THE U.S. PUSH FOR WORLDWIDE PATENT PROTECTION FOR DRUGS MEETS THE AIDS CRISIS IN THAILAND: A DEVASTATING COLLISION

Rosemary Sweeney†

Abstract: In response to pressure from the United States, Thailand amended its Patent Act in 1992 and 1999 to provide patent protection for drugs and to limit its control on the pricing, importation, and compulsory licensing of patented drugs. These amendments and, perhaps even more importantly, the threat of U.S. trade sanctions, will probably ensure continued high prices and thus restricted access to new, patented Acquired Immune Deficiency Syndrome ("AIDS") drugs in Thailand. These drugs have dramatically changed the length and quality of life of patients infected with Human Immunodeficieny Virus ("HIV") in developed countries. About one million Thais are infected with HIV, but few have the resources to pay for these drugs. The U.S. pressure on Thailand to provide strong patent protection for drugs has undermined Thailand's ability to combat its AIDS epidemic. The United States should allow Thailand to manufacture less-expensive generic copies of patented AIDS drugs without imposing trade sanctions for this annulment of the intellectual property rights of drug companies. If the United States and Western Europe could prevent the import of these generic copies of AIDS drugs, which would entail only the enforcement of existing laws, it could protect the primary markets that the pharmaceutical companies were relying on when the new AIDS drugs were developed. Thus, the price of AIDS drugs in Thailand could be lowered, making them accessible to more HIV-infected Thais, without destroying the economic incentives of drug companies to develop new AIDS drugs.

I. INTRODUCTION

As Thailand struggles with an Acquired Immune Deficiency Syndrome ("AIDS") epidemic,1 U.S. economic pressure has resulted in amendments to Thailand's Patent Act that provide for strict patent protection for drugs.2 These amendments and, perhaps more importantly, the threat of...

† The author would like to thank Professors Toshiko Takenaka and Mike Townsend of the University of Washington for comments, discussions, ideas, and encouragement; Chayatawatch Atibaedya of Anek & Brischon Co. Ltd. in Bangkok for his assistance in understanding the meaning and substance of the amendments to the Thai Patent Act; Say Sujintaya of Tilleke & Gibbins for sending an English translation of the 1998 amended version of the Thai Patent Act; Orakanoke Phanraksa, a Thai LL.M. student at the University of Washington, for her help with understanding Thailand and its laws; Tom Moran of Cooley Godward for his comments on the viewpoint of the drug industry with respect to protection of intellectual property; and Mark Ahn of Bristol-Myers Squibb for his insights into the role of drugs in fighting the AIDS crisis.


U.S. trade sanctions, will ensure continued high prices for patented drugs. Effective, but expensive, patented drugs have dramatically changed the length and quality of life of patients infected with Human Immune Deficiency Virus ("HIV"), the virus that causes AIDS, in developed countries during the past four years.¹ Most HIV-infected Thais are unable to benefit from these drugs because of their expense.² Although Thailand has not produced less-expensive generic versions of these drugs, it could arguably do so legally under its domestic laws and a recent international agreement. The reasons for Thailand's failure to do this may be complex, but fear of U.S. economic sanctions is probably a major consideration.³

AIDS emerged in Thailand in the mid-1980s and spread rapidly.⁴ In 1984, the first case of AIDS was reported in Thailand,⁵ and by the early 1990s an AIDS epidemic had taken hold.⁶ Currently, an estimated one million people in Thailand are infected with HIV.⁷ AIDS is a crisis in Thailand; three percent of the population is currently infected,⁸ and AIDS is now the leading cause of death.⁹ Several hundred children have already been orphaned by this epidemic, and this number is expected to increase. The situation is particularly severe in the northern and northeastern parts of the country, where more than half of Thailand's HIV-infected citizens live.¹⁰

Protease inhibitors¹¹ are new AIDS drugs that came into widespread use in 1996 in the United States¹² as part of a triple drug therapy that

---

⁴ Sivaraman, supra note 1.
⁵ Id.
⁶ Id.
⁷ Id.
⁸ Id.
⁹ See Crispin, supra note 4.
¹¹ Moreau, supra note 1.
¹² Sivaraman, supra note 1.
¹³ Protease inhibitors inhibit the activity of an HIV-encoded protein that is essential for the production of infectious virions. Christopher D. Holzer & Michelle Roland, The Use of Combination Antiretroviral Therapy in HIV-Infected Patients, 33 ANN. PHARMACOTHER. 198, 200 (1999).
¹⁴ Id. at 205.
includes two different nucleoside analogs and a single protease inhibitor. This is now the standard of care in developed countries and has significantly prolonged life and delayed the progression to AIDS symptoms in HIV-infected patients in these countries. Protease inhibitors came into widespread use in the United States in 1996. AIDS deaths in the United States dropped twenty-three percent between 1995 and 1996, another forty-two percent between 1996 and 1997, and a further twenty percent between 1997 and 1998. Unfortunately, these drugs also have unpleasant side effects, require adherence to a strict schedule of administration, and cost $12,000 per year. In Thailand, citizens and nongovernmental organizations have appealed to the government to make AIDS drugs more affordable, but only a very small percentage of HIV-infected Thais receive these drugs. U.S. pressure on Thailand to protect drug patents has made it difficult for most HIV-infected Thais to obtain access to AIDS drugs.

15 Nucleoside analogs indirectly interfere with the activity of the HIV RNA-Dependent DNA polymerase by terminating further insertion of nucleotides into an elongating chain of viral DNA. Id. at 199.

16 Moyle & Gazzard, supra note 3, at 299 (1999).

17 "Developed" is a term used to refer to wealthy countries such as the United States, Japan, or a Western European country. A. P. THIRLWALL, GROWTH AND DEVELOPMENT 20-28 (2d ed. 1977). It is not suggested that this is the only definition of "developed." See generally TOWARDS A RE-DEFINITION OF DEVELOPMENT (Alain Birou et al. eds., 1977).

18 Moyle & Gazzard, supra note 3, at 300, 304 (1999); Bynum, supra note 3. However, triple drug therapy does not work for all patients, and its long-term effects are unknown. Holtzer & Roland, supra note 13, at 199, 207.

19 Holtzer & Roland, supra note 13, at 205.

20 Id.

21 Bynum, supra note 3.

22 Id.

23 These side effects include nausea, vomiting, and redistribution of body fat from the extremities to the body trunk. Moyle & Gazzard, supra note 3, at 308-11.

24 Patients may be taking up to 40 pills per day, taking medication every two to three hours over a span of 16 hours. Some doses must be taken with food and some on an empty stomach. Holtzer & Roland, supra note 13, at 198, 206-07.


