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Promoting Public Health Through State Sovereign Immunity

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*During the COVID-19 outbreak, the United States experienced widespread shortages of patented drugs and goods. But although states negotiated with foreign governments to obtain needed medical equipment, they were seemingly powerless to obtain or produce their own supply of scarce drugs. This Essay proposes an unorthodox solution to drug shortages during public health emergencies: states could disregard the Patent Act and directly produce or import needed patented drugs. The doctrine of state sovereign immunity shields states from having to pay damages when they violate federal law, including patent law. Moreover, courts and agencies are generally unwilling to award injunctions or other prospective relief if it disservices the public interest. State action is admittedly not a perfect solution*

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*to patent-related drug shortages and comes with a variety of costs and risks, including retaliation from the U.S. Food & Drug Administration. But at minimum, it could serve as a means for pressuring the federal government and pharmaceutical companies to work to provide drugs to the public.*

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## I. INTRODUCTION

During the COVID-19 pandemic, the United States experienced shortages of needed drugs and medical equipment.<sup>1</sup> Some state governments were able to broker deals with foreign governments and import needed personal protective equipment and medical devices.<sup>2</sup> But when it came to

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<sup>1</sup> See Joseph Walker, *All Remdesivir Supplies to Be Distributed in U.S. by Maker Gilead Sciences*, WALL ST. J. (Oct. 1, 2020, 4:13 PM), <https://www.wsj.com/articles/all-remdesivir-supplies-to-be-distributed-in-u-s-by-maker-gilead-sciences-11601575201> (noting that remdesivir was in short supply from when it became authorized for emergency use, with the shortage dissipating only in late September 2020); Daniel Joseph Finkenstadt et al., *Why the U.S. Still has a Severe Shortage of Medical Supplies*, HARV. BUS. REV. (Sept. 17, 2020), <https://hbr.org/2020/09/why-the-u-s-still-has-a-severe-shortage-of-medical-supplies> (discussing the 2020 personal protective equipment shortage).

<sup>2</sup> See Beth Healy & Christine Willmsen, *‘I Have A Guy In China’: Inside The Pandemic Market For Medical Masks*, WBUR (June 11, 2020), <https://www.wbur.org/investigations/>

obtaining scarce patented drugs, states had few options. This led to U.S. hospitals being forced to ration remdesivir,<sup>3</sup> despite abundant supply in some low-income countries.<sup>4</sup>

Ideally, in situations like this, the United States would take action. The federal government may produce patented goods without permission,<sup>5</sup> and it can use this power as a bargaining chip.<sup>6</sup> The President also has powers under the Defense Production Act (DPA) that can be used to facilitate drug production.<sup>7</sup> For example, in March 2021, the Biden Administration used the DPA to help secure an agreement for Merck to produce Johnson & Johnson's COVID-19 vaccine.<sup>8</sup> However, these tools are only useful if the federal

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2020/06/11/massachusetts-mask-brokering-chaos-characters (detailing how Massachusetts obtained N95 masks from China); Pamela Wood & Luke Broadwater, *Maryland Secures 500,000 Coronavirus Tests from South Korea; Hogan's Initiative Sparks Criticism from Trump*, BALT. SUN (Apr. 20, 2020), <https://www.baltimoresun.com/coronavirus/bs-md-hogan-testing-20200420-atxs3grvbjdgphzzt4tfhuhnbm-story.html> (discussing how Maryland secured 500,000 coronavirus tests from South Korea); Tina Sfondeles, *Illinois Gets Second PPE Shipment from China with 'Lots of Surgical Masks'*, CHI. SUN-TIMES (Apr. 20, 2020, 1:44 PM), <https://chicago.suntimes.com/coronavirus/2020/4/20/21228325/illinois-ppe-shipment-china-surgical-masks-coronavirus-covid-19> (discussing Illinois's two purchases of personal protective equipment from China).

<sup>3</sup> See Eric Boodman & Casey Ross, *Doctors Lambaste Federal Process for Distributing Covid-19 Drug Remdesivir*, STAT NEWS (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); Elizabeth Cohen, *Covid-19 Drug Rationed in the US is Plentiful in Developing Countries*, CNN (Sept. 9, 2020), <https://www.cnn.com/2020/09/09/health/covid-remdesivir-us-vs-other-countries/index.html> (discussing how doctors in Texas were forced to choose which patients would receive remdesivir in July 2020); Eric Boodman, *From Houston to Miami, Hospitals Running Short of Remdesivir for Covid-19 Patients*, STAT NEWS (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).

<sup>4</sup> See Sapna Kumar, *Compulsory Licensing of Patents During Pandemics*, 54 CONN. L. REV. (forthcoming Mar. 5, 2021) (discussing the 2020 remdesivir shortage).

<sup>5</sup> If the government provides funding for research resulting in an invention, it retains a royalty-free license under the Bayh-Dole Act and may issue a compulsory license to a third party to produce the invention. See *id.*; 35 U.S.C. § 202(c)(4). If the government or its contractor infringes a non-government funded invention, the patent holder's compensation is limited to "reasonable and entire compensation." See *id.*; 28 U.S.C. § 1498.

<sup>6</sup> See *infra*, Part III.C.

<sup>7</sup> See 50 U.S.C. § 4501 et. seq. (2018).

<sup>8</sup> See Press Release, U.S. Dep't 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> (noting that Biden invoked the Defense Production Act (DPA) to support vaccine production). An anonymous government official noted that the DPA provided an "implicit" incentive to

government is willing to use them, something that was not the case in 2020.<sup>9</sup>

Under background principles of the U.S. Constitution and the Eleventh Amendment, states enjoy sovereign immunity and cannot be sued by private parties for damages when they violate federal law, absent their express consent.<sup>10</sup> Although state sovereign immunity can be waived by Congress under § 5 of the Fourteenth Amendment,<sup>11</sup> a prior attempt to do so for patent infringement was declared unconstitutional by the Supreme Court.<sup>12</sup> As a result, patent holders are currently unable to sue state infringers for damages.<sup>13</sup>

This protection presents an opportunity for states to alleviate shortages of patented drugs during public health emergencies. States could attempt to import patented drugs or produce drugs themselves, and then use their sovereign status to shield against damages. Although individual state officers could still be sued for prospective relief,<sup>14</sup> public welfare considerations would make it difficult for the patent holder to receive a permanent injunction or an exclusion order.<sup>15</sup>

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cooperate, given “the potential to use the DPA if there isn’t cooperation.” Tamara Keith, *How the White House Got 2 Pharma Rivals to Work Together on COVID-19 Vaccine*, NPR (Mar. 3, 2021), <https://www.npr.org/2021/03/03/973117712/how-the-white-house-got-2-pharma-foes-to-work-together-on-covid-19-vaccine>.

<sup>9</sup> The Republican-controlled government was hostile to compulsory licensing for drugs, with HHS Secretary Alex Azar referring to the practice as “socialist.” James Love, *Hits and Misses from the Senate HELP Committee Hearing on the President’s Blueprint for Lower Drug Prices*, HARV. L. PETRIE-FLOM CTR.: 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/>. President Trump was criticized for his lack of willingness to use his powers under the DPA to alleviate shortages of needed medical supplies. See Andrew Jacobs, *Despite Claims, Trump Rarely Uses Wartime Law in Battle Against Covid*, N.Y. TIMES (Sept. 22, 2020), <https://www.nytimes.com/2020/09/22/health/Covid-Trump-Defense-Production-Act.html>.

<sup>10</sup> See *infra*, Part II.A.

<sup>11</sup> See *City of Boerne v. Flores*, 521 U.S. 507, 519 (1997) (discussing Congress’s authority to abrogate sovereign immunity under the Fourteenth Amendment).

<sup>12</sup> See *Fla. Prepaid Postsecondary Educ. Expense Bd. v. College Savs. Bank*, 527 U.S. 627, 634 (1999) (striking down Congress’s abrogation of state sovereign immunity for patent law under the Patent Remedy Act); see also *Allen v. Cooper*, 140 S. Ct. 994, 1007 (2020) (holding that Congress’s waiver of state sovereign immunity under the Copyright Remedy Clarification Act was unconstitutional).

<sup>13</sup> See *Fla. Prepaid*, 527 U.S. at 634.

<sup>14</sup> See *infra*, Part II.A.1; *Ex parte Young*, 209 U.S. 123, 159-60 (1908) (establishing a legal fiction allowing a state officer to be sued for prospective relief).

