member states amended their laws to make compulsory licensing easier for the duration of the public health emergency, and both Israel and Hungary issued pandemic-related compulsory licenses for drugs. At least some of this shift was driven by the United States out-spending other countries on vaccines early in the pandemic.

Section A examines Canada's pandemic-related compulsory licensing legislation. Section B discusses Israel's issuance of a compulsory license for

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[201] *See* Cohen, *supra* note 196 (noting how several developing countries had adequate supplies of remdesivir while the United States experienced shortages).

[202] Ping-Hsun Chen, *Taiwan's Efforts to Recreate Remdesivir*, 40 BIOTECHNOLOGY L. REP. 174, 177–80 (2021).

[203] *See* Amy Kapczynski, Paul Biddinger & Rochelle Walensky, *Remdesivir Could Be in Short Supply. Here's a Fix.*, N.Y. TIMES (July 28, 2020), https://www.nytimes.com/2020/07/28/opinion/remdesivir-shortage-coronavirus.html (calling for compulsory licensing of remdesivir); Morten & Duan, *supra* note 44, at 74–75 (noting that the remdesivir shortage is the result of patent rights).

[204] *See* Kallol Bhattacherjee, *Coronavirus: Bangladesh Gifts India 10,000 Remdesivir Vials*, HINDU, https://www.thehindu.com/news/national/coronavirus-bangladesh-gifts-india-10000-remdesivir-vials/article34499574.ece (May 6, 2021) (discussing Bangladesh's donation of remdesivir to India).

[205] *Id.*

[206] Alexander Marrow, *Russian Court Rejects U.S. Firm's Lawsuit over COVID-19 Drug Remdesivir*, REUTERS (May 28, 2021, 6:02 AM), https://www.reuters.com/business/healthcare-pharmaceuticals/russian-supreme-court-rejects-gilead-lawsuit-over-covid-19-drug-2021-05-27.

the first time in its history. Section C focuses on actions taken by the EU and its member states.

A. *Canada*

Canada has historically been a strong proponent of compulsory licensing.[207] Prior to the passage of the North American Free Trade Agreement, Canada freely issued compulsory licenses to increase patient access to drugs.[208] Canada's Patent Act formerly permitted generic drug manufacturers to stockpile generic drugs prior to the relevant patent's expiration, and it only changed the law after a WTO panel held that it violated TRIPS.[209]

Prior to the pandemic, Canada's Patent Act already permitted the government to use patents during national emergencies and for public non-commercial use.[210] But what constitutes a national emergency is somewhat narrow under the Emergencies Act of 1985:

> [A] *national emergency* is an urgent and critical situation of a temporary nature that . . . seriously endangers the lives, health or safety of Canadians and is of such proportions or nature as to exceed the capacity or authority of a province to deal with it . . . and that cannot be effectively dealt with under any other law of Canada.[211]

The governmental power to use patents can only be invoked once a public health emergency becomes large enough to exceed provincial governments' ability to control it, which is far less effective than if the federal government could act immediately.[212] This is the result of Canada's constitutional division of powers, under which health is not assigned to either provincial or federal governments, forcing both to share responsibilities.[213]

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[207] None of the top twenty pharmaceutical companies by revenue are headquartered in Canada. Eric Sagonowsky, *The Top 20 Pharma Companies by 2019 Revenue*, FIERCE PHARMA (Apr. 20, 2020, 3:00 AM), https://www.fiercepharma.com/special-report/top-20-pharma-companies-by-2019-revenue.

[208] HO, ACCESS TO MEDICINE, *supra* note 16, at 153.

[209] *See* Panel Report, *Canada—Patent Protection of Pharmaceutical Products*, WTO Doc. WT/DS114/13, ¶ 20 (arbitration award circulated Aug. 18, 2000) (holding that § 55.2(2) of Canada's Patent Act violates TRIPS Article 28.1 and was not covered by the exception under Article 30).

[210] Patent Act, R.S.C. 1985, c P-4, ss 19, 19.1 (Can.). The North American Free Trade Agreement ("NAFTA") prohibited Canada's widespread use of compulsory licensing for pharmaceuticals. North American Free Trade Agreement, Dec. 17, 1992, 32 I.L.M. 605, 670–81.

[211] Emergencies Act, R.S.C. 1985, c 22 (4th Supp.), s 3 (Can.).

[212] Amy Swiffen, *The Limits of Canada's Federal Emergency Law During the Coronavirus Pandemic*, CONVERSATION (Apr. 1, 2020, 10:27 AM), https://theconversation.com/the-limits-of-canadas-federal-emergency-law-during-the-coronavirus-pandemic-134309 (noting the limited utility of the Emergencies Act, given that the Canadian government can respond "only after the spread has exceeded the response capacities of the provinces").

[213] *Id.*

In 2004, Canada amended its laws to create Canada's Access to Medicines Regime (CAMR), which authorizes generic manufacturers to export fifty-seven drugs and vaccines to poor countries, primarily for the treatment of HIV/AIDS.[214] Canadian pharmaceutical company Apotex entered into an agreement with Médecins San Frontières to test the law by manufacturing a fixed-dose combination of three existing HIV/AIDS drugs, later known as TriAvir.[215] In July 2007, Rwanda became the first country to notify the WTO of its intent to import drugs manufactured under compulsory license,[216] and in October, Canada became the first country to authorize the manufacture and export of a generic drug produced under compulsory license.[217] However, CAMR's narrow list of covered drugs and bureaucratic hurdles make it difficult to use.[218]

Under Canada's COVID-19 Emergency Response Act, the Minister of Health gained temporary authority to issue compulsory licenses, even if the patent holder could produce the patented invention.[219] The government was not obligated to negotiate with the patent holder before granting a compulsory license. It merely required that the government "pay the patentee any amount that the Commissioner [of Patents] considers to be adequate remuneration in the circumstances, taking into account the economic value of the authorization and the extent to which they make, construct, use and sell the patented invention."[220] The provision further clarified that producing drugs under compulsory licensing "in relation to a public health emergency . . . is not an infringement of the patent."[221] Although the emergency patent provision expired on September 30, 2020,[222] it provides a template for future health emergencies.

B. *Israel*

In 2020, Israel issued a COVID-19-related compulsory license. Israel was unable to obtain a sufficient supply of AbbVie's Kaletra,[223] which held

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[214] *See* Reichman, *supra* note 27, at 255 (noting that the Canadian legislation was limited to only fifty-seven drugs or vaccines, primarily for treating AIDS).

[215] Holger P. Hestermeyer, *Canadian-Made Drugs for Rwanda: The First Application of the WTO Waiver on Patents and Medicines*, AM. SOC'Y OF INT'L L.: INSIGHTS (Dec. 10, 2007), https://www.asil.org/insights/volume/11/issue/28/canadian-made-drugs-rwanda-first-application-wto-waiver-patents-and.

[216] *Canada Is First to Notify Compulsory License to Export Generic Drug*, WORLD TRADE ORG. (Oct. 4, 2007), https://www.wto.org/english/news_e/news07_e/trips_health_notif_oct07_e.htm.

[217] Hestermeyer, *supra* note 215.

[218] Reichman, *supra* note 27, at 255.

[219] COVID-19 Emergency Response Act, S.C. 2020, c 5, s 51 (Can.).

[220] Patent Act, R.S.C. 1985, c P-4, s 19.4(5) (Can.).

[221] *Id.* s 19.4(7).

[222] COVID-19 Emergency Response Act, S.C. 2020, c 5, ss 10–11 (Can.).

