



# Two Faces on Access to Pharmaceutical Patents: A Look into U.S. Policies on Compulsory Licensing During Public Health Emergencies

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**Two Faces on Access to Pharmaceutical Patents: A Look into U.S. Policies on Compulsory Licensing During Public Health Emergencies**

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## **Abstract**

Historically, the United States has strongly promoted intellectual property (IP) rights, playing a heavy role to ensure that IP was included in international trade negotiations. This paper describes the influence of the pharmaceutical industry on U.S. trade policies with respect to intellectual property, and the ensuing consequences on access to medicines, both domestically and abroad, during public health emergencies. More specifically, the paper focuses on compulsory licensing as a means of government intervention to ensure adequate access to patented drugs. Despite the U.S. government's legal ability to implement a compulsory licensing scheme, compulsory licensing for pharmaceutical patents may be altogether unnecessary due to a combination of factors, including the unique relationship between the pharmaceutical industry and the U.S. government, the U.S. tradition of using IP protections for innovation incentives, and the overall domestic manufacturing and production capacity for drugs.

## Introduction

Between bioterrorism and the ever-looming threat of national pandemic, the United States has faced a growing need for an effective and efficient drug dissemination scheme during public health emergencies. However, the U.S. has firmly positioned itself in the international community as a strong proponent of rigid intellectual property (IP) protections, with much of the push stemming from the pharmaceutical industry, which bases much of its business and investment strategies on patent protections for novel drugs. This has resulted in criticisms concerning not only the implications of these strong protections on developing countries in need of access to affordable medicines, but also the implications within the U.S. during domestic public health crises. That is, the strong IP position of the U.S. internationally may handcuff its ability to access patented drugs in an efficient manner during domestic public health emergencies.

Compulsory licensing, where the government grants a license for someone other than the patent holder to use a patent without the patent holder's authorization,<sup>1</sup> is one method employed by countries to access drugs for public health purposes. Some reasons for utilizing compulsory licenses include prohibitive costs of drugs, anti-competitive practices by pharmaceutical companies, insufficient market supply, public health emergencies, and the need for a pharmaceutical industrial base.<sup>2</sup> Most of these reasons, though, are more relevant to developing countries than to developed countries such that compulsory licensing has proven a relatively contentious issue. Where developing countries view compulsory licensing as "necessary to

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<sup>1</sup> CARLOS M. CORREA & ABDULQAWI YUSUF, IP AND INTERNATIONAL TRADE: THE TRIPS AGREEMENT 436–437 (2d ed. 2008).

<sup>2</sup> *Id.* at 437.

ensure access to socially beneficial technologies,” countries like the U.S. see compulsory licensing as harmful to both innovation “and creation of the very technology at issue.”<sup>3</sup>

Before the 1970s, the U.S. was one of the few countries that issued patents on pharmaceutical products.<sup>4</sup> By the 1970s and ‘80s, other developed countries began to incorporate pharmaceuticals among their patented subject matter, but the majority of developing countries continued to resist.<sup>5</sup> Currently in the U.S., product patents are granted for a twenty-year period from the date on which the patent application was filed,<sup>6</sup> and include the exclusive right to make, use, sell, offer to sell, or import the patented drug.<sup>7</sup> The benefits of the twenty-year exclusivity period, however, are not fully realized by inventors of pharmaceutical products because of the time added by the Food and Drug Administration (FDA) approval process.<sup>8</sup> To compensate, the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act)<sup>9</sup> was implemented in part to extend the term of patents that fell subject to the FDA approval process during which the patentee is unable to sell or market the product.<sup>10</sup>

The decision to invest in developing a new drug depends upon whether the expected return is sufficient to cover research and development (R&D) and marketing costs.<sup>11</sup> While some have argued that the Hatch-Waxman Act, as it impacts the pharmaceutical industry today,

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<sup>3</sup> Christopher A. Cotropia, *Compulsory licensing under TRIPS and the Supreme Court of the United States’ Decision in eBay v. MercExchange*, in *PATENT LAW & THEORY: A HANDBOOK OF CONTEMPORARY RESEARCH* (Toshiko Takenaka ed., 2009).

<sup>4</sup> Sumner La Croix & Ming Liu, *Patents and Access to Essential Medicines*, in *FRONTIERS OF ECONOMICS AND GLOBALIZATION VOLUME 2: INTELLECTUAL PROPERTY, GROWTH AND TRADE* 437 (Keith E. Maskus ed., 2008). For a more detailed explanation of the development of pharmaceutical patent protections globally, see *id.* at 437–438.

<sup>5</sup> *Id.* at 437–438.

<sup>6</sup> 35 USC. § 154(a)(2) (2008).

<sup>7</sup> § 154(d)(1)(a)(i).

<sup>8</sup> See La Croix & Liu, *supra* note 4, at 433.

<sup>9</sup> Pub. L. No. 98-417, 98 Stat. 1585. Hatch-Waxman as a whole represented a compromise between the brand name and generic drug industries, by providing for the expedited approval of generic drugs, while also increasing the effective market exclusivity period of pharmaceutical patents. See *id.*

<sup>10</sup> 35 USC. § 156. The maximum extension granted can be five years, with the total period of market exclusivity not being able to exceed fourteen years. *Id.*

<sup>11</sup> La Croix & Liu, *supra*, note 4, at 427.

has proven inadequate to compensate for the investment necessary to develop new drugs,<sup>12</sup> thereby discouraging pharmaceutical innovation, the pharmaceutical industry has nevertheless been successful in promoting its cause within the international community. According to the Pharmaceutical Research and Manufacturers of America (PhRMA), “only one of every 10,000 potential medicines investigated by America’s research-based pharmaceutical companies makes it through the research and development pipeline and is approved for patient use by the [FDA]. Winning approval, on average, takes 15 years of research and development and costs over \$800 million dollars.”<sup>13</sup> From this standpoint, issuing compulsory licenses during times of public health emergencies could devastate the pharmaceutical industry because of the risk of being unable to recoup R&D dollars.

This paper provides a historical overview of compulsory licensing from the U.S. perspective specifically as it relates to public health and pharmaceuticals. Pervading throughout this overview is the persistence of U.S. policies in maintaining rigorous IP protections despite emerging needs for increased, and sometimes immediate, access to pharmaceutical products both domestically and abroad. Part I begins with an account of the essential role that the U.S. played in ensuring that IP was made a part of international trade negotiations. U.S. efforts in these negotiations resulted in the adoption of what is now the primary international IP agreement, the Agreement on Trade-Related Aspects of IP Rights (TRIPS). The section concludes with a brief overview of TRIPS, focusing on the articles relevant to compulsory licensing. Section II continues on to describe the post-TRIPS compulsory licensing situation with respect to HIV/AIDS in developing countries, the subsequent Doha Declaration clarifying certain TRIPS provisions, and the ensuing U.S. response. The latter part of Section II then proceeds to discuss

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<sup>12</sup> See Gerald J. Mossinghoff, *Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process*, 54 FOOD & DRUG L.J. 187, 194 (1999).

<sup>13</sup> PhRMA, Innovation, <http://www.phrma.org/innovation> (last visited Apr. 22, 2010).

the current state of U.S. trade policy with respect to compulsory licensing, describing the country's continued efforts to promote IP rights.

Section III transitions into a detailed description of one of the main mechanisms that the U.S. government can employ to issue compulsory licenses domestically, 28 U.S.C. § 1498, which provides the government with broad discretion to intentionally infringe on patent rights. This statute has been implicated during both of the most recent public health crises faced by the U.S., the 2001 anthrax attacks and the 2005 avian flu pandemic scare, forcing the U.S. to make strategic decisions on accessing patented drugs domestically without undermining its strong defense of IP rights abroad. In addition, Section III provides a brief summary of two other compulsory licensing schemes that are relevant to public health emergencies—the Bayh-Dole Act “march-in” provision, and injunction denials by courts in patent infringement actions in light of *eBay v. MercExchange*. Finally, Part IV concludes by tying the pieces together to suggest that despite past attempts, a standard compulsory licensing scheme for pharmaceutical products during public health emergencies is unlikely to be achieved within the U.S, and may ultimately be unnecessary.

## **I. US Involvement in Intellectual Property and International Trade Agreements**

### **a. TRIPS**

The Agreement on Trade-Related Aspects of IP Rights (TRIPS)<sup>14</sup> currently stands as the cornerstone of international IP law as it exists today. Administered by the World Trade Organization (WTO), TRIPS sets the minimum standards for many IP regulations for all WTO member countries. TRIPS was among a number of agreements to which WTO membership was

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<sup>14</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, THE LEGAL TEXTS: THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 320 (1999), 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS].

conditioned, and was negotiated during the Uruguay Round of trade talks that ultimately resulted in the creation of the WTO in 1994, replacing the General Agreement on Tariffs and Trade (GATT) as the international organization responsible for trade.<sup>15</sup> Notably, IP regulations and standards were not always under the auspices of the WTO. In fact, placing the primary international IP regime under the WTO's domain stemmed from an idea that was promoted by the U.S. since the 1980s.<sup>16</sup> As summarized by one author, during the IP negotiations at the Uruguay Rounds, the U.S. "was able to persuade more than 100 other countries that they, as net importers of technological and cultural information, should pay more for the importation of that information."<sup>17</sup>

Prior to TRIPS adoption, there already existed the World Intellectual Property Organization (WIPO), founded in 1967, with a mandate "to promote the protection of intellectual property throughout the world through cooperation among states and in collaboration with other international organizations."<sup>18</sup> WIPO became a specialized agency of the United Nations (UN) in 1974<sup>19</sup> and currently has 184 member states,<sup>20</sup> as compared the WTO's 153 members.<sup>21</sup> It was

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<sup>15</sup> GATT regulated world trade from 1948 to 1994, but was a provisional agreement throughout that time. While considered successful in liberalizing trade, GATT became increasingly unable to keep up with the growing complexity of the world market and after considerable effort the Uruguay Round of discussions began in 1986. The final deal creating the WTO was signed on April 15, 1994. *See id.* For more information on the history of the WTO and GATT, see World Trade Organization, Understanding the WTO—The GATT Years: From Havana to Marrakesh, [http://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/fact4\\_e.htm](http://www.wto.org/english/thewto_e/whatis_e/tif_e/fact4_e.htm) (last visited Apr. 22, 2010); World Trade Organization, Understanding the WTO—Uruguay Round, [http://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/fact5\\_e.htm](http://www.wto.org/english/thewto_e/whatis_e/tif_e/fact5_e.htm) (last visited Apr. 22, 2010).

<sup>16</sup> *See generally* JOHN BRAITHWAITE & PETER DRAHOS, GLOBAL BUSINESS REGULATION 39–87 (2000).

<sup>17</sup> Peter Drahos, *Global Property Rights in Information: The story of TRIPS at the GATT*, 13 *Prometheus* 6, 7 (1995).

<sup>18</sup> World Intellectual Property Organization, What is WIPO?, [http://www.wipo.int/about-wipo/en/what\\_is\\_wipo.html](http://www.wipo.int/about-wipo/en/what_is_wipo.html) (last visited Apr. 22, 2010).

<sup>19</sup> World Intellectual Property Organization, WIPO Treaties—General Information, <http://www.wipo.int/treaties/en/general/> (last visited Apr. 22, 2010).