27 A study of 2,000 HIV-infected patients at Bamrasnaradul Hospital indicated that one percent of these patients were receiving triple drug therapy. Sakboon, supra note 4. See also Crispin supra note 4.
patent confers the right to exclusively market the patented product for a limited time.\textsuperscript{28} Since a patentee has a temporary monopoly, the patentee normally charges a higher price than it could in a competitive market. This allows the patentee to recover research and development costs. Therefore, products protected by patent are often more expensive than those that are not. In the pharmaceutical industry, where the cost of research and development is especially high,\textsuperscript{29} the difference in price between patented drugs and generic copies can be large.\textsuperscript{30} The price of a patented drug can usually be substantially reduced by the production of generic copies because production costs are often far lower than the prices set by the patentee.\textsuperscript{31}

This Comment discusses the U.S. actions that have contributed to Thailand's failure to make AIDS drugs available to its HIV-infected citizens at affordable prices. Part II examines the current law governing the protection of drugs as intellectual property in Thailand. Part III discusses the U.S. actions that precipitated the amendments to Thailand's Patent Act. Part IV argues that by enforcing existing U.S. laws against importing patented drugs, the United States could allow developing countries such as Thailand to make less-expensive generic copies of patented AIDS drugs without threatening the lucrative U.S. market for these drugs. This solution would make less-expensive drugs available in Thailand without destroying the incentives for pharmaceutical companies to develop new AIDS drugs.

II. LAWS GOVERNING PATENT PROTECTION FOR DRUGS IN THAILAND

Patent protection for drugs in Thailand is governed by Thailand's Patent Act\textsuperscript{32} and its obligations under the Agreement for Trade Related Aspects of Intellectual Property Rights ("TRIPs"), which came into effect in

\textsuperscript{28} FRITZ MACHLUP, AN ECONOMIC REVIEW OF THE PATENT SYSTEM 6, 9 (Subcomm. on Patents, Trademarks, and Copyrights of the Senate Comm. on the Judiciary, Study No. 15, 85th Cong., 2d Sess. (GPO, 1958)), at 6.


\textsuperscript{31} Id.

\textsuperscript{32} 1999 Act, supra note 2.
In 1992 and 1999, Thailand amended its Patent Act in response to U.S. economic pressure. Under Thailand’s previous Patent Act, which was passed in 1979, drugs did not receive patent protection. The 1992 amendments provided patent protection for drugs for the first time in Thailand but provided liberal opportunities for compulsory licensing and parallel importing, thereby softening the impact of patent protection on drug prices. However, the 1999 amendments significantly narrowed opportunities for compulsory licensing and virtually eliminated parallel importing. TRIPs, on the other hand, arguably leaves the decision on parallel importing to the discretion of each signatory country and provides for compulsory licensing in specific sets of circumstances, which are different from those that allow compulsory licensing under Thailand’s current Patent Act.

A. The Nature and Limits of Patent Protection

Under many legal regimes worldwide, new inventions with practical utility are protected with patents, which give the inventor the right to exclude unauthorized persons from commercially using the patented product for a limited time. Unauthorized copiers of the patented product can be

---


34 1992 Act, supra note 2; see infra notes 143-169 and accompanying text.


36 1992 Act, supra note 2, §§ 3, 55 bis.

37 A compulsory license is a grant by a patent-issuing government to a third party of the right to make, use, or sell a patented product without the patent holder's consent. MARTIN J. ADELMAN ET AL., PATENT LAW 1235 (1998).

38 Parallel importing is the practice of buying a patented product in one country and reselling it in a second country. If the price of a drug is less in the first country than it is in the second, the parallel importer will sell the product at a lower price than the patentee in the second country. Patented drugs are sometimes sold at different prices in different countries by patentees and are always sold at lower prices by copiers in countries with no patent protection for drugs. Blood and Gore: Office of the US Trade Representative Goes Too Far in Promoting Interests of US Drug Companies Abroad, NATION, July 19, 1999, at 16 [hereinafter Blood and Gore].

39 That is, Sections 46 bis and 55 bis (2) were eliminated in the 1999 Act. Compare 1992 Act, supra note 2, with 1999 Act, supra note 2.

40 1999 Act, supra note 2, § 36(7).

41 See infra notes 95-103 and accompanying text.

42 TRIPs, supra note 33, art. 31.

43 1999 Act, supra note 2, pt. V.

44 MACHLUP, supra note 28, at 6, 9.
stopped by an infringement suit. This system offers economic incentives to inventors to produce new products because their monopoly allows them to charge a premium price for their product, recoup their investment in research and development, and earn a profit. Without this protection, copiers can undersell the inventor because the copiers have no need to recoup research and development costs. With current levels of patent protection for drugs worldwide, it is estimated that pharmaceutical companies lose between one and five billion dollars per year from the unauthorized copying of patented drugs.

A patentee’s rights can be limited in some situations. In the United States, judges have the power to deprive a patentee of her monopoly should enforcement of a patent endanger public health. Such a judicial or governmental annulment of patent rights is called a compulsory license. If a country issues a compulsory license for a particular patented drug, or if it provides no patent protection for drugs, there is nothing that prevents citizens of that country from producing that drug, typically at a much lower price.

The practice of parallel importing can also erode a patentee’s rights. Parallel importing occurs when a distributor buys a product in a country where it is sold at a low price, with or without patent protection, and resells it without authorization in a second country in direct competition with the patentee or authorized distributor. Parallel importers normally sell the product for less than the patentee. Parallel importing is generally

---

46 MACHLUP, supra note 28, at 33.
49 ADELMAN ET AL., supra note 37, at 1235.
50 Love, supra note 20.
forbidden in developed countries\textsuperscript{53} and has been the subject of intense international debate.\textsuperscript{54}


1. Drugs Are Patentable

In 1992, Thailand amended its Patent Act to provide patent protection for pharmaceuticals for the first time.\textsuperscript{55} Patent protection became available for any invention.\textsuperscript{56} According to the 1992 Patent Act, "any innovation or invention which creates a new product or process, or any improvement of a known product or process" is patentable.\textsuperscript{57} Part VII of the Patent Act, which deals exclusively with drug patents, confirms that this broad definition includes drugs.\textsuperscript{58}

2. Compulsory Licensing

In addition to providing patent protection for drugs, the 1992 amendments created a Pharmaceutical Patents Board ("Patents Board"), which had the power to initiate proceedings that could lead to the compulsory licensing of drugs.\textsuperscript{59} The Patents Board may have been created to mitigate the domestic political consequences of the 1992 amendments, which were unpopular.\textsuperscript{60} The Patents Board, which consisted of government officials and appointees,\textsuperscript{61} supervised drug patent holders to ensure that Thailand received patented drugs in adequate quantities and at reasonable prices.\textsuperscript{62} If patent holders did not comply, the Patents Board could initiate proceedings that would culminate in a compulsory license.\textsuperscript{63} The Patents Board also had the power to require drug companies to submit information

\textsuperscript{53} Harold C. Wegner, Parallel Imports of Patented Goods Killing the Technology Transfer Goose, 14-18, 23 (Presentation at the Fordham University School of Law, Sixth Annual Conference on International Intellectual Property Law & Policy, Apr. 16-17, 1998) (on file with author).

\textsuperscript{54} See generally id.

\textsuperscript{55} 1992 Act, supra note 2, §§ 3, 55 bis.

\textsuperscript{56} Id. § 3.

\textsuperscript{57} Id.

\textsuperscript{58} Id. § 55.

\textsuperscript{59} Id. §§ 46 bis, 55 bis-septem.


\textsuperscript{61} 1992 Act, supra note 2, § 55 ter.

\textsuperscript{62} Id. §§ 55 bis, 55 ter, 55 quarter.