[223] Tal Band, *Unusual Times, Unusual Measures: The Israeli Ministry of Health Permits the Exploitation of Abbvie's Patents Covering KALETRA® to Allow Importation of Generic Version*,

promise as a treatment. Section 104 of Israel's Patents Law allows the government to issue compulsory licenses if the Minister "finds that that is necessary in the interests of the National security or of the maintenance of essential supplies and services."[224] Using these provisions for the first time, the Minister of Health authorized a license to a third-party producer.[225] Shortly thereafter, AbbVie announced that it would not enforce its patent rights on Kaletra.[226] It is likely that AbbVie feared that more countries would follow Israel's lead and issue their own licenses, setting precedent that could promote more widespread use of compulsory licensing during future health emergencies.[227]

C. *European Union*

The EU and its member states are more comfortable than the United States with using compulsory licensing for drugs.[228] Under Regulation (EC) No 816/2006, the EU ratified the WTO's decision regarding the export of medicines to countries that lack sufficient manufacturing capacity.[229] Member states are required to grant a compulsory license to anyone making a valid request to manufacture drugs for export.[230] Beyond this circumstance,

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LEXOLOGY (Mar. 19, 2020), https://www.lexology.com/library/detail.aspx?g=12272bd5-c581-4c21-a1af-f253595d23e4.

[224] § 104, Patents Law, 5727-1967 (Isr.), https://www.wipo.int/edocs/lexdocs/laws/en/il/il040en.pdf.

[225] Band, *supra* note 223.

[226] Phil Taylor, *AbbVie Won't Enforce Patents for COVID-19 Drug Candidate Kaletra*, PHARMAPHORUM (Mar. 25, 2020), https://pharmaphorum.com/news/abbvie-wont-enforce-patents-for-covid-19-drug-candidate-kaletra/.

[227] *See* Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets*, 5 YALE J. HEALTH POL'Y L. & ETHICS 193, 226 (2005) (maintaining that voluntary royalty-free licenses should be viewed in the context of compulsory licensing laws, given "such licenses can be seen as responses to the looming threat of compulsory licensing").

[228] This higher comfort level may be because EU member states already regulate drug prices and permit EU-wide parallel importation. *See* Abbott & Reichman, *supra* note 37, at 556–57 (noting that no significant difference exists between mandating drug prices and threatening compulsory licensing if a drug is priced too high); Joined Cases C-267/95 & C-268/95, Merck & Co. v. Primecrown Ltd., ECLI:EU:C:1996:468, ¶ 54 (Dec. 5, 1996) (reaffirming the right of EU member states to import patented drugs from other member states).

[229] Regulation (EC) 816/2006, of the European Parliament and of the Council of 17 May 2006 on Compulsory Licensing of Patents Relating to the Manufacture of Pharmaceutical Products for Export to Countries with Public Health Problems, 2006 O.J. (L 157) ("This Regulation establishes a procedure for the grant of compulsory licences in relation to patents and supplementary protection certificates concerning the manufacture and sale of pharmaceutical products, when such products are intended for export to eligible importing countries in need of such products in order to address public health problems."); *see also* Reichman, *supra* note 27, at 256 (noting that the EU's regulation "appears to successfully incorporate most of the flexibilities available to WTO Members").

[230] Regulation (EC) 816/2006, *supra* note 229, art. 1; *see also* Nafsika Karavida, Dara Onofrio & Deena Merlen, *Patent Rights and Wrongs in the COVID-19 Pandemic: EU and U.S. Approaches to Compulsory Licensing*, IP WATCHDOG (May 19, 2020), https://www.ipwatchdog.com/2020/05/19/patent-rights-wrongs-covid-19-pandemic-eu-u-s-approaches-compulsory-licensing/id=121709/ (noting that "EU law provides that every EU Member State shall grant a compulsory license for the manufacturing and

legislation regarding compulsory licensing is primarily handled at the national level.[231] Notwithstanding the fact that the EU is home to several major pharmaceutical companies, various member states have made changes to their laws to facilitate compulsory licensing, and the EU has moved towards streamlining its use.

1. *France*

Prior to the pandemic, France already had compulsory licensing legislation. In the early 2000s, France amended its patent law to allow the broader use of ex officio licenses, which permit the government to license medicines, medical devices, and tests to third-party manufacturers "[w]here the interests of public health demand, and in the absence of a voluntary agreement with the patent holder."[232] This provision can be utilized if an "insufficient quantity or quality" of patented products exists or if they are sold "at abnormally high prices."[233]

In March 2020, France declared a COVID-19-related state of health emergency[234] and passed Emergency Law n° 2020-290, which added Article L.3131-15 to the Code of Public Health.[235] The law states that, for the duration of France's health emergency, the Prime Minister may temporarily control the prices of products and services related to COVID-19 and take measures to ensure the availability of medicines to treat it.[236] These measures must be "strictly proportionate to the health risks at stake and appropriate to

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distribution of medicine to least-developed and developing countries, so long as the conditions in TRIPS (Article 31) on compulsory licensing are fulfilled").

[231] Michael Mezher, *European Commission Says Compulsory Licensing Can Only Happen at National Level*, REGUL. FOCUS (June 26, 2015), https://www.raps.org/regulatory-focus%E2%84%A2/news-articles/2015/6/european-commission-says-compulsory-licensing-can-only-happen-at-national-level.

[232] LOVE, *supra* note 99.

[233] Code de la propriété intellectuelle [Intellectual Property Code] art. L613-16 (Fr.); *see also* Esther van Zimmeren & Gilles Requena, *Ex-Officio Licensing in the Medical Sector: The French Model*, *in* GENE PATENTS AND PUBLIC HEALTH 123, 125 (Geertrui Van Overwalle ed., 2007) (providing a detailed analysis of French compulsory licensing).

[234] Stéphanie Dagron, *COVID-19 in France: Health as a Constitutional Value and Limitations on Civil Liberties*, BILL OF HEALTH (May 28, 2020), https://blog.petrieflom.law.harvard.edu/2020/05/28/france-global-responses-covid19/ (citing French law permitting the government to declare a state of health emergency).

[235] Francois Pochart, Mathilde Rauline, Océane de La Verteville & August Debouzy, *Compulsory Licenses Granted by Public Authorities: An Application in the Covid-19 Crisis in France? Part 1*, WOLTERS KLUWER: KLUWER PAT. BLOG (Apr. 23, 2020), http://patentblog.kluweriplaw.com/2020/04/23/compulsory-licenses-granted-by-public-authorities-an-application-in-the-covid-19-crisis-in-france-part-1 [hereinafter Pochart, *Part 1*]. The law was extended, and it is now set to expire on December 31, 2021. Francine Le Péchon-Joubert & Carlyne Sevestre, *Covid-19 Vaccines: Intellectual Property Issues, Including Sharing of Patents, Licensing and Government Rights to Compulsory Licensing – The French Perspective*, INT'L BAR ASS'N (May 25, 2021), https://www.ibanet.org/covid-19-vaccines-intellectual-property-issues-French-perspective#_ednref6 (discussing a February 2021 law that extended the state of health emergency).