<sup>20</sup> World Intellectual Property Organization, Members and Observers, <http://www.wipo.int/members/en/> (last visited Apr. 22, 2010).

<sup>21</sup> World Trade Organization, Members and Observers, [http://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/org6\\_e.htm](http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm) (last visited Apr. 22, 2010).



tasked with administering the Paris Convention for the Protection of Industrial Property of 1883 and the Berne Convention for the Protection of Literary and Artistic Works of 1886—the former an attempt to provide national treatment of patents and trademarks, while the latter an attempt to do so for copyrights. Given WIPO’s mandate, it at first glance would have seemed to be the more appropriate avenue by which to establish minimum standards for the regulation of IP rights on an international scale. However, the nature of the WIPO regime was such that “[s]tates retained enormous sovereign discretion over IP standard-setting,” where the principle of “national treatment” was all that governed.<sup>22</sup> With developing countries disinclined to abide by the Paris and Berne Conventions, in part because of their concern that granting strong IP rights would make technologies prohibitively expensive, WIPO’s lack of strong enforcement mechanisms became problematic.

WIPO’s relative impotence in its ability to harmonize international IP was indicative of the different needs of developing versus developed countries. Developing countries were interested in global IP provisions that would give them increased access to patent protected technologies—these countries were generally consumers and importers of IP.<sup>23</sup> For example, some countries had compulsory licensing laws that allowed local firms to manufacture generic versions of patented drugs shortly after, or in the case of Argentina even before, those drugs hit the markets of developed countries.<sup>24</sup> They viewed this as a “rational social policy for the educational and health-care needs of its citizens.”<sup>25</sup> On the other hand, developed countries were keen on taking measures to protect their own IP interests and saw decreased patent protections as

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<sup>22</sup> BRAITHWAITE & DRAHOS, *supra* note 17, at 60. *See also* ROBERT E. GROSSE, INTERNATIONAL BUSINESS AND GOVERNMENT RELATIONS IN THE 21<sup>ST</sup> CENTURY 347 (2005) (“regulatory heterogeneity was legitimized by these treaties, making regulatory homogeneity in IP laws that much more difficult to attain.”)

<sup>23</sup> SUSAN K. SELL, PRIVATE POWER, PUBLIC LAW: THE GLOBALIZATION OF INTELLECTUAL PROPERTY RIGHTS 9 (2003).

<sup>24</sup> GROSSE, *supra* note 22, at 347, 349-350.

<sup>25</sup> BRAITHWAITE & DRAHOS, *supra* note 16, at 61.

free-riding.<sup>26</sup> The U.S. was especially frustrated with the lax standards of the international community because their industries were heavily dependent upon IP protections as industry backbones.<sup>27</sup>

It was under these circumstances that an idea was developed to link IP with trade in order to first, globalize IP standards and make them consistent, and second, extend the enforcement mechanisms available in the trade context to IP.<sup>28</sup> Linking these two fields would give the U.S. strategic leverage over developing countries, which while having little desire to enforce stringent IP standards nevertheless had strong interests in international trade.<sup>29</sup> Conversely, developing countries were more inclined to prefer WIPO as the setting for global IP discussion because it offered a one-state-one-vote rule that increased their voting influence.<sup>30</sup> In addition, the Paris and Berne Conventions lacked enforcement mechanisms for non-compliance, providing developing countries with more reason to seek WIPO as the IP regulatory organization as opposed to the WTO.<sup>31</sup>

Growing discontent with WIPO's inability to establish stronger IP protections resulted in coordination by industry to urge the U.S. to change its trade policy in international negotiations. The U.S. pharmaceutical industry had a particular interest in more rigorous protections because of the heavy investment required to successfully develop commercially profitable drugs combined with the ease of subsequent reverse engineering by generic manufacturers— average research and development costs in the 1980s were 18% as compared to 4–6% in other

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

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

<sup>28</sup> *Id.*

<sup>29</sup> Drahos, *supra* note 17, at 7. Michael Ryan called this negotiation tactic, “linkage-bargain diplomacy” where “[a] negotiator offers to the opposing negotiator something important in order to receive in return a concession that otherwise would not have been offered.” MICHAEL P. RYAN, KNOWLEDGE DIPLOMACY: GLOBAL COMPETITION AND THE POLITICS OF INTELLECTUAL PROPERTY 92 (Brookings Institution Press ed. 1998).

<sup>30</sup> BRAITHWAITE AND DRAHOS, *supra* note 16, at 566; DUNCAN MATTHEWS, GLOBALISING INTELLECTUAL PROPERTY RIGHTS: THE TRIPS AGREEMENT 10 (2002).

<sup>31</sup> MATTHEWS, *supra* note 20, at 11. *See also* BRAITHWAITE AND DRAHOS, *supra* note 16, at 61.

technology industries.<sup>32</sup> Pfizer, a large U.S. pharmaceutical company that had made a long-term commitment to expand business to developing countries,<sup>33</sup> emerged as the leader of the pharmaceutical industry lobbying movement because of the commitment of its CEO, Edmund Pratt. Pratt had strong views on the need for IP reform and worked to notify other companies of the wisdom in basing the reform in trade, despite potential free-rider problems of fighting on their behalves.<sup>34</sup> Perhaps his main mode of influence was through his position as chairman of the Advisory Committee for Trade Negotiations (ACTN) from 1981 to 1987. The ACTN served to provide advice from the business industry to the U.S. Trade Representatives (USTR), which in turn represented the U.S. in international trade negotiations. Through Pratt's leadership, the ACTN succeeded in recommending that the U.S. "have a long-term goal of placing IP in the GATT."<sup>35</sup> The idea, ultimately promoted by the Task Force on IP established by ACTN, was to take advantage of developing countries' dependency on the U.S. market by conditioning privileges, like duty-free trading, on IP concessions (i.e. increasing protections).<sup>36</sup>

As the private sector took on an increasingly active role in its attempts to formulate U.S. trade policy in the 1980s, the government finally adopted an official position linking IP and trade

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<sup>32</sup> GROSSE, *supra* note 22, at 349. Grosse speculates that the reason pharmaceutical industries in other high-income countries did not initiate efforts to reform IP laws was because

only US pharmaceutical firms had a home government powerful enough to lead the fight to change global IP rules. None of the European nations . . . had sufficient leverage over trading partners to force them to reform IP laws, and getting the European Community to act in unison on any issue, including IP, would have been difficult. It might also be argued that by the 1980s the US government was much more receptive to policy advice from the private sector than was the European Commission to similar advice from firms in member countries. *Id.* at 350.

<sup>33</sup> Drahos, *supra* note 17, at 8; GROSSE, *supra* note 22, at 350 ("In 1990, developing countries accounted for only 10–12 percent of Pfizer's total sales, but [Pfizer's CEO] Pratt believed these markets had high growth potential and would be increasingly important to the firm."); BRAITHWAITE AND DRAHOS, *supra* note 16, at 62.

<sup>34</sup> GROSSE, *supra* note 22, at 350; Drahos, *supra* note 17, at 8; SELL, *supra* note 23, at 83 ("Pratt of Pfizer was active in Washington rallying others to the cause of incorporating intellectual property into the trade agenda. He called upon the membership of the PMA [Pharmaceutical Manufacturers of America, now the Pharmaceutical Research and Manufacturers of America] and CMA [Chemical Manufacturers Association] to lobby vigorously for stronger IP protection.").

<sup>35</sup> BRAITHWAITE AND DRAHOS, *supra* note 16, at 62; Drahos, *supra* note 17, at 9.

<sup>36</sup> BRAITHWAITE AND DRAHOS, *supra* note 16, at 62.

in 1984.<sup>37</sup> Then, Gerald J. Mossinghoff, the assistant secretary of commerce and commission of patents and trademarks, “delivered a strong statement outlining the relationship between patents, trademarks, and international trade.”<sup>38</sup> By this point, private industry had convincingly framed its IP objectives as imperative to U.S. trade policy, or as one author described, “the IP activists captured the imagination of policymakers and persuaded them to adopt their private interests as U.S. national interests.”<sup>39</sup> To exemplify the private industry’s success, in a statement Congress on TRIPS, Carla A. Hills, a U.S. Trade Representative, commented that the U.S. estimated losses caused by inadequate IP protections were between \$43 and \$61 billion in 1986.<sup>40</sup> Furthermore, not only were U.S. businesses losing money, “but more importantly, our economy is losing the competitive edge we gain from research and development, innovation and creativity.”<sup>41</sup>

Throughout the 1980s, the U.S. adopted both bilateral and multilateral approaches to strengthen intellectual protections. On the bilateral front, the U.S. enacted the Trade and Tariff Act of 1984,<sup>42</sup> amending Section 301 of the Trade Act of 1974,<sup>43</sup> to impose trade sanctions on foreign governments that did not adequately provide for IP protections.<sup>44</sup> On the multilateral front, the ACTN was initially unsuccessful in convincing the rest of the international community

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<sup>37</sup> SELL, *supra* note 23, at 81–82.

<sup>38</sup> *Id.* at 83.

<sup>39</sup> *Id.* at 8. Drahos also gives an account of the Mark Twain-like “beautifully simple” story that IP lobbyists were able to tell on Capital Hill: “Stronger property rights were needed to protect American ideas and industry. Better protection meant more jobs and these intellectual property based industries were the very ones that would restore the US to a positive trade balance with the world.” Drahos, *supra* note 17, at 8.

<sup>40</sup> *Trade-Related Aspects of Intellectual Property Rights: Hearings Before the Subcommittee on Courts, Intellectual Property, and the Administration of Justice of the H. Comm. On the Judiciary*, 101st Cong. (1989) (testimony of Carla A. Hills), available at [http://findarticles.com/p/articles/mi\\_m1079/is\\_n2152\\_v89/ai\\_8355287/?tag=content;coll](http://findarticles.com/p/articles/mi_m1079/is_n2152_v89/ai_8355287/?tag=content;coll).

<sup>41</sup> *Id.* In particular, the US became concerned with remaining competitive in the global economy in light of the growing success of Asia in the 1980s. Drahos, *supra* note 17, at 7–8.

<sup>42</sup> Trade and Tariff Act of 1984, Pub. L. No. 98-573, 98 Stat. 3000 (codified as amended at 19 U.S.C. § 2101 et. seq.).

<sup>43</sup> Trade Act of 1974, Pub. L. No. 93-618, 88 Stat. 1978 (codified as amended at 19 U.S.C. § 2101 et. seq.).