\textsuperscript{63} Id. §§ 55 quinque, 46 bis.
concerning production costs and pricing, information that drug companies are loathe to divulge and that can be crucial in determining whether a drug is reasonably priced. The 1999 amendments narrowed the rights of the government to issue compulsory licenses. Under both the 1992 and 1999 amendments, when “no product [is] produced under the patent for sale in any domestic market, or there are some but they are sold at unreasonably high prices or do not meet the public demand without any legitimate reason,” then a compulsory license can be issued for that product. Under the 1992 Act, such a compulsory license could be issued either upon an uninvited application of a prospective licensee or by an application in response to an announcement of the Director-General of the Department of Intellectual Property inviting applications for a compulsory license. The 1999 amendments eliminated the Director-General’s power to issue a public invitation for compulsory license applications. The Patents Board, which had the power to require the disclosure of the production costs of drugs, was also eliminated by the 1999 amendments. Without the Patents Board, it could be difficult to determine whether a drug’s price is unreasonable, a determination that justifies the issuance of a compulsory license. These changes greatly decrease the likelihood that compulsory licenses will be issued in Thailand for patented drugs.

64 Id. § 55 bis. Interestingly, by 1993 the Thai government was already considering adjusting the role of the Pharmaceutical Patents Board and assigning the Committee on Price Fixing and Anti-Monopoly to control drug prices instead. British Broadcasting Corporation, USA-Protection for Foreign Patented Medicine Planned, Mar. 31, 1993, available in LEXIS, News Library, Asia/Pacific Rim Stories.
65 Glaxo-Wellcome, a large drug company, refused to disclose the cost of manufacturing AZT. See Alex Duvall Smith, Focus AIDS: A Continent Left to Die: the AIDS Virus Will Kill 30 Million Africans in the Next 20 Years. Are the Drug Companies Making the Situation Worse?, INDEPENDENT, Sept. 5, 1999, at 16.
67 1992 Act, supra note 2, § 46(2); 1999 Act, supra note 2, § 46(2).
68 1992 Act, supra note 2, §§ 46, 46 bis.
69 That is, this aspect of the 1992 Act was eliminated by the 1999 Act. Compare id. with 1999 Act, supra note 2.
70 See 1992 Act, supra note 2, § 55 bis.
71 That is, Section 55 bis (2) of the 1992 Act was eliminated in the 1999 Act. 1999 Act, supra note 2.
72 1999 Act, supra note 2, § 46.
3. **Parallel Importing**

The 1992 Patent Act is ambiguous on the subject of parallel importing. Parallel importing is the practice of importing a product bought in one country into a second country where the product is protected by patent and often sold by the patentee at a much higher price.\(^7\) The 1992 Patent Act provides that the patentee has the exclusive right to “produce, use, sell, possess for sale, offer for sale or import” the patented product.\(^4\) It is, however, ambiguous on the subject of exhaustion of these rights. Exhaustion of intellectual property rights refers to the point at which a patentee’s rights end.\(^5\) The key issue is whether one who legally buys a patented product remains under some limitation on what she can do with this product. The 1992 Patent Act provides that “any act connected with products acquired in good faith” is exempt from an assertion of infringement by the patent holder.\(^6\) This language suggests that parallel importing might be tolerated because less-expensive drugs bought in a country with or without patent protection for drugs could arguably be acquired in good faith.

In contrast to the 1992 amendments, the 1999 amendments clearly forbid the importation of generic copies of patented drugs made without the patentee’s consent.\(^7\) In 1999, the exemption of importers of “products acquired in good faith” from infringement suits was narrowed. Currently, the exception only applies if the original sale or manufacture of the imported products was consented to by the patentee.\(^7\) Therefore, importation of generic copies, even from countries where generic production is legal because drugs are not protected by patents, was forbidden by the 1999 amendments.

In making these two sets of amendments, Thailand has radically changed its patent policies with respect to drugs. Before the amendments, Thailand offered no patent protection for drugs,\(^8\) and it was therefore legal to make and sell or to import any drug patented in another country without compensating the owner of the foreign patent. Now a patent can be obtained for a drug in Thailand.\(^8\) Under current Thai law, it constitutes infringement

---

\(^7\) Barfield & Groombridge, *supra* note 51, at 185.
\(^5\) ADELMAN ET AL., *supra* note 37, at 1284-86.
\(^6\) 1992 Act, *supra* note 2, § 36(3).
\(^7\) 1999 Act, *supra* note 2, § 36(7).
\(^8\) 1992 Act, *supra* note 2, § 36(3).
\(^0\) Tilleke & Gibbins R.O.P., *supra* note 66.
\(^1\) 1999 Act, *supra* note 2, § 3.
to make or sell a drug patented in Thailand unless a license is obtained from
the patentee or the government issues a compulsory license. It is also
illegal to import inexpensive generic copies of a drug patented in Thailand if
the drug is made in another country without the patentee’s consent. Thus,
the only legal avenue open to obtain a patented drug at inexpensive prices is
that of a compulsory license issued by the Thai government.

C. TRIPS: An International Standard for the Protection of Intellectual
Property

TRIPS imposes minimum standards for the protection of intellectual
property on signatory states in exchange for most-favored-nation treatment
by all other signatory states with regard to the protection of intellectual
property, as well as a vague assurance to developing countries that
technology will be transferred to them. In a sense, TRIPS serves as a
yardstick against which intellectual property laws are measured, since
signatory states must, if necessary, alter their domestic laws and practices to
make them consistent with TRIPS. Although TRIPS is a product of
multilateral negotiation, the inequities inherent in the different bargaining
positions of developed and developing countries is apparent in the TRIPS
agreement, which largely serves the interests of corporations from developed
countries. However, TRIPS does include some concessions to developing
countries.

---

82 See id. §§ 45-52.
83 Id. § 36(7).
84 The 1993 Uruguay Round of multilateral trade negotiations produced TRIPs, and both Thailand
and the United States are signatory states. See Myles Getlan, TRIPs and the Future of Section 301: A
85 TRIPs, supra note 33, art. 4.
86 Id. art. 66(2).
87 Id. art. 1(1).
88 “[M]any public interest advocates generally believe the TRIPs agreement inappropriately favors
 corporations.” Africa Policy Information Center, Africa-at-Large: AIDS Drugs Policy, AFRICA NEWS,
Sept. 7, 1999, available in LEXIS, News Library, News, Documents & Commentary; see also McCabe,
supra note 29, at 67 n.1.
89 See TRIPs, supra note 33, arts. 6 (does not address the issue of exhaustion of intellectual property
rights), 27(2), (3) (allows signatory states to exclude some subject matter from patentability), 31(b)
(provides for the issuance of compulsory licenses in some situations), 41(5) (places no obligation on
signatory states to put in place a judicial system specifically for the enforcement of intellectual property
rights), 65-67 (gives developing countries additional time to implement TRIPs and encourages developed
countries to transfer technology to developing countries).
1. **TRIPs Requires Patent Protection for Pharmaceuticals**

As a signatory of TRIPs, Thailand is required to provide patent protection for inventions "in all fields of technology." An exception to this provision is that patents need not be granted for "diagnostic, therapeutic, and surgical methods for the treatment of humans and animals." Although this phrase could be construed to mean that drugs need not be protected by patents, Article 70(8) of TRIPs requires member countries to set up a means of collecting applications for pharmaceutical patents, suggesting that pharmaceuticals are protected under TRIPs. The rights granted under the patent must include the right to prevent third parties from making, using, offering for sale, selling, or importing the product without the consent of the patentee. As of 1992, Thailand's laws met this requirement.