[236] Pochart, *Part 1*, *supra* note 235.

the circumstances of the time and place" and end when they are no longer necessary.[237] During a discussion at the French Parliament, the Minister of Health stated that he would consider using compulsory licensing or price controls on drugs that were not produced in France.[238] France has also joined the United States in supporting a TRIPS waiver for COVID-19 vaccines.[239]

There are limitations, however, under the French provisions. For example, French Senator Ronan Le Gleut introduced a bill to extend the ex officio license to encompass inventions that do not yet have issued patents, as well as to permit licensing in situations in which a future drug shortage is merely probable.[240] Furthermore, he observed that French law currently does not address circumventing data and marketing exclusivities for drugs,[241] a problem that exists under U.S. law as well.[242]

2. *Germany*

Germany is the world's fourth-largest pharmaceutical market and has several major pharmaceutical companies.[243] Its views on compulsory licensing have evolved significantly over the past few years. The German Patent Act permits compulsory licensing when it is in the interest of public welfare or a matter of national security, although the government must pay "equitable remuneration" to the patent holder.[244] Under section 24(1), a third party seeking a license must show that negotiations with the patent holder failed and that a license is in the public interest.[245] The court will not award

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[237] Code de la santé publique [Public Health Code] art. L3131-15 (Fr.); *see* Pochart, *Part 1*, *supra* note 235 (translating article L3131-15).

[238] Francois Pochart, Mathilde Rauline, Océane de La Verteville & August Debouzy, *Compulsory Licenses Granted by Public Authorities: An Application in the Covid-19 Crisis in France? Part 2*, WOLTERS KLUWER: KLUWER PAT. BLOG (Apr. 24, 2020), http://patentblog.kluweriplaw.com/2020/04/24/compulsory-licenses-granted-by-public-authorities-an-application-in-the-covid-19-crisis-in-france-part-2/ [hereinafter Pochart, *Part 2*].

[239] Ashleigh Furlong, *Macron Backs Waiving COVID-19 Vaccine Patents Ahead of G7 Summit*, POLITICO (June 10, 2021, 12:04 AM), https://www.politico.eu/article/macron-backs-waiving-covid-19-vaccine-patents-ahead-of-g7-summit/.

[240] Matthieu Dhenne, *French Bill Proposal Authorizing the Granting of an Ex Officio License in the Interest of Public Health in the Event of an Extreme Health Emergency*, WOLTERS KLUWER: KLUWER PAT. BLOG (Apr. 28, 2021), http://patentblog.kluweriplaw.com/2021/04/28/french-bill-proposal-authorizing-the-granting-of-an-ex-officio-license-in-the-interest-of-public-health-in-the-event-of-an-extreme-health-emergency/.

[241] *Id.*

[242] *See supra* Part IV.A.

[243] *See* GER. TRADE & INV., THE PHARMACEUTICAL INDUSTRY IN GERMANY 3 (2021/2022) (discussing the scope of the pharmaceutical market in Germany).

[244] Patentgesetz [PatG] [Patent Act], Dec. 16, 1980, BGBL I at 1, as amended by Act of Oct. 8, 2017, BGBL I at 3546, § 13 (Ger.).

[245] *Id.* § 24(1).

a compulsory license if another product can substitute for it,[246] and a drug to treat a serious illness must have some "specific therapeutic characteristics" that other drugs lack.[247]

In the 2017 case *Merck Sharp & Dohme Ltd.* v. *Shinogi & Co.*, the German Federal Court of Justice (FCJ) affirmed, for the first time, the Federal Patent Court's (FPC) award of a section 24(1) license.[248] Merck Sharp & Dohme Ltd. (Merck) produced an HIV antiretroviral drug containing raltegravir. Although Shionogi & Co. (Shionogi) held the raltegravir patent, it neither practiced it nor licensed it to anyone, including Merck.[249] After a year of fruitless negotiations, Shionogi sued Merck for patent infringement.[250] The FPC granted Merck a compulsory license, and the FCJ affirmed, observing that although few patients were using Merck's drug, there was a risk of adverse health effects if they switched to a different one.[251]

In response to the COVID-19 outbreak, Germany passed the Prevention and Control of Infectious Diseases in Humans Act.[252] This provided the Federal Ministry of Health with a range of extra powers in the event of a parliament-declared national epidemic,[253] including the ability to compel pharmaceutical companies to make patented vaccines and medicines available to the public in exchange for fair compensation.[254] The new legislation was intended to remedy the slow pace of section 24 proceedings.[255]

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[246] Christof Hohne, *Compulsory Licenses in Germany: A Tool for Licensing Negotiations?*, EUR. PHARM. REV. (Mar. 8, 2019), https://www.europeanpharmaceuticalreview.com/article/84768/compulsory-licenses-in-germany-a-tool-for-licensing-negotiations/.

[247] EUR. PAT. OFF., COMPULSORY LICENSING IN EUROPE: A COUNTRY-BY-COUNTRY OVERVIEW 30 (2018), http://documents.epo.org/projects/babylon/eponot.nsf/0/8509F913B768D063C1258382004FC677/$File/compulsory_licensing_in_europe_en.pdf.

[248] BGH, July 11, 2017, X ZB 2/17 17, juris (Ger.) http://juris.bundesgerichtshof.de/cgi-bin/rechtsprechung/document.py?Gericht=bgh&Art=en&Datum=2017-7-11&nr=79269&pos=22&anz=24.

[249] Hohne, *supra* note 246.

[250] *Id.*

[251] EUR. PAT. OFF., *supra* note 247, at 31. Note that the patent at issue was eventually cancelled, but a royalty was paid until the cancellation. Thomas Hirse, *Compulsory Licensing in Germany*, CMS (Feb. 15, 2021), https://cms.law/en/int/expert-guides/cms-expert-guide-to-compulsory-licensing/germany.

[252] Adam Houldsworth, *The Key COVID-19 Compulsory Licensing Developments So Far*, IAM (Apr. 7, 2020), https://www.iam-media.com/coronavirus/the-key-covid-19-compulsory-licensing-developments-so-far. Although this legislation was originally set to last until March 31, 2021, the provisions applying to patents appear to have been extended. *See* Gesetz zur Verhütung und Bekämpfung von Infektionskrankheiten beim Menschen [IfSG] [Act on the Prevention and Control of Infectious Diseases in Humans], July 20, 2000, BGBL I at 1045, as amended by Act of Sept. 27, 2021, BGBL I at 4530, §§ 4, 5 (Ger.) (authorizing the Federal Ministry of Health, in accordance with section 13.1 of the Patent Act, to license patented inventions to ensure an adequate supply of pharmaceuticals).

[253] Houldsworth, *supra* note 252.

[254] CLAUDIA MILBRADT & FLORIAN REILING, PATENT LAW: APPROPRIATE BALANCE BETWEEN PRIVATE AND PUBLIC HEALTH INTERESTS IN TIMES OF CORONAVIRUS CRISIS, CLIFFORD CHANCE 2 (2020).

[255] *Id.* at 4.

3. *Hungary*

In 2020, Hungary issued Government Decree No. 212/2020, permitting the Hungarian Intellectual Property Office to issue a public health compulsory license for patented medicines, procedures, and medical devices.[256] The Hungarian government then approached local drug manufacturer Richter to manufacture remdesivir.[257] By October 2020, Richter was able to produce enough remdesivir to treat 3,000 patients and began clinical trials.[258] BIO and the U.S. Chamber of Commerce both opposed this measure, maintaining that the EU Joint Procurement Agreement provided Hungary with an adequate supply.[259]

4. *The EU's Response to U.S. Government Actions*

Both the Trump and Biden administrations have pushed the EU towards broader acceptance of compulsory licensing, though in different ways. The Trump administration attempted to outspend the EU for priority access to COVID-19 vaccines, creating significant backlash, while the Biden administration backed a patent-related waiver to TRIPS that forced the EU to offer its own counterproposal to the WTO.

a. The Trump Administration

The Trump administration attempted to buy priority access to German and French companies' vaccines. In March 2020, President Trump met with the chief executive of Germany-based CureVac and offered him a "large sum" of money for exclusive access to a vaccine that CureVac was developing.[260] The German newspaper *Die Welt am Sonntag* reported that President Trump offered CureVac $1 billion and that he wanted the vaccine to be available "only for the United States."[261] German Health Minister Jens Spahn

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[256] 212/2020. (V. 16.) Korm. r. a Belföldi Hasznosításra Szolgáló Közegészségügyi Kényszerengedélyről (Governmental Decree No. 212/2020 (V. 16.) on Public Health Compulsory Licenses for Exploitation Within Hungary) (Hung.).