<sup>44</sup> SELL, *supra* note 23, at 85–86. “These amendments also included IP protection as a new criterion for assessing developing countries’ eligibility for non-reciprocal trade concessions under the Generalized System of Preferences (GSP) program.” *Id.* at 86. For more information on the bilateral approach, see *id.* at 81–95; Drahos, *supra* note 17, at 9–12; RYAN, *supra* note 29, at 67–89.

for the need to incorporate IP in GATT discussions. Consequently, proceeding from the work of ACTN, the IP Coalition (IPC)<sup>45</sup> was formed as an effort to combine the weight of industry across all technology fields in order gain support from Europe, Canada, Japan, and other members of the Quad—“the most powerful enclave committee” at GATT—whose support was necessary for success within GATT.<sup>46</sup> The IPC was able to come to a consensus on what they wanted from GATT negotiations prior to the Uruguay Rounds and eventually gained the support of the business communities within Japan and Europe as well.<sup>47</sup> With Japan and Europe on board, the U.S. was able to overcome resistance from the “Group of Ten” developing countries that strongly opposed IP inclusion in GATT and by 1989, the remaining dissenting voice, India, accepted IP as an international trade concern.<sup>48</sup>

The private sector’s ability to so successfully influence trade negotiations and reform IP was nothing short of impressive. “In effect, twelve corporations made public law for the world.”<sup>49</sup> While GATT negotiations on IP were by no means uncomplicated or effortless, the ultimate success of the IPC has been attributed to three main factors. First, the U.S. applied continuous pressure on developing countries through threats of trade sanctions, leaving these countries with little room to hold onto their IP objections.<sup>50</sup> Second, IP presented a uniquely technical issue requiring the kind of significant expertise held by members of the IPC. This overhanging “intellectual power” gave developed countries a leg up over developing countries at

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<sup>45</sup> The original founding members of the IPC included Pfizer, Merck, Bristol-Myers, Johnson and Johnson, IBM, Hewlett-Packard, Warner Communications, Du Pont, Monsanto, General Electric, General Motors, and Rockwell International. GROSSE, *supra* note 22, at 353.

<sup>46</sup> SELL, *supra* note 23, at 109.

<sup>47</sup> *Id.* at 106. For a more detailed account of consensus building leading up to the Uruguay Rounds and during GATT negotiations, see *id.* at 96–120.

<sup>48</sup> RYAN, *supra* note 29, at 111. The “Group of Ten” was led by Brazil and India, and included Argentina, Cuba, Egypt, India, Nicaragua, Nigeria, Peru, Tanzania, and Yugoslavia. SELL, *supra* note 23, at 108 n. 12.

<sup>49</sup> SELL, *supra* note 23, at 96.

<sup>50</sup> For examples of the kinds of pressures faced by developing countries, see *id.* at 109–110.

the negotiating table because of the latter's lack of expert knowledge in this field.<sup>51</sup> Finally, TRIPS cannot be viewed in isolation. GATT negotiations encompassed a very broad range of trade subjects that required a lot of give and take in various ways—a loss on TRIPS may have meant a win on another trade-related agreement that would ultimately payoff for a particular country in the overall package that emerged at the end of the Uruguay Round.<sup>52</sup>

### **b. TRIPS and Compulsory Licenses**

TRIPS accomplished a number of objectives: 1) it required many countries to expand the subject matter of inventions that would qualify for IP rights, 2) it increased patent durations to twenty years and enacted new rights, 3) it required countries to increase their enforcement mechanisms, and 4) it established the TRIPS Council to oversee TRIPS operation and implementation.<sup>53</sup> Because developing countries were left with the burden of having to make more drastic changes to their IP laws as compared to developed countries, TRIPS allowed for some transition periods and did not require immediate compliance.<sup>54</sup> With respect to pharmaceutical subject matter, those developing countries that did not yet allow for pharmaceutical patents were given until 2005 to transition, but were required to establish

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<sup>51</sup> Drahos, *supra* note 17, at 15.

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

<sup>53</sup> Drahos, *supra* note 17, at 6–7.

TRIPS adopts a patent law minimum well above the previous standards of the 1883 Paris Convention, extending both subject matter covered and term of protection. Patent rights are extended to virtually all subject matter (with exception to plants and animals other than micro-organisms), including pharmaceutical products, chemicals, pesticides, and plant varieties, and are to be granted for twenty years from the date the application is filed . . . States are required to provide adequate and effective enforcement mechanisms both internally and at the border . . . Infractions in IP can lead to sanctions on goods. SELL, *supra* note 23, at 8.

<sup>54</sup> “Three transition periods are provided for in the Agreement: 1) the 1995–2000 period, at the end of which developing countries were obliged to implement the TRIPS Agreement; 2) the 2000–2005 period, which provided an additional period of 5 years to put in place product patent protection pharmaceuticals or agro-chemicals for those countries without such protection at the entry into force of the Agreement; and 3) the 1995–2006 period, after which least-developed countries would be required to implement their TRIPS obligations.” SISULE F. MUSUNGU & CECILIA OH, COMM’N ON INTELLECTUAL PROPERTY RIGHTS, INNOVATION AND PUBLIC HEALTH, THE USE OF FLEXIBILITIES IN TRIPS BY DEVELOPING COUNTRIES: CAN THEY PROMOTE ACCESS TO MEDICINES? 5 (2005), available at <http://www.who.int/entity/intellectualproperty/studies/TRIPSFLEXI.pdf>. The TRIPS Council extended the third transition period until 2016 when it implemented paragraph 7 of the Doha Declaration in 2002. *Id.* For more information on the Doha Declaration, see *infra* Section II(a).

mailboxes “to register pharmaceutical product patent applications during the transition period, thereby establishing priority for future review.”<sup>55</sup> However, some have argued that these transition periods inadequately acknowledged the actual level of change that was being required of developing countries where “mechanisms aiming at controlling restrictive business practices or the misuse of intellectual property rights are weak or non-existent.”<sup>56</sup> Article 31 is the main compulsory licensing provision in TRIPS, but there are several other relevant Articles—notably, TRIPS never uses the phrase “compulsory license” in any of these Articles. The following subsection will provide an overview of these TRIPS Articles, highlighting some of the provisions that touch on tensions between developing and developed countries, which later debated in the Qatar negotiations.<sup>57</sup>

To begin, Article 31—Other Use Without Authorization of the Right Holder—contains the bulk of the framework for countries to implement compulsory licensing regimes. This Article pertains to all instances where a patent is used without the patent holder’s authorization, including uses by the government and government authorized parties. Generally, Article 31 only permits unauthorized use if the user has made efforts to obtain a voluntary license “on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time.”<sup>58</sup> This requirement can be waived, however, in three circumstances: 1) cases of national emergency, 2) other circumstances of extreme urgency, or 3) cases of public non-commercial use.<sup>59</sup> Importantly, no member country is *required* to implement these exceptions to the voluntary license requirement. When the exceptions are implemented, though,

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<sup>55</sup> La Croix & Liu, *supra* note 4, at 439.

<sup>56</sup> Carlos M. Correa, *Intellectual Property Rights and the use of Compulsory License: Options for Developing Countries* 1 (South Centre, Trade-Related Agenda, Development and Equity Working Paper No. 5, Oct. 1999).

<sup>57</sup> See *supra* Section II(a).

<sup>58</sup> TRIPS Art. 31(b).

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

the patent holder must be informed after the fact—“as soon as reasonably practicable” in cases of national emergency or extreme urgency, and “promptly” in cases of public-noncommercial use.<sup>60</sup> All instances of use without authorization of the patent holder are subject to “adequate remuneration . . . taking into account the economic value of the authorization.”<sup>61</sup> Other requirements include that the scope and duration of the use must be limited to the authorized purpose<sup>62</sup>, and that the use must be non-exclusive<sup>63</sup>, non-assignable<sup>64</sup>, and “predominantly for the supply of the domestic market.”<sup>65</sup> Although the private industry was averse to compulsory licensing generally, these particular TRIPS provisions were seen as victories by the IPC “because, in the past, a number of developing countries reserved the right to issue exclusive compulsory licenses.”<sup>66</sup>

Other relevant TRIPS Articles describe the basic structure of TRIPS and affect how member countries may implement compulsory licensing in their own IP infrastructures. As a basic matter, Article 1 states that member countries are not required to provide more extensive IP protections than as are described in TRIPS.<sup>67</sup> Some of the other TRIPS Articles work to flag the potential problems that may arise as different countries behave inconsistently with respect to the precarious balance between promoting public health through access to necessary patented technologies, and protecting IP rights. For example, Article 7 provides an explanation of the TRIPS objective to promote technological innovation and to transfer and disseminate technology

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<sup>60</sup> *Id.*

<sup>61</sup> TRIPS Art. 31(h)

<sup>62</sup> TRIPS Art. 31(c)

<sup>63</sup> TRIPS Art. 31(d)

<sup>64</sup> TRIPS Art. 31(e)

<sup>65</sup> TRIPS Art. 31(f). This clause was amended in August 2003 such that it can be waived if several conditions are met. *See* Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health, Decision of WTO General Council, August 30, 2003, WT/L/540, *available at* [http://www.wto.org/english/tratop\\_E/TRIPS\\_e/implem\\_para6\\_e.htm](http://www.wto.org/english/tratop_E/TRIPS_e/implem_para6_e.htm) [hereinafter August 2003 Decision].

<sup>66</sup> SELL, *supra* note 23, at 117.

<sup>67</sup> TRIPS Art. 1



“to the mutual advantage of producers and users of technological knowledge and in a manner conducive to the social and economic welfare, and to a balance of rights and obligations” through IP protections and enforcement.<sup>68</sup> Article 8 furthers this tension, which says that member countries may, consistent with other TRIPS provisions, “adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development.”<sup>69</sup> For an explicit TRIPS clause relevant to compulsory licensing, advocates of strong IP protections sometimes appeal to Article 27.1, the so-called anti-discrimination clause, which declares that patent right should be available and enjoyable “without discrimination as to . . . the field of technology.”<sup>70</sup> The argument here is that targeting pharmaceutical patents for compulsory licenses violates this provision of TRIPS. Finally, Article 30 contains the general exceptions clause to patent rights, allowing member countries to provide limited exceptions in certain circumstances<sup>71</sup>, and Article 44 contains the provision on injunctions, allowing member countries to deny injunctive relief, and limit remedies to payment of remuneration, for unauthorized patent uses by government and government authorized entities<sup>72</sup>.

## **II. Post-TRIPS**

### **a. HIV/AIDS in Developing Countries and Doha Declaration**

Prior to 1995 and TRIPS implementation, developing countries participated in the importation of generic and recently marketed drugs from countries where these drugs were not

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<sup>68</sup> TRIPS Art. 7

<sup>69</sup> TRIPS Art. 8

<sup>70</sup> TRIPS Art. 27.1. This argument was made by the pharmaceutical companies involved in the South African Medicines Act litigation, see *supra* Section II(a), who argued that issuing compulsory licenses for HIV/AIDS drugs was discriminatory with respect to patents in the pharmaceutical field. See JAMES LOVE, CONSUMER PROJECT ON TECHNOLOGY, COMPULSORY LICENSING: MODELS FOR STATE PRACTICE IN DEVELOPING COUNTRIES, ACCESS TO MEDICINES AND COMPLIANCE WITH THE WTO TRIPS ACCORD para. 43 (2001) (prepared for the United Nations Development Program), available at <http://www.cptech.org/ip/health/cl/recommendedstatepractice.html#fn11>.

<sup>71</sup> TRIPS Art. 30.