<sup>15</sup> See *infra*, Part III.A.1; see also, *eBay v. MercExchange*, 547 U.S. 388, 391 (2006) (holding a party seeking a permanent injunction must satisfy a four-factor test, including demonstrating “that the public interest would not be disserved by a permanent injunction”); *Nichia Corp. v. Everlight Americas*, 955 F.3d 1328, 1341 (Fed. Cir. 2017) (holding that a party seeking injunctive relief “must prove that it meets all four equitable factors”).

State-driven solutions admittedly have serious drawbacks. Even if a drug is approved by a foreign regulatory agency, it can be seized by the U.S. Food & Drug Administration (FDA) for lacking U.S. approval.<sup>16</sup> Although the FDA granted emergency waivers to states importing unapproved medical equipment, including masks and ventilators,<sup>17</sup> it is unclear that the FDA would be willing to do the same with drugs. Forcing states to act individually is also inefficient. For example, in 2020, states ended up in bidding wars against each other for needed medical equipment, which likely drove up prices.<sup>18</sup> Pharmaceutical companies could furthermore retaliate by declining to open new facilities or create jobs in states that disregard patent rights. Nevertheless, a state action could serve as a catalyst for getting the federal government and the patent holder to work out a solution.<sup>19</sup>

This Essay considers whether states could utilize state sovereign immunity to alleviate drug shortages. Part II discusses the doctrine's scope and discusses how it has been applied by the Supreme Court and the Federal Circuit in patent infringement cases. Part III then discusses how states might use sovereign immunity to shield against damages while providing patented drugs to their citizens. It considers various obstacles that a state might face if it contracts with a domestic or foreign third-party supplier, and it discusses the possibility of states producing their own drugs. It then argues that even if states are not ultimately successful, merely attempting to obtain patented drugs could have a valuable shaming effect, pressuring the federal government and the relevant pharmaceutical company to reach a solution. Part IV consequently concludes that state patent infringement could serve a

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<sup>16</sup> See Phil Galewitz, *Amid Pandemic, FDA Seizes Cheaper Drugs from Canada*, MIAMI HERALD (Apr. 17, 2020), <https://www.miamiherald.com/news/health-care/article-242085586.html> (discussing how the FDA has increased seizures of prescription drugs being sent to U.S. customers from Canadian and other foreign pharmacies).

<sup>17</sup> Press Release, U.S. Food & Drug Admin., Coronavirus Disease 2019 (COVID-19) Emergency Use Authorizations for Medical Devices (updated June 30, 2021), <https://www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices> (providing emergency authorization for personal respiratory protective devices and other medical devices related to the COVID-19 pandemic).

<sup>18</sup> See Lauren Feiner, *States are Bidding Against Each Other and the Federal Government for Important Medical Supplies—and it's Driving Up Prices*, CNBC (Apr. 11, 2020, 8:44 AM), <https://www.cnbc.com/2020/04/09/why-states-and-the-federal-government-are-bidding-on-ppe.html> (documenting that in 2020, states ended up in bidding wars against other states and the federal government for medical supplies, including ventilators and personal protective equipment).

<sup>19</sup> The federal government possesses the ability to use patents without the patent holder's permission under 28 U.S.C. § 1498 and the Bayh Dole Act. It can also issue compulsory licenses to third parties to produce needed drugs, shielding the third party from suit. See generally Sapna Kumar, *Compulsory Licensing of Patents During Pandemics*, 54 CONN. L. REV. (forthcoming Mar. 5, 2021).

useful role during pandemics and other public health emergencies.

## II. AN INTRODUCTION TO STATE SOVEREIGN IMMUNITY

Dual state and federal sovereignty is “a defining feature” of the U.S. Constitution.<sup>20</sup> After joining the Union, states retained certain attributes of their former independence, including immunity from private suits.<sup>21</sup> Although state sovereign immunity is not absolute, it limits plaintiffs’ recovery from states that violate federal law. Section A examines the scope of state sovereign immunity and looks at which state-related entities are shielded. Section B then discusses how courts have applied the doctrine in patent infringement cases.

### A. *The Scope of State Sovereign Immunity*

Although the Eleventh Amendment directly addresses state sovereign immunity, much of the doctrine is based on background principles of the Constitution that have been articulated by federal courts. Courts of appeal remain divided, however, with regard to whether immunity extends to state government contractors.

#### 1. The Scope of State Sovereign Immunity under the Constitution

The Eleventh Amendment provides that “[t]he Judicial power of the United States shall not be construed to extend to any suit in law or equity, commenced or prosecuted against one of the United States by Citizens of another State, or by Citizens or Subjects of any Foreign State.”<sup>22</sup> However, the doctrine of state sovereign immunity arises from a broader constitutional background principle: that each state is a sovereign entity that may not be sued absent its consent.<sup>23</sup> As the Supreme Court noted in *Seminole Tribe v. Florida*: “For over a century we have reaffirmed that federal jurisdiction over suits against unconsenting States ‘was not contemplated by the Constitution

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<sup>20</sup> Fed. Mar. Comm’n v. S.C. State Ports Auth., 535 U.S. 743, 751 (2002) (quoting Blatchford v. Native Village of Noatak, 501 U.S. 775, 779 (1991)); see Edelman v. Jordan, 415 U.S. 651, 673 (1974) (finding state waiver of immunity “where stated ‘by the most express language or by such overwhelming implication from the text as [will] leave no room for any other reasonable construction.’” (quoting Murray v. Wilson Distilling Co., 213 U.S. 151, 171 (1909))).

<sup>21</sup> Fed. Mar. Comm’n, 535 U.S. at 751.

<sup>22</sup> U.S. CONST. amend. XI.

<sup>23</sup> Seminole Tribe v. Florida, 517 U.S. 44, 54 (1996) (“It is inherent in the nature of sovereignty not to be amenable to the suit of an individual without its consent.” (quoting Hans v. Louisiana, 134 U.S. 1, 13 (1890))).

when establishing the judicial power of the United States.”<sup>24</sup>

The doctrine serves the purpose of “accord[ing] States the dignity that is consistent with their status as sovereign entities.”<sup>25</sup>

State immunity is not absolute. By ratifying the U.S. Constitution, states consented to be sued by other states and by the federal government.<sup>26</sup> The Eleventh Amendment’s reach is “necessarily limited by the enforcement provisions of § 5 of the Fourteenth Amendment,” meaning that Congress may abrogate immunity legislatively without state consent.<sup>27</sup> However, the Supreme Court has held that Congress cannot do so absent a pattern of constitutional violations and “a congruence and proportionality between the injury to be prevented or remedied and the means adopted to that end.”<sup>28</sup> These requirements sharply limit Congress’s power to abrogate.<sup>29</sup>

Under *Ex parte Young*, a plaintiff may still sue a state employee in the employee’s official capacity to obtain prospective relief.<sup>30</sup> *Ex parte Young* creates a legal fiction that when a state officer violates federal law, he or she is “stripped” of official status for the purpose of establishing federal subject matter jurisdiction.<sup>31</sup> In such a circumstance, “[t]he state has no power to impart” to the officer “any immunity from responsibility to the supreme authority of the United States,”<sup>32</sup> notwithstanding the fact that the injunction or declaratory judgment sought would effectively be against the state. This legal fiction serves the purpose of allowing federal courts “to vindicate federal rights and hold state officials responsible.”<sup>33</sup> To utilize *Ex parte Young*, the plaintiff must sue a state officer with “some connection with the enforcement of the act.”<sup>34</sup> As the Federal Circuit has observed, injunctive

<sup>24</sup> *Id.* (quoting *Hans*, 134 U.S. at 15).

<sup>25</sup> *Fed. Mar. Comm’n*, 535 U.S. at 760.

<sup>26</sup> *Id.* at 752.

<sup>27</sup> *Atascadero State Hosp. v. Scanlon*, 473 U.S. 234, 238 (1985) (quoting *Fitzpatrick v. Bitzer*, 427 U.S. 445, 456 (1976)).

<sup>28</sup> *Fla. Prepaid Postsecondary Educ. Expense Bd. v. College Savs. Bank*, 527 U.S. 627, 639 (1999) (quoting *City of Boerne v. Flores*, 521 U.S. 507, 519–20 (1997)).

<sup>29</sup> *Infra*, Part II.B.

<sup>30</sup> *Ex parte Young*, 209 U.S. 123, 159–60. The plaintiff may not use an *Ex parte Young* suit to get damages of any sort, though ancillary relief is available. *See Edelman v. Jordan*, 415 U.S. 651, 677 (1974) (noting that “a federal court’s remedial power . . . is necessarily limited to prospective injunctive relief” and consequently “may not include a retroactive award which requires the payment of funds from the state treasury”).