2. **TRIPs Is Ambiguous on Parallel Importing**

Parallel importing generated so much disagreement in the TRIPs negotiations that this issue was specifically left unresolved in TRIPs. Under Article 6 of TRIPs "nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights." On its face, this provision seems to leave the decision of whether to permit parallel importing to each individual country. If a country decides that the first sale of a product anywhere in the world exhausts the rights of a patentee, then parallel importing is allowed. If a country decides that it is, rather, the first sale of the product within the country in which it is patented that exhausts the patentee’s rights, then parallel importing is not allowed. However, there is debate about the meaning of this provision given the dual purposes of TRIPs to promote unfettered world trade and to promote the protection of intellectual property rights. Furthermore, a patentee’s exclusive right under TRIPs “to prevent third parties not having his consent from the acts

---

90 *Id.* art. 27(1). Thailand must comply with TRIPs by either 2000, if it takes no special action, or by 2006, if it applies for and is granted least-developed member country status. *Id.* arts. 65-66.
91 *Id.* art. 27(3)(a).
92 See Foster, supra note 47, at 290 (citations omitted).
93 TRIPs, supra note 33, art. 28(1)(a).
94 1992 Act, supra note 2, §§ 1-23, 55 bis-septem.
95 Barfield & Groombridge, supra note 51, at 190; TRIPs, supra note 33, art. 6; see also supra note 38 for a definition of parallel importing.
96 TRIPs, supra note 33, art. 6.
98 *Id.*
99 Barfield & Groombridge, supra note 51, at 191-93.
of: making, using, offering for sale, selling or importing" might be construed as being in conflict with Article 6. However, a footnote to this provision states that it is subject to the provisions of Article 6. Moreover, even the European Union, whose members are highly developed countries, practices a limited form of parallel importing. On the other hand, the effect of the laws of the United States and Japan is to prohibit parallel importing.

3. TRIPs Allows Compulsory Licensing in National Emergencies

Under TRIPs, a country that grants a patent on a product may grant a third party the right to produce this patented product without the patent holder’s consent in some situations. Such compulsory licensing can reduce prices of drugs by as much as ninety-five percent. Under TRIPs, if "the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and . . . such efforts have not been successful within a reasonable period of time," and if "the right holder [is] paid adequate remuneration," a compulsory license can be issued. This requirement may be waived in "the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use" as long as the right holder is informed as soon as possible and remunerated. Any compulsory license is limited to the

---

100 TRIPs, supra note 33, art. 28(1)(a).
101 Id. art. 28(1)(a) n.6.
102 The first sale of a product in any European Union member country exhausts the patentee's rights. For example, if a patented drug is first sold in Spain, the patentee's rights within the European Union end with this sale. The same drug can then be legally resold anywhere in the European Union by anyone who purchased the drug in Spain. Since drugs are sold at far lower prices in Spain and Portugal than they are in the rest of Europe due to government price controls, this rule allows all of Europe to benefit from these price controls. Great Britain and the Netherlands take advantage of this situation to obtain cheaper drugs. Karine Cunqueiro, Health Trade: Hostile AIDS Activists Target Gore, INTERPRESS SERVICE, July 18, 1999, available in LEXIS, News Library. However, the sale of a patented product outside the European Union does not exhaust the patentee's rights within the European Union. For example, if a drug is protect-ed by patent in France and a generic copy of this drug is bought in India, the buyer of the Indian generic copy cannot resell it in France without the patentee's consent. However, if he does obtain the patentee's permission and does sell the drug in France, any buyer can legally resell the drug anywhere in the European Union without the patentee's consent. Wegner, supra note 53, at 12.
104 TRIPs, supra note 33, art. 31.
105 Love, supra note 30.
106 TRIPs, supra note 33, art. 31(b).
107 Id. art. 31(h).
108 Id. art. 31 n.7.
109 Id. art. 31(b).
purpose for which it is authorized and is non-exclusive and non-assignable. These conditions differ from the conditions under which a compulsory license can be granted under Thailand’s Patent Act, a discrepancy that might be significant should Thailand try to impose compulsory licenses on holders of drug patents.

4. **The Thai Patent Act Arguably Meets All TRIPs Requirements**

Thailand’s Patent Act arguably meets, and in some areas exceeds, the minimum requirements called for by TRIPs with respect to patent protection for drugs. Even as of 1992, it could be argued that Thailand’s Patent Act met all of these requirements. Like TRIPs, the 1992 Patent Act required patent protection for drugs and was ambiguous on the subject of parallel importing. The provisions on compulsory licensing arguably conflict with TRIPs. TRIPs provides for a specific set of conditions under which compulsory licenses might be issued, which are somewhat different from the conditions under which compulsory licenses are granted under Thailand’s Patent Act. However, in any given factual scenario, these provisions might produce the same results. They can therefore be seen as harmonious even though they are different. As of 1999, Thailand’s Patent Act gave more protection against parallel importing than did TRIPs. It also made it more difficult to obtain compulsory licenses for drugs than it had been under the 1992 Patent Act. Most of the requirements for the issuance of compulsory licenses remained unchanged and slightly different from the TRIPs requirements.

---

110 *Id.* art. 31(c).
111 *Id.* art. 31(d), (e).
112 Although the suit was recently dropped, South Africa was sued by drug companies in its own courts for passing a law that allows the compulsory licensing of drugs. Gumisai Mutume, *Trade: U.S. Drug Companies Ease Up on South Africa, INTERPRESS SERVICE, Sept. 12, 1999, available in LEXIS, News Library.* See also James Love, *AI Gore’s Drug Problem,* WKLY. STANDARD, Aug. 9, 1999, at correspondence 7; *Drugs for AIDS Victims, supra note 25; Cunquiero, supra note 102.
113 TRIPs, *supra note 33, arts. 27(1), 70(8); 1992 Act, supra note 2, §§ 55 bis-septem, 36(3).*
114 TRIPs, *supra note 33, art. 31.*
116 Compare 1999 Act, *supra note 2, § 36(7), with TRIPs, supra note 33, art. 6.
117 See *supra* notes 66-72 and accompanying text.
118 Compare 1992 Act, *supra note 2, §§ 46, 47, 48, 51, 52, with 1999 Act, supra note 2, §§ 46, 47, 47bis, 48, 51, 52; TRIPs, *supra* note 33, art. 31.
D. Thailand Could Legally Issue Compulsory Licenses for AIDS Drugs

Arguably, Thailand could issue compulsory licenses for AIDS drugs without violating either TRIPs or the 1999 Patent Act, but it has not. TRIPs authorizes the issuance of compulsory licenses in national emergencies, and the AIDS crisis in Thailand is arguably a national emergency. Thus, Thailand could issue compulsory licenses for AIDS drugs without violating TRIPs. Under the 1999 Patent Act, Thailand can issue compulsory licenses for products "sold at unreasonably high prices or ... not meet[ing] the public demand." AIDS drugs would arguably fit into one or both of these categories. Therefore, issuance of compulsory licenses for AIDS drugs would also be legal under Thailand’s Patent Act. However, Thailand has failed to issue such compulsory licenses. The threat of U.S. trade sanctions is the likely reason for this failure.

