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## **HIV/AIDS Drugs, Patents and the TRIPS Agreement: Issues and Options**

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# HIV/AIDS Drugs, Patents and the TRIPS Agreement: Issues and Options

## Summary

AIDS (“Acquired Immune Deficiency Syndrome”) is a serious medical condition that predisposes patients towards opportunistic infections, tumors, dementia and death. Human Immunodeficiency Virus (“HIV”) is the viral agent associated with AIDS. HIV/AIDS remains a leading cause of death in the United States. Exposure rates in some other parts of the world, such as sub-Saharan Africa, substantially exceed those in the United States. The global HIV/AIDS pandemic has had a severe impact upon many states within the developing world, and future social and economic consequences could be devastating.

Recently introduced antiretroviral drugs have reduced the number of deaths caused by HIV/AIDS. These medicines can keep HIV from replicating and causing further damage to the immune system. Although the cost of an annual supply of different HIV/AIDS drugs varies. The prices of these drugs are beyond the ability of most residents of the developing world to pay. Because some HIV/AIDS drugs are subject to patent protection, others may not manufacture these drugs without the permission of the patent owner.

International disagreement has arisen regarding patents on HIV/AIDS drugs. Until recently, many nations did not allow patents to issue on pharmaceuticals. However, one component of the World Trade Organization agreements, the Agreement on Trade-Related Aspects of Intellectual Property Rights (the “TRIPS Agreement”), requires member states to grant pharmaceutical patents. Demand for increased availability of HIV/AIDS drugs has led to perceived conflicts with this TRIPS Agreement obligation. Although patent disputes concerning Brazil and South Africa have recently been resolved, a fundamental conflict persists between the goals of providing broad access to HIV/AIDS drugs, on one hand, and maintaining an environment conducive to pharmaceutical research and development, on the other.

Legislation has been introduced in the 107<sup>th</sup> Congress relating to the availability of drugs for treating HIV/AIDS. These and other options for dealing with this issue are discussed. Other options include: providing the U.S. Trade Representative with policy guidance that balances TRIPS Agreement compliance with the availability of HIV/AIDS drugs; encouraging the differential pricing of HIV/AIDS drugs in the developed and developing world; promoting market-based solutions, such as a global settlement between entrepreneurial pharmaceutical companies and nations seeking greater access to HIV/AIDS drugs; and offering humanitarian aid to the recently announced United Nations global fund for fighting HIV/AIDS.

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# HIV/AIDS Drugs, Patents and the TRIPS Agreement: Issues and Options

## Introduction

Pharmaceuticals remain an important industry both for the economy of the United States and for the health of its citizens. With the United States serving as the world's largest market for pharmaceutical sales, the U.S. pharmaceutical industry is among the nation's most profitable.<sup>1</sup> U.S. manufacturers have consistently maintained a positive international trade balance and are responsible for nearly half of the major pharmaceutical products marketed worldwide. Excluding public sanitation improvements, the most significant advances in medicine were fueled by the discovery of innovative drugs.<sup>2</sup> Ongoing advances in biotechnology, genetics, information technology and other fields suggest that the pharmaceutical industry will continue progress towards the discovery and development of new pharmaceuticals.

Drug discovery and development is a costly and time-consuming undertaking.<sup>3</sup> One widely quoted report found that, on average, this process consumes 12 to 15 years and costs \$500 million per new drug brought to market.<sup>4</sup> Most new drugs can be copied quickly and cheaply, however. Given a technical environment where products are difficult to develop but easy to copy, the pharmaceutical industry has been described as particularly dependent upon the patent system.<sup>5</sup> By providing proprietary rights in innovative pharmaceutical compounds, patents protect research-based drug companies from direct competition for a limited period of time. Patents may allow pharmaceutical companies to appropriate the benefits of their research and development efforts, thereby stimulating them to engage in such efforts in the first place. One study concluded that 65% of new drugs would not have been commercially introduced in the absence of patent protection.<sup>6</sup>

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<sup>1</sup>Rai, Arti K, "The Information Revolution Reaches Pharmaceuticals," 2001 *University of Illinois Law Review* 173.

<sup>2</sup>Nash, Duane, "South Africa's Medicines and Related Substances Control Amendment Act of 1997," 15 *Berkeley Technology Law Journal* (2000), 485.

<sup>3</sup>See Congressional Research Service, *Pharmaceutical Research and Development: A Description and Analysis of the Process*, by Richard E. Rowberg, CRS Report for Congress RL30913, 2 April 2001.

<sup>4</sup>Drews, Jurgen, *In Quest of Tomorrow's Medicine* (New York: Springer 1998).

<sup>5</sup>Levin, Richard, et al., "Appropriating the Returns from Industrial Research and Development," *Brookings Papers on Economic Activity*, No. 3 (1987), 783.

<sup>6</sup>Mansfield, Edwin, "Patents and Innovation: An Empirical Study," *Management Science* (continued...)

Although patents have long been available on pharmaceuticals in the United States, not all countries traditionally allowed pharmaceutical patents. Some commentators believe that lack of effective patent protection abroad has cost U.S. firms billions of dollars per year in lost revenue. The advent of the so-called “TRIPS Agreement,” the Agreement on Trade-Related Aspects of Intellectual Property Rights of the World Trade Organization (“WTO”),<sup>7</sup> was expected to increase the availability of patent protection for pharmaceuticals abroad.<sup>8</sup> Under the TRIPS Agreement, all WTO members agreed to amend their patent laws to allow patents to issue on pharmaceuticals. WTO members also agreed to restrict their use of compulsory licenses, a procedure through which a government obliges patentees to allow others to practice the patented invention.

The efforts of some foreign countries to counter the spread of Acquired Immune Deficiency Syndrome (“AIDS”) have brought controversy to the intersection of the patent system and the pharmaceutical industry. Certain drugs, developed and patented by U.S. companies, have dramatically changed the length and quality of life of patients infected with Human Immunodeficiency Virus (“HIV”). Some developing countries have sought access to these drugs at low cost. Authorities have called for the importation of generic versions of brand-name HIV/AIDS drugs, for example, while others have encouraged local production of generic drugs whether the patent owner agrees to such measures or not.

Many commentators regard the fulfillment of these requests as a moral imperative.<sup>9</sup> The unprecedented devastation worked by the HIV/AIDS pandemic threatens to undermine the governments, economy, and social fabric of many states within the developing world. Efforts to curb the AIDS pandemic could amount to a security imperative as well, in view of the economic difficulties and political instability that could otherwise result in Africa and potentially other parts of the developing world.<sup>10</sup>

Some observers are of the view, however, that initiatives that weaken or circumvent patent rights may limit the ability of research-based pharmaceutical companies to obtain returns sufficient to refund their investments and allow further investment in drug development, including HIV/AIDS research. As stated by

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<sup>6</sup>(...continued)  
(Feb. 1986), 175.

<sup>7</sup>Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments--Results of the Uruguay Round vol. 31, 33 I.L.M. 81 (1994) [hereinafter TRIPS Agreement].

<sup>8</sup>Weissman, Robert, “A Long Strange, TRIPS: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining WTO Legal Alternatives Available to Third World Countries,” 17 *University of Pennsylvania Journal of International Economic Law* (1996), 1069.

<sup>9</sup>See Congressional Research Service, *AIDS in Africa: Issue Brief*, by Copson, Raymond W., CRS Issue Brief IB10050, 14 May 2001.

<sup>10</sup>*Ibid.*

Economist Robert J. Barro of Harvard University, “it is probably a bad idea to take the profitability out of this business because any cure or vaccine for AIDS is likely to emerge from the efforts of profit-seeking corporations.”<sup>11</sup> These controversies seem to admit no easy answers, but they have significant potential impact upon public health, international drug development and the future of the nascent international patent regime.

This report considers the current dispute between the research-based pharmaceutical industry, on one hand, and certain foreign governments, patient advocacy groups and generic manufacturers, on the other, regarding patented HIV/AIDS pharmaceuticals. After introducing fundamentals of patent protection for pharmaceuticals domestically and abroad, this report discusses medications used in treating HIV/AIDS. It then describes contemporary international controversies regarding patents on HIV/AIDS drugs and the potential consequences of these disputes for entrepreneurial drug companies. This report closes with a discussion of legislative issues and options.

