

# Note

## Free for the “Taking”: Why States Should Not Be Able to Invoke Sovereign Immunity in Patent Infringement Disputes

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*“The patent system . . . added the fuse of interest to the fire of genius.”*

– Abraham Lincoln<sup>1</sup>

### *Introduction*

There is a crisis looming on America’s horizon, whether in the form of bioterrorism, an avian flu pandemic, or the bankrupting of the federal government due to the aging population’s need for health care. All of these crises demand widespread access to patented inventions, such as pharmaceuticals, to prevent the enormous suffering of Americans. Emergency situations, such as the flu pandemic, will require production of patented products on a scale so massive that it would require circumventing a patent’s normal protections.<sup>2</sup> Even the

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<sup>1</sup> A. LINCOLN, *Second Lecture on Discoveries and Inventions*, in 3 THE COLLECTED WORKS OF ABRAHAM LINCOLN 356, 363 (Roy P. Basler ed., 1953) (emphasis omitted). The author viewed this quotation engraved on the U.S. Department of Commerce building in Washington, D.C.

<sup>2</sup> See Matthew S. Bethards, *Condemning a Patent: Taking Intellectual Property by Eminent Domain*, 32 AIPLA Q.J. 81, 115 (2004).

aging baby boomer population's need for access to low-cost prescription drugs through programs like Medicare could be considered an emergency situation.<sup>3</sup> Never before has the health and well-being of our nation been so inexorably linked to patented inventions.

In recent years, Congress has attempted to address the coming crises and has proposed a number of changes to the patent laws; these changes, however, have failed to provide adequate solutions.<sup>4</sup> States, therefore, are becoming increasingly proactive with regard to their residents' needs in these crisis situations and are beginning to look to a loophole created by the Eleventh Amendment that exists in the patent laws.<sup>5</sup> This loophole threatens to destabilize the United States' incredibly successful patent system and the hundreds of years of technological innovation this system has provided to the nation.<sup>6</sup>

This Note examines the delicate balance between the public's need for ready access to patented goods and the patent protections necessary to promote innovation, within the framework of the present patent system. Also discussed in this Note are problems that result from the approaches to patent "takings" and compulsory licensing that states and local governments have begun to employ. This Note proposes a vital amendment to the patent laws that would alleviate the aforementioned crises while still encouraging innovation and protecting the basic tenets of the patent system. Furthermore, this Note advocates that state sovereign immunity in patent cases be abrogated to curtail states' abilities to impose compulsory licenses upon patent holders.

By allowing only Congress to wield the power to extract compulsory licenses, rather than state or local governments or officers or appointees of the executive branch of the federal government, this proposal protects the sanctity and stability of the patent system. This protection furthers the aims of the Constitution and fosters the progress of the useful arts and sciences. In cases of national emergency, however, Congress would retain the authority to implement takings or compulsory licensing of patents.

Part I provides background information regarding the U.S. patent system. This Part discusses the balance between incentives for innovation and disclosure of information; mechanisms and rationales for pat-

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<sup>3</sup> *See id.*

<sup>4</sup> *See infra* Part II.C.3.

<sup>5</sup> *See infra* Part II.D.

<sup>6</sup> *See infra* Part II.D.

ent exclusivity; and the condemnation of patents through both takings and compulsory licensing.

Part II analyzes the necessity for striking a balance between promoting innovation and ensuring public health and safety. This Part addresses the current authority of local, state, and federal governments to implement takings and compulsory licenses, and discusses the historical implementation of compulsory licensing (including how and why changes to the present system are necessary and where these changes would have a positive impact). Finally, this Part analyzes the threat that state sovereign immunity poses to the patent system and explores why the system must be protected.

Part III proposes an amendment to the patent laws that would abrogate state sovereign immunity in patent infringement cases. This Part also explains how this amendment will meet the Supreme Court's "congruence and proportionality" test<sup>7</sup> and how the amendment is within Congress's power under the Fourteenth Amendment.

### *I. Background*

#### *A. The U.S. Patent System: Procedures and Policy*

##### *1. Introduction to the U.S. Patent System*

The U.S. Constitution states: "Congress shall have the power . . . [t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."<sup>8</sup> This "exclusive right" grants patent holders a "monopoly" of limited duration.<sup>9</sup> The monopoly encompasses the inventor's exclusive rights to make, use, offer to sell, or sell her patented invention.<sup>10</sup>

To receive this protection, an applicant must meet a series of requirements imposed by statute and administered by the United States Patent and Trademark Office ("USPTO"). To receive a patent, the invention must be useful,<sup>11</sup> novel,<sup>12</sup> nonobvious,<sup>13</sup> and must belong to

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<sup>7</sup> See *Fla. Prepaid Postsecondary Educ. Expense Bd. v. Coll. Sav. Bank*, 527 U.S. 627, 639 (1999).

<sup>8</sup> U.S. CONST. art. I, § 8, cl. 8.

<sup>9</sup> See 35 U.S.C. § 154(a)(2) (2000) (granting patentees a term of exclusive rights for twenty years from the date of filing).

<sup>10</sup> *Id.* § 271(a) (stating that infringement occurs when someone other than the inventor attempts to make, use, offer to sell, or sell the patented invention).

<sup>11</sup> *Id.* § 101 (establishing the condition that the patented subject matter have a useful purpose).

<sup>12</sup> *Id.* §§ 101, 102 (providing the novelty requirement and prescribing what is considered novel). Inventions are not deemed novel if they were previously in the public domain, if they

a valid category of patentable subject matter.<sup>14</sup> If these criteria are met and the patent is valid, the inventor is eligible to receive damages,<sup>15</sup> an injunction,<sup>16</sup> and possibly attorney's fees<sup>17</sup> if the patented invention is infringed.<sup>18</sup> The "right to exclude exists even if the infringing party developed the infringing product independently and without knowledge of the patent."<sup>19</sup> In return for this privilege, the inventor must disclose (or "enable"<sup>20</sup>), in a written description, the best mode by which to perform the invention.<sup>21</sup>

## 2. Rationale for Granting Patent Rights

The patent system provides both an incentive to invest in developing new inventions and an incentive to disclose these inventions, thereby increasing the domain of public knowledge.<sup>22</sup> The incentive

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were described in a printed publication older than one year, or if they were offered for sale in the United States more than one year prior to submission of the patent application. *Id.* § 102(a); see also PATENT & TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE §§ 2131–2133 (8th ed. 2001).

<sup>13</sup> 35 U.S.C. § 103 (noting that an invention would not meet the nonobviousness requirement "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains").

<sup>14</sup> *Id.* § 101 (permitting patents to issue for a "process, machine, manufacture, or composition of matter, or any new and useful improvement thereof"). Pharmaceutical substances and chemicals qualify under the "composition of matter" prong. See *Shell Dev. Co. v. Watson*, 149 F. Supp. 279, 280 (D.D.C. 1957) (stating that "all compositions of two or more substances . . . , whether they be the results of chemical union, or of mechanical mixture," have been construed as compositions of matter).

<sup>15</sup> 35 U.S.C. § 284 (allowing the wronged inventor to receive "damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer, together with interest and costs as fixed by the court").

<sup>16</sup> *Id.* § 283 (describing the circumstances under which a patent holder may be granted an injunction).

<sup>17</sup> *Id.* § 285 (permitting recovery of attorney's fees only in "exceptional cases").

<sup>18</sup> Infringement occurs when another party, without the inventor's permission, makes, uses, offers to sell, or sells the patented invention. *Id.* § 271.

<sup>19</sup> Daniel R. Cahoy, *Treating the Legal Side Effects of Cipro®: A Reevaluation of Compensation Rules for Government Takings of Patent Rights*, 40 AM. BUS. L.J. 125, 131 (2002).

<sup>20</sup> 35 U.S.C. § 112 (detailing the enablement requirement). The enablement requirement mandates that the patent specification state how to make and how to use the claimed invention. *Id.* The enablement requirement also ensures that the claimed invention is communicated to the public in a meaningful way. See *id.*; see also PATENT & TRADEMARK OFFICE, *supra* note 12, § 2164.

<sup>21</sup> 35 U.S.C. § 112 (noting that the written description must be "in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains . . . to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention").