<sup>72</sup> TRIPS Art. 44.

patent protected.<sup>73</sup> This trade enabled developing countries to purchase medicines at affordable prices, and many viewed TRIPS as favoring the interests of the pharmaceutical industry at the expense of hindering these countries' abilities to access essential medicines.<sup>74</sup> Many developing countries hoped that their TRIPS negotiation concessions would reduce pressures imposed on them by the U.S. through Section 301 sanctions,<sup>75</sup> but even after TRIPS adoption, the U.S. continued to closely monitor international IP rights.<sup>76</sup> On top of 301 sanctions, the U.S. now had the ability to enforce these rights in the WTO forum—the U.S. “has filed more WTO TRIPS complaints than all other member countries combined.”<sup>77</sup> As with TRIPS negotiations, the pharmaceutical industry through PhRMA continued to play a role in pushing the USTR to bring these complaints.<sup>78</sup>

In 1997, South African President Nelson Mandela signed into law the South Africa Medicines and Related Substance Act (Medicines Act), which, among other things, allowed the minister of health to provide for the parallel importation of patented drugs “so as to protect the

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<sup>73</sup> Vanessa Bradford Kerry & Kelley Lee, *TRIPS, the Doha Declaration and Paragraph 6 Decision: What are the Remaining Steps for Protecting Access to Medicines?*, 3 GLOBALIZATION AND HEALTH 1, 2 (2007).

<sup>74</sup> See *id.* WHO developed a Model List of Essential Medicines that has been updated every two years since 1977 and is currently on its 16th edition. World Health Organization, WHO Model Lists of Essential Medicines, <http://www.who.int/medicines/publications/essentialmedicines/en/> (last visited Apr. 22, 2010). “The core list presents a list of minimum medicine needs for a basic health care system, listing the most efficacious, safe and cost-effective medicines for priority conditions. Priority conditions are selected on the basis of current and estimated future public health relevance, and potential for safe and cost-effective treatment. The complementary list presents essential medicines for priority diseases, for which specialized diagnostic or monitoring facilities, and/or specialist medical care, and/or specialist training are needed.” WORLD HEALTH ORGANIZATION, WHO MODEL LIST OF ESSENTIAL MEDICINES, 16TH LIST, 3 (2010), available at [http://www.who.int/entity/medicines/publications/essentialmedicines/Updated\\_sixteenth\\_adult\\_list\\_en.pdf](http://www.who.int/entity/medicines/publications/essentialmedicines/Updated_sixteenth_adult_list_en.pdf).

<sup>75</sup> See *supra* p. 9.

<sup>76</sup> SELL, *supra* note 23, at 123–124 tbl.6.1 (US Trade Representative monitoring and enforcement of IP rights, 1996–2000).

<sup>77</sup> *Id.* at 129. The US began its pursuit of TRIPS enforcement in 1996, bringing six cases against Japan (“for failure to protect sound recordings”), India and Pakistan (both for failure “to establish a so-called ‘mailbox’ system for administering patent applications for pharmaceutical and agricultural chemicals”), Portugal (for failure to comply with the TRIPS mandated twenty-year patent term), and Turkey (for a “discriminatory box office tax”), Indonesia (for “discriminatory trademark practices”). *Id.* at 129–132.

<sup>78</sup> See *id.* at 130–138.

health of the public.”<sup>79</sup> At the time, one in five South Africans was HIV positive<sup>80</sup> and only the wealthy were able to afford the \$10,000 to \$15,000 per year costs of antiretroviral therapies (ARTs).<sup>81</sup> Following the passage of the Medicines Act, thirty-nine members of South Africa’s local version of PhRMA filed suit challenging the Act’s legality.<sup>82</sup> The U.S. government, under pressure from PhRMA, reacted to South Africa’s move in the same way that it had reacted throughout TRIPS negotiations: “[i]nertia led trade regulators to treat generic AIDS medicine on the model they use for pirated music discs and computer games—as a threat to the profits of copyright-holders, to be suppressed.”<sup>83</sup> On the whole, the U.S. treated pharmaceutical access as an IP and trade issue, not as a public health issue,<sup>84</sup> and placed South Africa on its Section 301 “Watch List” to pressure the South African government to repeal its law.<sup>85</sup>

The U.S. similarly targeted Brazil, which began manufacturing generic HIV/AIDS drugs in 1998, by bringing a WTO action for TRIPS violations. Unlike the case in South Africa, Brazil had already implemented a compulsory licensing regime by having generic manufacturers copy patented ART drugs. Brazil was able to produce these drugs for \$3,000 per year and provide them to HIV/AIDS patients for free.<sup>86</sup> As of 2001, Brazil’s death rate was cut by fifty percent and the country saved hundreds of millions of dollars in reduced hospitalizations caused by HIV/AIDS related infections.<sup>87</sup> This bold move demonstrated to the world that HIV/AIDS could be tackled successful—pharmaceutical patent holders’ efforts to negotiate with developing

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<sup>79</sup> See Medicines and Related Substances Control Amendment Act, No. 90, Sec. 15C (1997) (S. Afr.).

<sup>80</sup> Barton Gellman, *A Conflict of Health and Profit*, WASH. POST, May 21, 2000, at A01.

<sup>81</sup> Tina Rosenberg, *Look at Brazil*, N.Y. TIMES MAG., Jan. 28, 2001.

<sup>82</sup> SELL, *supra* note 23, at 151.

<sup>83</sup> Gellman, *supra* note 80.

<sup>84</sup> Gellman, *supra* note 80 (quoting US Trade Representative Charlene Barshefsky).

<sup>85</sup> SELL, *supra* note 23, at 152.

<sup>86</sup> Rosenberg, *supra* note 81.

<sup>87</sup> *Id.*

countries on a country-by-country basis were inefficient and perhaps ineffectual.<sup>88</sup> Nevertheless, Brazil's experience also demonstrated the strong political will and money necessary to successfully tackle a public health emergency by taking on the pharmaceutical industry: Brazil, "while it is a poor country, it is a rich poor country."<sup>89</sup>

Under pressure from advocacy organizations as well as from public perception concerns, the Joint United Nations Program on AIDS (UNAIDS), along with five major pharmaceutical companies, agreed in 2000 to voluntarily reduce HIV/AIDS drug prices for certain African countries.<sup>90</sup> While this tactic may have created a temporary fix to access issues, it did not resolve the underlying issue of the pharmaceutical industry's stronghold over preserving IP protections—with continued U.S. backing, the industry would be able to maintain their rights by preempting compulsory licensing schemes. Pharmaceutical companies' profits from Africa, which only accounted for 1.3 percent of all sales in 2002, were not their underlying concern with compulsory licensing.<sup>91</sup> Instead, they most feared compulsory licensing in developing countries because of the impact it would have in developed countries: "They worry that publicity about generic prices will fuel the American demand for cheap imports or price controls."<sup>92</sup> However, the sentiment within the U.S. was changing. A passionate voice grew out of James Love, director of Ralph Nader's Consumer Project on Technology (CPT),<sup>93</sup> as well as activist organizations like Doctors Without Borders and ACT UP, concerning the increasing costs of

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<sup>88</sup> See *id.* Drug companies' negotiations with individual countries were "controlled and largely secret." *Id.* Quoting a Doctors Without Borders campaign staffer: "Having country-by-country confidential negotiations is not justified. This way, it stays in the charity corner and it hampers the development of more sustainable ways to get medicines to people." *Id.*

<sup>89</sup> *Id.*

<sup>90</sup> SELL, *supra* note 23, at 154–155; DEBORAH J. HALBERT, RESISTING INTELLECTUAL PROPERTY 102 (2005). "In June 2001, over ten African countries finished their negotiations with pharmaceutical companies who were offering reduced pricing in conjunction with a UNAIDS program." *Id.* at 104.

<sup>91</sup> Rosenberg, *supra* note 81.

<sup>92</sup> *Id.*

<sup>93</sup> CPT is now Knowledge Ecology International.

pharmaceuticals.<sup>94</sup> Also, much to PhRMA's dismay,<sup>95</sup> President Clinton issued an executive order in May of 2000 stating that, in administering the Trade Act of 1974, the U.S. would not seek "the revocation or revision of any intellectual property law or policy of a beneficiary sub-Saharan African country . . . that regulates HIV/AIDS pharmaceuticals or medical technologies" if the country's law promoted access to medicines and was compliant with TRIPS.<sup>96</sup> The Bush Administration declared that it would follow Clinton's approach when Bush took office the following year, committing \$200 million to a global AIDS fund, however simultaneously emphasizing the need to maintain stringent IP protections to promote innovation.<sup>97</sup>

In early 2001, Cipla, an Indian generic manufacturer, announced that it would sell the three-drug ART cocktail for \$350 per patient per year to Doctors Without Borders, a group that had been advocating for this cause for quite some time.<sup>98</sup> The overall idea was to acquire the patents to these drugs via compulsory licensing within each developing country in need, and sell them as cheaply as possible.<sup>99</sup> In the midst of the pressures imposed on non-generic pharmaceutical companies by Cipla's announcement, PhRMA and its thirty-nine member companies eventually dropped their lawsuit against South Africa weeks before the trial was set to

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<sup>94</sup> See SELL, *supra* note 23, at 147–150. See also Gellman, *supra* note 80. These groups caught more steam throughout 1999 because of Al Gore's presidential campaign and the general political climate in the US—they targeted Gore for supporting the pharmaceutical industry in its legal battles against developing countries. HALBERT, *supra* note 89, at 102 ("ACT UP members in February 1999 disrupted Gore's campaign kick-off in Tennessee with signs reading 'Gore's Greed Kills – AIDS Drugs for Africa.'")

<sup>95</sup> See HALBERT, *supra* note 90, at 102.

<sup>96</sup> Exec. Order No. 13,155, 65 FR 30521 (2000).

<sup>97</sup> Press Release, White House, President Announces Proposal for Global Fund to Fight HIV/AIDS, Malaria and Tuberculosis (May 11, 2001), available at <http://georgewbush-whitehouse.archives.gov/news/releases/2001/05/20010511-1.html>.

<sup>98</sup> Donald G. McNeil, Jr., *Indian Company Offers to Supply AIDS Drugs at Low Cost in Africa*, N.Y. Times, Feb. 7 2001. Doctors Without Borders "won the Nobel Peace Prize in 1999 for its work in war-torn and impoverished areas." *Id.* "The Cipla drug combination is two tablets of 40 milligrams of stavudine, two tablets of 150 milligrams of lamivudine and two tablets of 200 milligrams of nevirapine. In the United States and many other countries, the Bristol-Myers Squibb Company holds the patent on stavudine, also known as Zerit or d4T; Glaxo-Wellcome of Britain holds the patent on lamivudine, also known as Heptovir or 3TC, and Boehringer Ingelheim G.m.b.H. of Germany holds the patent on nevirapine, or Viramune." *Id.*

<sup>99</sup> SELL, *supra* note 23, at 156.

start in March of 2001. The suit had become a “high profile event marked by protesters, grim images of dying mothers and babies, street demonstrations, and extensive media coverage.”<sup>100</sup> The U.S. also felt increasing pressure to tone down its IP enforcement efforts in the WTO forum after the criticism it received concerning the litigation in South Africa, especially given Brazil’s successful generic manufacturing scheme.<sup>101</sup> As a result, the U.S. withdrew its case against Brazil during the UN General Assembly Special Session dedicated to issues of public health, opening the door for potential exceptional treatment of pharmaceutical products with respect to public health situations as was desired by the African WTO contingent.<sup>102</sup>

This notion ultimately resulted in the Doha Declaration, from the WTO’s Doha, Qatar Ministerial meeting in November 2001, which broadly stated that TRIPS was not to prevent member countries from “taking measures to protect public health,” and that it should be interpreted “to promote access to medicines for all.”<sup>103</sup> Moreover, the Doha Declaration explicitly stated that member countries have “the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted,”<sup>104</sup> as well as the right to “determine what constitutes a national emergency or other circumstances of extreme urgency.”<sup>105</sup> In 2002, Zimbabwe was the first country to implement government use provisions for ARTs, in the form of compulsory licensing, post-Doha.<sup>106</sup> In August 2003, paragraph 6 of the Doha Declaration, which tabled discussions on compulsory licenses for pharmaceutical patents in countries with little or no manufacturing capacity, was clarified and the TRIPS

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<sup>100</sup> *Id.* at 157.