[257] *Hungary's Richter Has Manufactured Remdesivir for 3,000 COVID-19 Patients*, REUTERS (Oct. 7, 2020, 9:44 AM), https://www.reuters.com/article/us-health-coronavirus-remdesivir-richter/hungarys-richter-has-manufactured-remdesivir-for-3000-covid-19-patients-idUSKBN26S283. Note that the Hungarian government owns a 5.25% stake in Richter. *Id.*

[258] *See id.* (noting that Richter had manufactured enough remdesivir to treat 3,000 patients); Romhanyikatalin, *Hungarian Remdesivir Is Already in Use at Three Clinics of Semmelweis University*, SEMMELWEIS UNIV. (Oct. 19, 2020), https://semmelweis.hu/english/2020/10/the-hungarian-remdesivir-is-already-in-practice-at-three-clinics-of-semmelweis-university/ (discussing clinical trials of Richter's remdesivir).

[259] PHRMA SPECIAL 301 SUBMISSION, *supra* note 114, at 250; BIOTECHNOLOGY INNOVATION ORG., *supra* note 114, at 9–10; U.S. CHAMBER OF COM., 2021 SPECIAL 301 SUBMISSION 17 (2021), https://www.keionline.org/wp-content/uploads/USCC_2021_Special_301_Filing.pdf.

[260] Katrin Bennhold & David E. Sanger, *U.S. Offered 'Large Sum' to German Company for Access to Coronavirus Vaccine Research, German Officials Say*, N.Y. TIMES, https://www.nytimes.com/2020/03/15/world/europe/cornonavirus-vaccine-us-germany.html (June 16, 2021).

[261] *Id.*

subsequently assured Germans that the deal was "off the table," and he promised that any developed vaccine would be "for the entire world."[262] Economy Minister Peter Altmaier stated more succinctly that "Germany is not for sale."[263] The German government subsequently bought a twenty-three percent equity stake in CureVac.[264]

In May 2020, Sanofi Chief Executive Officer Paul Hudson claimed that the United States would have "the right to the largest pre-order" for any developed vaccine because BARDA "invested in taking the risk" by providing $600 million in funding.[265] The French government was outraged, noting that it provides Sanofi with major tax exemptions.[266] Sanofi subsequently backed away from its initial position.[267]

President Trump's actions pushed the EU towards embracing compulsory licensing. In 2020, for the first time, more conservative members of the European Parliament voiced support for compulsory licensing.[268] Peter Liese—a German Christian Democratic Union member of European Parliament and spokesperson for the center-right European

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[262] Owen Dyer, *Covid-19: Trump Sought to Buy Vaccine Developer Exclusively for US, Say German Officials*, BMJ (Mar. 17, 2020), https://www.bmj.com/content/368/bmj.m1100 (quoting Jens Spahn).

[263] *Id.*; Hans von der Burchard & Jakob Hanke Vela, *EU Weighs Into German-American Spat over Vaccine Company*, POLITICO (Mar. 16, 2020, 10:29 PM), https://www.politico.eu/article/eu-weighs-into-german-american-spat-over-vaccine-company/ (quoting Peter Altmaier).

[264] Joint Press Release, Fed. Ministry of Econs. & Energy & dievini Hopp Biotech Holding, German Fed. Gov't Invests 300 Million Euros in CureVac (June 15, 2020), https://www.curevac.com/en/2020/06/15/bundesregierung-beteiligt-sich-mit-300-millionen-euro-an-curevac/.

[265] *See* James Paton, Riley Griffin & Cynthia Koons, *U.S. Likely to Get Sanofi Vaccine First If It Succeeds*, BLOOMBERG, https://www.bloomberg.com/news/articles/2020-05-13/u-s-to-get-sanofi-covid-vaccine-first-if-it-succeeds-ceo-says (May 13, 2020, 4:34 PM) (quoting Paul Hudson); Eleanor Beardsley, *French Drug Giant Sanofi Takes Heat After Suggesting U.S. May Get 1st Vaccine Access*, NPR (May 15, 2020, 2:10 PM), https://www.npr.org/2020/05/15/856293764/french-drug-giant-sanofi-takes-heat-after-suggesting-u-s-may-get-1st-vaccine-acc (noting that, according to President of the Sanofi board Serge Weinberg, the U.S. government has contributed $600 million towards Sanofi's research); Dina Spencer, *COVID-19 Vaccine: Sanofi CEO Paul Hudson Commits to "Bring a Solution to Everybody, Everywhere"*, PHARMA BOARDROOM (May 28, 2020), https://pharmaboardroom.com/articles/sanofi-ceo-paul-hudson-commits-to-bring-a-solution-to-everybody-everywhere/ (discussing Sanofi's financial relationship with BARDA).

[266] Beardsley, *supra* note 265.

[267] *See Macron to Meet Sanofi CEO After U-turn on 'U.S. Priority' for Covid-19 Vaccine*, RFI (May 15, 2020), http://www.rfi.fr/en/france/20200515-macron-to-meet-sanofi-ceo-after-u-turn-on-us-priority-for-covid-19-vaccine (quoting Serge Weinberg as stating that "[t]here will be no particular advance given to any country" for a COVID-19 vaccine). In the end, the vaccine candidate at issue failed. Adam Plowright, *Sanofi Looks to Restore Lost French Pride with New Vaccine*, MED. XPRESS (Mar. 12, 2021), https://medicalxpress.com/news/2021-03-sanofi-lost-french-pride-vaccine.html.

[268] Éanna Kelly & Goda Naujokaitytė, *Transatlantic Tensions over Access to COVID-19 Vaccines Mount After Sanofi CEO Says US Is First in Queue*, SCI. BUS. (May 15, 2020), https://sciencebusiness.net/news/transatlantic-tensions-over-access-covid-19-vaccines-mount-after-sanofi-ceo-says-us-first.

People's Party (EPP)[269]—threatened to use compulsory licensing if President Trump hoarded drugs or vaccines.[270] Liese noted that although Europe supports a collaborative approach, "plan B" is to use compulsory licensing.[271] He furthermore expressed support for licensing remdesivir.[272] This shift in position is noteworthy, given that the EPP has been "a staunch defender of the interests of the pharmaceutical industry."[273]

In November 2020, the European Commission formally embraced compulsory licensing in its Intellectual Property Action Plan. Although the Commission recognized that compulsory licenses are "to be used as a means of last resort and a safety net," it highlighted the broad flexibility that TRIPS provides.[274] It furthermore called on member states to pass "fast-track procedures for issuing compulsory licenses in emergency situations"[275] and encouraged member states to coordinate with each other regarding the duration of any licenses and the remuneration to be paid.[276] The Commission said that it would consider "the possibility of creating an emergency co-ordination mechanism, to be triggered at short notice when Member States consider issuing a compulsory license."[277]

The EU has also committed to facilitating low-income countries' use of compulsory licensing during the COVID-19 pandemic. The Chair of the European Parliament's Committee on International Trade, Bernd Lange, sent a letter to the EU Commissioner for Trade, Phil Hogan, noting that low-income countries may need to utilize compulsory licensing to get COVID-19 drugs and expressing concern that the EU's recent free trade

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[269] *See Our History*, EUR. PEOPLE'S PARTY, https://www.epp.eu/who-we-are#timeline (last visited Aug. 14, 2021) (describing itself as the "EU's centre-right party and its largest and most influential political family").