<sup>31</sup> *See Ex parte Young*, 209 U.S. at 160 (“The state has no power to impart to [an officer under suit] any immunity from responsibility to the supreme authority of the United States”); Laura S. Fitzgerald, *Is Jurisdiction Jurisdictional?*, 95 NW. U. L. REV. 1207, 1210–11 (2001) (discussing *Ex parte Young*’s legal fiction).

<sup>32</sup> *Ex parte Young*, 209 U.S. at 160.

<sup>33</sup> *Pennhurst State Sch. & Hosp. v. Halderman* (Pennhurst II), 465 U.S. 89, 105 (1984) (quoting *Ex parte Young*, 209 U.S. at 160).

<sup>34</sup> *Id.* at 157.

relief is limited to the named state officer who is violating federal law and does not bind the state as a whole.<sup>35</sup>

## 2. What is the “State”?

To determine “whether a state instrumentality may invoke the State’s immunity” courts consider “the relationship between the State and the entity in question.”<sup>36</sup> Courts may also “examine[] the essential nature and effect of the proceeding” or “the nature of the entity created by state law to determine whether it should be treated as an arm of the State.”<sup>37</sup> Applying this framework, the Supreme Court has held that state agencies including public universities are entitled to sovereign immunity.<sup>38</sup> However, local governments and municipalities are not covered,<sup>39</sup> despite sharing some state powers.<sup>40</sup>

There is uncertainty regarding whether state sovereign immunity extends to private state government contractors. In *Shands Teaching Hospital and Clinics, Inc. v. Beech Street Corp.*, the Eleventh Circuit applied a balancing test and extended sovereign immunity to third-party health insurance administrators.<sup>41</sup> The court maintained that the “pertinent inquiry” is with regard to the corporation’s “function or role in a particular context,” and observed that the administrators were “acting at the behest of the State” and were controlled by it.<sup>42</sup> It further observed that Florida would have been liable for any damages award against the administrators.<sup>43</sup>

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<sup>35</sup> *Pennington Seed, Inc. v. Produce Exch. No. 299*, 457 F.3d 1334, 1342-43 (Fed. Cir. 2006).

<sup>36</sup> *Regents of the Univ. of Cal. v. Doe*, 519 U.S. 425, 429 (1997).

<sup>37</sup> *Id.*

<sup>38</sup> *See id.* (holding the University of California is shielded from suit by the Eleventh Amendment); *Raygor v. Regents of Univ. of Minn.*, 534 U.S. 533, 536 (2002) (noting that the University of Minnesota is “an arm of the State of Minnesota” for sovereign immunity purposes); *Edelman v. Jordan*, 415 U.S. 651, 669 (1974) (finding the Eleventh Amendment barred retroactive payment of benefits from the Illinois Department of Public Aid); *see also* Paul J. Heald & Michael L. Wells, *Remedies for the Misappropriation of Intellectual Property by State and Municipalities*, 55 WASH. & LEE L. REV. 849, 877 (1998) (discussing what is a state for sovereign immunity purposes).

<sup>39</sup> *See Monell v. Dep’t Soc. Serv. of the City of N.Y.*, 436 U.S. 658 (1978) (partially overruling *Monroe v. Pape*, and holding that the City of New York could be subjected to suit under § 1983 without its consent).

<sup>40</sup> *Mt. Healthy City Sch. Dist. Bd. of Educ. v. Doyle*, 429 U.S. 274, 280 (1977).

<sup>41</sup> 208 F.3d 1308, 1311 (11th Cir. 2000). The court noted sovereign immunity “may extend to defendants other than the State based upon: (1) how state law defines the entity; (2) what degree of control the State maintains over the entity; and (3) from where the entity derives its funds and who is responsible for judgments against the entity.” *Id.* at 1311.

<sup>42</sup> *Id.*

<sup>43</sup> *Id.* at 1312-13.



Other courts of appeal have declined to extend state sovereign immunity to private companies, while leaving open the possibility of doing so in future cases. For example, in *United States ex rel. Barron v. Deloitte & Touche, LLP*, the Fifth Circuit held that a private Medicaid provider was ineligible for sovereign immunity.<sup>44</sup> The court applied a six-factor test<sup>45</sup> to determine whether “the state is the real, substantial party in interest” that would ultimately pay any judgment.<sup>46</sup> In distinguishing *Shands*, the Fifth Circuit emphasized the fact that the state would bear no financial liability for any judgment rendered against the contractor.<sup>47</sup>

The Ninth Circuit has taken the least permissive approach, categorically declining to expand sovereign immunity to any private entity.<sup>48</sup> Although it employs a multifactor test,<sup>49</sup> a private contractor will always fail at least four of the five requirements.<sup>50</sup> The Ninth Circuit noted that the Supreme Court has been cautious about expanding the doctrine and maintained that extending sovereign immunity to private contractors would impermissibly limit Congress’s Article I power to create privately-enforceable federal causes of action.<sup>51</sup>

## B. *Sovereign Immunity in Patent Law*

### 1. Overview

Sovereign immunity shields both the federal and state governments from

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<sup>44</sup> *United States ex rel. Barron v. Deloitte & Touche, L.L.P.*, 381 F.3d 438, 441 (5th Cir. 2004).

<sup>45</sup> The six factors are: (1) “Whether the state statutes and case law view the agency as an arm of the state;” (2) “The source of the entity’s funding;” (3) “The entity’s degree of local autonomy;” (4) “Whether the entity is concerned primarily with local as opposed to statewide, problems;” (5) “Whether the entity has the authority to sue and be sued in its own name;” and (6) “Whether the entity has the right to hold and use property.” *Id.* (quoting *Hudson v. City of New Orleans*, 174 F.3d 677, 679 (5th Cir. 1999)).

<sup>46</sup> *Id.* at 440 (quoting *Hudson*, 174 F.3d at 681).

<sup>47</sup> *Id.* Both the Second and Third Circuit emphasize whether the state treasury is liable as the definitive factor in whether state sovereign immunity applies. *Hess v. Port Auth. Trans-Hudson Corp.*, 513 U.S. 30, 51 (1994).

<sup>48</sup> *Del Campo v. Kennedy*, 517 F.3d 1070, 1078 (9th Cir. 2008).

<sup>49</sup> The Ninth Circuit considers: “(1) whether a money judgment would be satisfied out of state funds; (2) whether the entity performs central governmental functions; (3) whether the entity may sue or be sued; (4) whether the entity has the power to take property in its own name or only in the name of the state; and (5) the corporate status of the entity.” *Id.* at 1077 (quoting *United States ex rel. Ali v. Daniel, Mann, Johnson & Mendenhall*, 355 F.3d 1140, 1147 (9th Cir. 2004)).

<sup>50</sup> *Id.* at 1078.

<sup>51</sup> *Id.* at 1076.

patent damages suits.<sup>52</sup> The federal government has partially consented to be sued for patent infringement,<sup>53</sup> allowing a patent holder to recover “reasonable and entire compensation for the use and manufacture” of the patented invention in the U.S. Court of Federal Claims.<sup>54</sup> Patent holders must sue within six years of the infringement,<sup>55</sup> cannot seek injunctive or declaratory relief,<sup>56</sup> and cannot demand a jury trial.<sup>57</sup>

However, the same is not true with regard to states. If a state sues a private party for patent infringement, then it waives sovereign immunity with regard to the cause of action, as well as relevant defenses and counterclaims.<sup>58</sup> But no state appears to have legislatively consented to be sued for patent infringement. Consequently, if a state uses a patent without permission, the patent holder cannot recover any damages and is limited to prospective relief against relevant state officials under *Ex parte Young*. This can sometimes result in public universities engaging in bad behavior, such as acting like “patent trolls.”<sup>59</sup>

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<sup>52</sup> Prior to 1910, patent holders were completely barred from suing the U.S. government for patent infringement. Gerald J. Mossinghoff & Robert F. Allnutt, *Patent Infringement in Government Procurement: A Remedy Without a Right*, 48 J. PAT. OFF. SOC’Y 755, 757 (1966).

<sup>53</sup> 28 U.S.C. § 1498 also waives federal sovereign immunity for copyright infringement.

<sup>54</sup> 28 U.S.C. § 1498 (1998). *See generally* Kumar, *supra* note 4.

<sup>55</sup> All claims that are brought in the U.S. Court of Federal Claims are subject to a six-year statute of limitations. 28 U.S.C. § 2501. The statute of limitations may be tolled if the patentee files an administrative claim. *Bondyopadhyay v. United States*, 2020 U.S. Claims LEXIS 1003, at \*36-37 (Fed. Cl. 2020) (discussing 35 U.S.C. § 286).