<sup>101</sup> *Id.* at 158.

<sup>102</sup> *Id.* at 159–159.

<sup>103</sup> Declaration on the TRIPS Agreement and Public Health para. 4., Nov. 14, 2001, WT/MIN(01)/DEC/W/2, available at [http://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_trips\\_e.pdf](http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.pdf) [hereinafter Doha Declaration].

<sup>104</sup> *Id.* para. 5(b).

<sup>105</sup> *Id.* para. 5(c).

<sup>106</sup> MUSUNGU & OH, *supra* note 54, at 18–19.

Council waived TRIPS Article 31(f) (requiring drugs produced pursuant to compulsory licenses be made “predominantly for the domestic market.”)<sup>107</sup>

As will be discussed in Section III(a)(ii), during the discussions leading up to the Declaration, the U.S. was positioned precariously because of the 2001 anthrax attacks that occurred weeks before the Doha discussions were set to take place—it was faced with handling domestic access issues to the antibiotic Cipro, without undermining its strong position against compulsory licensing. Nevertheless, the U.S. and Switzerland “led the resistance,” arguing that TRIPS did not need clarification in the form of a declaration.<sup>108</sup> The U.S. was reluctant to concede to a broad statement concerning protecting public health generally, hoping to restrict discussions to the HIV/AIDS issue.<sup>109</sup> Although the Doha Declaration was not enacted into TRIPS, and thus lacks binding force, the movement from TRIPS, to the Doha Declaration, and finally to the WTO Decision on Paragraph 6, which collectively embody the WTO’s legal framework on compulsory licensing and access to medicines, demonstrates a shift in the international IP discussion framework away from trade and towards public health.<sup>110</sup> The shift has been slow and the effectiveness of Doha has been questioned, but the once all-power voice of the pharmaceutical industry, supported by the US, has arguably been somewhat overshadowed by global public health concerns.

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<sup>107</sup> August 2003 Decision, *supra* note 65.

<sup>108</sup> HALBERT, *supra* note 90, at 104.

<sup>109</sup> *Id.* at 105.

<sup>110</sup> None of these three WTO texts are self-executing and must be implemented legislatively by each member country. For an extensive review on countries that have enacted TRIPS into their own laws, see generally MUSUNGU & OH, *supra* note 54.

## **b. Post-TRIPS: Current U.S. Trade Policy**

In November 2007, the USTR issued a Fact Sheet summarizing its “Mission to Protect Intellectual Property Rights.”<sup>111</sup> Beginning with the USTR’s primary goal to “promote intellectual property and innovation around the world,” the Fact Sheet lists eight key parts of the USTR’s IP mission including, among other things, the previously discussed Section 301 sanctions,<sup>112</sup> ongoing Anti-Counterfeiting Trade Agreement (ACTA) negotiations, and pharmaceutical innovation promotion.<sup>113</sup> The US, as in the Doha negotiations, indicates that it still leans in favor of IP protections over public health promotion: “USTR seeks to eliminate market access barriers faced by U.S. pharmaceutical companies in many countries, and to promote affordable health care today, while supporting the innovation that assures improved health care tomorrow.”<sup>114</sup> This attitude was further exemplified by the U.S.’ decision in 2007 to move Thailand from the Watch List to the Priority Watch List under Section 301 in part because of Thailand’s decision to issue compulsory licenses for medicines including ARTs.<sup>115</sup>

The most recent developments in U.S international IP policy are contained in the ACTA negotiations. The ACTA was initiated in 2006 by the U.S. and Japan to combat counterfeiting and piracy and to ultimately “negotiate an agreement that enhances international co-operation

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<sup>111</sup> See OFFICE OF THE U.S. TRADE REP., TRADE FACTS: USTR’S MISSION TO PROTECT U.S. INTELLECTUAL PROPERTY RIGHTS (2007), *available at* [http://www.ustr.gov/sites/default/files/uploads/factsheets/2007/asset\\_upload\\_file285\\_13523.pdf](http://www.ustr.gov/sites/default/files/uploads/factsheets/2007/asset_upload_file285_13523.pdf).

<sup>112</sup> In 2009, 77 countries were examined for their IP rights protections and enforcement under Section 301. OFFICE OF THE U.S. TRADE REP., EXECUTIVE SUMMARY, 2009 SPECIAL 301 REPORT, *available at* <http://www.ustr.gov/sites/default/files/Executive%20Summary.pdf>. Resulting from this, 46 countries were placed on the Priority Watch List, Watch List, and/or Section 306 Monitoring status. *Id.*

<sup>113</sup> *Id.*

<sup>114</sup> *Id.*

<sup>115</sup> “While the United States acknowledged a country’s ability to issue such licenses in accordance with WTO rules, the lack of transparency and due process exhibited in Thailand represents a serious concern.” OFFICE OF THE U.S. TRADE REP., 2007 SPECIAL 301 REPORT 27, *available at* [http://www.ustr.gov/sites/default/files/asset\\_upload\\_file230\\_11122.pdf](http://www.ustr.gov/sites/default/files/asset_upload_file230_11122.pdf).



and contains effective international standards for enforcing intellectual property rights.”<sup>116</sup> With negotiations set to conclude in 2010, the main goal of the ACTA is to pick up where TRIPS left off by strengthening enforcement issues and establishing more complete legal frameworks in certain areas.<sup>117</sup> As for compulsory licensing, negotiations have incorporated discussions on injunctions and damages as a means by which to stop infringement—the U.S. proposed language on this subject requires ACTA members to give judicial authorities the power to issue injunctions for infringement, with no exceptions.<sup>118</sup> If adopted, this provision would run contrary to one of the current mechanisms used in the U.S. to grant compulsory licenses, 28 USC. § 1498, which provides that infringing use by or for the government can only be remedied by reasonable compensation.<sup>119</sup> It may also work to negate the holding of *eBay v. MercExchange*, which increased the burden on patent infringement plaintiffs who desire injunctive relief.<sup>120</sup> This move is perhaps further indicative of the U.S.’ unwillingness to take any steps that would effectively weaken IP rights, despite the increased worldwide cognizance of public health crises, including domestic crises as well.<sup>121</sup>

### III. Compulsory Licensing and the US

Calls for compulsory licensing of specific pharmaceutical patents during large-scale situations of significant public health concern have been relatively infrequent—notable examples include the 2001 anthrax attacks, and the avian flu pandemic scare in 2005. Interestingly, despite

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<sup>116</sup> OFFICE OF THE U.S. TRADE REP., THE ANTI-COUNTERFEITING TRADE AGREEMENT—SUMMARY OF KEY ELEMENTS UNDER DISCUSSION 1, *available at* [http://www.ustr.gov/webfm\\_send/1479](http://www.ustr.gov/webfm_send/1479).

<sup>117</sup> *Id.* at 2.

<sup>118</sup> Knowledge Ecology International (KEI), Comments on ACTA Provisions on Injunctions and Damages 7 (2010), *available at* [http://keionline.org/sites/default/files/kei\\_rn\\_2010\\_1.pdf](http://keionline.org/sites/default/files/kei_rn_2010_1.pdf).

<sup>119</sup> 28 USC. § 1498. For a more extensive discussion on § 1498, see Section III(a).

<sup>120</sup> 547 U.S. 388 (2006). For further discussion on *eBay*, see Section III(b).

<sup>121</sup> It must be acknowledged, however, that ACTA negotiations encompass the seven realms of IP covered by TRIPS—copyright and related rights, trademarks, geographical indications, industrial designs, patents, layout-design of integrated circuits, protection of undisclosed information—and are not limited to pharmaceutical patents. *See* Knowledge Ecology International, ACTA to cover seven categories of intellectual property, <http://keionline.org/node/812> (last visited Apr. 22, 2010).

the U.S.’ strong objection to compulsory licensing abroad,<sup>122</sup> the U.S. itself issues compulsory licenses for various reason employing a several different legal methods.<sup>123</sup> For example, U.S. laws contain provisions for compulsory licensing programs for nuclear materials and atomic energy,<sup>124</sup> and air pollution.<sup>125</sup> The following sections will outline some of the ways that issues of compulsory licensing have arisen regarding pharmaceutical products, focusing on 28 USC. § 1498, the Bayh-Dole Act, and court issued injunctions.<sup>126</sup> Of these three legal mechanisms, none have been successfully invoked to issue a compulsory license over a drug patent during a public health emergency.

#### **a. 28 U.S.C § 1498**

##### **i. Generally**

The U.S. government often appeals to 28 USC. § 1498 on Patent and Copyright Cases to justify the use of patented inventions without the permission of the patentee. The statute, which was initially conceived for use during wartime urgencies,<sup>127</sup> states that when a patented invention is used by or for the U.S. government without a license, the patentee’s remedy shall be “for the recovery of his reasonable and entire compensation for such use and manufacture.”<sup>128</sup> In other words, the statute, while entitling the patentee to compensation in the event that the government or a government authorized actor uses the patent without permission, does not allow the patentee

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<sup>122</sup> See *infra* Sections I and II.

<sup>123</sup> Correa Working Paper, *supra* note 56, at 13.

<sup>124</sup> 42 U.S.C § 2183.

<sup>125</sup> 42 U.S.C § 7608.

<sup>126</sup> The Federal Trade Commission also issues effective compulsory licenses for antitrust reasons, but compulsory licensing in this context will not be discussed because of its relative inapplicability to public health emergencies.

<sup>127</sup> Colleen Chien, *Cheap Drugs at What Price to Innovation*, 18 BERKELEY TECH. L. J. 853, 863 (citing *Richmond Screw v. United States*, 375 U.S. 331, 345 (1928) (“The intention and purpose of Congress . . . was to stimulate contractors to furnish what was needed for the war, without fear of becoming liable themselves for infringements to inventors or the owners or assignees of patents.”)).

<sup>128</sup> 28 USC. § 1498(a). The full text of the statute states: “Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner’s remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture.” *Id.*

to enjoin such an act. Thus, the statute effectively serves as a waiver of the government's sovereign immunity, while also functioning as a grant of compulsory licensing power. Because the need for compulsory licensing of pharmaceutical patents would presumably require government intervention in times of public health emergencies, understanding the limits and reach of § 1498 is of particular import.<sup>129</sup>

An early invocation of § 1498 occurred in the 1970s resulting from concerns over increasing drug prices. The idea stemmed from a staff economist of the Senate Small Business Committee's monopoly subcommittee, Benjamin Gordon, who proposed that the National Institutes of Health (NIH) reverse engineer patented drugs in order to determine if brand name manufacturers were excessively pricing them.<sup>130</sup> If so, he proposed that generic manufacturers should be contracted to produce and distribute the drugs at lower costs.<sup>131</sup> From this idea, the government targeted the tranquilizer meprobamate, which was purchased by the Veterans Administration in Denmark for \$1.55 per 500 tablets, while sold in the U.S. for \$26 by Carter-Wallace.<sup>132</sup> Carter-Wallace attempted to sue the U.S. government for infringement, but the patent was held invalid and the § 1498 issue ultimately not litigated.<sup>133</sup>

Since *Carter-Wallace*, the specific mechanics of § 1498 have been hashed out over the years. Generally, the Federal Circuit has stated “the coverage of § 1498 should be broad so as not to limit the Government’s freedom in procurement by considerations of private patent infringement.”<sup>134</sup> Still, determining what actions are encompassed by the phrase “by or for the United States” must be considered carefully in order to ensure that private parties acting under

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<sup>129</sup> Currently, the US Department of Defense is the most frequent invoker of § 1498. *See* KEI Comments on ACTA, *supra* note 118, at 6.