[270] Peter Liese, *Europe Will Not Tolerate an 'America First' Vaccine*, BARRON'S (May 15, 2020, 6:20 AM), https://www.barrons.com/articles/if-trump-hoards-a-coronavirus-vaccine-we-will-break-u-s-patents-says-a-key-european-politician-51589538038.

[271] *Id.*

[272] *See* Andreas Becker, *Compulsory Licensing of Remdesivir an Option?*, DEUTSCHE WELLE (July 9, 2020), https://beta.dw.com/en/is-compulsory-licensing-of-remdesivir-a-feasible-option/a-54103280 (noting that Peter Liese is "threatening to introduce compulsory licensing" of remdesivir).

[273] Reflector, *The Specter of Compulsory Licensing Haunts Vaccine Debate*, 40 PHARM. EXEC., June 2020, at 7, 7, http://files.alfresco.mjh.group/alfresco_images/pharma//2020/06/11/ed4e6d3f-dde4-464e-849a-0f41157b242b/PE%20June%202020.pdf.

[274] *Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of Regions, Making the Most of the EU's Innovative Potential: An Intellectual Property Action Plan to Support the EU's Recovery and Resilience*, at 12, COM (2020) 760 final (Nov. 25, 2020) (emphasis omitted).

[275] *Id.*

[276] *Id.* The goal of coordinating is to "help secure maximum benefits whilst at the same time avoiding excessive distortions." *Id.*

[277] *Id.*

agreements might hinder such use.[278] Hogan responded by reaffirming the EU's commitment to TRIPS flexibilities and the use of the Doha Declaration for EU trade partners. He further noted that, if needed, the EU would be open to changing its status under TRIPS Article 31*bis* to allow for the importation of drugs produced by other countries under compulsory licenses.[279]

b. The Biden Administration

In October 2020, India and South Africa petitioned the WTO to permit countries to waive IP rights related to fighting the COVID-19 pandemic.[280] Many high-income countries were opposed at the time.[281] In May 2021, however, the Biden administration announced support for waiving IP protection for COVID-19 vaccines.[282] U.S. Trade Representative Katherine Tai noted that "the extraordinary circumstances of the COVID-19 pandemic call for extraordinary measures" and expressed support for expanding vaccine manufacturing and distribution.[283]

Under pressure, the EU submitted its own three-element WTO proposal. First, it called on governments to ensure COVID-19-related drugs and their components can freely cross borders—something that the United States had

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[278] Letter from Bernd Lange, Chair of the Eur. Parliament Comm. on Int'l Trade, to Phil Hogan, Trade Comm'r of the Eur. Comm'n (May 14, 2020), https://www.europarl.europa.eu/cmsdata/207560/D(2020)15256_Lange%20to%20Commissioner%20Hogan%20on%20IPR-1.pdf.

[279] Letter from Phil Hogan, *supra* note 37. *See also* Thiru Balasubramaniam, *EU Trade Commissioner Phil Hogan Issues Statement on European Union Compulsory Licensing in Context of COVID-19, Makes Important Statement About TRIPS Article 31bis*, KNOWLEDGE ECOLOGY INT'L (June 3, 2020), https://www.keionline.org/33284 (noting that Hogan's statement about the EU's willingness to revisit its opt-out of Article 31 is significant due to the uncertainty of whether opted-out countries could reverse course).

[280] Communication from India and South Africa, *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of Covid-19*, ¶ 12, WTO Doc. IP/C/W/669 (Oct. 2, 2020). Note that talks regarding the waiver are currently stalled. Alex Lawson, *WTO Nominee Sees Vaccine IP Waiver Talks as 'Sort of Stuck'*, LAW360 (Oct. 26, 2021), https://www.law360.com/articles/1434276.

[281] *See* Ann Danaiya Usher, *South Africa and India Push for COVID-19 Patents Ban*, LANCET (Dec. 5, 2020), https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)32581-2/fulltext (discussing the opposition, in late 2020, from high-income countries, including the United States, United Kingdom, and EU member states).

[282] *See* Press Release, Katherine Tai, Ambassador, Off. of the U.S. Trade Representative, Exec. Off. of the President, Statement from Ambassador Katherine Tai on the Covid-19 Trips Waiver (May 5, 2021), https://ustr.gov/about-us/policy-offices/press-office/press-releases/2021/may/statement-ambassador-katherine-tai-covid-19-trips-waiver (supporting the waiver of IP protections for COVID-19 vaccines). *See also* Sapna Kumar, *WTO Global Health: Shifting Away from a Punishment Mindset*, PATENTLY-O (May 9, 2021), https://patentlyo.com/patent/2021/05/shifting-punishment-mindset.html (discussing the Biden administration's support for a COVID-19 waiver).

[283] Press Release, Katherine Tai, *supra* note 282. This led the EU to argue that the United States was hoarding both vaccines and raw materials needed to produce COVID-19 vaccines. Joao Lima, Arne Delfs & Viktoria Dendrinou, *EU Tells Biden to Export Vaccines Now and Worry About IP Later*, BLOOMBERG (May 8, 2021, 11:03 AM), https://www.bloomberg.com/news/articles/2021-05-08/eu-tells-biden-to-export-vaccines-now-and-worry-about-ip-later.

hindered.[284] Second, it "call[ed] on governments to strongly encourage and support vaccine manufacturers and developers to expand production and ensure the affordable supply of vaccines to low- and middle-income countries," through methods including licensing agreements, tiered pricing for lower-income countries, and the sharing of expertise.[285] Third, it called for facilitating the use of compulsory licensing under TRIPS.[286]

The slow pace for dealing with IP rights and drug access once a pandemic arises highlights a need for countries to plan for drug shortages before they occur. Part V makes suggestions for how the United States can better streamline compulsory licensing and make it work for more complex drugs, including vaccines.

V. COMPULSORY LICENSING AS A TOOL FOR PROTECTING U.S. PUBLIC HEALTH

During the COVID-19 pandemic, a surge in demand for treatments and vaccines led to widespread shortages and rationing. Notwithstanding the crisis, pharmaceutical companies were under no obligation to license out their technology to third parties to increase supply. Although compulsory licensing under TRIPS Article 31 can be helpful in such situations, it does not compel companies to share the know-how needed to produce complicated drugs. Section A examines differences in the efficacy of compulsory licensing for small-molecule drugs versus more complex biologic drugs, and explains why know-how is important for producing vaccines. Section B proposes that Congress pass legislation facilitating the use of compulsory licensing, and that the government require federal funding recipients to out-license patents, technology, and know-how when drug shortages arise.