<sup>56</sup> *See* *Coakwell v. United States*, 372 F.2d 508, 511 (Ct. Cl. 1967) (“It is clear that [35 U.S.C. § 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 Corp. v. Blane*, 806 F.2d 1057, 1059-60 (Fed. Cir. 1986) (observing that legislative history supports the purpose of § 1498 is “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).

<sup>57</sup> Suits against the U.S. government must be brought in the Article I Court of Federal Claims, which does not offer jury trials. 28 U.S.C. § 1498; *see also* Mark Lemley, *Why Do Juries Decide If Patents Are Valid?*, 98 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”).

<sup>58</sup> *Univ. of Fla. Res. Found. v. Gen. Elec. Co.*, 916 F.3d 1363, 1365 (Fed. Cir. 2019).

<sup>59</sup> *See* Walter D. Valdivia, *Patent Infringement Suits Have a Reputational Cost for Universities*, BROOKINGS INSTITUTION (Nov. 10, 2015), <https://www.brookings.edu/blog/techtank/2015/11/10/patent-infringement-suits-have-a-reputational-cost-for-universities-2/> (discussing the Wisconsin Alumni Resource Foundation’s and other public universities’ patent troll-like behavior in extracting revenue from companies); *see also* James Boyle & Jennifer Jenkins, *Mark of the Devil: The University as a Brand Bully*, 31 FORDHAM INTELL. PROP. MEDIA & ENT. L. J. (forthcoming 2021), available at [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=3780381](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3780381) (discussing how the Ohio State University, Boise State

## 2. Patent-Related Case Law on Sovereign Immunity

In *Florida Prepaid Postsecondary Education Expense Board v. College Savings Bank*, the Supreme Court held that Congress's waiver of state sovereign immunity under the Patent and Plant Variety Protection Remedy Clarification Act was unconstitutional.<sup>60</sup> The statute expressly held that states, state instrumentalities, and state officers and employees were not immune under the Eleventh Amendment and doctrine of sovereign immunity for patent infringement.<sup>61</sup> However, the Court observed that "Congress identified no pattern of patent infringement by the States, let alone a pattern of constitutional violations."<sup>62</sup> It further noted that state patent infringement "does not by itself violate the Constitution," unless "the State provides no remedy, or only inadequate remedies, to injured patent owners for its infringement of their patent."<sup>63</sup> Finding "scant support" for states "depriving patent owners of property without due process of law," the Court concluded that the provisions "are 'so out of proportion to a supposed remedial or preventive object that [they] cannot be understood as responsive to, or designed to prevent, unconstitutional behavior.'"<sup>64</sup>

If a state chooses to sue a defendant for patent infringement, then the defendant may challenge the validity of its patents. For example, in *University of Florida Research Foundation v. General Electric Co.*, the University of Florida Research Foundation (UFRF) sued General Electric (GE) for patent infringement. GE moved to dismiss, arguing that the patent was directed towards ineligible subject matter under § 101 of the Patent Act, while UFRF claimed that its sovereign status blocked GE's attempt to invalidate its patent.<sup>65</sup> The Federal Circuit affirmed the district court, holding that the patent was invalid. It noted that UFRF waived its immunity by "voluntarily appearing in federal court,"<sup>66</sup> and that that this waiver extended "to any relevant defenses and counterclaims."<sup>67</sup>

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University, and the University of Texas have all acted as "trademark bullies").

<sup>60</sup> Fla. Prepaid Postsecondary Educ. Expense Bd. v. College Savs. Bank, 527 U.S. 627, 647-48 (1999).

<sup>61</sup> *Id.* at 632 (discussing 35 U.S.C. § 296(a)).

<sup>62</sup> *Id.* at 640.

<sup>63</sup> *Id.* at 643.

<sup>64</sup> *Id.* at 646 (alteration in original) (quoting *City of Boerne v. Flores*, 521 U.S. 507, 532 (1997)). The Court has ruled similarly with regard to copyrights, affirming a lower court's decision to strike down the Copyright Remedy Clarification Act as unconstitutional. *Allen v. Cooper*, 140 S. Ct. 994, 1007 (2020) (holding that "*Florida Prepaid* all but prewrote" the decision to strike down the Copyright Remedy Clarification Act as unconstitutional).

<sup>65</sup> *Univ. of Fla. Res. Found. v. Gen. Elec. Co.*, 916 F.3d 1363, 1364 (Fed. Cir. 2019).

<sup>66</sup> *Id.* at 1365 (quoting *Regents of the Univ. of N.M. v. Knight*, 321 F.3d 1111, 1124 (Fed. Cir. 2003)).

<sup>67</sup> *Id.* (quoting *Vas-Cath, Inc. v. Curators of Univ. of Mo.*, 473 F.3d 1376, 1381 (Fed.

States are furthermore not immune from inter partes review (IPR) challenges in the Patent Trial and Appeals Board. In *Regents of Univ. of Minn. v. LSI Corp.*, the University of Minnesota claimed sovereign immunity shielded it from an IPR challenge of several of its patents.<sup>68</sup> The Federal Circuit acknowledged that sovereign immunity applies “to agency adjudications brought by private parties that are similar to court adjudications.”<sup>69</sup> However, it noted that the Supreme Court in *Cuozzo Speed Techs., LLC v. Lee* “concluded that IPR proceedings are essentially agency reconsideration of a prior patent grant.”<sup>70</sup> The Federal Circuit consequently held that state sovereign immunity does not apply, given “that IPR is in key respects a proceeding between the government and the patent owner.”<sup>71</sup>

The three judges who issued the decision also provided “additional views,” noting that sovereign immunity should not apply to in rem proceedings, even for adversarial proceedings.<sup>72</sup> The Supreme Court has stated “at least in some contexts,” in rem proceedings do not “interfere with state sovereignty” even if state interests are impacted.<sup>73</sup> The judges noted that IPRs—which do not involve a state’s territory—appear to be the “type of in rem proceedings to which state sovereign immunity does not apply.”<sup>74</sup>

Overall, the relatively broad scope of state sovereign immunity raises the possibility that states could utilize it to protect themselves from damages if they infringe patents to safeguard public health. Part III explores mechanisms by which states might attempt this, such as by importing or directly producing drugs.

### III. PROTECTING PUBLIC HEALTH THROUGH STATE SOVEREIGN IMMUNITY

As discussed above, states sometimes use sovereign immunity to engage in bad behavior and avoid paying damages for patent infringement. But could states use the doctrine to protect public health instead? This Part discusses two possibilities: states purchasing generic versions of patented drugs from third parties or alternatively producing patented drugs themselves.

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Cir. 2007)).

<sup>68</sup> *Regents of Univ. of Minn. v. LSI Corp.*, 926 F.3d 1327, 1330 (Fed. Cir. 2019).

<sup>69</sup> *Id.* at 1337.

<sup>70</sup> *Id.* at 1338 (citing *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144 (2016)).

<sup>71</sup> *Id.* at 1339.

<sup>72</sup> *Id.* at 1342 (additional views of Dyk, Wallach, and Hughes, Circuit Judges).

<sup>73</sup> *Id.* at 1343 (quoting *Cent. Va. Cmty. Coll. v. Katz*, 546 U.S. 356, 370 (2006)).

<sup>74</sup> *Id.* at 1346.

### A. *States Obtaining Patented Drugs from Third Parties*

There are two ways that a state could obtain drugs from third parties. First, a state could contract with a domestic company to produce patented drugs on its behalf. However, as noted earlier, most courts of appeal have declined to extend state sovereign immunity to state contractors.<sup>75</sup> Consequently, the patent holder could potentially sue a domestic third-party manufacturer for patent infringement, even if the manufacturer was producing drugs on behalf of a state.

Alternatively, a state could import patented drugs from a country that either does not offer drug patents<sup>76</sup> or has issued a compulsory license authorizing third-party manufacturing.<sup>77</sup> Although a court could hold a foreign manufacturer liable as an infringer, the patent holder could have trouble collecting damages if the manufacturer lacks U.S.-based assets.<sup>78</sup> Moreover, if the state were to pay a reasonable royalty to the patent holder, it is unclear that the state's action would rise to the level of a due process violation under *Florida Prepaid*.<sup>79</sup>

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<sup>75</sup> See *supra*, Part II.A.2.

<sup>76</sup> World Trade Organization member countries that are classified as Least-Developed Nations are exempt until 2033 from having to offer patents on drug compounds under the TRIPS Agreement. LDC Portal, *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 March 30, 2021). Consequently, countries such as Bangladesh may produce drugs such as remdesivir that are patented in most other countries. See Zeba Siddiqui, *Bangladesh's Beximco to Begin Producing COVID-19 Drug Remdesivir*, REUTERS (May 5, 2020), <https://www.reuters.com/article/us-health-coronavirus-bangladesh-remdesi/exclusive-bangladesh-beximco-to-begin-producing-covid-19-drug-remdesivir-coo-idUSKBN22H1DD>.