## Patent Protection for Pharmaceuticals

### Patent Law Fundamentals

The U.S. patent law allows individuals to obtain proprietary rights in their inventions. Inventors must submit applications to the United States Patent and Trademark Office (“USPTO”) if they wish to obtain patent rights.<sup>12</sup> USPTO officials known as examiners then assess whether the application merits the award of a patent.<sup>13</sup>

In deciding whether to approve a patent application, a USPTO examiner will consider whether the submitted application fully discloses and distinctly claims the invention.<sup>14</sup> The examiner will also determine whether the invention itself fulfills certain substantive standards set by the patent statute. To be patentable, an invention must be useful, novel and nonobvious. The requirement of usefulness, or utility, is satisfied if the invention is operable and provides a tangible benefit.<sup>15</sup> To be judged novel, the invention must not be fully anticipated by a prior patent, publication or other knowledge within the public domain.<sup>16</sup> A nonobvious invention must not have

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<sup>11</sup>Barro, Robert J., “Why Would A Rock Star Want to Talk to Me?,” *Business Week* (16 July 2001), 24.

<sup>12</sup>35 U.S.C. § 111.

<sup>13</sup>35 U.S.C. § 131.

<sup>14</sup>35 U.S.C. § 112.

<sup>15</sup>35 U.S.C. § 101.

<sup>16</sup>35 U.S.C. § 102.

been readily within the ordinary skills of a competent artisan at the time the invention was made.<sup>17</sup>

If the USPTO allows the patent to issue, the patent proprietor obtains the right to exclude others from making, using, selling, offering to sell or importing into the United States the patented invention.<sup>18</sup> Patent title therefore provides inventors with limited periods of exclusivity in which they may practice their inventions, or license others to do so. The grant of a patent permits the inventor to receive a return on the expenditure of resources leading to the discovery, often by charging a higher price than would prevail in a competitive market.

The term of patent protection is set at 20 years from the date the application is filed.<sup>19</sup> The issuance of a patent also places the technical information disclosed in the patent instrument within the public domain. During the term of the patent, competitors are stimulated to invent around the patented invention to provide for parallel technical developments or meet similar market needs. Once the patent expires, others are free to practice the invention without compensation to the inventor.

Significantly, U.S. patents provide their owners with rights only within the United States.<sup>20</sup> If inventors desire intellectual property protection in another country, they must specifically procure a patent in that jurisdiction. Usually this effort requires submitting a patent application before a foreign patent office. As a practical matter, multinational corporations often obtain a set of different national patents for each of their significant inventions.

## Patents on Pharmaceuticals

Inventors of pharmaceutical compounds have obtained U.S. patents for many years. Such inventors faced difficulties when they sought patent protection abroad, however. The patent laws of many other nations did not allow patents to issue on pharmaceutical inventions.<sup>21</sup> As a result, although research-based pharmaceutical companies could obtain patents in the United States and some other countries, their drugs could be freely copied elsewhere.

With the advent of the World Trade Organization in 1995, patents on pharmaceuticals became more widely available. One component of the WTO Agreement is the so-called TRIPS Agreement, or Agreement on Trade-Related

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<sup>17</sup>35 U.S.C. § 103.

<sup>18</sup>35 U.S.C. § 271(a).

<sup>19</sup>35 U.S.C. § 154.

<sup>20</sup>*Quality Tubing, Inc. v. Precision Tube Holdings Co.*, 75 F.Supp.2d 613, 619 (S.D. Tex. 1999).

<sup>21</sup>Scherer, F.M., "The Pharmaceutical Industry and World Intellectual Property Standards," 53 *Vanderbilt Law Review* (2000), 2247-48.

Aspects of Intellectual Property Rights.<sup>22</sup> Under Article 27 of the TRIPS Agreement, WTO members agreed to allow patents to issue on inventions “in all fields of technology.”<sup>23</sup> One consequence of this requirement is that many WTO member states will begin to allow patents to issue on pharmaceuticals.

The TRIPS Agreement allows some exceptions to its basic requirement that patents issue “in all fields of technology.” One of these exceptions, provided in Article 27(2), may be pertinent to the patenting of pharmaceuticals. That provision states:

Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

WTO members did not have to comply with Article 27 of the TRIPS Agreement immediately. For WTO members other than developing and least developed countries, the compliance date for all requirements of the TRIPS Agreement was set to January 1, 1996. For signatory states designated as developing countries, the TRIPS Agreement set the general compliance date as January 1, 2000. However, there is one exception to this general date. If on January 1, 2000, a developing country did not extend patent protection to all areas of technology within the meaning of Article 27, that developing country may delay implementation of these provisions for an additional five years. The practical effect of this additional transition period was that developing countries need not allow patents on pharmaceuticals until January 1, 2005.

The TRIPS Agreement also allows a signatory state designated as a least-developed country to delay implementing the TRIPS Agreement until January 1, 2010. A showing of hardship may qualify least-developed countries for further delays and other concessions.

The TRIPS Agreement does not oblige its signatories to protect subject matter that fell into the public domain prior to the time its obligations became effective.<sup>24</sup> For example, many HIV/AIDS drugs were developed and marketed prior to the advent of the TRIPS Agreement. Such drugs may not be subject to patent protection in those jurisdictions that did not grant patents on pharmaceuticals prior to the TRIPS Agreement. In effect, the TRIPS Agreement apparently requires its signatories to provide patent protections for any HIV/AIDS drugs developed after 1995 and into the future.

As with other obligations imposed by the TRIPS Agreement, these commitments are subject to enforcement through the WTO Dispute Settlement Body (DSB). If one WTO member state believes that another member state is in violation of the TRIPS

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<sup>22</sup>See TRIPS Agreement, *supra* note 6.

<sup>23</sup>TRIPS Agreement, *supra* note 6, at Art. 26.

<sup>24</sup>See TRIPS Agreement, *supra* note 6, at Art. 70.



Agreement, the member states may enter into consultation through the DSB. If the member states cannot resolve their dispute, the DSB will convene a panel to hear and resolve the dispute. Panel decisions are subject to review by the DSB Appellate Body. The WTO Agreement calls for compensatory trade measures in circumstances where the DSB finds a WTO member state to be in violation of the TRIPS Agreement, yet that member state does not amend its laws.

## **Pipeline Protection**

Although the TRIPS Agreement allows developing countries to delay implementing their patent law obligations, it requires that they immediately establish so-called pipeline protection for pharmaceuticals. Some sources refer to pipeline protection as the “mailbox rule.”<sup>25</sup> Under this requirement, countries that do not allow pharmaceutical patents to issue must nonetheless accept patent applications. These patent applications will essentially be held at the national patent office until it comes time for the patent application to be considered.

Pipeline protection is valuable because it allows inventors to establish a date of priority of invention. Although many years might pass between the application’s filing date and the date on which it would be examined, the inventiveness of the claimed invention must be judged as of its filing date. Pipeline protection allows inventors to maintain their priority of invention in the face of subsequent technical advances.

## **Exclusive Marketing Rights**

The TRIPS Agreement also mandates that WTO member states award an Exclusive Marketing Right (“EMR”) to pharmaceutical innovators in specified circumstances. The holder of an EMR concerning a particular product is designated as the only entity authorized to distribute that product within the member state. The award of EMRs provides innovators with transitional, patent-like market exclusivity in member states that do not yet offer patent protection for pharmaceuticals.

In order for an enterprise to obtain an EMR in one WTO member state, that enterprise must obtain both a patent and marketing approval on that pharmaceutical in another WTO member state. That enterprise must also take two additional steps within the jurisdiction in which an EMR is sought. First, the enterprise must obtain marketing approval for the pharmaceutical. Second, that enterprise must file a patent application claiming that pharmaceutical. Upon completing these two steps, the enterprise may obtain an EMR with a maximum duration of five years. The EMR will expire prior to the expiration of five years if either the marketed product is patented, or the local patent office rejects the enterprise’s patent application.

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<sup>25</sup>Giust, John E., “Noncompliance with TRIPS by Developed and Developing Countries: Is TRIPS Working?,” 8 *Indiana International and Comparative Law Review* (1997), 69.