A. *Compulsory Licensing for Small-Molecule Drugs Versus Biologic Drugs*

Small-molecule drugs comprise ninety percent of global drug sales.[287] They are manufactured through chemical synthesis, typically taken orally as pills or tablets, and work within the cells in the body.[288] The production of small-molecule drugs can be scaled up, making it possible to produce them

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[284] Press Release, European Commission, EU Proposes a Strong Multilateral Trade Response to the COVID-19 Pandemic (June 4, 2021), http://ec.europa.eu/commission/presscorner/detail/en/ip_21_2801.

[285] *Id.*

[286] *Id.*

[287] Helen Wang, *Small vs Big: Understanding the Differences Between Small Molecule Drugs and Biologic Drugs*, IMMPRESS MAG. (Aug. 19, 2019), https://www.immpressmagazine.com/small-vs-big-understanding-the-differences-between-small-molecule-drugs-and-biologic-drugs.

[288] *Small Molecules, Large Biologics and the Biosimilar Debate*, AZBIO (Feb. 18, 2013), https://www.azbio.org/small-molecules-large-biologics-and-the-biosimilar-debate.

in large quantities.[289] It is relatively straight-forward to create generic forms of small-molecule drugs in different manufacturing conditions, given that the active ingredient is generally a unique molecule reproduceable through a predictable chemical process.[290] So long as the generic manufacturer can show that a generic drug contains the same active ingredient and is a bioequivalent of the approved reference drug, and that its manufacturing facility meets various standards, regulators can assume that the generic drug shares the same safety and efficacy features.[291]

Biological products or "biologics" are narrowly defined as large-molecule drugs derived from living organisms.[292] Broader definitions characterize them as any drug comprised of biologically-derived material,[293] including all vaccines.[294] Biologics are typically injected or taken intravenously to interact in the bloodstream or on the surface of the cells, rather than within the cells.[295] Because they are derived from living organisms and are structurally complex,[296] they are far more difficult to produce than small-molecule drugs.[297]

Biologics do not have truly identical generic counterparts—"biosimilars" are similar, but not completely identical, to an existing biologic.[298] Because small manufacturing process changes can cause side effects in patients, biologics are difficult to replicate and must go through rigorous testing to ensure both safety and efficacy.[299] Moreover, unlike with small-molecule

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[289] Thomas Morrow & Linda Hull Felcone, *Defining the Difference: What Makes Biologics Unique*, BIOTECHNOLOGY HEALTHCARE, Sept. 2004, at 24, 26 (comparing the production of small-molecule drugs with biologics).

[290] *See id.* at 26 (observing that "the active ingredient of a chemical pharmaceutical is usually a unique molecule subject to well-established analytical tests"); *Small Molecule Versus Biological Drugs*, *supra* note 8; Fernando de Mora, *Biosimilar: What It Is Not*, 80 BRIT. J. CLINICAL PHARMACOLOGY 949, 950–52 (2015) (discussing why generics of small-molecule drugs are substantially easier to replicate and to get approved compared to biosimilars).

[291] *See* de Mora, *supra* note 290, at 950 (noting that, if a generic manufacturer can establish bioequivalence, "it can then be assumed on scientific grounds that both the original and the generic candidate products will share the safety and the efficacy profile"); *Overview and Basics*, U.S. FOOD & DRUG ADMIN. (Sept. 13, 2017), https://www.fda.gov/drugs/generic-drugs/overview-basics (discussing the process of approving generic drugs).

[292] *See* Morrow & Felcone, *supra* note 289, at 25 (discussing various definitions of biologic drugs).

[293] *Id.*

[294] *See* 21 C.F.R. § 600.3(h) (2021) (classifying all vaccines as "biological product[s]").

[295] *Small Molecules, Large Biologics and the Biosimilar Debate*, *supra* note 288.

[296] Wang, *supra* note 287 ("A biologic drug is a substance that is extracted from, semi-synthesized by, or manufactured in living organisms.").

[297] *See* Morrow & Felcone, *supra* note 289, at 26 (discussing the difficulty of scaling up biologic production).

[298] *See Biosimilar and Interchangeable Biologics: More Treatment Choices,* U.S. FOOD & DRUG ADMIN., https://www.fda.gov/consumers/consumer-updates/biosimilar-and-interchangeable-biologics-more-treatment-choices (Oct. 12, 2021) (noting that "[a] biosimilar is a biologic that is highly similar to, and has no clinically meaningful differences from, another biologic that's already FDA-approved").

[299] *See* Wang, *supra* note 287 ("The differences in extraction source, processing protocols, and isolation methods between biosimilars and their reference biologic drugs can affect the safety and effectiveness of the product in patients."); de Mora, *supra* note 290, at 952 (discussing "the difficulty of

drugs, there is no one test that can prove a biosimilar is equivalent to its reference biologic.[300] These technical and regulatory challenges mean that bringing a biosimilar to market can be time-consuming.[301]

Although small-molecule drugs and biologics are subject to the same level of U.S. patent protection, they receive differing levels of data protection under the Hatch-Waxman Act.[302] Patent holders for new small-molecule drugs are provided with five years of data exclusivities that prevent competitors from utilizing the patent holder's clinical data for the purpose of gaining regulatory approval, which can be extended to eight years if a new indication is found.[303] Only after that period can the FDA begin to review applications from potential generic manufacturers, leading to a longer de facto period of protection.[304] Biologics, by contrast, enjoy twelve years of data exclusivity based on a theory that biologics are more time-consuming to bring to market.[305] Note that there is no waiver to data exclusivity provisions under U.S. law or TRIPS.

These differences mean that the utility of compulsory licensing during public health emergencies varies based on drug type. Compulsory licensing is a valuable tool for producing small-molecule drugs because, even without know-how, a generic manufacturer may be able to replicate a drug quickly. For example, remdesivir is regarded as a more complex small-molecule drug, given that its production requires a series of sequential steps.[306] Yet, as mentioned above, it was quickly replicated and produced by others.

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exactly mimicking the molecular structure of the original biological product" as a hurdle to the creation of biosimilars).

[300] De Mora, *supra* note 290, at 952.

[301] Jennifer Fox, *Biosimilars: Challenges and Barriers to Entering the U.S. Market*, AM. PHARM. REV. (July 25, 2018), https://www.americanpharmaceuticalreview.com/Featured-Articles/352224-Biosimilars-Challenges-and-Barriers-to-Entering-the-U-S-Market/.

[302] Note that in the European Union, the terms of data exclusivity are the same for both types of drugs.

[303] 21 U.S.C. § 355(c)(3)(E)(ii). *See also* Adam Houldsworth, *Covid-19 Emergency May Expose Compulsory Licensing Limits*, IAM (Mar. 24, 2020), https://www.iam-media.com/coronavirus/covid-19-emergency-may-expose-compulsory-licensing-limits ("[T]he US grants five years' data and market exclusivity for new small molecule drugs, with an additional three years for new indications."). Note that orphan drugs are eligible for a seven-year data exclusivity. *Id.*

[304] Reed F. Beall, Thomas J. Hwang & Aaron S. Kesselheim, *Pre-Market Development Times for Biologic Versus Small-Molecule Drugs*, 37 NATURE BIOTECHNOLOGY 708, 709 (2019) (noting the U.S. data exclusivity for small-molecule drugs is, in practice, closer to seven years, given that the FDA may not begin reviewing an application from a generic competitor until the five-year period ends). Note that a generic manufacturer may submit an application after four years if it can certify that its products do not infringe on the patents of the reference drug or if it can establish the patents at issue are invalid. 21 U.S.C. § 355(j)(5)(ii); Brennan, Kapczynski, Monahan & Rizvi, *supra* note 61, at 342.