<sup>22</sup> See *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480–81 (1974) ("The patent laws promote this progress by offering a right of exclusion for a limited period as an incentive to

to innovate is best explained by noting that without patent protection, inventors “may be unable to appropriate enough of the social value of the invention to justify the initial research and development expenditures.”<sup>23</sup> Without patent protection, imitators would enter the market and reduce prices to such an extent that an inventor could not recoup his or her initial investment.<sup>24</sup>

In addition, the enablement requirement “ensures that useful technology becomes accessible to the general public by putting it in the public domain.”<sup>25</sup> In the absence of patent protection, inventors may maintain trade secrets to prevent competitors from exploiting their ideas.<sup>26</sup> It appears “likely that the patent system at least facilitates disclosure by creating rights in inventions that survive disclosure.”<sup>27</sup> The benefits from conveying the knowledge associated with new inventions include incentives for others to design around or improve the invention, thereby generating further innovation.<sup>28</sup>

In the United States, the patent owner’s right to exclude others from making, using, or selling a patented invention extends even where the owner is not “working”<sup>29</sup> the patent or granting licenses to others to “work” the patent.<sup>30</sup> The Patent Act specifically states that a patent owner is not guilty of misuse for “refus[ing] to grant a license or use any rights to the patent.”<sup>31</sup> The possibility exists, therefore,

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inventors to risk the often enormous costs in terms of time, research, and development. The productive effort thereby fostered will have a positive effect on society through the introduction of new products and processes of manufacture into the economy, and the emanations by way of increased employment and better lives for our citizens.”).

<sup>23</sup> Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1025 (1989).

<sup>24</sup> See *id.*

<sup>25</sup> Paul Gormley, Comment, *Compulsory Patent Licenses and Environmental Protection*, 7 TUL. ENVTL. L.J. 131, 133 (1993). Compliance with the enablement requirement provides the information required for others to make, use, and sell the patented invention after the expiration of the patent term. See *id.*; see also 35 U.S.C. § 112.

<sup>26</sup> See Eisenberg, *supra* note 23, at 1028.

<sup>27</sup> *Id.* at 1029.

<sup>28</sup> See Cahoy, *supra* note 19, at 131–32.

<sup>29</sup> In the context of patents, the term “working” is used to denote actions taken by or on behalf of the patent owner to bring the patented good or service into the public domain prior to the expiration of the patent term. See Gormley, *supra* note 25, at 134.

<sup>30</sup> See *id.* at 134–35 & n.17 (contrasting the United States’ system with the United Kingdom’s patent laws, which require that the owner work the patent or risk the Comptroller of the patents granting a compulsory license).

<sup>31</sup> 35 U.S.C. § 271(d)(4) (2000); see also *Cont’l Paper Bag Co. v. E. Paper Bag Co.*, 210 U.S. 405, 425 (1908) (noting that if a patentee sees fit he can reserve the exclusive right of the invention to himself, and he is “neither bound to use his discovery himself or to permit others to use it”).

that the inventor may choose to withhold the patent from the public domain entirely for the twenty-year patent term.<sup>32</sup> This possibility undermines the public benefit arguments outlined above, at least until the patent term expires. One way in which other countries, and the United States to a limited extent, deal with this issue is through the use of compulsory licensing.<sup>33</sup>

### B. *Limitations on Exclusivity of Patent Rights*

There are two ways in which the government can condemn a patent.<sup>34</sup> First, the government can "take" the entire patent, through its eminent domain powers or by issuing a secrecy order.<sup>35</sup> Second, the government can force the patent owner to license the invention to nonpatent owners. This second option is known as compulsory licensing.<sup>36</sup>

#### 1. *Patent Takings: Secrecy Orders and Eminent Domain*

Although the patent owner has exclusive rights regarding her patented invention, the exclusive nature of those rights is not absolute. There are at least two means by which the government can limit these rights: orders of secrecy and eminent domain.

Where a disclosed invention is "important to the armament or defense of the United States," an application can become the property of the United States.<sup>37</sup> In any instance where a patent is withheld by an "order of secrecy and/or for the use of the invention by the Government," however, the applicant can apply for or bring suit to gain compensation for the damage and use of the patent.<sup>38</sup>

After the patent is granted, any limitations imposed by the government are governed by the Fifth Amendment.<sup>39</sup> "[A]ny government action that affects existing patent rights—whether the act of a

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<sup>32</sup> See Gormley, *supra* note 25, at 135 (noting that "the long term gains of securing a greater market share, or even of driving a competitor out of business, might well be of far greater benefit to the patent holder" than exploiting the patented invention for the period of exclusivity).

<sup>33</sup> See *infra* Part I.B.2.

<sup>34</sup> Condemnation is the "determination and declaration that certain property (esp. land) is assigned to public use, subject to reasonable compensation; the exercise of eminent domain by a government entity." BLACK'S LAW DICTIONARY 310 (8th ed. 2004).

<sup>35</sup> See U.S. CONST. amend. V.

<sup>36</sup> See *infra* Part I.B.2.

<sup>37</sup> 35 U.S.C. § 267 (2000).

<sup>38</sup> *Id.* § 183.

<sup>39</sup> The Fifth Amendment provides that private property shall not be taken for public use without just compensation. U.S. CONST. amend. V.

government employee that impacts a single patent or a congressional act that retrospectively narrows the enforceability of all U.S. patents—is properly considered an appropriation of patent property.”<sup>40</sup> Courts have long maintained that patents are subject to the eminent domain power.<sup>41</sup> More recent cases have noted that the government maintains the power to take an invention when the public interest warrants, as long as adequate compensation is provided to the patent owner.<sup>42</sup>

When exercising its eminent domain powers, the government is authorized, without the license or consent of the patent owner, to take or use the patented invention.<sup>43</sup> This ability extends even to cases where the patented invention is being utilized by another *for* the United States (e.g., a government contractor).<sup>44</sup> In these cases, the sole remedy available to the patentee is recovery of “reasonable and entire compensation.”<sup>45</sup> This precludes a patent owner from obtaining an injunction against future infringement by the government.<sup>46</sup>

One instance when the government may choose to condemn an entire patent is during times of war.<sup>47</sup> During World War I, it was

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<sup>40</sup> Cahoy, *supra* note 19, at 134.

<sup>41</sup> See, e.g., *James v. Campbell*, 104 U.S. 356, 357–58 (1881) (“[T]he government of the United States when it grants letters-patent for a new invention . . . confers upon the patentee an exclusive property in the patented invention which cannot be appropriated or used by the government itself, without just compensation, any more than it can appropriate or use without compensation land.”).

<sup>42</sup> See, e.g., *King Instruments Corp. v. Perego*, 65 F.3d 941, 950 (Fed. Cir. 1995) (discussing 28 U.S.C. § 1498). Some scholars argue that takings are not limited solely to the executive and legislative branches. They argue that courts’ decisions in patent cases often effectuate “judicial takings” and that the Takings Clause should encompass these acts, thereby requiring “just compensation.” See, e.g., J. Nicholas Bunch, *Takings, Judicial Takings, and Patent Law*, 83 TEX. L. REV. 1747, 1752–69 (2005).

<sup>43</sup> See Bunch, *supra* note 42, at 1752–54.

<sup>44</sup> See 28 U.S.C. § 1498(a) (2000) (noting that “[w]hen an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same,” the owner can bring an action for recovery (emphasis added)).

<sup>45</sup> *Id.* (stating that the patent holder’s “remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture” (emphasis added)). According to the statute, “[c]ompensation shall include the owner’s reasonable costs, including reasonable fees for expert witnesses and attorneys, in pursuing the action against the United States.” *Id.*

<sup>46</sup> See *Pitcairn v. United States*, 547 F.2d 1106, 1114 (Ct. Cl. 1976) (“The nature of the property thus taken is a license in the patent, the claimed invention of which is used or manufactured by or for the Government, and such license continues throughout the life of the patent, or the period of the infringing procurement, whichever is shorter.”).

<sup>47</sup> See Bethards, *supra* note 2, at 114 (noting that “in times of war, the government tries to

impossible to manufacture aircraft in the United States without utilizing the Wright<sup>48</sup> and Curtiss<sup>49</sup> patents.<sup>50</sup> In 1917, the Aircraft Manufacturers' Association was formed to "overcom[e] obstacles to the production of airplanes arising from disputes between patentees that were embarrassing the Government in its need for airplanes."<sup>51</sup> The government agreed to pay royalties to the patent owners on each airplane that utilized the patents, whether manufactured by the government, purchased by the government from original subscribers to the cross license, or purchased from nonsubscribers.<sup>52</sup> Essentially, the government created a patent pool to allow for relatively inexpensive production of aircraft to be used in World War I.<sup>53</sup> Although the members of the Aircraft Manufacturers' Association technically retained patent rights in their inventions, the government was the largest purchaser of aircraft.<sup>54</sup> The patent owners, therefore, were only receiving government-dictated royalties for their inventions rather than the monopoly prices they would have received absent government-mandated patent pooling.<sup>55</sup>

Scholars note the possibility that national emergencies could also justify the taking of an entire patent.<sup>56</sup> For example, a taking, rather than a compulsory license, would be useful in cases where an "outbreak required the treatment or vaccination of the entire U.S. popula-

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take over an entire industry, including the associated [intellectual property]" and discussing President Truman's attempt to seize the nation's steel mills).