III. Events Precipitating the Amendments to Thailand’s Patent Act

In 1992 Thailand amended its Patent Act in response to economic pressure, largely from the United States. Although the 1992 amendments were compliant in some respects with U.S. wishes that Thailand provide strong legal protection for patented drugs, these amendments left Thailand with significant legal leverage to control drug prices. However, in the wake of a devastating economic crisis in 1997, Thailand amended its Patent Act again, virtually eliminating this control. These amendments likely resulted from fear of losing access to the U.S. market, Thailand’s biggest export market. The legal tools employed to effect these amendments were

---

119 Crispin, supra note 4; Achura Pongvutitham, Thailand Wins Praise for Protection of IP Rights, NATION (Bangkok), Feb. 18, 2000.
120 TRIPs, supra note 33, art. 31(b).
121 1999 Act, supra note 2, § 46(2).
122 Crispin, supra note 4; Pongvutitham, supra note 119.
123 Crispin, supra note 4.
124 See infra notes 143-169 and accompanying text.
125 See 1992 act, supra note 2, §§ 3, 55 bis-septem.
126 Id. §§ 36(3), 55 bis-septem.
two U.S. laws, the Generalized System of Preferences ("GSP")\textsuperscript{128} and Section 301 of the Omnibus Trade and Competitiveness Act.\textsuperscript{129}

\section*{A. Instruments of Unilateral Persuasion: The GSP and Section 301}

Developing countries can realize substantial trade benefits if they cooperate with the United States on intellectual property issues. Under the GSP, the U.S. president has the discretion to grant duty-free treatment to "any eligible article from a beneficiary developing country."\textsuperscript{130} Among other things, the president considers whether the beneficiary developing country "is providing adequate and effective means under its laws for foreign nationals to secure, to exercise, and to enforce exclusive rights in intellectual property."\textsuperscript{131} The effects of this law terminated on June 30, 1999, as specified by its sunset clause.\textsuperscript{132}

Whereas the GSP offered incentives to developing countries to promulgate and enforce intellectual property laws, Section 301 potentially punishes countries that fail to comply with U.S. wishes. Section 301 provides for a threat of trade sanctions against any trade partner that fails to provide "adequate and effective protection of intellectual property rights"\textsuperscript{133} or denies "fair and equitable market access to United States persons who rely upon intellectual property protection."\textsuperscript{134} The United States Trade Representative ("USTR") must list such suspect countries within thirty days of issuing its yearly National Trade Estimate Report and must subsequently investigate these countries.\textsuperscript{135} Investigation of a country can also be precipitated at the request of an interested U.S. party, often a trade group that claims its intellectual property rights have been violated in the country in question.\textsuperscript{136} Countries are classified as (1) "priority foreign countries," (for the most egregious violations), (2) "priority watch list countries" (for lax protection of intellectual property), or (3) "watch list countries" (for


\textsuperscript{130} 19 U.S.C. § 2461; see also 19 U.S.C. §§ 2462, 2463, 2467 (outlining how "beneficiary countries" and "eligible articles" are defined and designated).

\textsuperscript{131} Id. § 2463(c).

\textsuperscript{132} Id. § 2465.

\textsuperscript{133} Id. § 2242(a)(1)(A).

\textsuperscript{134} Id. § 2242(a)(1)(B).

\textsuperscript{135} Id. § 2412(b)(2)(A).

\textsuperscript{136} Id. § 2242(b)(2)(B), (f)(2)(A).
The investigations are intended to lead to negotiations, but the USTR may increase import duties or impose other restrictions on imports if a priority country does not alter its intellectual property policies to meet the expectations of the United States. Despite the existence of a dispute resolution system under TRIPs, the United States has continued its unilateral activities under Section 301, even though these actions may conflict with TRIPs and other international agreements.

B. U.S. Pressure on Thailand to Change Its Laws Prior to 1992

Starting with the passage of the Omnibus Trade and Competitiveness Act in the United States in 1988, Thailand was subjected to continual U.S. pressure to amend its patent laws to provide protection for drugs. On January 19, 1989, the United States reduced Thailand’s GSP benefits by $165 million. The USTR included Thailand in the “priority watch list” in the first National Trade Estimate Report of May 25, 1989, demanded improved patent protection from Thailand for all types of inventions, and threatened action if no further progress was made by November 1, 1989. In 1991, the USTR moved Thailand from the “priority watch list” to the status of a “priority foreign country,” a classification that reflects egregious violations of U.S. intellectual property rights. Thailand was already under investigation by the USTR for alleged violations of American intellectual property rights after complaints were made by the International Intellectual Property Alliance and the Pharmaceutical Manufacturer’s Association (“PhRMA”). Instead of launching a new investigation, the USTR decided to continue its ongoing investigation.

---

138 Id. at 263.
139 Kirchanski, supra note 60, at 587-88 (citations omitted).
140 TRIPs, supra note 33, pt. V.
142 See generally Getlan, supra note 84.
143 Bello & Holmer, supra note 137, at 259.
144 O’Neill, supra note 35, at 616.
145 Kirchanski, supra note 60, at 588 (citation omitted).
146 Id. at 588-89 (citation omitted).
147 Id. at 590.
148 Id. at 590 n.144.
149 Id. at 589.
Because the United States was Thailand’s largest export market, economic retaliation by the United States for failure to amend its intellectual property laws was a primary concern for Thailand. Thai officials worried about U.S. “retaliation which could result in . . . raising import tariffs by up to 100 percent on some items.” Although the changes to Thailand’s intellectual property law were unpopular in Thailand, government officials announced in May of 1991 that they would take the steps necessary to ease U.S. pressure on Thailand. The 1992 Patent Act was passed on February 27, 1992.

C. Events Leading up to the 1999 Amendments

Even after Thailand passed the 1992 amendments to its Patent Act, the patent protection offered for drugs in Thailand did not satisfy the United States. Within one week after the passage of the 1992 amendments, Sandra Kristoff, deputy assistant to the USTR, suggested that Thailand could eliminate the Patents Board and narrow the conditions under which it would grant compulsory licenses. These views were shared by USTR Carla Hill, who called Thailand’s policies unreasonable and harmful to U.S. companies, and PhRMA, the president of which commented that the “amendments contain onerous and punitive provisions.” By April 1993, Thailand remained on the USTR’s list of “priority foreign countries,” and the USTR had listed Thailand’s twenty most active exports, from which Hill would select items for prohibitive tariffs should the United States decide on

---

150 See Thai P.M., supra note 127.
151 See Kirchanski, supra note 60, at 591.
152 Opponents of reform argued that (1) protection of drugs by patent was objectionable on public health policy grounds, (2) changing laws in response to U.S. browbeating betrays Thailand’s national honor, and (3) the United States lacks the moral imperative to force Thailand to abandon pirate production since it pirated many goods from Western Europe in the nineteenth century. O’Neill, supra note 35, at 619-22.
154 Kirchanski, supra note 60, at 592.
155 See infra notes 156-158 and accompanying text.
harsher sanctions.\textsuperscript{159} In September 1993, the USTR removed Thailand from the list of "priority foreign countries" and placed it on the less serious "priority watch list" because Thailand had made progress in curbing widespread copyright violations,\textsuperscript{160} another area of conflict between the two countries. Finally, in November 1994, following the passage of a new copyright law in Thailand, the USTR removed Thailand from the "priority watch list" and placed it on the "regular watch list."\textsuperscript{161}