<sup>130</sup> Morton Mintz, *Still Hard to Swallow*, Wash. Post, Feb. 11, 2001, at B01.

<sup>131</sup> *Id.*

<sup>132</sup> *Id.*

<sup>133</sup> *See* *Carter-Wallace, Inc. v. U.S.*, 449 F.2d 1374 (Ct. Cl. 1971); *see also* *Carter-Wallace, Inc. v. U.S.*, 496 F.2d 535 (Ct. Cl. 1974).

<sup>134</sup> *TVI Energy Corp. v. Blane*, 806 F.2d 1057, 1060 (Fed. Cir.1986).

government direction can claim protection under § 1498.<sup>135</sup> For example, in *TVI Energy Corp. v. Blane*, the Federal Circuit held that the defendant’s infringing use of the plaintiff’s patent to bid on a government contract was within the scope of § 1498 where the defendant had not yet received the contract—the defendant’s only purpose for engaging in infringing activity “was to comply with the Government’s bidding requirements.” The court held that the government did not have to explicitly require that the third party infringe in order for the infringing activity to qualify as a use or manufacture by or for the government.<sup>136</sup> Despite some clarification by cases such as *TVI* as to what kinds of third party infringement activities fall within § 1498, there nevertheless remains some ambiguity.<sup>137</sup>

More recently in the 2006 case, *Zoltek Corp. v. United States*, the Federal Circuit held that plaintiff Zoltek could not bring an action under § 1498 where the government contractor, Lockheed Martin, allegedly infringed a process patent for manufacturing silicide fiber products for use in F-22 Fighters.<sup>138</sup> The Federal Circuit reasoned that because part of Lockheed’s manufacturing process occurred outside of the US, § 1498(a) did not apply.<sup>139</sup> This conclusion resulted from a previous Federal Circuit decision holding that “direct infringement under section 271(a)<sup>140</sup> is a necessary predicate for government liability under section 1498”<sup>141</sup> where “a

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<sup>135</sup> “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.” 28 U.S.C. § 1498.

<sup>136</sup> *TVI*, 806 F.2d at 1060.

<sup>137</sup> See, e.g., *Madey v. Duke University*, 307 F.3d 1351, 1359–1360 (Fed. Cir. 2002) (holding that the court could not make a determination as to whether research involving patent infringement met the requirements of § 1498(a) when it was funded by an Office of Naval Research Grant).

<sup>138</sup> 442 F.3d 1345 (Fed. Cir. 2006).

<sup>139</sup> *Id.* at 1350. “We have further held that ‘a process cannot be used ‘within’ the United States as required by section 271(a) unless each of the steps is performed within this country.” *Id.* (citing *NTP, Inc. v. Research in Motion, Ltd.*, 418 F.3d 1282, 1316 (Fed. Cir. 2005)).

<sup>140</sup> “Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States, or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.” 35 U.S.C. § 27(a).

<sup>141</sup> *NTP, Inc. v. Research In Motion, Ltd.*, 418 F.3d 1282, 1316 (Fed. Cir. 2005).

process cannot be used ‘within’ the United States as required by section 271(a) unless each of the steps is performed within this country.”<sup>142</sup> Furthermore, the court denied *Zoltek*’s claim that the government’s infringement was a “taking of private property for public use under the Fifth Amendment.”<sup>143</sup> According to the court, in enacting § 1498, “Congress provided a specific sovereign immunity waiver for a patentee to recover for infringement by the government. Had Congress intended to clarify the dimensions of the patent rights as property interests under the Fifth Amendment, there would have been no need for the new and limited sovereign immunity waiver.”<sup>144</sup>

The Federal Circuit’s holding on the Takings Clause has stirred some controversy<sup>145</sup> because of an earlier case in 1999 where the court stated that patents “are surely included within the ‘property’ of which no person may be deprived by a State without due process of law.”<sup>146</sup> Judge Plager in his *Zoltek* dissent observed that “absolving the Government from liability, now and forever, for the wrongful conduct of its agents just because any one step of a multi-step patented method can be found to have occurred outside the United States [is] an invitation to strategic conduct if ever there was one.”<sup>147</sup> Nevertheless, although this case did not involve a pharmaceutical patent, it represents the current reach of § 1498 as it exists today and indicates that the Federal Circuit may be leaning towards a more generous implementation of compulsory licensing schemes for government use—this inclination may perhaps be furthered in the event of

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<sup>142</sup> *Id.* at 1318.

<sup>143</sup> *Zoltek*, 442 F.3d at 1350.

<sup>144</sup> *Id.* at 1352.

<sup>145</sup> See, e.g., Posting of Douglas Sorocco to phosita, Supreme Court ‘Taking’ a Break From Patents; Denies Cert. in *Zoltek Corp. v. U.S.*, <http://dunlapcoddling.com/phosita/?s=28+USC+1498> (June 11, 2007, 16:35 EST); Posting of Nicole Tepe to Patent Baristas, *Zoltek Corp. v. U.S.*: Protection Patent Holders from Government Infringement, <http://www.patentbaristas.com/archives/2007/04/22/zoltek-corp-v-us-protecting-patent-holders-from-government-infringement/> (Apr. 22, 2007). But see Davida H. Isaacs, *Not All Property is Created Equal: Why Modern Courts Resist Applying the Takings Clause to Patents, and Why They Are Right to Do So*, 15 Geo. Mason L. Rev. 1 (2007).

<sup>146</sup> *Fla. Prepaid v. College Sav. Bank*, 527 U.S. 627, 642 (1999).

<sup>147</sup> *Zoltek*, 442 F.3d at 1382.

immediate necessity as in the case of a public health emergency. Nonetheless, if the U.S. is successful in its ACTA negotiations, Congress may be forced to amend this long-existing law to allow for injunctive relief for *any* infringing use of a patent, including that of the government.

## **ii. Anthrax**

The 2001 anthrax scare, code-named “Amerithrax” by the FBI,<sup>148</sup> was the first instance where § 1498 was implicated because of the potential need for mass access to a patented drug caused by a public health emergency—bioterrorism. Anthrax is a disease caused by the spore-forming bacteria *Bacillus anthracis* and is categorized by the Centers for Disease Control and Prevention (CDC) as a Category A agent (those that “pose the greatest possible threat for a bad effect on public health”).<sup>149</sup> Symptoms from anthrax vary depending on the way in which the individual is exposed (types of anthrax include cutaneous, inhalation, and gastrointestinal), and can appear within seven days of initial exposure.<sup>150</sup> Antibiotic treatment can be successful depending on how soon after exposure treatment begins and the type of anthrax involved.<sup>151</sup> In the fall of 2001, a number of individuals were exposed to anthrax through letters delivered via the U.S. Postal Service resulting in five deaths and seventeen other cases of infection.<sup>152</sup> Although anthrax did not ultimately pan out to become a full-fledged public health emergency, this example aptly demonstrates the discrepancy between U.S. sentiment about strong IP rights abroad, and its attempts to lift those protections during domestic public health situations.

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<sup>148</sup> Fed. Bureau of Investigation, Amerithrax Investigation, <http://www.fbi.gov/anthrax/amerithraxlinks.htm> (last visited Apr. 22, 2010).

<sup>149</sup> Ctrs. for Disease Control and Prevention, Anthrax: What You Need to Know, <http://emergency.cdc.gov/agent/anthrax/needtoknow.asp> (last visited Apr. 22, 2010).

<sup>150</sup> *Id.*

<sup>151</sup> *Id.*

<sup>152</sup> Scott Shane & Eric Lichtblau, *Scientist's Suicide Linked to Anthrax Inquiry*, N.Y. TIMES, Aug. 2, 2008.

During the 2001 attacks, access to the antibiotic ciproflaxin (Cipro),<sup>153</sup> approved by the FDA for anthrax treatment, became a major point of contention because of the conflicts between public health necessity and the rights of Cipro's patent holder, Bayer.<sup>154</sup> Senator Charles Schumer (D-NY) called for generic manufacturing of Cipro in October 2001, despite Bayer's willingness to ramp up production, to deal with the potential need for increased quantities at lower costs in the event of a full-scale anthrax attack.<sup>155</sup> Cipro's profits in 1999 were \$1.04 billion, where Bayer charged \$4.67 per pill wholesale and retail prices reached up to \$7 per pill.<sup>156</sup> At that time, the Department of Health and Human Services (HHS) was hesitant—"If we have an emergency, the manufacturers can turn this around quickly. We have to be careful about patent protections—there's a balance there"<sup>157</sup>—but was still "nudging . . . Bayer to relax the patent on Cipro."<sup>158</sup> In fact, HHS Secretary Tommy Thompson seemed largely unaware of § 1498, believing that allowing generic manufacturers to produce Cipro before its patent expired

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<sup>153</sup> For more information on Cipro, see Ctrs. for Disease Control and Prevention, Emergency Preparedness and Response, Patient Information: Ciproflaxin, <http://emergency.cdc.gov/agent/anthrax/treatment/cipropatient.asp> (last visited Apr. 22, 2010). The CDC also issued guidelines on the administration of other antibiotics, including doxycycline and amoxicillin, for anthrax treatment, but Cipro remained the focus of debate. See Ctrs. for Disease Control and Prevention, Emergency Preparedness and Response, Patient Information: Doxycycline, <http://www.bt.cdc.gov/agent/anthrax/treatment/doxypatient.asp> (last visited Apr. 22, 2010); Ctrs. for Disease Control and Prevention, Emergency Preparedness and Response, Patient Information: Amoxicillin, <http://www.bt.cdc.gov/agent/anthrax/treatment/amoxicillinpatient.asp> (last visited Apr. 22, 2010). See also Elisabeth Bumiller, *Administration Won't Allow Generic Versions of Drug*, N.Y. TIMES, Oct. 18, 2001 ("Nonetheless, doctors and researchers said Cipro was the first drug approved for use against anthrax because it is the drug for which scientists had the best data. Doctors expect that doxycycline and penicillin will work as well, but so far the public remains focused on Cipro.").

<sup>154</sup> Bayer's patent exclusivity period lasted until December 2003. Reuters, *NY Senator urges US to purchase generic Cipro*, Oct. 16, 2001.

<sup>155</sup> CNN Money, *Senator Seeks Generic Cipro*, Oct. 16, 2001, [http://money.cnn.com/2001/10/16/news/generic\\_cipro/](http://money.cnn.com/2001/10/16/news/generic_cipro/) (last visited Apr. 22, 2010).