<sup>48</sup> U.S. Patent No. 821,393 (filed Nov. 23, 1903).

<sup>49</sup> U.S. Patent No. 1,011,106 (filed Apr. 8, 1909).

<sup>50</sup> This is distinct from the government issuing a secrecy order or withholding a patent application. In this case, the patents had already issued to both Wright and Curtiss. *Mfrs. Aircraft Ass'n v. United States*, 77 Ct. Cl. 481, 514 (Ct. Cl. 1933).

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

<sup>52</sup> *Id.* at 503.

<sup>53</sup> As one scholar describes:

Prior to the creation of the patent pool, the Wright Brothers were asking \$1,000 per aircraft as a royalty (about 5 percent of the cost of a plane then) for a single patent. The federal government forced patent owners to accept a \$200 flat fee for each airplane that was manufactured, and later lowered this to \$100 per plane. The royalties were divided 67.5 percent to the Wright Brothers, and 20 percent to the Curtiss-Burgess company, with the remainder used to support the [Aircraft Manufacturers' Association]. The royalties to both the Wright and Curtiss patent owners were reduced once they accumulated \$2 million in royalty payments, to \$25 per airplane.

James Love, Consumer Project on Technology, An Essential Health Care Patent Pool (July 8, 2002), <http://www.cptech.org/slides/jameslove-barcelona.ppt>.

<sup>54</sup> See *Mfrs. Aircraft Ass'n*, 77 Ct. Cl. at 514.

<sup>55</sup> See *id.*

<sup>56</sup> See Bethards, *supra* note 2, at 115 (2004) (speculating that a smallpox or anthrax outbreak "might justify the taking of an entire patent").



tion” because “[e]veryone in the country would have used and benefited from the technology, and there would no longer be a demand for a patented vaccine after the entire country ha[d] been inoculated.”<sup>57</sup> One example of such a benefit occurred in the case of polio. Widespread administration of vaccinations almost completely eradicated the disease in the United States over a period of five years.<sup>58</sup> Although this did not involve a taking or a compulsory license because both Jonas Salk and Albert Sabin refused to patent their inventions,<sup>59</sup> it is illustrative of the notion that once vaccines are administered and the disease eradicated, the demand is substantially diminished, if not eliminated entirely.

## 2. *Compulsory Licenses*

Compulsory licenses are distinct from patent takings. When a patent is taken, in part or in its entirety, the patent owner does not retain the rights to practice all or part of the patented invention.<sup>60</sup> When the government or a court grants a compulsory license, the patent owner retains the rights to practice her invention and can still exclude others from doing so.<sup>61</sup> Only the recipient of the compulsory license can make, use, or sell the patented invention, and the recipient must pay a reasonable royalty to the patent owner for this privilege.<sup>62</sup> The government, by itself or through third parties, facilitates compulsory licensing to force the distribution of the invention to its citizens.<sup>63</sup>

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<sup>57</sup> *Id.*

<sup>58</sup> See Bonnie A. Maybury Okonek, Development of Polio Vaccines (Linda Morganstein ed.), <http://www.accessexcellence.org/AE/AEC/CC/polio.html> (last visited Nov. 12, 2006) (“In 1960, there were 2,525 cases of paralytic polio in the United States. By 1965, there were 61 . . . . There has not been a single case of polio caused by the wild virus since 1979 . . . . In 1994, polio was declared eradicated in all of the Americas.”).

<sup>59</sup> James Stuart, Note, *The Academic Industrial Complex: A Warning to Universities*, 75 U. COLO. L. REV. 1011, 1014 (2004).

<sup>60</sup> This is analogous to a real property taking where the property owner can no longer utilize the taken property. See Gormley, *supra* note 25, at 133–34.

<sup>61</sup> The patent holder still has the right to make, use, offer to sell, or sell her patented invention. *Id.* at 138.

<sup>62</sup> See Dora Kripapuri, *Reasoned Compulsory Licensing: Applying U.S. Antitrust’s “Rule of Reason” to TRIP’s Compulsory Licensing Provision*, 36 NEW ENG. L. REV. 669, 670 (2002) (noting that “compulsory licensing generally represents a modest return on invested capital and rarely includes the monopoly premium that a patent holder otherwise can receive by controlling the supply”); see also J. THOMAS MCCARTHY, MCCARTHY’S DESK ENCYCLOPEDIA OF INTELLECTUAL PROPERTY 51–52 (1991).

<sup>63</sup> Kripapuri, *supra* note 62, at 670 (referring to the price at which a license must be offered).

The owner "is compelled to license at a rate thought to be 'reasonable' by the government."<sup>64</sup>

The government and courts rarely employ compulsory licensing under U.S. patent law.<sup>65</sup> There are exceptions, however, and compulsory licenses have been issued in the areas of atomic energy,<sup>66</sup> new varieties of plants,<sup>67</sup> and air pollution controls.<sup>68</sup> The government and courts generally employ compulsory licenses to advance some "political or social objective."<sup>69</sup> In addition, legislation that permits the federal government and its contractors to make or use any patented invention<sup>70</sup> essentially creates a "pseudo-compulsory license provision."<sup>71</sup>

Governments and courts choose to create compulsory licenses for a variety of reasons.<sup>72</sup> "Courts will often create compulsory licenses when the patentee's actions constitute an antitrust violation or patent misuse."<sup>73</sup> A number of countries also employ compulsory licensing when a patentee suppresses her invention.<sup>74</sup> Compulsory licenses can be granted for patents that "affect the public's health, safety, environment, and national defense."<sup>75</sup> Strong public interest concerns are

<sup>64</sup> MCCARTHY, *supra* note 62, at 51–52.

<sup>65</sup> DONALD S. CHISUM & MICHAEL A. JACOBS, UNDERSTANDING INTELLECTUAL PROPERTY LAW § 4[E]7 (1992).

<sup>66</sup> 42 U.S.C. § 2183(g) (2000).

<sup>67</sup> 7 U.S.C. § 2321 (2000).

<sup>68</sup> 42 U.S.C. §§ 7401, 7608.

<sup>69</sup> MCCARTHY, *supra* note 62, at 51–52.

<sup>70</sup> See 28 U.S.C. § 1498 (2000).

<sup>71</sup> See Alan M. Fisch, *Compulsory Licensing of Pharmaceutical Patents: An Unreasonable Solution to an Unfortunate Problem*, 34 JURIMETRICS J. 295, 301 (1994).

<sup>72</sup> See, e.g., Agreement on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods art. 31, Dec. 15, 1993, 33 I.L.M. 81, 95 ("TRIPS Agreement") (providing five grounds for granting compulsory licenses: (1) refusal to deal; (2) national emergency; (3) anticompetitive practices; (4) noncommercial use; and (5) dependent patents). Many conditions must be fulfilled under the TRIPS Agreement before compulsory licenses are granted, including: (1) review on individual merits; (2) previous efforts to authorize; (3) limitation of license to purpose for which it was authorized; (4) nonexclusivity; (5) nonassignability; (6) predominant authorization for domestic market; (7) revocation; (8) remuneration; and (9) judicial review of remuneration. Cole M. Fauver, Comment, *Compulsory Patent Licensing in the United States: An Idea Whose Time Has Come*, 8 NW. J. INT'L L. & BUS. 666, 668–74 (1988).

<sup>73</sup> Bethards, *supra* note 2, at 105. Bethards also notes that in Europe, the patentee's refusal to license an invention is seen as an antitrust violation. See *id.*

<sup>74</sup> Bethards notes that the United Kingdom, Australia, and other countries in continental Europe, Southeast Asia, and Latin American often employ compulsory licensing in these instances. See *id.* at 106–07; see also Gormley, *supra* note 25, at 133–36.

<sup>75</sup> Bethards, *supra* note 2, at 110; see also *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1547 (Fed. Cir. 1995) (noting that courts can, "in rare instances, exercise their discretion to deny injunctive relief in order to protect the public interest"); Sheldon Burshtein, *Sublicense or Sup-*

usually examined on a case-by-case basis.<sup>76</sup> Other countries have also employed compulsory licensing, or the threat thereof,<sup>77</sup> in cases where the price for patented goods is “too high.”<sup>78</sup>

When courts choose in their discretion not to enjoin infringement for public policy reasons, these courts are effectuating a de facto compulsory license. Bethards notes several instances where courts employed this judicial tool.<sup>79</sup> In *City of Milwaukee v. Activated Sludge, Inc.*,<sup>80</sup> the Seventh Circuit blocked an injunction that would have led to the closure of a sewer plant.<sup>81</sup> The court noted that allowing an injunction would leave no means for disposing of raw sewage other than into Lake Michigan.<sup>82</sup> Although the patent owner could prove infringement, the court elected not to issue an injunction for public policy reasons such as those discussed in Bethards’s article.<sup>83</sup>

### 3. *Patents as Personal Property*

A final limitation can be imposed on patent rights because patents have the attributes of personal property and, therefore, are subject to similar rules regarding ownership and transfer.<sup>84</sup> The implications arising from the treatment of patents as personal property are numerous. One important implication is that the federal government creates and defines the scope of the property right.<sup>85</sup> Essentially, “the government can create rules affecting the scope of

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*ply Agreement? Supreme Court of Canada Interpretation Benefits Generic Pharmaceutical Industry*, 54 FOOD & DRUG L.J. 73, 74 (1999) (noting that until 1993, Canada required that all applicants be granted a license “to practice an invention intended or capable of being used for medicine, or for the preparation or production of medicine, unless there was a good reason not to grant them a license”).