In 1997, Thailand suffered a severe economic crisis that placed it in a weak position to resist U.S. attempts to dictate changes in its intellectual property laws. Between 1996 and 1998, the value of the Thai baht fell by almost one-half, and per capita income in Thailand fell by forty percent.\textsuperscript{162} Thai government officials expressed hopes during this period that Thailand could finally be removed from the USTR watch list so that more of its exports could enjoy the benefits of the GSP.\textsuperscript{163} Ties to the global economy in the form of International Monetary Fund support and access to the U.S. export market also became crucial to Thailand's economic survival.\textsuperscript{164} Nongovernmental organizations and citizen groups in Thailand protested the U.S. pressure and its likely consequences, that is, amendments to the Thai Patent Act narrowing Thailand's legal rights to produce inexpensive drugs.\textsuperscript{165} Nonetheless, the United States was successful in persuading Thailand to amend its Patent Act again in October 1998.\textsuperscript{166} These amendments eliminated the Pharmaceutical Patents Board\textsuperscript{167} and significantly narrowed the ability of Thais to produce or import generic versions of patented drugs.\textsuperscript{168} Even after this, Thailand remained on the


\textsuperscript{162} Pothisiri et al., supra note 25, tbl. 1.


\textsuperscript{164} Moreau, supra note 1.

\textsuperscript{165} Assavanonda, supra note 26.


\textsuperscript{167} Compare 1992 Act, supra note 2, §§ 55 bis-septem, with 1999 Act, supra note 2.

\textsuperscript{168} Compare 1992 Act, supra note 2, §§ 45-52, with 1999 Act, supra note 2, §§ 45-52.
USTR's watch list because of allegedly inadequate protection of patents, copyrights, and other intellectual property.\textsuperscript{169}

\section*{D. Thailand Has Put Economic Considerations Above Health Care for AIDS Patients}

Thailand has succumbed to U.S. pressure in order to help its economy, which has resulted in high prices for AIDS drugs.\textsuperscript{170} U.S. pressure has resulted in amendments to the Thai Patent Act that have cut off the possibility of parallel importing to obtain less-expensive, generic versions of these drugs and narrowed the situations in which compulsory licenses can be issued to produce generic versions of AIDS drugs locally.\textsuperscript{171} Even with these strict laws, Thailand might still legally issue compulsory licenses for AIDS drugs, though it has not. Despite recent indications that the United States might not impose trade sanctions if Thailand were to issue compulsory licenses for AIDS drugs,\textsuperscript{172} Thai officials continue to be wary of U.S. trade sanctions.\textsuperscript{173} Thailand could ill afford U.S. trade sanctions in the wake of its 1997 financial crisis.\textsuperscript{174}

\section*{IV. Thailand Should Be Allowed to Make AIDS Drugs Without Fear of U.S. Retribution}

The likely reason that Thailand has not already made generic copies of the drugs necessary for triple drug therapy is its fear of U.S. trade

\footnotesize

\textsuperscript{170} Sakboon, \textit{supra} note 4.

\textsuperscript{171} See \textit{supra} notes 60-79 and accompanying text.

\textsuperscript{172} In reply to a letter from the Network of People with HIV/AIDS in Thailand, USTR Joseph Papovich said that the United States will not raise objections if the Thai government is determined to issue compulsory licensing to address its health care crisis, provided it complies with TRIPs. Bhatiasevi \\& Maneerungsee, \textit{supra} note 5. Thai officials fear that the United States may interpret TRIPs differently than Thailand does. \textit{Thailand Battles AIDS Medicine Monopoly}, \textit{ASIAN ECON. NEWS}, Feb. 28, 2000, \textit{available in WESTLAW}, Allnewsplus [hereinafter \textit{Thailand Battles}]. U.S. President Bill Clinton appears also to have shifted his perspective. In 1998 the United States opposed World Health Organization policies supporting improved access to patented medicines in developing countries. However, Clinton recently stated, "But when HIV and AIDS epidemics are involved, the United States will henceforward implement its health-care and trade policies in a manner that ensures that people in the poorest countries won't have to go without the medicine they so desperately need." Crispin, \textit{supra} note 4.

\textsuperscript{173} Somsong Rukphao, head of the Thai Ministry of Health's Communicable Disease Centre, stated, "We must consider the livelihood of our 62 million people, not just our one million HIV patients." Crispin, \textit{supra} note 4. He has also stated that the letter from USTR. Papovich was merely "diplomatic." Bhatiasevi \\& Maneerungsee, \textit{supra} note 5.

\textsuperscript{174} See generally Pothisiri et al., \textit{supra} note 25.
sanctions. The United States should declare that it would not impose trade sanctions if Thailand were to make generic copies of AIDS drugs because Thailand is suffering from an AIDS emergency. This policy would allow Thailand to reduce the cost of AIDS drugs and thus make them available to a larger proportion of HIV-infected Thais. The markets for AIDS drugs in the developed world, and thus the incentives of drug companies to develop AIDS drugs, could be preserved by the enforcement of existing laws in the United States and Western Europe that prohibit parallel importing.

A. Why Hasn't Thailand Made Generic Copies of AIDS Drugs?

Even though Thailand could legally produce generic copies of AIDS drugs and probably has the technical capacity to do so, it has not made generic copies of the drugs necessary for triple drug therapy. Arguably, Thailand could legally issue compulsory licenses for these drugs under both its 1999 Patent Act and TRIPs.\textsuperscript{175} Only a small percentage of the HIV-infected Thai citizens are receiving any sort of antiretroviral\textsuperscript{176} drug therapy, and an even smaller percentage is receiving the triple drug therapy.\textsuperscript{177} There is a public demand for more affordable AIDS drugs.\textsuperscript{178} Thailand has demonstrated its ability to make generic copies of some drugs used in AIDS treatment.\textsuperscript{179} Under compulsory licenses, Thailand produced generic versions of two AIDS drugs, zidovudine and fluconazole, drastically reducing their prices.\textsuperscript{180} In the three years after generic production began, the price of zidovudine\textsuperscript{181} fell from $324 to $87 per month.\textsuperscript{182} The price of fluconazole\textsuperscript{183} fell from $14 to just over $1 per daily dose.\textsuperscript{184} Given these

\begin{itemize}
  \item See supra notes 120-121 and accompanying text.
  \item An antiretroviral drug treats the underlying disease by inhibiting the reproduction of HIV, whereas other AIDS drugs treat only the symptoms of HIV-infection.
  \item A study of 2,000 HIV-infected patients at Bamrasnaradul Hospital in northern Thailand indicated that five percent were receiving some antiretroviral therapy while another one percent were receiving triple drug therapy. Sakboon, supra note 4. See also Crispin, supra note 4; Thailand Battles, supra note 172.
  \item Assavanonda, supra note 26; Group Seeks Legislation, supra note 26; Ching, supra note 26; Groups Seek Cheaper Drugs, supra note 26; Crispin, supra note 4.
  \item Boseley, supra note 30.
  \item Id.
  \item Boseley, supra note 30.
  \item Fluconazole is the chemical name for an antifungal drug sold under the brand name Diflucan. Journal of the American Medical Association, supra note 181.
\end{itemize}
MAY 2000  THAILAND'S AIDS CRISIS  465

examples, it seems certain that the production of generic copies of the drugs
necessary for triple drug therapy would reduce their price substantially, thus making these drugs available to more HIV-infected Thais. Given the need and the demand, it is hard to understand why Thailand has not done this.