## Limitations on Patent Protection for Pharmaceuticals

Some nations have restricted the scope of exclusive rights provided by their patent laws. Two such restrictions, compulsory licenses and parallel importation, are particularly pertinent to pharmaceutical patents. A compulsory license allows a competitor of the patent owner to use the patented invention without the patent owner's permission.<sup>26</sup> The term "parallel importation" refers to the practice of acquiring drugs in one country and, without the authorization of the patent holder, importing them into another country.<sup>27</sup> These topics are reviewed in turn below.

Although compulsory licenses have played only a minor role in the United States patent system,<sup>28</sup> many foreign patent statutes include such provisions.<sup>29</sup> These statutes typically require an interested party formally to request the compulsory license from the foreign government. Competent authorities then decide whether to grant the license as well as the terms of any granted license. Grounds for granting a compulsory license include the abusive exercise of patent rights, lack of domestic manufacture of the patented product, commercialization of the patented good that does not satisfy the needs of the local market and national emergencies.<sup>30</sup> While some accounts suggest that formal compulsory licensing proceedings are commenced only infrequently, the mere existence of a compulsory licensing statute may do much to encourage bargaining between a foreign patentee and domestic industry, on terms favorable to local manufacturers.<sup>31</sup>

The TRIPS Agreement places some limits upon the ability of WTO member states to award compulsory licenses for the use of another's patented invention. Among the most detailed provisions of the TRIPS Agreement, Article 31 imposes in part the following restrictions upon the issuance of compulsory licenses:

- Each application for a compulsory license must be considered on its individual merits.

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<sup>26</sup>Sherwood, Robert, "Intellectual Property and Investment Stimulation: The Ratings of Systems in Eighteen Developing Countries," 37 *IDEA* (1997), 261.

<sup>27</sup>Andrade, Richard M., "The Parallel Importation of Unauthorized Genuine Goods: Analysis and Observations of the Gray Market," 14 *University of Pennsylvania Journal of International Business Law* (1993), 409.

<sup>28</sup>*Dawson Chemical Co. v. Rohm and Haas Co.*, 448 U.S. 176 n.21 (1980).

<sup>29</sup>Julian-Arnold, Gianna, "International Compulsory Licensing: The Rationales and the Reality," 33 *IDEA* (1993), 349.

<sup>30</sup>*Ibid.* For studies of specific compulsory licensing provisions of individual nations, see, for example, Baca, Rafael V., "Compulsory Patent Licensing in Mexico in the 1990's: The Aftermath of NAFTA and the 1991 Industrial Property Law," 8 *Transnational Lawyer* (1995), 33; Rosenthal, Robert E., "The Chinese Patent System," 17 *Law and Policy in International Business* (1985), 907; Wechkin, John M., "Drug Price Regulation and Compulsory Licensing for Pharmaceutical Patents: The New Zealand Connection," 5 *Pacific Rim Law & Policy Journal* (1995), 237.

<sup>31</sup>Boseley, Sarah, "Opinion: Pharmaceuticals move their battleground to Brazil to stem the tide of cheaper drugs," *Irish Times* (20 April 2001), 14.

- The proposed user must have made efforts to obtain authorization from the patent owner on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. However, this requirement may be waived in the case of a national emergency or other circumstances of extreme urgency.
- Any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use.
- The compulsory license must be revocable if and when its motivating circumstances cease to exist and are unlikely to recur.
- The patent owner must be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization.
- The legal validity of any decision relating to the authorization of such use shall be subject to judicial or other independent review.

The conditions for compulsory licensing within the TRIPS Agreement involve a number of ambiguities.<sup>32</sup> Such terms as “national emergency” or “circumstance of extreme urgency” are not further defined.<sup>33</sup> It is not clear what exactly is meant by the requirement that a compulsory license be granted primarily for the supply of the domestic market. Nor is there any clear definition of what level of “adequate remuneration” to the patent holder suffices. The precise application of these limitations to medications for treating AIDS will not be fully understood until a competent tribunal is called upon to interpret them, an event that has yet to occur.<sup>34</sup>

Despite these ambiguities, the possibility of a grant of a compulsory license may place meaningful limits upon the exercise of pharmaceutical patents. Under many foreign patent statutes, compulsory licenses may be invoked on such grounds as the public order and the ready availability of the patented product in the domestic market. If such compulsory licenses were issued in keeping with the procedural requirements of the Article 31, then they would likely be deemed compatible with the TRIPS Agreement.

Parallel importation presents another limitation upon the exercise of patent rights on pharmaceuticals. As a result of varying economic conditions and government

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<sup>32</sup>Ford, Sarah M., “Compulsory Licensing Provisions Under the TRIPS Agreement: Balancing Pills and Patents,” 15 *American University International Law Review* (2000), 941.

<sup>33</sup>The initial determination of whether a particular event amounts to a “national emergency” or “circumstance of extreme urgency” appears to be left to local authorities. Cf. “Kenya leaders clear way for cheaper drugs,” *Houston Chronicle* (13 June 2001), 26.

<sup>34</sup>A ruling issued by the Appellate Body of the WTO DSB would likely provide the most conclusive interpretation of the compulsory licensing provisions of the TRIPS Agreement. The judgments of national courts and/or officials of WTO member states might also provide persuasive authority as to the scope of these provisions. See Chua, Adrian T.L., “Precedent and Principles of WTO Panel Jurisprudence,” 16 *Berkeley International Law Journal* (1998), 171.

regulations, pharmaceuticals may be sold at different prices in different countries.<sup>35</sup> These price differences provide incentives for parallel importers to buy pharmaceuticals in countries where they are sold more cheaply and resell them in countries where they are sold at a higher price.<sup>36</sup> Parallel imports are genuine products in the sense that they originate from the brand name pharmaceutical company. However, the parallel importer acts independently of the brand name company, typically selling at a lower price than the patentee or its licensee in the country of importation. As a result, the practice of parallel importation has been referred to as the “gray market.”<sup>37</sup>

Parallel importation has yet to play a significant role in the U.S. pharmaceutical market. Although the 106th Congress passed a law allowing the parallel importation of drugs from overseas into the United States, the Clinton Administration refused to implement the law. According to the Clinton Administration, not only could the public be exposed to additional risks, but the cost of implementing the legislation would outweigh its benefits.<sup>38</sup> However, a considerable grey market exists in consumer goods subject to trademark rights within the United States.<sup>39</sup> In some other countries, parallel importation has played a greater role in providing lower cost goods imported from other nations across a number of market sectors.<sup>40</sup>

Commentators disagree over the effect of parallel importation upon the availability of pharmaceuticals in poor and developing countries. If conducted for humanitarian reasons, parallel importation could serve as an effective means for the developing world to obtain medicines at the lowest available commercial price.<sup>41</sup> The non-government organization Médecins sans Frontiers, for example, hopes that

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<sup>35</sup>For example, a 1997 study conducted by Dr. Larry D. Sasich for the nongovernmental organization Public Citizen found that the costs to pharmacists of the antidepressant drug clozapine varied widely among different countries. The Sasich study reported that 90 clozapine tablets dosed at 100 mg cost \$51.94 in Spain, \$73.72 in Sweden, \$131.51 in Italy and \$317.03 in the United States. See Sasich, Larry D., *International Comparison of Prices for Antidepressant and Antipsychotic Drugs* (available at <http://www.citizen.org/hrg/PUBLICATIONS/1446.htm>).

<sup>36</sup>See Andrade, *supra* note 27.

<sup>37</sup>*Ibid.*

<sup>38</sup>See Congressional Research Service, *The Cost of Prescription Drugs for the Uninsured Elderly and Legislative Approaches*, by Resources, Science, and Industry Division, CRS Report for Congress RL30373, 16 Jan. 2001.

<sup>39</sup>See Hiebert, Timothy H., *Parallel Importation in U.S. Trademark Law* (Greenwood Press, Westport, Connecticut, 1994).

<sup>40</sup>See Swanson, Tait R., Combating Gray Market Goods in a Global Market: Comparative Analysis of Intellectual Property Laws and Recommended Strategies, 22 *Houston Journal of International Law* (2000), 327 (observing that parallel importation is permissible in Australia, China, Indonesia, Japan, Korea, Mexico, New Zealand, Singapore, Thailand and other nations).