<sup>76</sup> Bethards, *supra* note 2, at 111.

<sup>77</sup> Brazil has employed the threat of compulsory licensing to obtain access to discounted pharmaceuticals. See *Intellectual Property: Patently Problematic*, ECONOMIST, Sept. 14, 2002, at 75, 76.

<sup>78</sup> The theoretical basis for this type of compulsory licensing is that compensation for a license is based upon reasonable royalties rather than lost profits. See Bethards, *supra* note 2, at 111–12.

<sup>79</sup> *Id.* at 110–12 (citing *City of Milwaukee v. Activated Sludge, Inc.*, 69 F.2d 577, 593 (7th Cir. 1934), as an example of a de facto compulsory license).

<sup>80</sup> *City of Milwaukee v. Activated Sludge, Inc.*, 69 F.2d 577 (7th Cir. 1934).

<sup>81</sup> *Id.* at 593.

<sup>82</sup> *Id.*

<sup>83</sup> *Id.*; see also Bethards, *supra* note 2, at 110–12 (discussing the effects of water pollution on public health).

<sup>84</sup> 35 U.S.C. § 261 (2000) (“Subject to the provisions of this title, patents shall have the attributes of personal property.”).

<sup>85</sup> Cahoy, *supra* note 19, at 132–33.

future grants without affecting any existing private property rights.”<sup>86</sup> Congress, therefore, can limit the term of patent rights for patents which have not yet been granted.<sup>87</sup>

## II. *The Importance of Ensuring the Stability and Uniformity of the Patent System*

As mentioned above, the patent system is designed to promote innovation and progress in the useful arts.<sup>88</sup> One mechanism by which it does so is the grant of an exclusive right to the patent owner, for a period of twenty years, to make, use, or sell the patented invention.<sup>89</sup> In recent years, debate has raged over whether the government should interfere with patent owners’ exclusive rights by granting compulsory licenses.<sup>90</sup>

### A. *How Compulsory Licensing Disrupts the Economics of Innovation*

If the United States elects to preempt the exclusive patent right through the grant of compulsory licenses for pharmaceutical patents, for example, it could undermine the economic incentives to pursue research and development in areas vital to the public welfare.<sup>91</sup> “[I]f the government uses its . . . powers to appropriate patent rights in technologies related to important health or safety concerns (e.g., pharmaceuticals, antiterrorism technologies), one would expect to see a corresponding reduction in investment and innovation in these very fields.”<sup>92</sup> Although this approach may solve immediate public health crises, the long-term effects could be devastating. “The needs of a few [individuals] for a period of ten [or twenty] years to obtain price pro-

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<sup>86</sup> *Id.* (noting that patent property rights do not exist until they are created by the act of the government, through the USPTO, issuing a patent).

<sup>87</sup> Cahoy analogizes this to a private landowner selling only a portion of his property. *Id.* at 133–34.

<sup>88</sup> See *supra* Part I.A.2.

<sup>89</sup> 35 U.S.C. § 154(a)(2).

<sup>90</sup> Compare B. Zorina Khan, *Federal Antitrust Agencies and Public Policy Toward Antitrust and Intellectual Property*, 9 CORNELL J.L. & PUB. POL’Y 133, 156 (1999) (“In general, analysts and policymakers who propose remedies such as compulsory licensing demonstrate a failure to understand the full implications of the economic model of induced innovation, a model that was implicitly supported by the framers of the United States Constitution.”), and Fisch, *supra* note 71, with Fauver, *supra* note 72, and Gormley, *supra* note 25, at 133.

<sup>91</sup> See Kripapuri, *supra* note 62, at 671.

<sup>92</sup> Cahoy, *supra* note 19, at 170.

hibitive pharmaceuticals do not outweigh the needs of many others to benefit from future pharmaceutical innovations.”<sup>93</sup>

Pharmaceutical companies must consider the potential for profit when determining where to focus their research and development budgets.<sup>94</sup> Pharmaceutical research is financially risky; only one out of every 4000 discovered compounds will ever become a marketable pharmaceutical.<sup>95</sup> The price of pharmaceuticals reflects a number of factors, including costs associated with the 3999 compounds that fail to reach the market and providing investors with “a rate of return on all research commensurate with the investment’s high risk.”<sup>96</sup> If compulsory licensing were to apply, it is likely that it would apply only to “patent protected breakthrough pharmaceuticals, and that the scheme would establish a licensing fee lower than lost profits, resulting in a decline of income for the companies whose products are licensed.”<sup>97</sup> In this position, pharmaceutical companies only have two choices: (1) raise prices (on drugs not subject to compulsory licenses) or (2) reduce expenditures (usually in the form of research and development).<sup>98</sup> Because the market will not bear increased costs,<sup>99</sup> the only choice for pharmaceutical companies is to reduce expenditures, which often translates into a reduction in the creation of breakthrough drugs.<sup>100</sup>

Some scholars cite the Canadian system to indicate why the United States should not favor a compulsory licensing scheme.<sup>101</sup> From 1923 until 1993, compulsory licenses were available for all pat-

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<sup>93</sup> Fisch, *supra* note 71, at 314.

<sup>94</sup> See Martin J. Adelman & Sonia Baldia, *Prospects and Limits of the Patent Provision in the TRIPS Agreement: The Case of India*, 29 VAND. J. TRANSNAT’L L. 507, 530 (1996) (discussing how pharmaceutical research and development in India is focused on products that have the largest domestic demand); Kripapuri, *supra* note 62, at 697.

<sup>95</sup> See Fisch, *supra* note 71, at 303; John Schwartz, *U.S. Drug-Testing Gantlet May Be World’s Toughest*, WASH. POST, Sept. 7, 1993, at A9.

<sup>96</sup> See Fisch, *supra* note 71, at 303. Other factors include the introduction of a competing product into the market, poor trial results, lack of acceptance by the medical community, invalidation of patents, or adverse side effects. *Id.*

<sup>97</sup> *Id.* at 304 (defining a breakthrough pharmaceutical as one that treats a currently incurable condition).

<sup>98</sup> *Id.*

<sup>99</sup> See *id.* at 305–07 (discussing competitive markets and monopolistic markets and concluding that pharmaceutical companies cannot recoup the revenue lost to compulsory licensing in either market).

<sup>100</sup> See *id.* at 308–13 (discussing manners by which expenditures could be reduced and concluding that such a reduction in expenditures will inevitably lead to a decline in the number of breakthrough pharmaceuticals).

<sup>101</sup> See, e.g., *id.* at 313 n.104.

ented medicines in Canada.<sup>102</sup> The royalty rate paid for this privilege was between four and six percent of the selling price of the finished product.<sup>103</sup> Because the generic drug manufacturers targeted commercially successful drugs and did not incur any risks or expenses associated with research, drug innovators found that Canada's compulsory licensing system resulted in an inability to recoup investments in research and development costs.<sup>104</sup> This made innovators reluctant to patent new pharmaceuticals in Canada during this period.<sup>105</sup>

*B. Why Compulsory Licensing Might Be the Answer*

For those who advocate for compulsory licensing, the most compelling argument relates to issues of public interest. The price of pharmaceuticals significantly impacts health care costs in the United States.<sup>106</sup> Many Americans cannot afford access to prescription pharmaceuticals.<sup>107</sup> Angela Jones, Executive Director of D.C. Action for Children, testified before the D.C. City Council that "prescription costs increased [at] four times the rate of inflation" and medical expenses are the cause of "more than half of all bankruptcy filings" in the United States.<sup>108</sup> When AIDS victims cannot access life-preserving pharmaceuticals, the value of a patent would seem paltry in comparison to these individuals' suffering.<sup>109</sup>

There are also economic arguments that favor compulsory licensing, at least in the case of pharmaceuticals. Through widespread and inexpensive public access to new medicines, compulsory licenses can

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<sup>102</sup> Burshtein, *supra* note 75, at 75 (noting that in 1993, as a result of the Canada–United States Free Trade Agreement and the North American Free Trade Agreement, Canada amended its Patent Act to eliminate compulsory licensing for medicines, but compulsory licenses that had already been granted were grandfathered).