Economic considerations probably play a role. Thai officials have expressed reluctance to issue compulsory licenses for needed drugs because they fear U.S. trade sanctions. Recently, in the case of didanosine ("ddl"), the Ministry of Health made an agreement with Bristol Myers Squibb ("BMS"), the supplier of ddi in Thailand, under which BMS agreed to reduce the price of ddi by more than half. This suggests that, at least for the moment, the Thai government prefers this route to issuing a compulsory license for ddi. It is difficult to obtain information on production costs of AIDS drugs. This cost may be much lower than the selling price, although a substantial proportion of the selling price could be due to unavoidable production costs. If production costs constituted only one-tenth of the current price of triple drug therapy, many Thais would probably still be unable to afford these drugs. However, such a reduction in cost would certainly make triple drug therapy available to more Thais

\[\text{184 See id. Such an embarrassingly large price difference between a patented drug and a generic copy has been cited as being reason enough for drug companies to oppose compulsory licensing and support patent protection worldwide. Such differences essentially put the world on notice of the proportion of the price of a patented drug that is profit. See Love, supra note 30.}\]

\[\text{185 If this were not true, it would be hard to understand the strenuous objections of the United States to the South African Medicines Act of 1997, which allows the production of generic copies of AIDS drugs. See, e.g., Cunqueiro, supra note 102; Love, supra note 30.}\]

\[\text{186 Recently, the demand for didanosine ("ddl"), a nucleoside analogue type antiretroviral drug that is one of the components triple drug therapy, has fueled a hot debate in Thailand. Thailand Battles, supra note 172.}\]

\[\text{187 Crispin, supra note 4; Bhatiaesi & Maneerungsee, supra note 5.}\]

\[\text{188 Didanosine is a nucleoside analogue type antiretroviral drug. Journal of the American Medical Association, supra note 181.}\]

\[\text{189 Groups Seek Cheaper Drugs, supra note 26.}\]

\[\text{190 Ching, supra note 26.}\]

\[\text{191 Glaxo Wellcome has refused to disclose the cost of manufacturing AZT, a nucleoside analogue-type antiretroviral AIDS drug, because it is "competitive information." Smith, supra note 65.}\]

\[\text{192 Another Appeal, supra note 5.}\]

\[\text{193 A variety of drug companies produce protease inhibitors. See generally Journal of the American Medical Association, supra note 181. Therefore, the pricing may be competitive.}\]

\[\text{194 One-tenth of the current price of triple drug therapy is $1,200 ($12,000 x 0.1). Drugs for AIDS Victims, supra note 25. The average predicted per capita gross domestic product in Thailand in 1999 was $2,258. Pothisiri et al., supra note 25. Only 18.5 million of the 60 million people in Thailand currently have health insurance, which means that most people must directly pay for their health care. Charoen Kittikanya, Blue Cross Looking to Provinces, BANGKOK POST, Dec. 15 1999, available in 1999 WL 28667545; Onnucha Hutasingh, HEALTH: Forum Bemoans Doctors Who Forsake Hippocratic Oath for Lucre, BANGKOK POST, Jan. 2, 2000, available in 2000 WL 4679250. Half of the average per capita domestic product is probably a price that few could afford.}\]
than currently have access to this therapy. But since producing these drugs under compulsory licenses might result in economic sanctions from the United States, the modest gains in the number of people able to afford triple drug therapy might not justify the detrimental effects on the economy in the eyes of the Thai government. Thus, the mere existence of Section 301 may impose a higher level of protection for drug patents than is provided under the Thai Patent Act or TRIPs. Although on two occasions the United States announced its intention not to impose Section 301 sanctions in the event that Thailand produces generic copies of AIDS drugs, neither of these assurances has been made directly to the Thai government. Thai officials remain unconvinced and wary of trade sanctions. If the United States communicated this assurance directly to the Thai government, it would make it possible for Thailand to produce these drugs and make them available to its citizens at lower prices without risking grave economic consequences.

B. U.S. Policy Threatens Health Care in Thailand

Advancing the economic interests of the United States by promoting strong worldwide patent protection for drugs restricts access to new AIDS drugs in Thailand. It is in the best interests of the pharmaceutical industry, as well as many other U.S. industries, to obtain worldwide protection of intellectual property rights. Political parties and individual officeholders may also have more personal motives for serving the interests of the pharmaceutical industry because drug companies are generous contributors to both U.S. political parties. However, patent protection drastically increases the price of critical drugs in developing countries. In countries such as Thailand, where most people do not have medical insurance, this cost is paid directly by the consumer. Price increases can therefore cut off access to drugs. Lack of access to lifesaving drugs is a serious threat to health care in Thailand. Thus, U.S. efforts to promote its economic interests

195 See supra notes 133-139 and accompanying text.
196 Ching, supra note 26.
197 See generally Crispin, supra note 4.
198 Id.
199 See Foster, supra note 47, at 297.
200 See id. at 298-99; see also Blood and Gore, supra note 38.
201 See generally Love, supra note 30.
202 Only 18.5 million of the 60 million people in Thailand currently have health insurance coverage. Kittikanya, supra note 194; Hutasingh, supra note 194.
threaten health care in Thailand, a basic human right\textsuperscript{203} that is presumably safeguarded by international agreement.\textsuperscript{204}

\begin{itemize}
  \item \textbf{C. Pharmaceutical Companies Focus Research on Diseases Endemic to Developed Countries}
  
  Drug companies are unwilling to invest in research to develop drugs for diseases that occur exclusively in developing countries; the disease must be present in developed countries to make research and development investments worthwhile.\textsuperscript{205} Medical needs and prevalent diseases differ profoundly between tropical and temperate areas in which developing and developed countries, respectively, are located.\textsuperscript{206} Thus, drugs for exclusively tropical diseases are not developed by drug companies.\textsuperscript{207} AIDS affects people in both temperate and tropical zones. Hence, drug companies have an economic incentive to invest in the development of AIDS drugs.\textsuperscript{208} However, the vast majority of AIDS victims reside in Africa.\textsuperscript{209} Although some drug companies have made generous charitable contributions to countries affected by the AIDS epidemic,\textsuperscript{210} none have surrendered patent protection for drugs they have spent millions developing.\textsuperscript{211}
\end{itemize}