<sup>41</sup>Dolmo, Bess-Carolina, “Examining Global Access to Essential Pharmaceuticals in the Face of Patent Protection Rights: The South African Example,” 7 *Buffalo Human Rights Law Review* (2001), 137.

parallel importation will allow low-cost pharmaceuticals to be supplied to treatment programs in the developing world. Other commentators argue that if drugs are effectively available everywhere at the lowest price sold anywhere, then pharmaceutical companies will sell drugs only in markets where they can command a high price.<sup>42</sup>

Where a pharmaceutical is protected by a patent in the country of importation, legal issues may arise with respect to parallel importation. Opponents of the grey market contend that parallel importers violate local rights when they sell patented drugs without the permission of the patent holder. Parallel importers assert that patentees should not be allowed to use intellectual property rights to enforce private product distribution arrangements. To do so, according to parallel importers, would be to prevent the free movement of legitimate goods in the international marketplace.

Countries have differed in their judgments on whether parallel importation violates domestic patent rights. For example, the Japanese Supreme Court decided in 1997 that the importation of a patented product does not violate Japanese patent rights.<sup>43</sup> Although the legal situation in the United States is not entirely clear, most observers believe that a court would decide that parallel importation constitutes infringement of a U.S. patent.<sup>44</sup> Because WTO member countries could not agree on the appropriate legal standard for parallel importation, Article 6 of the TRIPS Agreement expressly states that it does not govern this issue. As a result, WTO signatories are free to develop their own intellectual property laws either approving or disallowing parallel importation.

## Pharmaceuticals for Curbing HIV/AIDS

Patents issues have arisen with respect to pharmaceuticals for treating Acquired Immune Deficiency Syndrome ("AIDS"). AIDS has been described as "the most dramatic, pervasive and tragic pandemic in recent history."<sup>45</sup> HIV is associated with AIDS, a serious condition in which the body's defenses against some illnesses are broken down. Infected individuals are predisposed towards diseases that the body would usually fight off quite easily, resulting in a wide range of opportunistic infections, tumors, dementia and death.

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<sup>42</sup>Perkins, David, et al., "Exhaustion of Intellectual Property Rights," *Practising Law Institute: Patents, Copyrights, Trademarks, and Literary Property Course Handbook Series*, 574 PLI/Pat 41 (7-8 Oct. 1999).

<sup>43</sup>See *BBS Kraftfahrzeug Technik v. Kabushiki Kaisha Racimex Japan*, Case No. Heisei 7 (wo) 1988 (1 July 1997).

<sup>44</sup>Wilder, Richard, "Market Segmentation: techniques, actors and incentives - The use of intellectual property rights," *WHO/WTO Workshop on Differential Pricing and Financing of Essential Drugs* (8-11 April 2001), 6.

<sup>45</sup>Stine, Gerald J., *Acquired Immune Deficiency Syndrome: Biological, Medical, Social, and Legal Issues* xxi (Englewood Cliff, N.J.: Prentice Hall, 1993).

In the United States, AIDS is the fifth leading cause of death in people 25-44 years of age.<sup>46</sup> The Centers for Disease Control and Prevention report that, in total, 753,907 cases of AIDS have been reported in the United States.<sup>47</sup> The total number of reported deaths from AIDS in the United States is 438,795.<sup>48</sup>

HIV/AIDS exposure rates in some other parts of the world, such as sub-Saharan Africa, are significantly higher than in the United States. An estimated 34 million people living in sub-Saharan Africa have been infected with HIV/AIDS. Of those infected, approximately 11.5 million have died.<sup>49</sup>

The HIV/AIDS crisis is one of extreme severity in many developing countries. By 2010, it is projected that more than 44 million children in 34 developing countries will have lost at least one parent to the disease.<sup>50</sup> AIDS is devastating the education sector in many countries, killing teachers and leading to school dropouts who must care for ill parents. The gross domestic product of some sub-Saharan African countries could drop by 20 % over more in the next decade. Life expectancy is also dipping in many countries with high rates of HIV infection. In Botswana, for example, life expectancy is just 39 years and is expected to drop to 29 years by 2010, according to the U.S. Census Bureau. The high rate of HIV/AIDS infection observed in many developing countries holds the potential to intensify poverty and destabilize economies, governments and social infrastructures.<sup>51</sup>

In the United States, the number of deaths due to AIDS began to decrease in 1998. The principal reason for the decrease was the introduction of new drugs for treating HIV. Antiretroviral drugs in particular have had an impact.<sup>52</sup> These medicines can keep HIV from replicating (making copies of itself) and causing further damage to the immune system.

Individuals infected with HIV/AIDS currently use several sorts of antiretroviral medications. The first available anti-HIV agents were nucleoside reverse transcriptase inhibitors (NRTIs). This class of therapies includes lamivudine (3TC), stavudine (d4T) and zidovudine (AZT). These agents work by preventing HIV viral replication in infected cells. A second class consists of non-nucleoside reverse transcriptase inhibitors (NNRTIs). These drugs also prevent HIV viral replication, but act at a different binding site than NRTIs. NNRTIs include delavirdine, efavirenz and nevirapine. A third class of anti-AIDS agents consists of protease inhibitors (PI). A

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<sup>46</sup>Centers for Disease Control and Prevention, *HIV/AIDS Surveillance Report: U.S. HIV and AIDS cases reported through June 2000*, Midyear edition Vol. 12, No. 1 (available at [www.cdc.gov](http://www.cdc.gov)).

<sup>47</sup>*Ibid.*

<sup>48</sup>*Ibid.*

<sup>49</sup>See Copson, *supra* note 9.

<sup>50</sup>Stephens, Angela, "AIDS Becomes a National Security Issue," *National Journal* (18 Nov. 2000).

<sup>51</sup>*Ibid.*

<sup>52</sup>"Impact of HAART on AIDS-Related Death Examined," *AIDS Weekly* (24 July 2000).

PI inhibits viral replication by restricting cleavage of key HIV protein precursors. PIs available on the market include amprenavir, crixivan and invirase.

Under current standards, the use of a single one of these medications is disfavored. Such a therapy is believed to have low efficacy and high resistance rates.<sup>53</sup> The favored approach employs three antiretroviral medications in combination. For example, a doctor might prescribe the use of two NRTIs along with one PI, or one NNRTI plus two NRTIs. This “drug cocktail” technique is often referred to as highly active antiretroviral therapy, or HAART. It is believed to be highly effective, maximizing HIV eradication while minimizing the development of resistance to AIDS drugs. Dean Barry R. Bloom of the Harvard School of Public Health observed that these drug combinations have reduced AIDS deaths by 73 %.<sup>54</sup>

Some experts believe that providing HAART to large numbers of people in the developing world will require major health infrastructure improvements. Effective HAART requires supply channels that can make the drugs constantly available and regular monitoring of patients, both to deal with side effects and to adjust medications if drug resistance emerges. Many fear that if the drugs are taken irregularly, resistant strains will emerge that could cause untreatable infections worldwide. Infrastructure improvements are likely to come slowly, however, and the numbers receiving the drugs are expected to remain small, at least initially.<sup>55</sup>

The high costs of antiretroviral drugs have also concerned many observers. For example, Paulo Teixeira, the director of Brazil’s national health program, stated that the “prices of these drugs are beyond the realm of this world.”<sup>56</sup> Patients in developed countries reportedly pay \$10,000 to \$15,000 annually for these medicines.<sup>57</sup> Still, HIV drug therapy is cost effective in extending lives in comparison with treatments for other serious diseases. One recent study showed, for example, that coronary artery bypass surgery and dialysis cost \$113,000 and \$50,000 per life-year saved, respectively.<sup>58</sup>

In response to complaints over high drug prices, as well as other statements of concern, drug manufacturers have agreed to lower prices. For example, on March 7, 2001, Merck & Co. offered to sell both crixivan (a protease inhibitor) and stocrin (a non-nucleoside reverse transcriptase inhibitor) to developing countries at reduced prices. Crixivan would sell for \$600 per patient per year, as compared with \$6,016

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<sup>53</sup>Saunders, Carol S., “A practical update on antiretroviral therapy,” *Patient Care* (15 Jan. 2001).