[305] Note that at least one study has called this assumption into question. *See* Beall, Hwang & Kesselheim, *supra* note 304, at 709 (noting that data suggests that "development times for biologics are similar to, or possibly somewhat shorter than, for small-molecule drugs").

[306] *See* Andrew Joseph, *Gilead's Remdesivir Has Seen Success Against the Coronavirus. Now the Company Has to Make Enough to Supply the World*, STAT (Apr. 30, 2020), https://www.statnews.com

For biologics such as vaccines, however, compulsory licensing is not useful in the short term. There is no legal mechanism under TRIPS or U.S. law for requiring a patent holder to turn over know-how for producing drugs, and reverse-engineering alone is not sufficient for creating biosimilars.[307] This can make developing biosimilars a time-consuming and expensive process.[308] Consequently, any legislative reform to alleviate vaccine shortages must address know-how, given that a compulsory license alone may not be sufficient to quickly develop and deploy a biosimilar.

B. *Reforming Compulsory Licensing in the United States*

Current U.S. law is inadequate for dealing with pandemic-related drug shortages. Neither 28 U.S.C. § 1498 nor the Bayh-Dole Act require the government to license a drug to a suitable manufacturer during a public health emergency. Third parties cannot petition for a compulsory license for an invention that was not government-funded. The government has never granted a license under the Bayh-Dole Act, and even if it did, the license would not take effect until the patent holder exhausted all available appeals.[309] Federal reform is needed in two areas. First, Congress needs to make it easier for third parties to obtain compulsory licenses to alleviate drug shortages. Second, when government-funded medical research results in a patented drug, that drug should be subject to an out-licensing requirement that triggers automatically in the event of drug scarcity.

1. *Third-Party Compulsory License Requests*

Congress should pass legislation requiring the government to grant a compulsory license if a shortage of a patented drug arises and is detrimental to public health, regardless of whether the drug was government-funded. To achieve this, Congress could place an affirmative obligation on the Secretary of HHS to ensure an adequate supply of needed drugs. In the event of a shortage that is detrimental to public health, the Secretary would be obligated to produce the drug or seek bids from suitable drug manufacturers to produce it.

/2020/04/30/gileads-remdesivir-has-seen-success-against-the-coronavirus-now-the-company-has-to-make-enough-to-supply-the-world/ (discussing the complexity of manufacturing remdesivir).

[307] *See* W. Nicholson Price II & Arti K. Rai, *Manufacturing Barriers to Biologics Competition and Innovation*, 101 IOWA L. REV. 1023, 1028 (2016) (discussing the challenges that trade secrecy poses to biosimilar manufacturing).

[308] For example, in 2013, an Indian court authorized a third-party drug manufacturer, Biocon, to develop a biosimilar to Roche's patented biologic, trastuzumab. Cinthia Leite Frizzera, Borges Bognar, Brittany L. Bychkovsky & Gilberto de Lima Lopes Jr., *Compulsory Licensing for Cancer Drugs: Does Circumventing Patent Rights Improve Access to Oncology Medications?*, 2 J. GLOB. ONCOLOGY 292, 295 (2016). Although Biocon was able to create a biosimilar by January 2014, it was forced to conduct Phase III trials to demonstrate the efficacy of the biosimilar. *Id.*

[309] *See* discussion *supra* Section II.B.1.b.

One problem with traditional compulsory licensing is the time that it can take to reverse-engineer a drug, particularly for biologics. To overcome this, the level of compensation to the patent holder could be set based on its willingness to cooperate. If a patent holder shares manufacturing know-how with a third-party producer, then the government would pay a reasonable royalty that comes as close as possible to fully compensating the patent holder. If the patent holder does not share this information, then compensation would be set to the minimum amount required under TRIPS Article 31. This provides pharmaceutical companies with a financial incentive to prevent drug shortages and discourages rent-seeking behavior during public health crises.

Another problem under current law is that the government refuses to grant licenses notwithstanding drug shortages. Consequently, Congress should provide a citizen-standing provision in compulsory licensing legislation. Congress could permit third parties to sue HHS in federal court to compel it to issue a license to a suitable manufacturer. Constitutional standing requirements could be satisfied by a manufacturer able and willing to produce the drug at issue.[310]

This approach offers several improvements over current law. It would provide a way to compel the government to act when a drug shortage arises. In 2020, had such legislation existed, it would have forced Gilead Sciences to license remdesivir earlier and to more manufacturers, which would have lessened the shortage. The new provision would still reward the patent holder for its invention—money that the patent holder would not have received had the shortage been allowed to persist or if the government had utilized march-in rights under the Bayh-Dole Act. It would also encourage patent holders to proactively seek out third-party licensing agreements on their own terms before a shortage arises to avoid government intervention.

2. *Out-Licensing Requirement*

Whenever the government funds medical research, it should contractually require the funding recipient to produce any resulting drug in a sufficient quantity to meet public health needs. If a public health emergency arises or a shortage otherwise threatens public health, a patent holder would be required to utilize out-licensing to third-party manufacturers to keep pace with demand after an initial grace period. Failure to share manufacturing know-how could trigger steep penalties for the patent holder or its exclusive licensee.

Pharmaceutical companies already utilize out-licensing to supply drugs to some countries. As discussed earlier, Gilead Sciences voluntarily licensed

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[310] *See* Sapna Kumar, *Standing Against Bad Patents*, 32 BERKELEY TECH. L.J. 87, 108–111 (2017) (discussing constitutional standing requirements for suing an agency under the Administrative Procedure Act).

remdesivir to generic manufacturers in several countries to supply to mostly low- and mid-income countries.[311] Merck & Co voluntarily granted a royalty-free license to its new COVID-19 antiviral drug to 105 low- and middle-income countries for the duration of the public health emergency.[312] Such behavior is not limited to pandemics:[313] pharmaceutical companies are generally willing to license their drugs because lower-income countries comprise only a tiny percentage of the global pharmaceutical market,[314] and doing so may stave off future compulsory licensing.[315]

Less common, however, is the use of out-licensing to increase drug supply or alleviate shortages in high-income countries. The Biden administration helped secure an arrangement in which Merck & Co repurposed existing manufacturing facilities to produce J&J's COVID-19 vaccine.[316] President Biden announced that he invoked the DPA to help secure equipment, machinery, and supplies needed to produce vaccines.[317]

This agreement shows that the government can use existing tools to address drug shortages, but it also highlights problems. First, it requires the government to act proactively to address current or imminent drug shortages, which did not occur under the Trump administration.[318] Second, it requires the cooperation of the patent holder. The Biden administration had no way to compel J&J to share manufacturing know-how with third parties if it refused

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[311] Bauman, *supra* note 182.

[312] News Release, Merck & Co., The Medicines Patent Pool (MPP) and Merck Enter into License Agreement for Molnupiravir, an Investigational Oral Antiviral COVID-19 Medicine, to Increase Broad Access in Low- and Middle-Income Countries (Oct. 27, 2021, 6:00 AM), https://www.merck.com/news/the-medicines-patent-pool-mpp-and-merck-enter-into-license-agreement-for-molnupiravir-an-investigational-oral-antiviral-covid-19-medicine-to-increase-broad-access-in-low-and-middle-income-countri/.

[313] For example, Gilead Sciences also licensed its hepatitis C drugs sofosbuvir and ledipasvir to seven Indian generic manufacturers for export to ninety-one countries in exchange for royalties. Gardiner Harris, *Maker of Costly Hepatitis C Drug Sovaldi Strikes Deal on Generics for Poor Countries*, N.Y. TIMES (Sept. 15, 2014), https://www.nytimes.com/2014/09/16/business/international/maker-of-hepatitis-c-drug-strikes-deal-on-generics-for-poor-countries.html.