<sup>77</sup> See Marrakesh Agreement Establishing the World Trade Organization, Agreement on Trade-Related Aspects of Intellectual Property Rights art. 31, April 15, 1994, 1867 U.N.T.S. 154 (providing WTO members with the right to issue compulsory licenses in certain circumstances).

<sup>78</sup> Countries generally will not enforce foreign judgment awards that undermine public policy. If a U.S. court awarded damages against a foreign generic drug company, it may be difficult for the patent holder to collect that judgment. See Marketta Trimble, *When Foreigners Infringe Patents: An Empirical Look at the Involvement of Foreign Defendants in Patent Litigation in the U.S.*, 27 SANTA CLARA COMPUT. & HIGH TECH. L. J. 499, 508–09 (2011) (discussing the public policy exception to the enforcement of international IP judgments).

<sup>79</sup> See *Fla. Prepaid Postsecondary Educ. Expense Bd. v. College Savs. Bank*, 527 U.S. 627, 643 (1999) (noting that a due process violation arises “only where the State provides no remedy, or only inadequate remedies, to injured patent owners for its infringement of their patent”). Indeed, a state could choose to pay nothing to the patent holder, though this could lead to future abrogation of sovereign immunity by Congress if it helps establish a pattern of infringement.

## 1. Prospective Relief Against States in Federal Court

Although a patent holder cannot sue a state for damages in federal court, it could sue an appropriate state official and seek an injunction prohibiting the importation and distribution of the patented drug.<sup>80</sup> However, there is no guarantee that a patent holder would be able to obtain an injunction against the state infringer if the infringement benefitted public health. Under *eBay, Inc. v. MercExchange, L.L.C.*, “a plaintiff seeking a permanent injunction must satisfy a four-factor test,” demonstrating:

(1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.<sup>81</sup>

The Federal Circuit has held that a party seeking injunctive relief “must prove that it meets all four equitable factors,”<sup>82</sup> and has noted in dicta that a court may not issue an injunction “[i]f a plaintiff fails to show ‘that the public interest would not be disserved by a permanent injunction.’”<sup>83</sup>

Based on existing precedent, it is unclear how the Federal Circuit would apply *eBay* to a situation involving a drug shortage. Many scholars regard the Federal Circuit as being pro-patent<sup>84</sup> and the court has claimed in unpublished

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<sup>80</sup> See *Ex parte Young*, 209 U.S. 123, 157 (1908) (noting that suits against individual state officers “to enjoin the enforcement of an act alleged to be unconstitutional” are permissible if the officer has “some connection with the enforcement of the act”); *Pennington Seed, Inc. v. Produce Exch. No. 299*, 457 F.3d 1334, 1341 (Fed. Cir. 2006) (“Thus, continuing prospective violations of a federal patent right by state officials may be enjoined by federal courts under the *Ex parte Young* doctrine[.]”).

<sup>81</sup> *eBay v. MercExchange*, 547 U.S. 388, 391 (2006).

<sup>82</sup> *Nichia Corp. v. Everlight Americas*, 855 F.3d 1328, 1341 (Fed. Cir. 2017) (emphasis added).

<sup>83</sup> *Amgen Inc. v. Sanofi*, 872 F.3d 1367, 1381 (Fed. Cir. 2017) (quoting *eBay*, 547 U.S. at 391). Furthermore, if the state had an articulated policy regarding access to medicine, an argument can be made that the court could consider it under *eBay*, so long as it does not conflict with congressional intent. See Dan L. Burk, *Patents and State Constitutionally Protected Speech*, 15 DUKE J. CONST. L. & PUB. POL’Y 1, 18 (2020) (noting that “there is nothing that would prevent a federal court from taking into account state articulations of public policy” and relying on them so long as they do not conflict with Congressional intent).

<sup>84</sup> See Ryan T. Holte & Christopher B. Seaman, *Patent Injunctions on Appeal: An Empirical Study of the Federal Circuit’s Application of eBay*, 92 WASH. L. REV. 145, 201 (2017) (“In sum, the Federal Circuit’s apparent inclination toward injunctive relief—and thus more valuable patent rights—lends supports to the claim that the Federal Circuit has used its position as the primary appellate court over patent claims to shape the law in a pro-patentee direction.”); Arti K. Rai, *Engaging Facts and Policy: A Multi-Institutional Approach to Patent System Reform*, 103 COLUM. L. REV. 1035, 1114 (2003) (“[T]he Federal Circuit’s major decisions in recent years may have been influenced by bias toward patent holders”).

dicta that the public has a “strong interest” in protecting patent rights.<sup>85</sup> This pro-patent view was illustrated in *Amgen v. Sanofi*, in which the Federal Circuit issued an injunction against a company that was manufacturing an infringing cholesterol-lowering drug.<sup>86</sup> Although the patent holder sold a version of the drug to the public, some physicians allegedly preferred the 75mg dose that only the infringer offered.<sup>87</sup> However, the *Amgen* decision was based on the fact that drug options were still available, just not in the preferred dose. In the event of a true drug shortage, such as what occurred in 2020 with remdesivir, the state would have a much stronger argument that an injunction would harm the public welfare and would therefore be impermissible under *eBay*.

## 2. Agency Actions Against a State Infringer

A state that attempts to import infringing drugs would also be vulnerable to U.S. agency actions. The U.S. International Trade Commission (ITC) and the FDA both have jurisdiction over imported drugs and may seize unauthorized shipments. Of these two agencies, the FDA poses the greatest risk to states.

### a. U.S. International Trade Commission

A patent holder could file an action in the ITC under § 1337 of the Tariff Act. The ITC has the power to issue “exclusion orders,” which block infringing goods from entering into the United States and are enforced by the U.S. Customs and Border Protection.<sup>88</sup> Although ITC proceedings are adversarial, the agency’s jurisdiction for exclusion orders is in rem,<sup>89</sup> meaning that state sovereign immunity would not necessarily apply.<sup>90</sup> The ITC can also issue cease-and-desist orders against parties that it has in personam jurisdiction over.<sup>91</sup>

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<sup>85</sup> *Glaxo Group Ltd. v. Apotex, Inc.*, 64 Fed. App’x 751, 756 (Fed. Cir. 2003) (unpublished).

<sup>86</sup> *Amgen*, 872 F.3d at 1381–82.

<sup>87</sup> *Amgen Inc. v. Sanofi*, No. 14-1317-SLR, 2017 U.S. Dist. LEXIS 1351, at \*8-9 (D. Del. Jan. 5, 2017), *rev’d in part*, 872 F.3d 1367 (Fed. Cir. 2017).

<sup>88</sup> See 19 U.S.C. § 1337(d). For an overview of the ITC, see Sapna Kumar, *Expert Court, Expert Agency*, 44 U.C. DAVIS L. REV. 1547, 1553-58 (2011).

<sup>89</sup> See Sapna Kumar, *Regulating Digital Trade*, 67 FLA. L. REV. 1909, 1917-18, 1929 (2015) (discussing the ITC’s in rem jurisdiction for issuing exclusion orders and its enforceability).

<sup>90</sup> See *Regents of Univ. of Minn. v. LSI Corp.*, 926 F.3d 1327, 1343-45 (Fed. Cir. 2019) (additional views) (noting in dicta that states cannot use sovereign immunity to shield themselves from non-adversarial in rem proceedings).

<sup>91</sup> See 19 U.S.C. § 1337(f).

It is unclear, however, whether ITC actions can be brought against state infringers. Limited exclusion orders apply only to “persons” determined to be violating § 1337,<sup>92</sup> and cease-and-desist orders are limited to “any person” violating or believed to be violating § 1337.<sup>93</sup> Although the Tariff Act notes that “[t]he word ‘person’ includes partnerships, associations, and corporations,” it fails to include states.<sup>94</sup> Likewise, penalties under various sections of the Tariff Act refer to “persons,”<sup>95</sup> and 19 C.F.R. § 101.1 defines an “importer” as “the *person* primarily liable for the payment of any duties on the merchandise, or an authorized agent acting on his behalf.”<sup>96</sup> In *Return Mail, Inc. v. United States Postal Service*, the Supreme Court held that “[i]n the absence of an express statutory definition,” courts shall apply the “presumption that ‘person’ does not include the sovereign.”<sup>97</sup> Given this presumption and the fact that the Tariff Act definitions omit states, it is unlikely that a state importer could be a direct target of an ITC investigation.