<sup>54</sup>Bloom, Barry, R., “AIDS: The Drugs Won’t Be Enough,” *Washington Post* (9 Mar. 2001), A27.

<sup>55</sup>See Copson, *supra* note 9.

<sup>56</sup>Buckley, Stephen, “U.S., Brazil Clash Over AIDS Drugs,” *Washington Post* (6 Feb. 2001), A1.

<sup>57</sup>Murphy, John F., “S. African president denies emergency,” *Baltimore Sun* (15 March 2001), 1A.

<sup>58</sup>Centers for Disease Control and Prevention Report, *supra* note 46.

per year in the United States. Stocrin would sell for \$500 per patient per year, as compared with \$4,730 per year in the United States.<sup>59</sup> Other pharmaceutical companies, including Bristol-Myers and Abbott Laboratories, have also agreed to lower the prices of certain medications in the developing world.<sup>60</sup>

These pricing arrangements were achieved at a time when international disputes regarding patents on HIV/AIDS drugs were ongoing in Brazil and South Africa. At the time of the publication of this report, both of these controversies appear to have been resolved. In order to provide additional context to the present debate regarding patents on HIV/AIDS drugs, as well as more specific experiences regarding the interaction between the TRIPS Agreement and domestic patent laws, this report next considers these disputes in turn.

## International Disputes Regarding HIV/AIDS Drug Patents

### Brazil

The Brazilian government has sponsored an anti-HIV/AIDS campaign that, among other components, includes a drug distribution program. Government facilities manufacture seven anti-HIV/AIDS medications, including antiretroviral combination therapies, and distribute them to HIV/AIDS patients free of charge.<sup>61</sup> Many of these medicines are the subject of patent protection in other countries. However, because Brazil did not allow patents to issue on pharmaceuticals prior to its accession to the TRIPS Agreement, these drugs are not subject to Brazilian patent rights. Many observers believe the Brazilian program to be highly successful and should serve as a model for other nations.<sup>62</sup> Brazil has been identified as “the only developing nation that has found a successful formula to combat the AIDS menace.”<sup>63</sup>

In support of its anti-HIV/AIDS program, Brazil has purchased two patented drugs called efavirenz and nelfinavir. U.S.-based Merck & Co. sells efavirenz in the United States under the trademark Stocrin for an annual wholesale price of \$4,730 per patient. U.S.-based Pfizer, Inc. and Switzerland’s Hoffman-La Roche Inc. share rights to nelfinavir. This drug is sold under the trademark Viracept for a wholesale price of about \$7,100 per year in the United States. However, in late 2000, the Brazilian government announced that if the prices of efavirenz and nelfinavir were not

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<sup>59</sup>Nessman, Ravi, “S. Africa: AIDS Drug Need Is Heeded,” *AP Online* (8 March 2001).

<sup>60</sup>Harris, Gardiner, “Adverse Reaction: AIDS Gaffes in Africa Come Back to Haunt Drug Industry at Home,” *Wall Street Journal* (23 April 2001), A1.

<sup>61</sup>Buckley, Stephen, “Brazil Becomes Model in Fight Against AIDS,” *Washington Post* (17 Sept. 2000), A22.

<sup>62</sup>*Ibid.*

<sup>63</sup>Rubin, Trudy, “Brazil sets standard in fight against AIDS,” *Times Union (Albany, New York)* (3 July 2001), A7.



reduced, it would allow Brazilian companies to manufacture the medicines despite any local patents.<sup>64</sup>

Some observers believe that this dispute formed one round in an ongoing discussion between the United States and Brazil regarding a compulsory licensing provision found within the Brazilian patent law.<sup>65</sup> After seven months of unsuccessful negotiations, the United States on January 8, 2001, asked the WTO to form a dispute settlement panel regarding Brazilian patent law. The United States specifically requested the WTO to consider the compatibility of Article 68 of Brazil's 1996 industrial property code with the TRIPS Agreement. According to the United States, Brazilian law imposes a so-called "local working" requirement. Article 68 stipulates that a patent shall be subject to compulsory licensing if the patented invention is not manufactured in Brazil within three years from the date the patent issues.<sup>66</sup>

The Brazilian government countered by charging the United States with its own set of TRIPS Agreement violations before the WTO. On January 31, 2001, the Brazilian government requested consultations with the United States on the compatibility of P.L. 96-517 (commonly known as the "Bayh-Dole Act") with the TRIPS Agreement.<sup>67</sup>

On its face, the U.S. complaint against Brazil seemed to have little to do with public health or access to drugs. The local working requirement of the Brazilian patent law applies to all patented inventions, not just pharmaceuticals. Another provision of the Brazilian patent law, Article 71, permits compulsory licenses for the purpose of addressing national health emergencies. The United States did not challenge Article 71.<sup>68</sup>

Nonetheless, some commentators considered the U.S. WTO complaint to act in opposition to Brazil's anti-AIDS campaign. Mr. Michael Bailey, senior policy advisor at Oxfam, a humanitarian non-governmental organization, reportedly claimed that the U.S. suit is "part of the systematic intimidation of Brazil and developing countries to say if you step out of what we define as the line on intellectual property, we will

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<sup>64</sup>"Merck Brings Down Price of 2 AIDS Drugs in Brazil," *Chicago Tribune* (31 Mar. 2001).

<sup>65</sup>See Buckley, *supra* note 61.

<sup>66</sup>"WTO Dispute-Resolution Panel Will Review Brazil Patent Law," *Generic Line* (9 Feb. 2001).

<sup>67</sup>Capdevila, Gustavo, "Health-Trade: Low-Cost Medicine Debate Grips WTO, WHO," *Inter Press Service* (28 Mar. 2001). The Bayh-Dole Act primarily addresses the distribution of patents resulting from federally-funded research and development performed by outside organizations, and provides for the licensing of government-owned patents. See Congressional Research Service, *Patent Ownership and Federal Research and Development (R&D): A Discussion on the Bayh-Dole Act and the Stevenson-Wydler Act*, by Schacht, Wendy H., CRS Report for Congress RL30320, 11 Dec. 2000.

<sup>68</sup>See Letter to Greg Gonsalves, Director of Treatment Advocacy, Gay Men's Health Crisis, from Joseph Papovich, Assistant United States Trade Representative for Services, Investment and Intellectual Property Rights (9 Feb. 2001).

clobber you in the courts.”<sup>69</sup> An article in the British medical journal *The Lancet* predicted that “if the USA does not withdraw its case, the wrath of the international community will be as furious as in South Africa and make Brazil the moral winner whatever happens.”<sup>70</sup>

This prediction proved prophetic. On June 25, 2001, the United States withdrew its complaint against Brazil. In a joint statement, Brazil and the United States said that they had reached a “mutually satisfactory solution” under which Brazil would consult with the United States prior to invoking the compulsory licensing provisions of Article 68. In addition, the two countries would discuss the matter during bilateral trade discussions scheduled for July 20, 2001.<sup>71</sup>

To the extent that the U.S. action against Brazil concerned pharmaceuticals, observers differ in their estimations of the value of domestic production. Some believe that local production of pharmaceuticals encourages local technical competence and promotes sustained development.<sup>72</sup> Others have expressed concerns that some developing countries may not be able to enforce manufacturing standards in order to ensure the consistent production of reliable drugs. They are concerned that generic drugs that are not manufactured at full strength hold the potential not only to fail the patient, but to foster the growth of drug resistant viruses that are difficult to treat and can be passed on to others.<sup>73</sup>

## South Africa

Alongside events in Brazil, international controversy has centered upon the South African Medicines and Medical Devices Regulatory Act (SAMMDRA).<sup>74</sup> Former South African President Nelson Mandela signed SAMMDRA into law in December 1997. SAMMDRA grants the South African Minister of Health the power to authorize parallel imports and compulsory licenses. Although SAMMDRA is of general application, most of the discussion concerning its provisions has been in the context of antiretroviral drugs for treating AIDS.