[314] *See* Michael A. Friedman, Henk den Besten & Amir Attaran, *Out-Licensing: A Practical Approach for Improvement of Access to Medicines in Poor Countries*, 361 LANCET 341, 341 (2003) (noting that "Africa, the Indian subcontinent, and the poorer countries of Asia total only 1.2%, 1.3%, and 2.6% of the global pharmaceutical market, respectively" and observing that "the proportions are even smaller for the sales of patented medicines").

[315] Outterson, *supra* note 227, at 226.

[316] Press Release, U.S. Dep't of Health & Hum. Servs., Biden Administration Announces Historic Manufacturing Collaboration Between Merck and Johnson & Johnson to Expand Production of COVID-19 Vaccines (Mar. 2, 2021), https://www.hhs.gov/about/news/2021/03/02/biden-administration-announces-historic-manufacturing-collaboration-between-merck-johnson-johnson-expand-production-covid-19-vaccines.html.

[317] *Id.*

[318] *See* Andrew Jacobs, *Despite Claims, Trump Rarely Uses Wartime Law in Battle Against Covid*, N.Y. TIMES, https://www.nytimes.com/2020/09/22/health/Covid-Trump-Defense-Production-Act.html (Jan. 20, 2021) (noting the Trump administration's failure to utilize the DPA to alleviate shortages on personal protective equipment and other supplies needed to combat the pandemic).

to cooperate, even though J&J received vaccine development funding.[319] Had the government relied upon march-in rights, that would have led to a lengthy delay before a biosimilar could be created and FDA-approved.[320]

By contrast, an out-licensing provision could reduce transaction costs, and reduce barriers to quickly scaling up needed drugs. Such a provision could automatically activate in the event of a declared public health emergency or if a drug shortage arises, preventing the relevant pharmaceutical company from refusing to license out relevant technology. It would be obligated to work with third-party manufacturers to share know-how needed to successfully produce the drug. The contract would also provide a means for calculating royalty rates to facilitate payment to the patent holder. The fact that the terms would be pre-negotiated is important, because it would reduce deadly delays in scaling up drug production.

A major benefit of using contractual provisions is the flexibility that they provide. Congress would not need to pass a statute for a federal agency to change its licensing terms. Researchers who are unwilling to accept the terms could refuse government funding. The government could choose to use out-licensing provisions for pandemic-specific funding, for particular classes of drug research, or for all medical research.

Out-licensing has potential utility beyond pandemics. For example, a drug shortage on Genzyme's Fabrazyme drug lasted for more than a year.[321] During this time, Fabry disease patients received only thirty percent of their usual drug dose, which harmed several patients.[322] Patients petitioned the National Institutes of Health (NIH) to exercise march-in rights.[323] But, although Genzyme repeatedly missed production targets, the NIH maintained that it would take too long for another manufacturer to produce the drug and gain

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[319] *See* Alex Keown, *J&J Secures Additional $1 Billion in Funding for COVID-19 Vaccine*, BIOSPACE (Nov. 16, 2020), https://www.biospace.com/article/j-and-j-vaccine-secures-additional-1-billion-in-funding-for-covid-19-vaccine/ (noting that J&J accepted more than $1.5 billion in funding from BARDA).

[320] *See* Price & Rai, *supra* note 307, at 1028 (discussing difficulties in reverse engineering biologics and creating successful biosimilars in a timely fashion, given that important drug production know-how is protected as trade secrets).

[321] *See* Andrew Pollack, *Genzyme Drug Shortage Leaves Users Feeling Betrayed*, N.Y. TIMES (Apr. 15, 2010), https://www.nytimes.com/2010/04/16/business/16genzyme.html (discussing how production problems from Genzyme led to a shortage of the Fabrazyme drug).

[322] *See id.* (discussing how the Fabrazyme drug shortage harmed U.S. patients and possibly caused one death). Genzyme conceded that reduced doses of Fabrazyme could lead to "aggravation" of the disease or "adverse events" such as "pain, cardiac manifestations and deafness." Susan Donaldson James, *Fabry Disease Patients Get Sicker as Drugs Go Overseas*, ABC NEWS (Aug. 29, 2011, 8:36 AM), https://abcnews.go.com/Health/fabry-disease-patients-sicker-sue-drug-company-lifesaving/story?id=14403759.

[323] Nat'l Insts. of Health, Off. of the Dir., Opinion Letter on Determination in the Case of Fabrazyme® Manufactured by Genzyme Corporation (Dec. 1, 2010), https://www.ott.nih.gov/sites/default/files/documents/policy/March-In-Fabrazyme.pdf.

regulatory approval.[324] Had an out-licensing provision been in place, Genzyme would have been obligated to work with other manufacturers to scale up production.

Out-licensing will admittedly not solve all drug shortages. Inadequate global drug manufacturing capacity and shortages of raw materials also drive drug scarcity.[325] However, an out-licensing requirement would place the government in a better position to address future pandemic-related drug shortages, and it would balance providing an incentive for pharmaceutical companies to develop new drugs while reducing the risk of drug shortages.

VI. CONCLUSION

The same patent laws that help spur innovation hinder the rapid production and dissemination of lifesaving drugs during public health emergencies. Shortages of remdesivir and COVID-19 vaccines have caused high-income countries to reassess their attitudes towards compulsory licensing. However, although the Biden administration has taken a more proactive stance on combating drug shortages by using the DPA, it is dependent upon time-consuming negotiations and lacks a means for compelling uncooperative pharmaceutical companies.

Several measures should be taken to prevent future drug shortages. First, Congress should streamline the process for third parties seeking compulsory licenses and require funding agencies to issue licenses in the event of drug shortages that harm public health. Congress should furthermore allow third parties to petition for a license even if a drug was not government-funded.

Second, funding agencies should utilize contractual provisions that tie government funding to out-licensing requirements for drugs. These dormant provisions could trigger in the event of a public health emergency declaration or during a drug shortage. Negotiating the terms of an out-license in advance would speed up the process when a shortage does emerge. The government would gain the ability to compel unwilling pharmaceutical companies to share know-how protected under trade secrecy law that is currently not subject to 28 U.S.C. § 1498 or the Bayh-Dole Act. Had such provisions been in place in 2020, the drug shortages that the United States experienced could have been greatly alleviated.

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[324] *Id.* In denying the license, the NIH cited to Genzyme's promise to have the drug back to full levels in the first half of 2011, a target that Genzyme was unable to meet. *Id.* at 2.

[325] *See* Rebecca Heilweil, *How Quickly Can the US Distribute a Covid-19 Vaccine? Here Are the Four Biggest Logistical Challenges.*, VOX (Dec. 7, 2020, 7:00 AM), https://www.vox.com/recode/22151473/vaccine-covid-19-pfizer-glass-syringes-needles-freezers (discussing how shortages of pharmaceutical glass, syringes, and needles contributed to vaccine shortages); Donna Young, *Lack of Raw Materials, Capacity May Delay Coronavirus Vaccines—Experts*, S&P GLOB. MKT. INTEL. (June 9, 2020), https://www.spglobal.com/marketintelligence/en/news-insights/latest-news-headlines/lack-of-raw-materials-capacity-may-delay-coronavirus-vaccines-8211-experts-58980598 (discussing how shortages of raw materials and manufacturing capacity may have contributed to vaccine production delays).