<sup>156</sup> Kavaljit Singh, Foreign Policy in Focus, *Anthrax, Drug Transnationals, and TRIPS*, Apr. 1, 2002, available at [http://www.fpif.org/articles/anthrax\\_drug\\_transnationals\\_and\\_trips](http://www.fpif.org/articles/anthrax_drug_transnationals_and_trips). For a comparison of Cipro prices internationally, see *id.* tbl.1.

<sup>157</sup> *Senator Seeks Generic Cipro*, *supra* note 155 (quoting a statement from HHS spokesman Kevin Keane).

<sup>158</sup> Matthew Herper, *Cipro, Anthrax and the Perils of Patents*, FORBES.COM, Oct. 17, 2001, <http://www.forbes.com/2001/10/17/1017cipro.html> (last visited Apr. 22, 2010) (describing comments made by HHS Secretary Tommy Thompson).

was illegal.<sup>159</sup> Overall, the initial sentiment expressed by the Bush Administration was one of extreme reluctance to intrude upon patent protections despite strong concerns surrounding access to potentially necessary medicines.<sup>160</sup>

Still, § 1498 was not overlooked. The New York Times reported that “American law is very clear: when the United States government needs a patented product, any official authorized to make purchases can ignore the patent and license someone else to make it.”<sup>161</sup> Unfortunately, the decision to appeal to § 1498 and authorize a compulsory license for Cipro was much more complicated politically—Cipro was used in Africa to cure secondary brain infections associated with AIDS patients.<sup>162</sup> To lift U.S. patent protections on Cipro for the potential anthrax pandemic, while simultaneously fighting against the very same thing for AIDS in Africa would place the U.S. in a difficult position.<sup>163</sup> On top of this, Qatar negotiations that would ultimately result in the Doha Declaration were looming a month away.<sup>164</sup> Aid organizations hoped that the U.S. government, after being presented with its own public health emergency of sorts, would become more sympathetic to the health needs of developing countries.<sup>165</sup> “If the United States presumably was willing to engage in compulsory licensing to address a national emergency (in the wake of several deaths, but uncertain about the magnitude of the threat) how could it possibly

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<sup>159</sup> Anthony York, *Is it Time to Bust the Cipro Patent?*, SALON, Oct. 18, 2001, [http://www.salon.com/technology/feature/2001/10/18/cipro\\_patent](http://www.salon.com/technology/feature/2001/10/18/cipro_patent) (last visited Apr. 22, 2010) (citing Thompson’s interview on the Today Show on October 17, 2001).

<sup>160</sup> See Herper, *supra* note 158 (“As elsewhere, it is important not to damage the US system with overly far-reaching emergency measures.”).

<sup>161</sup> Donald G. McNeil Jr., *A Rush for Cipro, and the Global Ripples*, N.Y. TIMES, Oct. 17, 2001.

<sup>162</sup> *Id.*

<sup>163</sup> See *id.* (“Recently, however, [the Bush Administration] has backed American pharmaceutical manufacturers against African countries that are trying to meet World Trade Organization rules so they can import drugs from the cheapest sources for public health reasons.”).

<sup>164</sup> See *supra* Section II(a).

<sup>165</sup> Julian Siddle, *Anthrax Fears Prompt Patent Law Review*, BBC NEWS, Oct. 18, 2001, <http://news.bbc.co.uk/2/hi/americas/1606792.stm> (last visited Apr. 22, 2010). “American reactions to the bioterror, anthrax, threat of autumn 2001 also provided an important opportunity to develop empathy for the victims of the HIV/AIDS pandemic, and the constraints posed by strict or narrow interpretations of TRIPS.” SELL, *supra* note 23, at 178.



deny that same prerogative to developing countries daily facing thousands of preventable deaths?”<sup>166</sup>

In the end, the § 1498 legal inquiry was rendered moot because the U.S. government was able to strike a deal with Bayer to purchase Cipro at reduced costs (\$1 per pill—equivalent to the prices that would have been charged by generic manufacturers) after Thompson publically demanded that Bayer cut prices under threat of appealing to generic alternatives pursuant to § 1498.<sup>167</sup> Regardless, the threat of an anthrax pandemic was never realized and the need for large quantities of Cipro never became reality.<sup>168</sup> The Bush Administration’s shift from unwillingness to consider generic alternatives at all to effectively forcing Bayer’s hand through threat of compulsory licensing could just be attributed to a blunder caused by inadequate legal information surrounding § 1498. Even though the Administration managed to save American taxpayers significant costs as a result of the deal, it nevertheless side-stepped the need to actually exercise its § 1498 power, and still tilted in favor of patent protection—“the agreement [was] based on the condition that the company would continue to remain the sole supplier of the drug in the U.S. till December 2003.”<sup>169</sup>

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<sup>166</sup> SELL, *supra* note 23, at 160. See also HALBERT, *supra* note 90, at 105 (“The USA lost significant international legitimacy when the overwhelming hypocrisy of its own efforts regarding anthrax were juxtaposed against developing country efforts to secure cheap access to AIDS drugs.”).

<sup>167</sup> See Keith Brasher & Edmund L. Andrews, *Cipro*, N.Y. TIMES, Oct. 24, 2001. Canada had already imposed on Bayer’s patent and made an agreement with a generic manufacturer, but rescinded on that deal shortly thereafter and reached an agreement with Bayer to purchase Cipro at reduced costs two days before the US struck the same deal. *Id.* See also Press Release, Dept. of Health and Human Serv., HHS, Bayer Agree to Cipro Purchase, Oct. 24, 2001, available at <http://www.hhs.gov/news/press/2001pres/20011024.html>.

<sup>168</sup> Because of the timing of the attacks post September 11, 2001, Al Qaeda was initially suspected to have been behind the anthrax attacks, but the FBI shifted to a different profile: “a disgruntled American scientist or technician, perhaps one specializing in biodefense, who wanted to raise an alarm about the bioterrorism threat.” Shane & Lichtblau, *supra* note 152 (describing the suicide of a scientist suspected to have been behind the anthrax attacks). “On February 19, 2010, the Justice Department, the FBI, and the US Postal Inspection Service formally concluded the investigation into the 2001 anthrax attacks and issued an Investigative Summary,” two years after the scientist to whom charges were about to be brought commit suicide. Amerithrax Investigation, *supra* note 145.

<sup>169</sup> Singh, *supra* note 156.

### iii. U.S. Influenza Pandemics

Despite the discussions of the previous sections, the 2005 avian flu pandemic scare is indicative of the possibility that the U.S. may not be faced with the need to invoke § 1498 because of cooperation, albeit reluctant, from the pharmaceutical industry. Avian influenza, H5N1, while primarily contained within the avian species, caused much concern in the U.S. because of a number of human cases that occurred that year in southeast Asia—overall, “98 human H5N1 cases with 43 deaths were reported from five countries,” including Cambodia, China, Indonesia, Thailand, and Vietnam.<sup>170</sup> There was a fear that the virus would mutate into a form that was more easily transmitted among humans, causing a pandemic situation.<sup>171</sup> Escalating the tension in the U.S. at the time was the production shortage of Roche/Gilead’s Tamiflu,<sup>172</sup> “the most efficient antiviral treatment” against avian flu.<sup>173</sup> Initially, Roche refused to give into the will of prominent national and international figures who pressed for compulsory licensing of Tamiflu, or at the very least, voluntary licensing by Roche to generic manufacturers.<sup>174</sup>

As in the case of Cipro, Senator Charles Schumer took a strong position demanding that Roche issue licenses for the generic manufacturing of Tamiflu under threat of legislative action

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<sup>170</sup> Ctrs. for Disease Control and Prevention, Avian Influenza A Virus Infection of Humans, <http://www.cdc.gov/flu/avian/gen-info/avian-flu-humans.htm> (last visited Apr. 22, 2010).

<sup>171</sup> See HOMELAND SEC. COUNCIL, NATIONAL STRATEGY FOR PANDEMIC INFLUENZA 1–2 (2005), available at <http://www.whitehouse.gov/homeland/nspi.pdf> (detailing the government’s strategy for handling a potential flu pandemic).

<sup>172</sup> Tamiflu was invented and patented by Gilead, who subsequently licensed commercial and manufacturing rights to Roche—patent protection for Tamiflu lasts until 2016. BRIAN T. YEH, CONGRESSIONAL RESEARCH SERVICE, INFLUENZA ANTIVIRAL DRUGS AND PATENT LAW ISSUES 8 (2007) [hereinafter INFLUENZA REPORT].

<sup>173</sup> Deborah L. Lu, Angela M. Collison & Thomas J. Kowalski, *Patentability Issues Surrounding Antivirals*, 25 *Nature Biotechnology* 1403, 1404 (2007). As of 2007, there were 787 patents for antiviral drugs. *Id.* at 1403.

<sup>174</sup> See Keith Bradsher, *Pressure Rises on Producer of a Flu Drug*, N.Y. TIMES, Oct. 11, 2005. Kofi Annan, secretary general of the UN, was among the voices pressuring Roche to license Tamiflu to support developing countries during public health emergencies. *Id.*

under § 1498.<sup>175</sup> Schumer's legislative proposal announcement cited that "[i]nfectious disease experts advise that each country have enough Tamiflu on hand for 40%– 50% of its population. That would require the U.S. to stockpile enough of the drug for over 100 million people."<sup>176</sup> Roche, in response, stated its intent to deliver an "eightfold expansion of its Tamiflu production capacity by the middle of 2006," refusing to sublicense Tamiflu for reasons such as the "complex and time-consuming" nature of the drug.<sup>177</sup> The company was supported by typical arguments against compulsory licensing, including disincentives to innovation, made by the PhRMA.<sup>178</sup> Although the Bush Administration impliedly backed Roche's position,<sup>179</sup> reputational costs as well as compulsory license threats likely contributed to Roche's eventual decision to agree and sublicense its Tamiflu production rights to generic manufacturers.<sup>180</sup> By April 2007, Roche had signed nineteen sublicensing agreements for Tamiflu production in nine different countries.<sup>181</sup> In addition, Roche took steps to increase access to Tamiflu by developing countries through donations and reduced prices.<sup>182</sup>

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<sup>175</sup> Press Release, Senator Charles Schumer, As Avian Flu Closes in on U.S., Schumer Calls for Immediate Action: Demands Suspension of Tamiflu Patent So Vaccine Can Be Mass-Produced, Dramatically Increasing Supply, Oct. 16, 2005, available at [http://schumer.senate.gov/new\\_website/record.cfm?id=260246](http://schumer.senate.gov/new_website/record.cfm?id=260246).

<sup>176</sup> *Id.*

<sup>177</sup> Bradsher, *supra* note 174.

<sup>178</sup> *Id.*

<sup>179</sup> INFLUENZA REPORT, *supra* note 172, at 12 ("At a congressional hearing on November 4, 2005, US Department of Health and Human Services Secretary Michael Leavitt stated that he did not intend to issue a compulsory license for Tamiflu, because he was concerned that "violating" the patent would remove incentives for future drug research and development" (citing *The National Pandemic Influenza Preparedness and Response Plan - Is the US Ready for Avian Flu?: Hearings Before the House Comm. on Gov't Reform*, 109th Cong., 1st sess. (Nov. 4, 2005) (testimony of Secretary Leavitt)).

<sup>180</sup> See INFLUENZA REPORT, *supra* note 172, at 11.

<sup>181</sup> *Id.* at 16.