The enactment of SAMMDRA initially provoked concerns from the United States Trade Representative (USTR). The USTR voiced concerns that SAMMDRA allowed the South Africa government to issue compulsory licenses on more liberal terms than the TRIPS Agreement allows. Upon receiving assurances from South

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<sup>69</sup>Boseley, Sarah, “Opinion: Pharmaceuticals move their battleground to Brazil to stem the tide of cheaper drugs,” *Irish Times* (20 April 2001), 14.

<sup>70</sup>South Africa’s moral victory,” *The Lancet* (28 Apr. 2001), 1303.

<sup>71</sup>DeYoung, Karen, “U.N. Chief Urges Billions for AIDS,” *Washington Post* (26 June 2001), A1.

<sup>72</sup>t Hoen, Ellen, “Affordable Medicines for Developing Countries,” *WHO/WTO Workshop on Differential Pricing and Financing of Essential Drugs* (8-11 April 2001).

<sup>73</sup>“Inside the Industry AIDS Rx: Experts Question Quality of Foreign Generics,” *American Political Network* (25 April 2001), 9.

<sup>74</sup>Medicines and Medical Devices Regulatory Act, No. 90 (1997) (S. Afr.).

African authorities that SAMMDRA would be applied in a fashion that comported with the TRIPS Agreement, the USTR ceased its objections.

The South African government was also the subject of a lawsuit commenced by the Pharmaceutical Manufacturers Association of South Africa along with 39 international pharmaceutical companies.<sup>75</sup> Filing suit in the Pretoria High Court in 1998, the plaintiffs challenged SAMMDRA in light of the TRIPS Agreement and on a number of other legal grounds. Three years later, in the face of mounting international scrutiny, the plaintiffs opted not to pursue the matter further. On April 19, 2001, the court approved the plaintiffs' request to dismiss the case, effectively ending the litigation.

Reaction to the South African legislation has been mixed. This dispute has attracted many detractors of research-based pharmaceutical companies, including Ramon Castellblanch of Quinnipiac University. Writing in the *Hartford Courant*, Mr. Castellblanch asserted that "no drug-maker's profit on one line of drugs is worth the risk of a holocaust."<sup>76</sup> Publishing in the UK newspaper *The Guardian*, commentator Madeline Bunting has stated: "Put baldly, patents are killing people."<sup>77</sup> A dispatch from the Cuban government stated that "it is unacceptable that commercial interests, technicalities or the desire for profit be pitted against the right of the people to find solutions to disease that constitute a scourge of humanity."<sup>78</sup>

HIV/AIDS patient Andrew Sullivan took a different view in a recent essay published in the Newark, New Jersey *Star-Ledger*.<sup>79</sup> Sullivan observes that the reason a treatment for HIV/AIDS exists is because a free-market system offers financial rewards for medical research. Sullivan's view is that "knockoff companies in India and Brazil . . . are at best copiers of American products and at worst thieves." He closes with the observation that the "American private sector, which has been responsible for the lion's share of HIV/AIDS research, is now offering to pay for 90 percent of the cost of drugs for the developing world at the expense of future profits and research."

Events in Brazil and South Africa underscore the policy trade-offs inherent in meeting two fundamental public health goals: ensuring broad access to existing pharmaceuticals, yet maintaining a research and development pipeline that encourages the introduction of new drugs. In developed nations with established intellectual property laws, the patent system strikes this balance by providing robust but short-term proprietary rights to the research-based pharmaceutical industry. Many commentators believe that this calculus may not be wholly appropriate in a developing

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<sup>75</sup>"South Africa's moral victory," *The Lancet* (28 Apr. 2001), 1303.

<sup>76</sup>Castellblanch, Ramon, "U.S. Should Let Brazil Continue Anti-AIDS Fight," *The Hartford Courant* (9 Mar. 2001), A15.

<sup>77</sup>Bunting, Madeline, "The profits that kill: Dying for drugs," *The Guardian* (12 Feb. 2001).

<sup>78</sup>"Cuba backs Brazil in AIDS drug patent row," *The Marketletter* (12 Mar. 2001).

<sup>79</sup>Sullivan, Andrew, "In defense of drug companies," *Star-Ledger (Newark N.J.)* (25 March 2001), 1.

world that not only faces a public health crisis of unprecedented proportions, but is unaccustomed to rigorous intellectual property laws. Present HIV/AIDS drug patent controversies will also likely hold consequences for the research-based pharmaceutical industry, considerations this report takes up next.

## Issues for the Research-Based Pharmaceutical Industry

Current disputes concerning patents on HIV/AIDS-related medications raise issues concerning public image, public health, research funding and intellectual property for the research-based pharmaceutical industry. Some observers believe that current controversies over HIV/AIDS drugs have cast drug companies in negative light.<sup>80</sup> Other commentators have stated that patent rights place the profits of the pharmaceutical industry over the health of individuals. Another reason for this negative impression, according to the *Wall Street Journal*, is that the HIV/AIDS crisis has caused pharmaceutical companies to lower prices significantly on drugs sold in the developing world.<sup>81</sup> Some critics believe that these price cuts have revealed what they see as overly high profit levels on innovative pharmaceuticals, as well as significant levels of executive compensation, advertising expenditures and marketing outlays.<sup>82</sup>

Supporters of the pharmaceutical industry have responded to these concerns by citing the need of entrepreneurial drug companies to obtain returns on investment and satisfy investors. The pharmaceutical industry further maintains that its profit levels are needed to support costly and time-consuming research and development efforts. If drugs are less profitable to research, develop and market, industry representatives explain, future research and development efforts could be diminished.

Some observers believe that patents have never served as a significant barrier between pharmaceuticals and HIV/AIDS patients. Patents on many HIV/AIDS drugs have not been sought in many developing countries. Research has not revealed a single patent infringement case filed against a health care provider of HIV/AIDS drugs anywhere in the developing world. Even public health activist James Love, director of the Consumer Project on Technology, has observed that “the patent situation in a lot of these African countries is really hard to nail down.”<sup>83</sup>

Events in South Africa may support this observation. Since the pharmaceutical industry’s April 19, 2001 abandonment of its challenge to the South African

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<sup>80</sup>Macken, Julie, “The Growing GM and Drug Disaster,” *Australian Financial Review* (22 Mar. 2001), 41.

<sup>81</sup>See *supra* text accompanying notes 59-60.

<sup>82</sup>Harris, Gardiner, “Adverse Reaction: AIDS Gaffes in Africa Come Back to Haunt Drug Industry at Home,” *The Wall Street Journal* (23 April 2001), A1.

<sup>83</sup>DeYoung, Karen & Brubaker, Bill, “Another Firm Cuts HIV Drug Prices,” *Washington Post* (15 Mar. 2001), A1.

Medicines and Medical Devices Regulatory Act, officials quickly stated that the South African government was unlikely to provide treatments to HIV/AIDS patients in the short term. According to Health Minister Manto Tshabalala-Msimang, South Africa continued to lack the finances and health care infrastructure to distribute antiretroviral drugs.<sup>84</sup> Some commentators have disputed her claims, however, stating that South Africa possesses sufficient resources to commence an anti-HIV/AIDS campaign but lacks the political will to act.<sup>85</sup> Some South Africa authorities have questioned the link between HIV and AIDS, for example, and no government drug program is in place to assist most South African AIDS sufferers.<sup>86</sup>

The HIV/AIDS crisis has nonetheless placed critical accounts of the patent law into the popular press. Some observers believe that adverse public opinion could impact the shape of the TRIPS Agreement itself. The incoming WTO Director-General, Panichadpki Supachai, reportedly has made reform of the TRIPS Agreement a top priority.<sup>87</sup> Some believe that this effort could result in changes to the ground rules of the international patent system before that system has the opportunity to become firmly rooted. It might also lead to broader acceptance of parallel importation as well as easing the conditions under which a WTO member could issue a compulsory license.