<sup>103</sup> *Id.* at 74.

<sup>104</sup> *See id.* at 74–75.

<sup>105</sup> *See* Chris Warden, *The Prescription for High Drug Prices*, CONSUMERS' RES. MAG., Dec. 1992, at 10, 12 (noting that from 1969 to 1989 there were only three new pharmaceuticals introduced in Canada, while in 1991 alone thirty new pharmaceuticals were introduced in the United States).

<sup>106</sup> *See* Daniel R. Cahoy, *Patent Fences and Constitutional Fence Posts: Property Barriers to Pharmaceutical Importation*, 15 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 623, 624–25 (2005) (noting that U.S. consumers are paying more for pharmaceuticals than consumers in other industrialized nations).

<sup>107</sup> *See Prescription Drug Compulsory Manufacture License Act of 2005: Public Hearing on Bill 16-114 Before the Comm. on Health* (D.C. 2005) (statement of Angela Jones, Executive Director, D.C. Action for Children).

<sup>108</sup> *Id.*

<sup>109</sup> *See* Johanna McGeary, *Paying for AIDS Cocktails: Who Should Pick Up the Tab for the Third World?*, TIME, Feb. 12, 2001, at 54, 54 (asking "at what point does the human benefit to desperate, destitute countries outweigh strict adherence to patents and profits?").

translate directly into an “overall savings to the economy in productive lives saved.”<sup>110</sup> Specifically in the case of AIDS, the vast number of afflicted individuals leads to a decrease in worldwide productivity.<sup>111</sup> Commentators such as Cole Fauver argue that an increase in public access to inventions will increase competition and thereby further innovation.<sup>112</sup> These economic arguments provide a marked counterpoint to the notion that compulsory licensing stymies innovation.

Finally, scholars have proposed equity arguments that favor compulsory licensing. They argue that it “allows inventors to receive a reasonable royalty, but simultaneously discourages them from preventing use of the invention. Such a system is fair to all parties interested in the patented product or process.”<sup>113</sup>

### C. *Who Has the Authority to Implement Patent Takings or Compulsory Licensing*

#### 1. *Local Authority*

It is not likely that a municipality<sup>114</sup> would be able to take an entire patent.<sup>115</sup> Courts have, however, upheld the taking of patent licenses by municipalities in certain limited circumstances.<sup>116</sup>

Most recently, an attempt by a municipality to employ compulsory licensing of pharmaceuticals was thwarted by the U.S. District

<sup>110</sup> Kripapuri, *supra* note 62, at 693.

<sup>111</sup> *See id.* (noting that thirty-five million people worldwide are infected with AIDS).

<sup>112</sup> *See* Fauver, *supra* note 72, at 667–68.

<sup>113</sup> Gormley, *supra* note 25, at 163.

<sup>114</sup> It is important to note that the doctrine of sovereign immunity available to states does not apply to political subdivisions of states such as counties, cities, or municipalities. *See* U.S. CONST. amend. XI; *Mt. Healthy City Sch. Dist. Bd. of Educ. v. Doyle*, 429 U.S. 274, 280 (1977) (“The bar of the Eleventh Amendment to suit in federal courts extends to States and state officials in appropriate circumstances . . . but does not extend to counties and similar municipal corporations.” (citation omitted)). Therefore, determining whether an infringer is a political subdivision or an entity of the state determines whether the infringer can be enjoined or required to pay treble damages for willful infringement. *See* *Hander v. San Jacinto Junior Coll.*, 519 F.2d 273, 278–79 (5th Cir. 1975) (“[M]ere ‘political subdivisions’ of the state do not enjoy constitutional immunity.”). Municipalities, counties, and other arms of local government not protected by the Eleventh Amendment do not, therefore, present insurmountable problems to patent holders attempting to protect their exclusive rights.

<sup>115</sup> *See* *Bethards*, *supra* note 2, at 96 (stating that this would “so substantially burden the interests of the municipality/patentee and its relevant public that it would never seem justified”).

<sup>116</sup> *See, e.g., City of Milwaukee v. Activated Sludge, Inc.*, 69 F.2d 577, 593 (7th Cir. 1934) (awarding the municipality a compulsory license to preserve the health and safety of the citizens of Milwaukee). For a further discussion of *Activated Sludge*, see *supra* notes 80–83 and accompanying text.

Court for the District of Columbia.<sup>117</sup> The D.C. City Council determined that the "excessive prices of prescription drugs [were] threatening the health and welfare of [its] residents . . . and these excessive prices directly and indirectly cause[d] economic harm to the District and damage[d] the health and safety of its residents."<sup>118</sup> As a result, the District enacted a bill that made it "unlawful for any drug manufacturer . . . to sell or supply for sale or impose minimum resale requirements for a patented prescription drug that results in the prescription drug being . . . sold in the District for an excessive price."<sup>119</sup>

The court held that the District of Columbia's Prescription Drug Excessive Pricing Act ("Act")<sup>120</sup> was preempted by federal patent laws relating to prescription drugs and had a per se invalid extraterritorial reach in violation of the Commerce Clause.<sup>121</sup> The court found that the Act violated the Supremacy Clause because it presented an obstacle to Congress's objectives in passing the patent laws regarding pharmaceuticals.<sup>122</sup> "Congress' regulation of our nation's pharmaceutical industry is grounded in large part in a complex balance of economic forces and regulatory exclusivity designed to encourage and reward the innovation, research, and development of new drugs."<sup>123</sup> The court noted that this Act would "[p]unish[ ] the holders of pharmaceutical patents."<sup>124</sup> After this decision, it is not likely that attempts by other municipalities to enact similar legislation will pass constitutional muster.

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<sup>117</sup> See *Pharm. Research & Mfrs. of Am. v. Dist. of Columbia*, 406 F. Supp. 2d 56, 72 (D.D.C. 2005).

<sup>118</sup> *Id.* at 59 (quotation omitted).

<sup>119</sup> Prescription Drug Excessive Pricing Act of 2005, 2005 D.C. Sess. Law Serv. 2-3 (West).

<sup>120</sup> Prescription Drug Excessive Pricing Act of 2005, 2005 D.C. Sess. Law Serv. 2-3 (West).

<sup>121</sup> See *Pharm. Research & Mfrs. of Am.*, 406 F. Supp. 2d at 70 (stating there was "no question that the D.C. Act was intended to and will control out-of-state conduct").

<sup>122</sup> *Id.* at 64.

<sup>123</sup> *Id.* at 65-66 (noting that the Patent Term Restoration Act, 35 U.S.C. § 156, was a result of compromises between various industries involved, people affected, senior citizens, generic pharmaceuticals manufacturers, and patent owners); see also *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150-51 (1989) (noting that the patent system "embodies a carefully crafted bargain for encouraging the creation and disclosure of new, useful, and nonobvious advances in technology and design in return for the exclusive right to practice the invention for a period of years").

<sup>124</sup> *Pharm. Research & Mfrs. of Am.*, 406 F. Supp. 2d at 66.



## 2. State Authority

Generally speaking, governments cannot take property outside of their jurisdictions. In the case of patents, however, there are no defined territorial limits.<sup>125</sup> The Commerce Clause prevents a state from taking an entire patent by eminent domain. In the case of a compulsory license, however, the Supreme Court has allowed takings.<sup>126</sup>

In *Florida Prepaid Postsecondary Education Expense Board v. College Savings Bank*,<sup>127</sup> the Supreme Court held that the State of Florida never consented to suit for patent infringement.<sup>128</sup> The Eleventh Amendment barred the suit, and the Supreme Court dismissed the case because there were no grounds upon which the patent infringement claim could proceed.<sup>129</sup> Although Congress had expressly attempted to abrogate states' patent infringement immunity<sup>130</sup> by enacting the Patent and Plant Variety Protection Remedy Clarification Act ("Patent Remedy Act"),<sup>131</sup> the Act was ruled unconstitutional.<sup>132</sup> The State of Florida, therefore, was able to avoid suit while effectively taking a compulsory license.<sup>133</sup>

This result is extremely troubling and will be addressed in more detail in Part II.D. This Note argues that the ability of states to claim compulsory licenses while avoiding suit in federal court (as a result of sovereign immunity), poses significant risks to the integrity of the U.S. patent system. As will be discussed, this result has already begun to threaten the delicate balance that exists between the promotion of innovation and the public good.<sup>134</sup>

## 3. Federal Authority

As previously discussed, the federal government retains the eminent domain authority under the Fifth Amendment to take a valid

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<sup>125</sup> See Bethards, *supra* note 2, at 90.

<sup>126</sup> See *Fla. Prepaid Postsecondary Educ. Expense Bd. v. Coll. Sav. Bank*, 527 U.S. 627, 630 (1999).