The patent holder could bring an action against the exporter of the patented drug, and seek to have the drugs seized at the border. However, it may not succeed if the infringing drugs would benefit public health. If the ITC determines that an imported good infringes a patent, it is required to issue an exclusion order “unless, after considering the effect of such exclusion

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<sup>92</sup> 19 U.S.C. § 1337(d)(1). Although general exclusion orders are also available, which are not limited to a particular person, they can only be issued if it “is necessary to prevent circumvention of an exclusion order limited to products of named persons” or if “a pattern of violation” exists “and it is difficult to identify the source of the infringing products.” 19 U.S.C. § 1337(d)(2).

<sup>93</sup> 19 U.S.C. § 1337(f).

<sup>94</sup> 19 U.S.C. § 1401(d). Also, in the context of antidumping and countervailing duties, the International Trade Administration defined “person” to include “any interested party as well as any other individual, enterprise, or entity, as appropriate.” 19 C.F.R. § 351.102(b)(37).

<sup>95</sup> See, e.g., 19 U.S.C. § 1592(a)(1) (prohibiting a “person” from importing merchandise into the United States with false or missing documentation); 19 U.S.C. § 1593a(a)(1) (prohibiting a “person” from receiving payment for goods from someone else based on false import documentation); 19 U.S.C. § 1436(b) (noting “[a]ny master, person in charge of a vehicle, or aircraft pilot who commits any violation listed in subsection (a)” with “master” defined in 19 U.S.C. § 1401 as “the person having the command of the vessel”); 19 U.S.C. § 1453 (subjecting “the master of such vessel or the person in charge of such vehicle and every other person who knowingly is concerned, or who aids therein” to penalties for merchandise and baggage lacking an appropriate license or permit).

<sup>96</sup> 19 C.F.R. § 101.1 (emphasis added).

<sup>97</sup> *Return Mail, Inc. v. United States Postal Serv.*, 139 S. Ct. 1853, 1861-62 (2019) (quoting *Vt. Agency of Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 765, 780-81 (2000)). That “presumption is ‘particularly applicable where it is claimed that Congress has subjected the States to liability to which they had not been subject before,’” *Vt. Agency*, 529 U.S. at 780-81 (quoting *Will v. Mich. Dep’t of State Police*, 491 U.S. 58, 64 (1989)), and “it may be disregarded only upon some affirmative showing of statutory intent to the contrary.” *Return Mail*, 139 S. Ct. at 1862 (quoting *Stevens*, 529 U.S. at 781).



upon the public health and welfare . . . it finds that such articles should not be excluded from entry.”<sup>98</sup> Although it is uncommon, the ITC has limited the use of exclusion orders when public health could be undermined.<sup>99</sup> For example, in *Certain Microfluidic Devices*, the ITC issued a Limited Exclusion Order and a Cease and Desist Order, both of which permitted the continued importation of infringing goods that were needed for ongoing medical research.<sup>100</sup> In a related Commission Opinion, the ITC noted that the technology at issue was needed for research related to cancer and cardiovascular disease, and it emphasized the importance of the research.<sup>101</sup> Based on this reasoning, it seems unlikely that the ITC would exclude life-saving drugs if the non-infringing alternative was scarce.

#### b. U.S. Food & Drug Administration

The greatest threat to states that unlawfully import drugs is the FDA. The FDA’s mission includes “protecting the public health by ensuring the safety, efficacy, and security” of drugs,<sup>102</sup> but its regulations can hinder states that try to improve drug access. For example, states cannot legally import prescription drugs from other countries.<sup>103</sup> A 2003 law authorizes Canadian drug imports, but requires the FDA to certify that such importation would not create a safety risk. No drug has ever been certified under this law.<sup>104</sup>

<sup>98</sup> 19 U.S.C. § 1337(d)(1).

<sup>99</sup> See Matthew J. Rizzolo & Rachael Bacha, *In a Rare Move, ITC Applies Public Interest Factors to Exempt Research-Related Microfluidic Devices from Exclusion Order*, ROPES & GRAY (Jan. 14, 2020), <https://www.ropesgray.com/en/newsroom/alerts/2020/01/In-a-Rare-Move-ITC-Applies-Public-Interest-Factors-to-Exempt-Research-Related-Microfluidic-Devices>; Kumar, *supra* note 88, at 1567-68 (collecting cases when exclusion orders were denied based on public welfare concerns).

<sup>100</sup> See *In the Matter of Certain Microfluidic Devices*, USITC Inv. No. 337-TA-1068, 2019 WL 7049092, Limited Exclusion Order, at \*2 (Dec. 18, 2019); Cease and Desist Order at 2-3 (Dec. 18, 2019); see also, Matthew J. Rizzolo & Rachael Bacha, *ITC Decision Shows Importance of Public Interest for Biotech*, LAW360 (Jan. 21, 2020, 4:40 PM), <https://www.law360.com/articles/1235697/itc-decision-shows-importance-of-public-interest-for-biotech> (discussing *Certain Microfluidic Devices*).

<sup>101</sup> *In the Matter of Certain Microfluidic Devices*, Inv. No. 337-TA-1068, 2020 WL 225020, Comm’n Op., at \*17 (Jan. 10, 2020).

<sup>102</sup> FDA, *What We Do* (Mar. 28, 2018), <https://www.fda.gov/about-fda/what-we-do>.

<sup>103</sup> See Rachel E. Sachs & Nicholas Bagley, *Importing Prescription Drugs from Canada—Legal and Practical Problems with the Trump Administration’s Proposal*, 382 NEW ENG. J. MED. 1777, 1777 (May 7, 2020) (discussing several legal problems with the Trump Administration’s proposal to allow states to import drugs from Canada and characterizing it as “political theater”); see also Patricia J. Zettler, *Pharmaceutical Federalism*, 92 IND. L.J. 845, 870 (2017) (observing that “[t]he FDA has consistently opined that importing unapproved drugs from other countries is prohibited under federal law,” due to safety concerns).

<sup>104</sup> See Zettler, *supra* note 103, at 871 (noting that no Secretary has determined that

Moreover, absent authorization by the Secretary of Health and Human Services for medical emergencies or shortages, only the manufacturer may import drugs.<sup>105</sup>

States have attempted to circumvent these stringent regulations without success.<sup>106</sup> In 2013, Maine passed a law permitting people to purchase drugs from several foreign pharmacies,<sup>107</sup> drawing on its power to regulate medical practice.<sup>108</sup> Under the state law, retail pharmacies in Canada, the United Kingdom, Australia, and New Zealand were exempt from state licensing requirements for retail pharmacies.<sup>109</sup> However, a federal district judge ruled that Maine's law was preempted by federal law because it regulated pharmacies outside Maine's borders.<sup>110</sup>

The FDA has shown some willingness to relax regulations during the COVID-19 pandemic. For example, the FDA made it easier for states to import personal protective equipment and other medical devices, and it issued an Emergency Use Authorization for various disposable masks.<sup>111</sup> However, it is unclear whether this tolerance would extend to non-FDA approved drugs. In April 2020, the FDA claimed to be "working to address the COVID-19 pandemic by facilitating imports of drugs to potentially treat COVID-19,"<sup>112</sup> but it does not appear to have made forward progress. It is therefore unclear how the FDA would react if a state were to attempt to import drugs that were only approved by a foreign regulatory agency for use abroad.

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Canadian drug imports "would be safe and cost-effective").

<sup>105</sup> Thomas J. Bollyky & Aaron S. Kesselheim, *Reputation and Authority: The FDA and the Fight over U.S. Prescription Drug Importation*, 73 VAND. L. REV. 1331, 1342 (2020).

<sup>106</sup> See Zettler, *supra* note 103, at 848-49 (discussing several efforts by states to establish drug policies that are less restrictive than federal ones).

<sup>107</sup> ME. REV. STAT. ANN. tit. 32, § 13731 (West 2020).

<sup>108</sup> See Zettler, *supra* note 103, at 871 (discussing Maine's unsuccessful attempt to permit importation of non-FDA approved foreign prescription drugs).

<sup>109</sup> ME. REV. STAT. ANN. tit. 32, § 13731(1)(B) (West 2020).

<sup>110</sup> *Ouellette v. Mills*, 91 F. Supp. 3d 1, 9 (D. Me. 2015) ("[Legislation] extend[s] beyond the traditionally local arena of public health and safety and into the traditionally federal spheres of foreign commerce and affairs.").