Pharmaceutical industry actions that decrease foreign drug prices could lead to diminished sales or lower prices in the United States. Price disparities may encourage individuals to import into the United States low-cost drugs purchased abroad. The availability of lower-cost drugs abroad may also strengthen efforts to obtain drugs more cheaply in the United States. For example, some states are considering measures to control the costs of medicines, including the creation of large drug-purchasing pools. The increased bargaining power of such pools may result in discounts for pharmaceutical purchases.<sup>88</sup>

Such efforts could result in noticeable short-term gains for consumers. Some observers anticipate, however, that these trends hold the potential to inflict significant financial losses for research-based pharmaceutical companies.<sup>89</sup> One mechanism for absorbing these revenue losses would be to increase the price of other products, in particular the price of patented drugs that are not subject to price controls or compulsory licenses. Some commentators believe that this possibility would be

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<sup>84</sup>“No antiretrovirals for S African public sec.,” *The Marketletter* (25 June 2001).

<sup>85</sup>See Beattie, Alan & Pilling, David, “A fund of high hopes and huge obstacles,” *Financial Times* (21 June 2001).

<sup>86</sup>Masland, Tom, “Botswana's Hope; This tiny African nation is leading the war against the AIDS pandemic,” *Newsweek International* (11 June 2001), 71.

<sup>87</sup>Capdevila, Gustavo, “Health-Trade: Low-Cost Medicine Debate Grips WTO, WHO,” *Inter Press Service* (28 Mar. 2001).

<sup>88</sup>See Harris, *supra* note 82.

<sup>89</sup>Singham, Shanker A., “Competition Policy and the Stimulation of Innovation: TRIPS and the Interface Between Competition and Patent Protection in the Pharmaceutical Industry,” 26 *Brooklyn Journal of International Law* (2000), 363.

politically unpalatable in markets where such conditions exist, including the United States. HIV/AIDS patients in the United States may object to paying more for the same medication than their counterparts in other countries.

A second technique that pharmaceutical companies could employ is to reduce expenditures, including advertising, marketing and research and development budgets. Companies might elect to engage in activities with lower associated risk, such as the production of generic drugs. Smaller research and development budgets may lead to the decreased development of new pharmaceuticals. There has also been a significant increase in mergers of enterprises within the pharmaceutical industry. These mergers have been inspired by a desire to reduce costs and to concentrate research and development efforts upon so-called “blockbuster drugs.” This outcome too could lead to an overall reduction in drug development, if competition in innovation is reduced and the incentive to invest substantially in research and development declines.

The conflict between encouraging innovative efforts on one hand, and disseminating the fruits of these labors on the other, has frequently pitted innovators and the user community against one another. But while the debate between drug developers and pharmaceutical users is a familiar one, experience has provided a paucity of rigorous analytical methods for investigating their competing claims. The relationship between innovation and patent rights remains poorly understood. Current economic and policy tools do not allow us to calibrate the patent system precisely in order to produce an optimal level of investment in innovation. As Congress monitors these issues, the debate will likely focus on how best to achieve a balance between contemporary public health needs and a traditional engine of innovation.

## **Legislative Issues and Options**

Legislation addressing some of these issues has been introduced in the 107<sup>th</sup> Congress. To some, the tremendous contributions of the U.S. research-based pharmaceutical industry to the global pharmacopeia suggest that modifications to the patent law should be approached with caution. For others, the unprecedented impact of the HIV/AIDS pandemic, as well as the nascent status of the patent law throughout much of the developing world, demand relaxation of TRIPS Agreement obligations. Should Congress review these issues, legislative options that could contribute to the availability of inexpensive drugs for treating HIV/AIDS in the developing world, yet sustain an environment conducive to pharmaceutical research and development domestically, are explored below.

### **Codify Executive Order 13,155**

One option may be to confirm legislatively an executive order concerning the international intellectual property issues with respect to HIV/AIDS drugs. Events in South Africa prompted a May 10, 2000, executive order from President Bill Clinton. Executive Order 13,155 declared that the United States would not pursue enforcement of intellectual property rights concerning patented HIV/AIDS drugs where infringements make the drugs more readily available in sub-Saharan Africa at lower prices. The executive order stated in part:

In administering sections 301-310 of the Trade Act of 1974, the United States shall not seek, through negotiation or otherwise, the revocation or revision of any intellectual property law or policy of a beneficiary sub-Saharan African country, as determined by the President, that regulates HIV/AIDS pharmaceuticals or medical technologies if the law or policy of the country:

(1) promotes access to HIV/AIDS pharmaceuticals or medical technologies for affected populations in that country; and

(2) provides adequate and effective intellectual property protection consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) . . . .<sup>90</sup>

On February 22, 2001, an official of the U.S. Trade Representative's office said the Bush Administration was not considering any change in current "flexible policy" on this issue.

On March 6, 2001, Senators Diane Feinstein and Russell Feingold introduced a bill that would in part legislatively codify Executive Order 13,155.<sup>91</sup> Titled "Global Access to AIDS Treatment Act of 2001," S. 463 would in part authorize expenditures for enhancing health care systems infrastructure in developing countries; establish a system of educational loan repayments in order to encourage medical professionals to provide HIV/AIDS treatment and care in developing countries; and call for the creation of an international HIV/AIDS pharmaceuticals database.

S. 463 also includes a policy declaration stating that "the United States will not seek, through negotiation or otherwise, the revocation or revision of intellectual property or competition laws or policies that regulate pharmaceuticals or medical technologies used to treat HIV/AIDS or the most common opportunistic infections that accompany HIV/AIDS in any foreign country undergoing an HIV/AIDS-related public health crisis if the laws or policies of that country—(1) promote access to the pharmaceuticals or medical technologies for affected populations; and (2) provide intellectual property protection consistent with the [TRIPS Agreement]."

As exemplified by the U.S. challenge of the Brazilian compulsory license clause, the effect of Executive Order 13,155 has been rather modest. That executive order limits the actions of the United States, and in particular the discretion of the U.S. Trade Representative, to the extent that a foreign patent law complies with the TRIPS Agreement. However, many developing nations and public health nongovernmental organizations wish to launch HIV/AIDS initiatives that may not comply with the TRIPS Agreement. If enacted, S. 463 might prevent the United States, and in particular the U.S. Trade Representative, from seeking additional commitments from other nations beyond those stated within the TRIPS Agreement. Otherwise S. 463 appears to confirm the balance of rights and responsibilities reached in the TRIPS Agreement.

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<sup>90</sup>Executive Order 13,155 (10 May 2000).

<sup>91</sup>Coile, Zachary, "Bill Would Boost Access to AIDS Drugs," *The San Francisco Chronicle* (7 March 2001), A5.

## Exemptions from International Obligations

On March 7, 2001, Representative Maxine Waters introduced H.R. 933, titled the “Affordable HIV/AIDS Medicines for Poor Countries Act.” Among other provisions, the bill would prohibit the U.S. Trade Representative from initiating a proceeding before the World Trade Organization challenging laws that promote access to HIV/AIDS pharmaceuticals or medical technologies for the population of the country. H.R. 933 would also direct the U.S. representative at the WTO to urge an exemption for “developing countries, including sub-Saharan African countries, from the application of any provision of the [TRIPS Agreement], or the application of any provision of any other international agreement relating to intellectual property rights, that would prohibit or otherwise restrict those countries from establishing or implementing any law or policy that promotes access to HIV/AIDS pharmaceuticals or medical technologies to their populations.”

One difference between S. 463 and H.R. 933 is that the House bill would require the United States to forgive certain violations of the TRIPS Agreement. In contrast, S. 463 supports foreign patent laws and policies regarding HIV/AIDS treatments only to the extent that they comply with the TRIPS Agreement. A consequence of this distinction is that H.R. 933 would effectively limit the actions the United States could commence before the WTO Dispute Settlement Body. Because intellectual property-based WTO actions necessarily involve claims of TRIPS Agreement violations, however, S. 463 would not limit the sorts of actions that the United States could bring before the WTO.

## Differential Pricing

During an April 2001 conference jointly sponsored by the WTO and World Health Organization, some observers announced their views that differential pricing would best balance the needs of AIDS patients and the research-based pharmaceutical industry.<sup>92</sup> Differential pricing potentially allows companies that make patented drugs to recover most of the costs of research and development in richer markets and at the same time sell or license production at lower prices in developing countries.<sup>93</sup>

Ellen ‘t Hoen, legal advisor for the international organization Médecins Sans Frontières, has raised objections to a differential pricing regime. According to Ms. ‘t Hoen, differential pricing does not guarantee that the drugs will be priced at the lowest possible level and will be available on a predictable, long-term basis. Ms. ‘t Hoen has also articulated concerns that differential pricing does not encourage sustainability, e.g., local production, in the developing world.<sup>94</sup>

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<sup>92</sup>See Otten, Adrian, “Closing remarks,” *WHO/WTO Workshop on Differential Pricing and Financing of Essential Drugs* (8-11 April 2001).