<sup>127</sup> *Fla. Prepaid Postsecondary Educ. Expense Bd. v. Coll. Sav. Bank*, 527 U.S. 627 (1999).

<sup>128</sup> *Id.* at 630–31. In the case, a New Jersey-based College Savings Bank brought an infringement action against a Florida state agency for its alleged use of a patented apparatus and method for administering a college investment program. *Id.*

<sup>129</sup> See *id.* at 647–48.

<sup>130</sup> The Eleventh Amendment immunizes states from "any suit in law or equity." U.S. CONST. amend. XI.

<sup>131</sup> Patent and Plant Variety Protection Remedy Clarification Act, Pub. L. No. 102-560, 106 Stat. 4230 (1992) (codified in scattered sections of 7 and 35 U.S.C.).

<sup>132</sup> See *Fla. Prepaid Postsecondary Educ. Expense Bd.*, 527 U.S. at 648.

<sup>133</sup> See *id.*

<sup>134</sup> See *infra* Part II.D.

patent or a compulsory license thereof for a public use.<sup>135</sup> When the federal government exercises this power, it waives its governmental immunity from suit.<sup>136</sup> Thus, the federal government consents to suit in the U.S. Court of Federal Claims for "reasonable and entire compensation" for the use or manufacture of the patented invention.<sup>137</sup> Although the patent owner cannot enjoin the federal government from infringement, she can obtain damages.<sup>138</sup> The fact that the federal government retains this right seems logical as it is the federal government, through the USPTO, that grants the property rights associated with patents.<sup>139</sup>

As one court has noted, however, Congress is in the best position to fully understand and appreciate the "complex balance of economic forces and regulatory exclusivity designed to encourage and reward . . . innovation, research and development."<sup>140</sup> This understanding is borne out by the fact that Congress presently only takes compulsory licenses in a few limited areas: atomic energy inventions,<sup>141</sup> certain new varieties of plants,<sup>142</sup> and certain air pollution control inventions.<sup>143</sup> Historically, Congress has limited itself with regard to compulsory licensing as well.<sup>144</sup>

There have been several attempts by the U.S. House of Representatives to provide for compulsory licensing of patents relating to health care emergencies, such as pharmaceutical patents.<sup>145</sup> The most

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<sup>135</sup> See *supra* Part I.B.

<sup>136</sup> See 28 U.S.C. § 1498(a) (2000) ("For the purposes of this section, the use or manufacture of an invention described in and covered by a patent of the United States by a contractor, a subcontractor, or any person, firm, or corporation for the Government and with the authorization or consent of the Government, shall be construed as use or manufacture for the United States.").

<sup>137</sup> *Id.*

<sup>138</sup> *Id.* § 1498.

<sup>139</sup> Bethards, *supra* note 2, at 89 ("The patentee takes his patent from the United States subject to the government's eminent domain rights to obtain what it needs from manufacturers and to use the same." (quotation omitted)).

<sup>140</sup> Pharm. Research & Mfrs. of Am. v. Dist. of Columbia, 406 F. Supp. 2d 56, 65 (D.D.C. 2005).

<sup>141</sup> 42 U.S.C. § 2183(g) (2000).

<sup>142</sup> 7 U.S.C. § 2321 (2000).

<sup>143</sup> 42 U.S.C. §§ 7401, 7608.

<sup>144</sup> The only historical implementation of a government-imposed compulsory licensing scheme was during World War I to allow for the manufacture of aircraft. See *supra* note 53 and accompanying text.

<sup>145</sup> See, e.g., Public Health Emergency Medicines Act, H.R. 4131, 109th Cong. (2005) (reintroduction of a November 2001 bill); To Provide for the Importation of Pharmaceutical Products Under a Compulsory License as Provided for Under the World Trade Organization, H.R. 4392, 109th Cong. (2005).

recent bill grants the government authority to take a compulsory license for the production of Tamiflu, a pharmaceutical believed to be most effective in combatting the bird flu.<sup>146</sup> The bill further authorizes the President “to import pharmaceutical products manufactured under a compulsory license to meet public health needs or to address situations of inadequate supply caused by insufficient domestic manufacturing capacity.”<sup>147</sup> Although the President would administer the importation of the necessary pharmaceuticals, Congress retains the authority to grant the compulsory license,<sup>148</sup> thereby maintaining the balance between promoting innovation and providing for the public welfare in national health crises. Instances where the federal government elects to take a compulsory license do not, therefore, pose the same dangers as state-by-state compulsory licensing.

*D. How State Sovereign Immunity in Patent Cases Undermines Necessary Incentives for Research and Development*

As mentioned briefly above, state sovereign immunity presents a number of problems in the context where the state is either a direct or contributory patent infringer.<sup>149</sup> One problem relates to the fact that the state avails itself of patent protections, but remains insulated from potential suit.<sup>150</sup> Another problem occurs when individual states act to take compulsory licenses for the benefit of their citizens. Congress has sought to abrogate this immunity in the context of patent infringement to ensure the stability of the patent system.<sup>151</sup> Unfortunately, the Supreme Court found that the measures taken by Congress were unconstitutional.<sup>152</sup> This holding has left a loophole through which states can act as patent infringers and, by refusing to consent to suit, take compulsory licenses for an unlimited number of U.S. patents.

An equity problem arises when states are able to avail themselves of federal patent protections without having to waive their sovereign immunity for patent infringement. Unlike the states, the federal government explicitly waives its sovereign immunity in cases where it

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<sup>146</sup> H.R. 4392.

<sup>147</sup> *Id.* § 3.

<sup>148</sup> H.R. 4392.

<sup>149</sup> *See supra* Part II.C.2.

<sup>150</sup> *See Fla. Prepaid Postsecondary Educ. Expense Bd. v. Coll. Sav. Bank*, 527 U.S. 627, 657 (1999) (Stevens, J., dissenting) (“States and their instrumentalities are heavily involved in the federal patent system.”).

<sup>151</sup> *See Patent and Plant Variety Protection Remedy Clarification Act*, 35 U.S.C. §§ 271(h), 296(a) (1994), *invalidated by Fla. Prepaid Postsecondary Educ. Expense Bd.*, 527 U.S. 627.

<sup>152</sup> *See Fla. Prepaid Postsecondary Educ. Expense Bd.*, 527 U.S. at 647–48.

manufactures or uses a patented invention.<sup>153</sup> States are, however, increasingly utilizing patent protections for their own interests while retaining sovereign immunity in patent infringement disputes.

In 1995, more than 362 utility patents<sup>154</sup> were issued to state universities,<sup>155</sup> and royalty earnings from licenses at U.S. universities totalled \$273.5 million, a twelve-percent increase over the prior year.<sup>156</sup> In 2004, more than 630 utility patents were issued to state universities.<sup>157</sup> The evidence indicates that states are availing themselves of the patent system as a means of generating revenues. This lack of equity in the present system arises from the states' sovereign immunity in patent infringement cases.

Congress has long been concerned with state sovereign immunity as it applies to patent infringement suits. In 1992, Congress amended the patent laws, with the Patent Remedy Act, to expressly remove states' sovereign immunity from claims regarding patent infringement.<sup>158</sup> The Patent Remedy Act stated that

[a]ny State, any instrumentality of a State, and any officer or employee of a State or instrumentality of a State acting in his official capacity, shall not be immune, under the eleventh amendment of the Constitution of the United States or under any other doctrine of sovereign immunity, from suit in Federal court by any person . . . for infringement of a patent under section 271, or for any other violation under this title.<sup>159</sup>

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<sup>153</sup> See 28 U.S.C. § 1498(a) (2000).

<sup>154</sup> A utility patent is the type of patent most commonly granted. Utility patents are issued for inventions that perform useful functions. This is in contrast to design patents that only protect the appearance of a claimed invention or plant patents that cover newly engineered or discovered plant types. See Joseph Scott Miller & James A. Hilsenteger, *The Proven Key: Roles and Rules for Dictionaries at the Patent Office and the Courts*, 54 AM. U. L. REV. 829, 838 n.28 (2005).

<sup>155</sup> U.S. PATENT & TRADEMARK OFFICE, PATENTING BY ORGANIZATIONS 8–29 (1995), [http://www.uspto.gov/web/offices/ac/ido/oeip/taf/topo\\_95.pdf](http://www.uspto.gov/web/offices/ac/ido/oeip/taf/topo_95.pdf). The report lists organizations that received more than thirty utility patents during 1995. Some notable grantees were the University of California system (213 patents), University of Texas (89), University of Michigan (30), and North Carolina State University (30). *Id.*

<sup>156</sup> 2 ECKSTROM'S LICENSING IN FOREIGN AND DOMESTIC OPERATIONS § 11.06 (David M. Epstein ed., 1998).