<sup>111</sup> U.S. FOOD & DRUG ADMIN., *Personal Protective Equipment EUAs* (May 12, 2021), <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/personal-protective-equipment-euas>; U.S. FOOD & DRUG ADMIN., *Importing Medical Devices During the COVID-19 Pandemic* (Apr. 23, 2021), <https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/importing-medical-devices-during-covid-19-pandemic>.

<sup>112</sup> U.S. FOOD & DRUG ADMIN., *Import of Drugs for Potential COVID-19 Treatment* (Apr. 7, 2020), <https://www.fda.gov/drugs/coronavirus-covid-19-drugs/import-drugs-potential-covid-19-treatment>.

### B. *States Directly Manufacturing Patented Drugs*

The United States has a critical shortage of domestic drug manufacturing facilities, and it is unclear what percentage of needed raw materials are domestically sourced.<sup>113</sup> In 2020, the Department of Health and Human Services announced a plan to partner with private industry to expand U.S. pharmaceutical manufacturing capacity “for use in producing medicines needed during the COVID-19 response and future public health emergencies.”<sup>114</sup> But rather than leave this issue to private industry, states with sufficient resources could create manufacturing facilities and produce their own drugs. Although production of complex drugs like vaccines may be out of reach in the short term, states could start with producing simpler drugs.<sup>115</sup> The long-term goals would be to increase domestic drug production capacity and to enable drug production during shortages.

Such facilities would have utility far beyond pandemics. Many older drugs including insulin are prohibitively expensive,<sup>116</sup> because few pharmaceutical companies manufacture them.<sup>117</sup> Were states involved in domestic drug manufacturing, they could put competitive pressure onto pharmaceutical companies to lower drug prices. Any excess manufacturing capacity could be contracted out to pharmaceutical companies during shortages.

States that manufacture patented drugs would still encounter legal and practical hurdles. Although a state cannot be forced to pay damages as a direct infringer, a few district court cases suggest that contractors and suppliers

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<sup>113</sup> *Safeguarding Pharmaceutical Supply Chains in a Global Economy Before the H. Comm. on Energy and Com., Subcomm. On Health*, 116th Cong. (2019), (Statement of Dr. Janet Woodcock, Director of the Center for Drug Evaluation and Research at the Food and Drug Admin.), <https://www.fda.gov/news-events/congressional-testimony/safeguarding-pharmaceutical-supply-chains-global-economy-10302019>.

<sup>114</sup> U.S. DEP’T HEALTH & HUM. SERVS., *Industry Partners Expand U.S.-Based Pharmaceutical Manufacturing for COVID-19 Response* (May 19, 2020), <https://www.hhs.gov/about/news/2020/05/19/hhs-industry-partners-expand-us-based-pharmaceutical-manufacturing-covid-19-response.html>.

<sup>115</sup> See Sapna Kumar, *Compulsory Licensing of Patents During Pandemics*, 54 CONN. L. REV. (forthcoming Mar. 5, 2021) (discussing how Bangladesh-based Beximco independently reproduced remdesivir and quickly ramped up its production in 2020 and observing that small-molecule drugs are easier to produce than vaccines and other biologics).

<sup>116</sup> Drug manufacturers have continued to raise prices for off-patent drugs, such as insulin. For example, Humalog, which cost \$21 in 1999, cost \$332 in 2019. The high cost of generic drugs has led to deaths of patients who could not afford their drugs. S. Vincent Rajkumar, *The High Cost of Insulin in the United States: An Urgent Call to Action*, 95 MAYO CLINIC PROC. 22, 22-23 (Jan. 2020), [https://www.mayoclinicproceedings.org/article/S0025-6196\(19\)31008-0/fulltext](https://www.mayoclinicproceedings.org/article/S0025-6196(19)31008-0/fulltext).

<sup>117</sup> *Id.*

could be held liable for indirect infringement under the Patent Act.<sup>118</sup> If the Federal Circuit agrees, then a company supplying the state with raw materials would potentially be a contributory infringer. A state would also have to go through the expensive and time-consuming process of obtaining FDA approval for any drug it produces. Finally, states could face barriers with regard to supply chains tailored to for-profit companies.<sup>119</sup>

Despite these obstacles, states should still consider producing drugs. By doing so, they would maximize avoidance of legal liability under state sovereign immunity. They could also take advantage of existing intrastate and interstate initiatives that use collective purchasing power to reduce drug costs. For example, the Minnesota Multistate Contracting Alliance for Pharmacy has operated since 1985, negotiating discounts on behalf of thousands of governmental facilities.<sup>120</sup> The Northwest Consortium allows various state agencies, local governments, businesses, and consumers to pool their purchasing power to obtain cheaper prescription drugs.<sup>121</sup> State-owned pharmaceutical manufacturers could directly serve these groups, providing a source of low-cost drugs. Outside of public health emergencies, state-led drug production could also help reduce the cost of generic drugs.

At least one state is currently pursuing producing its own drugs. In September 2020, California passed a state law requiring the California Health and Human Services Agency to enter into partnerships to produce or distribute prescription drugs, including at least one form of insulin.<sup>122</sup> The

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<sup>118</sup> See *Applera Corp. v. MJ Res., Inc.*, 311 F. Supp. 2d 293, 298 (D. Conn. 2004) (holding that even if the direct infringer “possesses a unique status precluding pecuniary liability for its direct infringement in federal court,” its supplier may still be held liable as an inducer under § 271(b)); *Syrrx, Inc. v. Oculus Pharms., Inc.*, Civil Action No. 02-321-JJF, 2002 WL 1840917, at \*3 (D. Del. Aug. 9, 2002) (“[A] jury or a court may find the required direct infringement on the part of a non-party State and/or their instrumentalities upon which to predicate a finding of inducement of infringement against a private party.”). The rationale is that although the state cannot be forced to pay damages, it is still an infringer, which can give rise to indirect infringement for those that assist it.

<sup>119</sup> See WAXMAN STRATEGIES, NONPROFIT PHARMACEUTICAL COMPANIES: BACKGROUND, CHALLENGES, AND POLICY OPTIONS 6 (Dec. 2019), <https://waxmanstrategies.com/wp-content/uploads/2020/01/Nonprofit-Pharmaceutical-Companies-White-Paper.pdf>.

<sup>120</sup> See JANE HORVATH, STATE INITIATIVES USING PURCHASING POWER TO ACHIEVE DRUG COST CONTAINMENT 2 (Nat’l Acad. for State Health Pol’y) (April 2019), [https://nashp.org/wp-content/uploads/2019/04/Rx-Purchasing-Paper-Jane-Horvath-FINAL-4\\_9\\_2019.pdf](https://nashp.org/wp-content/uploads/2019/04/Rx-Purchasing-Paper-Jane-Horvath-FINAL-4_9_2019.pdf).

<sup>121</sup> *Id.* at 3-4.

<sup>122</sup> See Office of Governor Gavin Newsom, *Governor Newsom Signs Legislation Advancing California’s Fight to Lower Prescription Drug Prices*, CA.GOV (Sept. 28, 2020), <https://www.gov.ca.gov/2020/09/28/governor-newsom-signs-legislation-advancing-californias-fight-to-lower-prescription-drug-prices/>; see also CAL. HEALTH & SAFETY CODE § 127693(a) (West 2021).

law was, in part, a response to problems that hospitals had with maintaining adequate supplies of drugs and medical equipment during the pandemic.<sup>123</sup> The shorter-term goal is for California to have third parties produce generic prescription drugs “that have the greatest impact on lowering drug costs to patients,” as well as to increase competition in drug manufacturing, prevent future drug shortages, improve public health, and reduce overall costs.<sup>124</sup> However, the long-term goal is even more ambitious: the agency will submit a report to the state legislature in July 2023 “that assesses the feasibility of directly manufacturing generic prescription drugs” and selling them “at a fair price.”<sup>125</sup>

Were California to directly produce its own drugs, it would pave the way for producing scarce patented drugs during future pandemics and public health emergencies. With the manufacturing infrastructure and raw materials already available, California would be able to quickly respond to drug supply problems with its own drug production. Admittedly, strict FDA regulations remain a problem.<sup>126</sup> But as Section C discusses below, the mere threat of manufacturing patented drugs may be sufficient to get the patent holder to negotiate or the federal government to use its broader powers.

### *C. State Action as a Catalyst for Change*

As discussed earlier, unclear legal doctrines and regulatory obstacles make it difficult to predict whether a state could be successful in obtaining or producing patented drugs. Given these hurdles, a state might believe that it is too risky to be worth attempting. However, were a state willing to face the legal challenges associated with producing or importing drugs, it could put pressure on both the federal government and patent holder to reach a solution.