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

## **b. Bayh-Dole Act**

Several developments in patent law occurred in the 1980s to increase patent protections,<sup>183</sup> including the University and Small Business Patent Act (Bayh-Dole Act), which transfers exclusive control for inventions developed through federally funded research from the government to the university or other organization in which the invention was created.<sup>184</sup> One provision of Bayh-Dole allows the federal agency, from which the research grant was obtained, to “march-in” and require that the contractor or exclusive licensee issue a license if one of four conditions is met.<sup>185</sup> Relevant here are the first two conditions that either “effective steps to achieve practical application of the subject invention” have not been taken within reasonable time,<sup>186</sup> or there is a need “to alleviate health or safety needs.”<sup>187</sup> These provisions effectively work as a commercialization requirement, allowing the government to issue compulsory licenses of patents obtained on research conducted via federal funding if the patent holder is doing an inadequate job of getting the invention to market. In so doing, the march-in provisions arguably impinge on IP rights more so than 28 U.S.C. § 1498 because they do not require that the patent holder be reasonably compensated for the compulsory license.

Four government agencies—the Department of Defense, the Department of Energy, NASA, and NIH—“rely on Commerce regulations for the Bayh-Dole Act and on their agencies’

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<sup>183</sup> Among other developments included *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), which broadened the scope of patentable subject matter to “anything under the sun that is made by man.” *Id.* at 309.

<sup>184</sup> 28 U.S.C. §§ 200–212. According to the General Accountability Office (GAO) report on Bayh-Dole issued in 2009:

A main goal of the act is to promote the utilization of inventions arising from federal supported research or development, and observers have judged the act a success in their regard. Prior to 1980, when the government routinely retained the patents on federally sponsored inventions, only 5 percent of these patents were ever used in the private sector. In contrast, some stakeholders, including federal and technology transfer officials, today believe that invention that arise from federally funded research are routinely commercialized, although comprehensive data are not available on how often this happens. U.S. GOV’T ACCOUNTABILITY OFFICE, INFORMATION ON THE GOVERNMENT’S RIGHT TO ASSERT OWNERSHIP CONTROL OVER FEDERALLY FUNDED INVENTIONS 2 (2009), *available at* <http://www.gao.gov/new.items/d09742.pdf> [hereinafter GAO REPORT].

<sup>185</sup> 28 U.S.C. § 203.

<sup>186</sup> 28 U.S.C. § 203(1)(a).

<sup>187</sup> 28 U.S.C. § 203(1)(b).

interpretations of the act to determine whether to exercise their march-in authority.”<sup>188</sup> These agencies reportedly rely on public and private sources of information to determine if exercising their march-in authority is worth investigation, but do not actively employ mechanisms to determine march-in candidates.<sup>189</sup> While three petitions have been made to the NIH asking the government to exercise its march-in rights, the NIH has never elected to do so.<sup>190</sup> In all three instances, the NIH determined that the inventions were already being marketed and that marching in would not alleviate health and safety concerns.<sup>191</sup> Some authors have suggested that despite this fact, there may be no need to strengthen the march-in rule because universities’ technology transfer offices often structure their licensing agreements with producers/manufacturers in terms of the Bayh-Dole provisions.<sup>192</sup> In other words, universities will agree to license their products only if manufacturers agree to actually use and produce the technology.

Overall, it seems unlikely that the Bayh-Dole march-in provisions will gain momentum as a compulsory licensing mechanism by the U.S. government. Agencies are reluctant to assert their march-in rights for reasons such as an inclination to leave drug-pricing issues for Congress (when petitioners argue that march-in rights should be exercised because of prohibitive drug costs)<sup>193</sup> and lack of specialized expertise in certain fields.<sup>194</sup> Furthermore, compulsory licensing through Bayh-Dole is of limited utility during public health emergencies because it

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<sup>188</sup> GAO REPORT, *supra* note 184, at 7.

<sup>189</sup> *Id.* at 9.

<sup>190</sup> *Id.* One petition was made in 1997 (involving a stem cell separation device), and two in 2004 (one involving an HIV/AIDS drugs, and the other a drug for glaucoma). *Id.* at 10–11.

<sup>191</sup> *Id.* at 10–11. As an example, NIH’s decision on the most recent march-in petition for Xalatan®, a glaucoma treatment owned by Pfizer, is available at Nat’l Inst. of Health, In the Case of Xalatan® Manufactured by Pfizer, Inc. (2004), available at <http://www.ott.nih.gov/policy/March-In-Xalatan.pdf>.

<sup>192</sup> Jerry Thursby & Marie Thursby, *Knowledge Creation and Diffusion of Public Science with Intellectual Property Rights*, in *FRONTIERS OF ECONOMICS AND GLOBALIZATION VOLUME 2: INTELLECTUAL PROPERTY, GROWTH AND TRADE* 218 (Keith E. Maskus ed. 2008).

<sup>193</sup> In the Case of Xalatan®, *supra* note 191, at 6.

<sup>194</sup> GAO REPORT, *supra* note 184, at 14–17.

may not be as efficient in bringing necessary drugs to the public as § 1498 (march-in proceedings tend to be lengthy).<sup>195</sup>

### c. Injunctions Issued by the U.S. Supreme Court—*eBay v. MercExchange*

After the Supreme Court’s 2006 decision in *eBay v. MercExchange*,<sup>196</sup> where the Court extended the application of the general four-factor test for injunctive relief to cases of patent infringement,<sup>197</sup> the ability of patent owners to obtain permanent injunctions under 35 USC. § 283 for infringing activities arguably diminished.<sup>198</sup> Because a denial of an injunction under *eBay* works as a compulsory license, the decision “creates a dynamic where every enforcement action for an intellectual property right can turn into a *de facto* compulsory licensing case.”<sup>199</sup> For example in 2008, the Federal Circuit vacated the District Court’s decision to grant an injunction, and instead issued a compulsory license to the defendant in an infringement action involving a diagnostic tool for the treatment of hepatitis C.<sup>200</sup> The Court based its decision on the fact that the district court had already granted reasonable royalties for future sales, which in effect acted as a compulsory license, and could not be granted in addition to an injunction—this went to the first prong of the *eBay* test (irreparable harm).<sup>201</sup> Although the *eBay* decision allowed courts to explore in the realm of compulsory licensing for reasons that include public

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<sup>195</sup> GAO REPORT, *supra* note 184, at 13, 14. But, the threat of the government exerting its march-in rights may have some effect. According to the Third World Network, the U.S. was reported to “have been forced to resort to a threat to use its ‘march-in rights’ (under the US Bayh-Dole Act) to exact a MedImmune license to Sanofi for the latter company to produce a quantity of prepandemic H5N1 vaccine.” EDWARD HAMMOND, THIRD WORLD NETWORK, SOME INTELLECTUAL PROPERTY ISSUES RELATED TO H5N1 INFLUENZA VIRUSES, RESEARCH AND VACCINES 21 (2008), available at <http://www.twinside.org.sg/title2/avian.flu/papers/patent.paper.pdf>.

<sup>196</sup> 547 U.S. 388 (2006).

<sup>197</sup> “A plaintiff must demonstrate: (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.” *Id.* at 391.

<sup>198</sup> See *id.* See also Christopher A. Cotropia, *Compulsory licensing under TRIPS and the Supreme Court of the United States’ Decision in eBay v. MercExchange*, in PATENT LAW & THEORY: A HANDBOOK OF CONTEMPORARY RESEARCH 557 (Toshiko Takenaka ed., 2009) (discussing the holding of *eBay* in light of TRIPS).

<sup>199</sup> KEI Comments on ACTA, *supra* note 118, at 25.

<sup>200</sup> *Innogenetics, N.V. v. Abbot Laboratories*, 512 F.3d 1363 (CAFC, 2008).

<sup>201</sup> *Id.* at 1380–1381.

interest concerns, the current U.S. position on injunctions in the ACTA negotiations may work to negate this judicial discretion.<sup>202</sup>

#### **IV. Conclusion**

Clearly, the U.S. is not immune to public health emergencies. While any potential emergencies are unlikely to reach the level of the AIDS crisis in South Africa, for instance, they may nevertheless involve the need for access to mass quantities of patented drugs in short periods of time. It is important to note, though, that the U.S. is in a unique position in having the capacity to handle access to medicines during public health emergencies without the implementation of a compulsory licensing scheme. Some potential factors that contribute to the U.S.' position include its domestic manufacturing capacity, its public health infrastructure (in being able to quickly disseminate important health information), and most importantly, its exceptional relationship with the pharmaceutical industry. Although recent developments in 28 U.S.C. § 1498 and patent infringement jurisprudence may be indicative of a shift in the judiciary towards expanding government authority over patents,<sup>203</sup> the U.S. stance in ACTA negotiations indicate that the executive branch is not headed in that direction and essentially remains in the same position in which it stood during TRIPS negotiations—heavily influenced by the pharmaceutical industry and therefore heavily in favor of maintaining strong IP rights. U.S. trade policy may not, however, accurately reflect public sentiment towards access to medicines given the heated debates surrounding the anthrax attack, where only 30,000 people were ultimately caused to take precautionary antibiotics,<sup>204</sup> and avian flu, where *no* Americans fell ill.

Still, the existing means by which the U.S. can issue compulsory licenses have, in the past, simply not been utilized, but perhaps for good reason. For instance, compulsory licensing

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<sup>202</sup> See *supra* Section II(b).

<sup>203</sup> See *supra* Section III.

<sup>204</sup> Singh, *supra* note 156.

through § 1498 is not an ideal mechanism for providing consistent remuneration to the patentee—court determinations of the compensation appropriate for a compulsory license are unlikely to provide an adequate level of consistency that will satisfy patent holders. Pharmaceutical companies may prefer to handle negotiations on their own and as the market demands, depending on the nature of the public health emergency itself, as well as public reaction to it. Moreover, some have argued that § 1498 is not in compliance with TRIPS because of its overall lack of requirements for a government justification prior to infringing a patent, further indicating the inadequacy of § 1498 as a compulsory licensing statute.<sup>205</sup> The other two compulsory licensing possibilities discussed in this paper, the Bayh-Dole march-in provisions and court imposed injunction denials, are similarly unlikely to play any kind of serious role in future public health emergencies. With respect to the former, the NIH has clearly expressed a reluctance to interfere with drug patents, and with respect to the latter, private parties will probably refrain from partaking in infringing activities for the sake of public health during a high-profile emergency situation. Finally, pending the outcome of ACTA negotiations, all of these legal methods to access patented products may have to be revisited.

Regardless of the legal compulsory licensing schemes, the Cipro and Tamiflu examples show that the U.S. may find it worth its while to do the back-and-forth with industry through threats and public negotiations whenever a public health emergency implicates a pharmaceutical patent. Because of this interplay between the U.S. and the pharmaceutical industry, the government is able to reap the initial benefits of appearing to its constituents as taking a strong stance against the profit-driven motives of drug companies, while drug companies are later able to take credit for cooperation and benevolence. These domestic disputes may invite ridicule

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<sup>205</sup> See LiLan Ren, *Comment: A Comparison of 28 U.S.C. § 1498(A) and Foreign Statutes and an Analysis of § 1498(A)'s Compliance with TRIPS*, 41 Hous. L. Rev. 1659 (2005).



from the international community, but nevertheless allow the U.S. to continue to cater to the pharmaceutical industry's interests in maintaining strong IP rights abroad.