<sup>157</sup> U.S. PATENT & TRADEMARK OFFICE, PATENTING BY ORGANIZATIONS 7–27 (2004), [http://www.uspto.gov/web/offices/ac/ido/oeip/taf/topo\\_04.pdf](http://www.uspto.gov/web/offices/ac/ido/oeip/taf/topo_04.pdf). The report also lists organizations receiving more than forty utility patents during 2004, including the University of California system (422 patents), University of Texas (99), University of Michigan (66), University of Illinois (58), University of Minnesota (43), and North Carolina State University (42). *Id.*

<sup>158</sup> See 35 U.S.C. § 296(a) (1994), *invalidated by Fla. Prepaid Postsecondary Educ. Expense Bd. v. Coll. Sav. Bank*, 527 U.S. 627 (1999).

<sup>159</sup> *Id.*

The Federal Circuit agreed with Congress's reasoning and determined that "significant harm results from state infringement of patents."<sup>160</sup> The Supreme Court, however, found that Congress had exceeded its authority both under its Article I powers,<sup>161</sup> and in attempting to secure Fourteenth Amendment protections against deprivation of property without due process of law.<sup>162</sup>

The Fourteenth Amendment provides that "[n]o State shall . . . deprive any person of life, liberty, or property, without due process of law."<sup>163</sup> Furthermore, it states that "Congress shall have the power to enforce, by appropriate legislation, the provisions of this article."<sup>164</sup> The Supreme Court has held that Congress has the authority to abrogate state sovereign immunity pursuant to the Fourteenth Amendment through appropriate legislation.<sup>165</sup> In *City of Boerne v. Flores*,<sup>166</sup> the Court determined whether Congress had the power to enact given legislation under Section 5 of the Fourteenth Amendment. There the Court held that to enact legislation pursuant to the Fourteenth Amendment, Congress must "identify conduct transgressing" the substantive provisions of the Fourteenth Amendment "and must tailor its legislative scheme to remedying or preventing such conduct."<sup>167</sup> In the case of the Patent Remedy Act, the Court found that Congress did not identify a pattern of patent infringement by the states.<sup>168</sup>

The Court has further noted that "a State's infringement of a patent . . . does not by itself violate the Constitution."<sup>169</sup> It is only when the state does not provide a remedy, or provides insufficient remedies, to patent owners that a due process violation occurs.<sup>170</sup> With regard to due process claims, the Court found that "[t]he need for uniformity in the construction of patent law is undoubtedly important," but that fac-

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<sup>160</sup> *Coll. Sav. Bank v. Fla. Prepaid Postsecondary Educ. Expense Bd.*, 148 F.3d 1343, 1353–54 (Fed. Cir.), *rev'd & remanded by* 527 U.S. 627 (1998).

<sup>161</sup> *Fla. Prepaid Postsecondary Educ. Expense Bd. v. Coll. Sav. Bank*, 527 U.S. 627, 636 (1998) ("[T]he Patent Remedy Act cannot be sustained under either the Commerce Clause or the Patent Clause."). Neither the Federal Circuit nor the respondents disagreed with this assertion. *See id.*

<sup>162</sup> *See id.* at 636–48.

<sup>163</sup> U.S. CONST. amend. XIV, § 1.

<sup>164</sup> *Id.* § 5.

<sup>165</sup> *See Fitzpatrick v. Bitzer*, 427 U.S. 445, 456 (1976).

<sup>166</sup> *See City of Boerne v. Flores*, 521 U.S. 507, 519–20 (1997).

<sup>167</sup> *Fla. Prepaid Postsecondary Educ. Expense Bd.*, 527 U.S. at 639 (discussing *City of Boerne*, 521 U.S. at 519–20).

<sup>168</sup> *Id.* at 641, 642–43 ("[D]eprivation by state action of a constitutionally protected interest . . . is not in itself unconstitutional . . .").

<sup>169</sup> *Id.* at 643.

<sup>170</sup> *Id.*

tor does not influence "whether a state plea of sovereign immunity deprives a patentee of property without due process of law."<sup>171</sup>

Finally, the Court criticized Congress for failing to tailor its legislation to prevent intentional or reckless infringement by the states.<sup>172</sup> The Court, therefore, held that Congress lacked the authority to enact the Patent Remedy Act.<sup>173</sup> Through this holding, the Court raised the possibility that states, by employing sovereign immunity, could take compulsory licenses without just compensation, something that local and federal governments cannot do. This creates a problem with far-reaching implications.

### *III. New Legislation Proposed to Abrogate State Sovereign Immunity in Patent Infringement Actions*

This portion of the Note proposes a framework and suggests language for an amendment to the patent laws that would abrogate state sovereign immunity while passing constitutional muster.<sup>174</sup> The proposed amendment responds to the Supreme Court's constitutional concerns regarding previous attempts to abrogate state sovereign immunity. Since the Court's decision in *Florida Prepaid Postsecondary Education Expense Board v. College Savings Bank*, much has occurred to indicate that the enactment of such an amendment is within Congress's powers under the Fourteenth Amendment.

#### *A. Language of the Proposed Legislation*

The purpose of the proposed amendment is to:

- (1) abrogate state sovereign immunity solely in cases where states or their instrumentalities, officers, or employees infringe federal patents;
- (2) assert the viability of relief against state officials who are violating or contributing to the violation of federal patents; and
- (3) promote innovation through the uniform protection of federal patent rights.

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<sup>171</sup> *Id.* at 645.

<sup>172</sup> *See id.* ("[N]egligent conduct . . . does not violate the Due Process Clause of the Fourteenth Amendment.").

<sup>173</sup> *Id.* at 647–48.

<sup>174</sup> Legislation has been proposed in the Senate that would prevent a state from receiving remedies in any suit it brings for patent infringement unless the state agrees to waive its sovereign immunity in patent infringement cases. *See* S. 2031, 107th Cong. (2002); S. 1191, 108th Cong. (2003).

INTELLECTUAL PROPERTY STATE SOVEREIGN IMMUNITY  
ABROGATION ACT

AMENDMENT TO PATENT LAW – Section 271 of title 35, United States Code is amended by the following:

‘(h)(1) As used in this section, the term “whoever” includes any State, any instrumentality of a State, and any officer or employee of a State or instrumentality of a State acting in his official capacity. Any State, and any such instrumentality, officer, or employee, shall be subjected to the provisions of this title *if they are violating the provisions of this section non-negligently. This shall include contributory violations.*

‘(h)(2) *Non-negligent infringement will be found if the State, or any such instrumentality, officer, or employee of the State, continues to engage in patent infringement after being put on notice by the patent owner or his assigns.’*

AMENDMENT TO PATENT LAW – Section 296 of title 35, United States Code is amended by the following:

‘(a)(1) Any State, any instrumentality of a State, and any officer or employee of a State or instrumentality of a State acting in his official capacity, shall not be immune, under the Eleventh Amendment of the Constitution of the United States or under any other doctrine of sovereign immunity, from suit in Federal court by any person, including any governmental or nongovernmental entity, *for non-negligent infringement, or non-negligent contributory infringement, of a patent under section 271, or for any other non-negligent violation under this title.*

‘(a)(2) *Non-negligent infringement will be found if the State, or any such instrumentality, officer, or employee of the State, continues to engage in patent infringement after being put on notice by the patent owner or his assigns.*

‘(b) In a suit described in subsection (a) for a violation described in that subsection, remedies (including remedies both at law and in equity) are available for the violation to the same extent as such remedies are available for such a violation in a suit against any private entity. Such remedies include damages, interest, costs, and treble damages under section 284, attorney fees under section 285, and the additional remedy for infringement of design patents under section 289.’

B. *The Proposed Amendment Is Within the Scope of Congress’s Power Under the Fourteenth Amendment*

1. *Congress Has the Power to Statutorily Limit the States’ Eleventh Amendment Rights*

For the proposed legislation to be constitutional, Congress must have the ability to statutorily limit states’ Eleventh Amendment rights. 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.”<sup>175</sup> Under the Eleventh Amendment, each state is viewed as a sovereign entity, and “inherent in the nature of sovereignty” is the notion that a state must consent to suit.<sup>176</sup> Although Eleventh Amendment jurisprudence has significantly limited Congress’s power to abrogate states’ sovereign immunity,<sup>177</sup> there is a notable exception. The Supreme Court has proposed a two-part inquiry to determine whether Congress has validly exercised an abrogation of state sovereign immunity.<sup>178</sup> If Congress has “unequivocally expresse[d] its intent to abrogate the immunity,” and if it has acted “pursuant to a valid exercise of power,” then Congress can validly abrogate state sovereign immunity.<sup>179</sup>

The proposed legislation makes its intent to abrogate state immunity unequivocally clear. It plainly states that the term “whoever” includes any state, or its instrumentalities, officers, or employees.<sup>180</sup> The Court’s requirement that the statement subjecting states to suit be “unmistakably clear”<sup>181</sup> is overwhelmingly met.