Pharmaceutical companies have voluntarily lowered drug prices and even temporarily suspended enforcement of their patents, rather than risk governments acting of their own accord. For example, Israel issued a compulsory license in 2020 for AbbVie’s drug Kaletra, which at the time was a promising COVID-19 treatment.<sup>127</sup> AbbVie subsequently announced that it

<sup>123</sup> Angela Hart & Samantha Young, *California May Be the First State to Develop its Own Generic Drugs*, LA TIMES (Sept. 1, 2020), <https://www.latimes.com/california/story/2020-09-01/california-may-dive-into-generic-drug-market>.

<sup>124</sup> CAL. HEALTH & SAFETY CODE § 127693(b)(5) (West 2021).

<sup>125</sup> CAL. HEALTH & SAFETY CODE § 127694(a) (West 2021).

<sup>126</sup> California would still have to go through the FDA approval process or risk seizure of its drugs. See U.S. DEP’T HEALTH AND HUM. SERVS., GUIDANCE FOR FDA STAFF AND INDUSTRY: MARKETED UNAPPROVED DRUGS—COMPLIANCE POLICY GUIDE Sec. 440.100 (2011), <https://www.fda.gov/files/drugs/published/Marketed-Unapproved-Drugs-Compliance-Policy-Guide.pdf> (providing non-binding guidelines with regard to non-FDA approved drugs marketed illegally in the United States).

<sup>127</sup> S. Horowitz & Co., *Unusual Times, Unusual Measures: The Israeli Ministry of*

would not enforce its patent rights on Kaletra.<sup>128</sup> It may have feared that other countries would follow, setting more bad precedent of countries refusing to honor drug patents.

Likewise, during the 2001 anthrax scare, the U.S. government sought a large supply of Bayer's patented antibiotic ciprofloxacin.<sup>129</sup> The wholesale pharmacy cost of the drug was \$4.67 per tablet, and Bayer offered it to the United States for \$1.75 to \$1.83.<sup>130</sup> Yet countries that were not subject to the relevant patents were producing it at significantly cheaper prices.<sup>131</sup> While negotiations were ongoing, the Canadian government licensed a domestic generic drug manufacturer to produce the drug on its behalf, notwithstanding Bayer's patents.<sup>132</sup> Consequently, Bayer offered a \$1.30 per tablet price for the Canadian government and in exchange, Canada acknowledged Bayer's patents and agreed to acquire the drug directly from Bayer.<sup>133</sup> Shortly after, the Bush Administration secured 100 million tablets for \$0.95 each, having also threatened to license Bayer's patent to a third-party manufacturer.<sup>134</sup> In a Securities and Exchange Commission filing, Bayer noted that it cooperated to preserve its patent rights.<sup>135</sup>

Pharmaceutical companies are somewhat sensitive to negative publicity. During the height of the AIDS epidemic, South Africa passed compulsory licensing legislation and sought to purchase patented antiretroviral drugs from India.<sup>136</sup> More than 3 dozen pharmaceutical companies sued, claiming

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*Health Permits the Exploitation of Abbvie's Patents Covering KALETRA® to Allow Importation of Generic Version*, LEXOLOGY (Mar. 19, 2020), <https://www.lexology.com/library/detail.aspx?g=12272bd5-c581-4c21-a1af-f253595d23e4>.

<sup>128</sup> Phil Taylor, *AbbVie Won't Enforce Patents for COVID-19 Drug Candidate Kaletra*, PHARMAFORUM (Mar. 25, 2020), <https://pharmaphorum.com/news/abbvie-wont-enforce-patents-for-covid-19-drug-candidate-kaletra/>.

<sup>129</sup> Matthew Herper, *Cipro, Anthrax and the Perils of Patents*, FORBES (Oct. 17, 2001, 4:13 PM), <https://www.forbes.com/2001/10/17/1017cipro.html>.

<sup>130</sup> 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), <https://www.nytimes.com/2001/10/24/business/a-nation-challenged-cipro-us-says-bayer-will-cut-cost-of-its-anthrax-drug.html>.

<sup>131</sup> Herper, *supra* note 129.

<sup>132</sup> *Patent Protection Versus Public Health*, 358 LANCET 1563, 1563 (2001).

<sup>133</sup> Canadian Government Acknowledges Patent Protection for Cipro, CHEMEUROPE.COM (Oct. 24, 2001), <https://www.chemeurope.com/en/news/5574/canadian-government-acknowledges-patent-protection-for-cipro.html>

<sup>134</sup> See Kumar, *supra* note 115, at 10; Bayer Aktiengesellschaft, Registration Statement Pursuant to Section 12(b) or 12(g) of the Securities Exchange Act of 1934, at 20 (Form 20FR12B/A) (Jan. 14, 2002), <https://www.sec.gov/Archives/edgar/data/1144145/000095013302000119/0000950133-02-000119.txt>.

<sup>135</sup> *Id.* at 9 (noting that Bayer cooperated "to ensure adequate supplies of ciprofloxacin while preserving our existing patent rights").

<sup>136</sup> See Heinz Klug, *Access to Medicines and the Transformation of the South African*

that South Africa was violating its international treaty obligations,<sup>137</sup> notwithstanding the fact that the South African government was struggling to provide medicine to its sick citizens. Under pressure from the U.S. pharmaceutical lobby, the Clinton Administration imposed various trade-related penalties.<sup>138</sup> These actions led to a massive public backlash, with tens of thousands of people demonstrating in support of South Africa.<sup>139</sup> In dropping their suit, GlaxoSmithKlein's CEO noted that as a large corporation, it is "not insensitive to public opinion" and that public opinion is "a factor in our decision-making."<sup>140</sup> An industry analyst noted that the lawsuit was "a public relations disaster" and that it was highly unlikely that a pharmaceutical company would sue a low-income country in the future.<sup>141</sup>

State governments can tap into that powerful public sentiment during times of crisis. If a state sought to procure unauthorized generic drugs for its citizens, any opposition from the federal government or the patent holder would generate immense public backlash. Even if a state ultimately did not succeed in obtaining the drugs directly, its attempt could be enough to bring the patent holder and federal government to the bargaining table. Moreover, states could use the mere threat of independent action as a mechanism for shaming pharmaceutical companies, in an attempt to encourage better behavior.<sup>142</sup>

#### IV. CONCLUSION

The COVID-19 pandemic has led to drug shortages and demonstrated the risks of limited access to patented lifesaving drugs. In an ideal world, states

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*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 L. & SOC. INQUIRY 297, 314 (2012); see also *The Price of Africa's Cheap Drugs*, THE 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).

<sup>137</sup> See David Barnard, *In the High Court of South Africa, Case No. 4138/98: The Global Politics of Access to Low-Cost AIDS Drugs in Poor Countries*, 12 KENNEDY INST. ETHICS J. 159, 163-64 (June 2002).

<sup>138</sup> See Kumar, *supra* note 115, at 15.

<sup>139</sup> See Debora Halbert, *Moralized Discourses: South Africa's Intellectual Property Fight for Access to AIDS Drugs*, 1 SEATTLE J. SOC. JUST. 257, 271-74 (2002).

<sup>140</sup> Rachel L. Swarns, *Drug Makers Drop South Africa Suit Over AIDS Medicine*, N.Y. TIMES (APR. 20, 2001), <https://www.nytimes.com/2001/04/20/world/drug-makers-drop-south-africa-suit-over-aids-medicine.html>.

<sup>141</sup> *Id.*

<sup>142</sup> See Sharon Yadin, *Shaming Big Pharma*, 36 YALE J. REG. BULL. 131, 136 (2019), (discussing how federal agencies can use shaming as a regulatory tool "to inflict reputational harm on business organizations and nudge them in the right direction").

would be able to depend upon the federal government to take appropriate action to secure needed drugs. However, some administrations have placed the interests of pharmaceutical groups over that of the public. Consequently, during such times of emergency, states should consider infringing patents and producing or procuring needed life-saving drugs. The doctrine of state sovereign immunity would shield states from paying any damages for patent infringement. And because such an action would clearly benefit the public welfare, a court or agency would be hesitant to award the patent holder prospective relief, such as an injunction or an exclusion order.

Admittedly, importing or directly producing patented drugs carries substantial risks for states, particularly with regard to the FDA's enforcement of its regulations. A state could spend time and money securing drugs, only to have them seized by the federal government. But attempts by the patent holder or federal agencies to prevent needed drugs from reaching consumers would almost certainly generate immense public backlash. Consequently, state patent infringement could put pressure onto the federal government to use its powers to alleviate the shortage, and shame the pharmaceutical company into doing the right thing.