<sup>93</sup>See Congressional Research Service, *The Cost of Prescription Drugs for the Uninsured Elderly and Legislative Approaches*, by Resources, Science, and Industry Division, CRS Report for Congress RL30373, 16 Jan. 2001.

<sup>94</sup>‘t Hoen, *supra* note 72.



In addition to these fundamental objections, several practical difficulties attend the proposed differential pricing system. Experience teaches that generic drugs sold in one part of the world may readily find their way into another. In particular, domestic laws that support parallel importation encourage the availability of grey market goods. Such arbitrage could cut into those markets that are supposed to provide the profits that support research and development. Some observers are concerned that this proposal might also require poor patients in the developed world to subsidize rich patients in the developing world.<sup>95</sup>

For some persons, another pragmatic concern with a differential pricing regime is that low drug prices in one country may spread to other countries.<sup>96</sup> Authorities in Canada, Italy, the Netherlands and other nations regulate local prices in part based on international comparisons. If these comparisons involved developing countries, then there is a possibility of substantially diminished drug prices in the developed world as well. Of course, some pharmaceutical consumers and other individuals would likely view this effect as a positive development.

If Congress believes differential pricing to be an appropriate policy, it could take steps to encourage this regime. These might include discouraging parallel importation by clarifying U.S. patent law on this point and encouraging other nations to take similar steps; more effective border controls could be established in order to control the importation of drugs designated for the developing world; and discouraging regulation based upon foreign pharmaceutical prices.

## Market Segmentation

Congress could also consider the recent proposal of economist Jean Lanjouw of Yale University. Ms. Lanjouw has suggested that drug companies ought to elect whether to procure and enforce patents in either the developed or developing world.<sup>97</sup> This scheme takes advantage of current patent laws that require drug companies that perform research activities in the United States to seek a so-called “foreign filing license” from the USPTO prior to seeking foreign patent rights.<sup>98</sup> The foreign filing licensing regime has traditionally allowed appropriate authorities to determine whether the invention contains information that implicates national security or other interests prior to its exportation.<sup>99</sup>

Ms. Lanjouw’s proposal would expand the function of a foreign filing license. In exchange for the grant of a foreign filing license, the U.S. government would

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<sup>95</sup>Phillips, Michael M., “AIDS-Drug Plan Envisions 2 Markets for Firms’ Patents,” *The Wall Street Journal* (13 June 2001), A2.

<sup>96</sup>Danzon, Patricia M., “Differential Pricing: Reconciling R&D, IP and Access,” *WHO/WTO Workshop on Differential Pricing and Financing of Essential Drugs* (8-11 April 2001).

<sup>97</sup>Phillips, *supra* note 95.

<sup>98</sup>35 U.S.C. §§ 181-188.

<sup>99</sup>Hausken, Gary L., “The Value of a Secret: Compensation for Imposition of Secrecy Orders under the Invention Secrecy Act,” 119 *Military Law Review* (1988), 201.

require pharmaceutical companies to elect whether to obtain patent rights in either the developed or developing world. Ms. Lanjouw hypothesizes that a company with a new malaria drug might elect to enforce patent rights in the developing world, because that is where most cases of malaria arise. But a company with a new HIV/AIDS drug would likely prefer to elect the developed world, Ms. Lanjouw explains, since that is where sales of such a drug would prove most profitable. If the foreign filing licensee violated its agreement, the licensee's U.S. patent would be rendered unenforceable.<sup>100</sup>

Some practical implementation issues arise with respect to Ms. Lanjouw's proposal. The developing world also has yet to establish a track record of pharmaceutical patent enforcement. As a result, there may be few takers of Ms. Lanjouw's option to relinquish patent rights in the developed world. Such a trend would effectively encourage drug companies to produce medicines for diseases suffered by residents of the developed world, offering few prospects for individuals who suffer from diseases common only in the developing world.

If the United States were the only nation to pursue the Lanjouw proposal, domestic entrepreneurs would also appear to suffer a disadvantage not shared by foreign competitors. Absent this policy, others would be free to both acquire and enforce patents everywhere. This initiative could, at an extreme, cause relocation of research and development activities outside the United States. As a result, such a strategy, if deemed useful, might be more appropriate for international agreement than unilateral action.

## **Global Settlement**

Another policy option would be encouragement of a global, negotiated settlement among the relevant actors. Congress might encourage a global, negotiated settlement between pertinent entrepreneurial pharmaceutical companies and those countries seeking increased access to HIV/AIDS pharmaceuticals. Such a settlement could allow these actors, including the United States, to avoid proceedings before the WTO Dispute Settlement Body. It also holds the potential to reduce the transaction costs associated with individual dispute settlement and diminish disparities of drug pricing and availability among different developing countries.

## **Humanitarian Aid**

African heads of state, meeting in Abuja, Nigeria, on April 26-27, 2001, declared an AIDS state of emergency on the continent and called for the creation of a Global AIDS fund backed by contributions of \$5 billion to \$10 billion annually. United Nations Secretary General Kofi Annan, returning from Abuja, told an April 30, 2001 meeting of the Council of Foundations in Philadelphia that a global "war chest" funded at \$7 billion to \$10 billion per year was needed to fight HIV/AIDS. On May 11, 2001, President Bush made what he termed a "founding contribution" of \$200 million to this war chest, which would also be used to fight malaria and tuberculosis.

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<sup>100</sup>Phillips, *supra* note 95.

At the time this report was published, significant congressional activity was directed towards authorizing heightened levels of U.S. contributions to this global fund.<sup>101</sup>

## Appropriate Incentives for Pharmaceutical Companies

In addition to subsidizing medical care in the developing world, Congress might also consider offering additional incentives to pharmaceutical companies in order to conduct HIV/AIDS research and distribute the results of this research to the developing world. A number of existing measures already appear to contribute to this goal, including laws that enable the transfer of patent rights resulting from government-sponsored research to the private sector;<sup>102</sup> offer a tax credit for research and experimentation;<sup>103</sup> and provide tax advantages when pharmaceutical companies make the charitable donations of medications.<sup>104</sup> In light of increasing recognition of the HIV/AIDS pandemic, Congress may wish to consider augmenting existing programs or supplementing them with additional incentives for private enterprise to engage in research and development.

## Concluding Observations

A central challenge raised by the impact of HIV/AIDS is the treatment of HIV/AIDS victims with advanced medications. The HIV/AIDS crisis may also challenge the ability of the patent law to provide an environment conducive to the development of new drugs. Achieving a balance between the needs of the research-based pharmaceutical industry, and those of HIV/AIDS patients, entails a careful weighing of moral, legal, economic and public health considerations. Humanitarian aid, encouragement of differential pricing and more precise specification or relaxation of TRIPS Agreement standards are among the options that Congress could consider in responding to the HIV/AIDS pandemic.

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<sup>101</sup>DeYoung, Karen, "U.N. Delegates Agree on AIDS Declaration," *Washington Post* (27 June 2001), A20.

<sup>102</sup>Congressional Research Service, *Patent ownership and federal research and development (R&D): A discussion on the Bayh-Dole Act and the Stevenson-Wydler Act*, by Wendy H. Schacht, RL 30320, Dec. 11, 2000.

<sup>103</sup>Congressional Research Service, *The Research and Experimentation Tax Credit: Current Law and Selected Policy Issues for 106<sup>th</sup> Congress*, by Gary Guenther, RL 30479, Jan. 23, 2001.

<sup>104</sup>See Crimm, Nina J., "A Tax Proposal to Promote Pharmacologic Research, to Encourage Conventional Prescription Drug Innovation and Improvement, and to Reduce Product Liability Claims," 29 *Wake Forest Law Journal* (1994), 1007.