The second prong of the test for valid abrogation inquires whether “the Act in question [was] passed pursuant to a constitutional provision granting Congress the power to abrogate.”<sup>182</sup> The Supreme Court has held that Section 5 of the Fourteenth Amendment allows Congress to abrogate state immunity from suit otherwise guaranteed by the Eleventh Amendment.<sup>183</sup> The proposed legislation is squarely

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<sup>175</sup> U.S. CONST. amend. XI.

<sup>176</sup> See *Hans v. Louisiana*, 134 U.S. 1, 13 (1890).

<sup>177</sup> See generally William A. Fletcher, *A Historical Interpretation of the Eleventh Amendment: A Narrow Construction of an Affirmative Grant of Jurisdiction Rather Than a Prohibition Against Jurisdiction*, 35 STAN. L. REV. 1033, 1033–34 (1983).

<sup>178</sup> See *Green v. Mansour*, 474 U.S. 64, 68 (1985).

<sup>179</sup> *Id.*

<sup>180</sup> See *supra* Part III.A.

<sup>181</sup> *Seminole Tribe of Fla. v. Florida*, 517 U.S. 44, 56 (1996).

<sup>182</sup> *Id.* at 59.

<sup>183</sup> See *id.* at 56; see also *Fitzpatrick v. Bitzer*, 427 U.S. 445, 453 (1976).



based on Congress's powers to legislate under Sections 1 and 5 of the Fourteenth Amendment, which govern the enforcement of provisions that prohibit states from depriving any person of property without due process of law.<sup>184</sup>

## 2. *Pattern of Infringement*

In prior analysis of Congress's powers to legislate under the Fourteenth Amendment, the Supreme Court has noted that "[t]here must be a congruence and proportionality between the injury to be prevented or remedied and the means adopted to that end."<sup>185</sup> Although Congress was unable to demonstrate "congruence and proportionality" in 1999,<sup>186</sup> much has changed in recent years. Several state and city governments have proposed drug importation plans in direct violation of federal patent laws.<sup>187</sup> The plan proposed by Minnesota envisions the government acting as a pharmaceutical wholesaler.<sup>188</sup> Other states such as Illinois, Wisconsin, Kansas, Missouri, and Vermont have forged an agreement that permits their citizens to receive discounted refills on a variety of drugs imported from Canada, the United Kingdom, and Ireland.<sup>189</sup> The existence of these programs should demonstrate a pattern of both direct and contributory patent infringement by the states. Further examination by Congress of these programs, and others, will provide sufficient legislative history to demonstrate the requisite "congruence and proportionality" to empower Congress to enact the proposed legislation.

## 3. *Intentional or Reckless Infringement*

The Patent Remedy Act did not focus on intentional or reckless infringement, and the Court found this problematic.<sup>190</sup> The Court noted that "a state actor's negligent act that causes unintended injury to a person's property does not 'deprive' that person of property within the meaning of the Due Process Clause."<sup>191</sup> The dissent right-

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<sup>184</sup> U.S. CONST. amend. XIV, §§ 1, 5.

<sup>185</sup> Fla. Prepaid Postsecondary Educ. Expense Bd. v. Coll. Sav. Bank, 527 U.S. 627, 639 (1999).

<sup>186</sup> *Id.* at 640–41 (finding little legislative history to support the drastic measures taken by Congress).

<sup>187</sup> See Cahoy, *supra* note 106, at 649–50 (citing programs in Minnesota; Illinois; Wisconsin; Vermont; New Hampshire; Iowa; Springfield and Boston, Massachusetts; Montgomery, Alabama; and Los Angeles, California).

<sup>188</sup> *Id.* at 651–52.

<sup>189</sup> *Id.*

<sup>190</sup> Fla. Prepaid Postsecondary Educ. Expense Bd., 527 U.S. at 645.

<sup>191</sup> *Id.*

fully noted that "[m]ost patent infringers are put on notice that their conduct may be actionable before an infringement suit is filed."<sup>192</sup> The proposed amendment addresses the Court's concerns by adding a requirement that the infringement be nonnegligent.<sup>193</sup> This requirement is further clarified to limit nonnegligent infringement to instances where the state or instrumentality, officer, or employee of the state has not received notice that the conduct may constitute patent infringement.

#### 4. *State Remedies Reconsidered*

The Court also stated that "only where the State provides no remedy, or only inadequate remedies, to injured patent owners for its infringement of their patent could a deprivation of property without due process result."<sup>194</sup> In cases involving intellectual property, however, there are strong federal interests to be considered. One motivation for the creation of the Court of Appeals for the Federal Circuit was Congress's determination that one court should have appellate jurisdiction over all patent appeals from federal trial courts.<sup>195</sup> It is important to note that the Federal Circuit does not have the authority to review state court decisions relating to patent law.<sup>196</sup> Although the Court in *Florida Prepaid Postsecondary Education Expense Board v. College Savings Bank* dismissed arguments involving the need for uniformity in patent decisions,<sup>197</sup> these arguments remain persuasive and should be reconsidered.

Numerous issues make state remedies in these situations problematic. As a policy matter, states should not be in the position of becoming individual compulsory licensors of patented inventions. This result undermines the stability of the patent system and can have a significant effect upon future investments in research and development in areas vital to the promotion of public health, safety, and welfare.<sup>198</sup> It is not feasible to expect patent owners to litigate in

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<sup>192</sup> *Id.* at 654 n.5 (Stevens, J., dissenting).

<sup>193</sup> *See supra* Part III.A.

<sup>194</sup> *Fla. Prepaid Postsecondary Educ. Expense Bd.*, 527 U.S. at 643.

<sup>195</sup> *Id.* at 651 (Stevens, J., dissenting); *see also* H.R. REP. NO. 97-312, at 20-21 (1981); S. REP. NO. 97-275, at 5 (1981), *reprinted in* 1982 U.S.C.C.A.N. 11, 15.

<sup>196</sup> *See Fla. Prepaid Postsecondary Educ. Expense Bd.*, 527 U.S. at 651 (Stevens, J., dissenting).

<sup>197</sup> *See id.* at 645 (majority opinion) (stating that the need for uniformity in patent law, while important, is not determinative of whether state sovereign immunity deprives a patent owner of property without due process of law).

<sup>198</sup> *See* Kirby W. Lee, Note, *Permitted Use of Patented Inventions in the United States: Why Prescription Drugs Do Not Merit Compulsory Licensing*, 36 *IND. L. REV.* 175, 180 (2003).

numerous forums to enforce their federally granted patent rights. This issue of whether the states will provide “reasonable royalties” after costly state court battles in up to fifty separate forums leads to destabilization and decreased promotion of innovation in the United States.

Another issue, which the Supreme Court did not address, is that some state judges and justices are elected by the voting public. In these instances, it is difficult to discount the possibility of bias in situations involving the public health and welfare of their constituents. The advantage of the proposed amendment is that it provides that all patent infringement litigation will occur in federal courts before judges who are appointed, not elected.

##### 5. *Result*

The proposed amendment should be sustained against any challenges to its constitutionality or Congress’s power to enact it. The amendment addresses the Court’s concerns regarding negligent infringement and provides legislative history demonstrating a “congruence and proportionality” of the congressional response. This Note further provides a reasonable basis for the Court to find that, even if state remedies are available, the lack of feasibility and the potential bias in bringing patent infringement suits in state courts warrant the enactment of the proposed legislation.

##### *Conclusion*

This Note highlights the details of the debate over whether compulsory licensing schemes benefit the public. Arguments in favor of compulsory licensing center around the immediate benefits to consumers, such as reduced prices for prescription pharmaceuticals. Those who disfavor compulsory licensing employ economic arguments to illustrate the pitfalls of removing the incentives for innovation that the patent system provides.

Specifically, this Note delves into the problems associated with state sovereign immunity from patent infringement suit, which effectuates state compulsory licenses for patented goods. Destabilization and lack of uniformity in the patent system present significant barriers to future investments in research and development in areas paramount to the public health and safety. State sovereign immunity, and the actions by a number of states in recent years, present a problem that Congress has attempted to rectify.

This Note proposes an amendment to the patent laws that meets the Supreme Court's standard detailed in *Florida Prepaid Postsecondary Education Expense Board v. College Savings Bank*.<sup>199</sup> In addition, this Note provides significant motivations for the Court to reexamine its stance on the issue of whether state remedies constitute sufficient due process in the case of patent infringement.

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<sup>199</sup> *Fla. Prepaid Postsecondary Educ. Expense Bd.*, 527 U.S. at 637–39, 643–45.