\textsuperscript{204} The tension between United States economic interests and health care availability in developing countries was demonstrated when a bitter argument erupted on the floor of the World Health Assembly between the United States and South Africa over the following seemingly innocuous words: "The Fifty-second World Health Assembly . . . URGES Member States . . . to reaffirm their commitment to developing, implementing and monitoring national drug policies and to taking all necessary concrete measures in order to ensure equitable access to essential drugs." This language is from World Health Assembly Res. WHA52.19 (1999). Ultimately, the United States reluctantly signed on to this agreement. Love, supra note 30. The squabble reflects the current dispute between the United States and South Africa on drug patents stemming from South Africa's insistence on its right to make generic copies of patented drugs to treat its huge population of HIV-infected citizens. \textit{Id.}
\textsuperscript{205} See Balms for the Poor, ECONOMIST, Aug. 14, 1999, at 63.
\textsuperscript{207} Malaria, for example, is largely confined to the tropics and kills between 1 and 2.5 million people per year. \textit{Id.} at 18. In spite of the potentially huge market, a vaccine for malaria does not yet exist. \textit{Id.} at 18-19. This situation reflects the fear of drug companies that their efforts to develop such a vaccine would not be remunerated because citizens of developing countries are unable to pay high prices for drugs. \textit{Id.} at 19.
\textsuperscript{208} Since vaccines are usually low in cost and administered only a few times, there is far more economic incentive for drug companies to produce expensive drugs for treating AIDS that must be taken continuously than to produce vaccines to prevent the disease. Hence, public interest organizations have sought to create incentives for drug companies to produce vaccines. See Balms for the Poor, supra note 205, at 63-64.
\textsuperscript{210} For example, Bristol Myers Squibb has contributed 100 million dollars to help HIV-infected women and children in sub-Saharan Africa. See Bristol-Myers Squibb, \textit{Bristol-Myers Squibb Commits
The U.S. pharmaceutical companies that produce new drugs have created the most successful pioneer drug industry in the world. These companies have a clear interest in obtaining high levels of protection for patented drugs worldwide. However, most of the income from patented drugs is generated from selling them at premium prices in places such as the United States, Europe, and Japan, where people can afford to pay these prices and where strong patent protection is available. Without the financial incentive of a market in the developed world, drug companies would be less willing to make the huge research investment necessary to develop a drug. The Pharmaceutical Research and Manufacturers of America estimated that drug companies spent over twenty-one billion dollars on research in 1999. The cost of developing a single drug is approximately $500 million, and only one out of 5,000 compounds investigated ever reaches the market. In spite of these expenditures, the U.S. pharmaceutical industry is hardly on tenuous financial ground but is, on the contrary, an enormously profitable industry.

Even though developing countries are unimportant markets to drug companies, patent protection in these countries is still important to these companies because of the possibility that inexpensive generic drugs made in developing countries might be sold in developed countries. The drug industry has been vociferous in its complaints of the inadequacy of patent protection offered by many countries. Some of these countries are capable of producing generic versions of patented drugs, which can often be sold at a fraction of the price charged by the patent holder in developed countries.

---


211 In contrast, Jonas Salk, who developed the polio vaccine, never patented it but instead gave it to the public without remuneration. MACHLUP, supra note 28, at 55.

212 Foster, supra note 47, at 297.

213 Balms for the Poor, supra note 205, at 63-64.

214 McCabe, supra note 29, at 48-49.

215 Roller, supra note 29, at CP1.

216 Id.

217 McCabe, supra note 29, at 48.


219 Sachs, supra note 206, at 18-19.

220 See Cunqueiro, supra note 102.

221 Letter to Ms. Harrison, supra note 47.

222 See, e.g., Foster, supra note 47, at 306-07.
countries. In India, for example, the pirate drug industry earns $900 million per year from domestic sales alone. If Indian generic drugs were to be resold in Spain or Portugal, holders of drug patents could suffer substantial losses throughout the European Union. Thus, from the perspective of the drug companies, it would clearly be preferable if no country in the world were producing generic versions of patented drugs. The primary concern of the drug companies in taking this position appears to be the protection of markets in the developed world from parallel importing.

D. U.S. Law Forbids Parallel Importing

U.S. case law has affirmed patent territoriality. Patent territoriality can be explained as two rules: (1) the sale within the United States of a product protected by a U.S. patent exhausts the patentee’s rights; and (2) the sale of a such a product outside the United States does not exhaust the patentee’s rights, and the patentee still has the right to prevent the resale of this product within the United States. This doctrine was first enunciated in the Supreme Court’s ruling in Boesch v. Graff in 1890. The few cases that have since addressed this issue have affirmed this view.

E. The United States Should Allow Thailand to Make Generic Copies of AIDS Drugs

Ideally, it would be desirable to preserve the incentives for drug companies to develop new drugs without denying people in developing countries access to these drugs at affordable prices. Present policies have met the former goal but not the latter. If Thailand can produce generic copies of the drugs necessary for triple drug therapy, the United States should decline to bring any sanctions under Section 301 and allow Thailand to produce these drugs. Since U.S. law forbids parallel importing, enforcement of existing law could preserve the valuable U.S. market for AIDS drugs while allowing Thailand to obtain these drugs at the lowest possible prices.

223 Boseley, supra note 30.
224 Foster, supra note 47, at 306-07.
225 See supra note 102 and accompanying text.
226 See Wegner, supra note 53, at 3.
229 See supra notes 133-145 and accompanying text.
The problems with enforcing laws prohibiting parallel importing are significant, though perhaps not insuperable. Under U.S. law, a patentee must sue an infringer, in this case an illegal importer, to obtain relief. With their huge financial resources, drug companies are well situated to do this, and U.S. law in this area favors patentees in such suits. Thailand’s cooperation in such international lawsuits would make this a feasible mechanism for enforcing the law against large-scale importers. However, even drug companies cannot sue every individual who goes to Thailand to buy less-expensive AIDS drugs and attempts to bring the drugs into the United States in a suitcase. However, since eighty-five percent of HIV patients in the United States and Western Europe are already receiving triple drug therapy, this may not be a significant problem.

Compulsory licensing of AIDS drugs in Thailand would preserve the incentives for the drug companies to produce AIDS drugs and would give Thailand an opportunity to make triple drug therapy available to more of its citizens. The United States has the largest number of HIV-infected citizens of any developed country. Western Europe has the bulk of the remaining HIV-infected people in the developed world. The United States and Western Europe therefore constitute the major markets for AIDS drugs. Without the incentives of these markets, it is unlikely that AIDS drugs would have been developed or that new and better AIDS drugs will be developed in the future. If these markets can be protected, then most of the incentive for drug companies to continue research and development of new AIDS drugs would be preserved. Since both the United States and the European Union already forbid parallel importing, this solution requires only that existing law be enforced. Thus, if the United States declined to bring sanctions against Thailand for manufacturing generic versions of AIDS drugs, the incentives of the drug companies to develop new AIDS drugs, as well as the intellectual property rights of these companies, could still be largely preserved. Although this solution would probably not make

---

231 See, e.g., supra note 218.
233 Crispin, supra note 4.
234 As of the end of 1997, the estimated numbers of HIV-infected people in various developed countries were as follows: Western Europe, 480,000; Japan, 6,800; Australia and New Zealand, 12,000; Canada, 44,000; and the U.S., 820,000. UNAIDS, Report on the Global HIV/AIDS Epidemic—June 1998 tbl. 1 (visited Feb. 20, 2000) <http://www.unaids.org/hivaidinfo/statistics/june98/global_report/data/tab1.xsl>.
235 Id.
236 See supra notes 102-103 and accompanying text.
triple drug therapy available to all HIV-infected Thai,\textsuperscript{237} it would certainly reduce the price of this therapy and make it available to a wider sector of the Thai population.\textsuperscript{238} This would fulfill a critical need in Thailand and would be a substantial benefit for the minor costs to the United States of declining to impose trade sanctions and enforcing existing law.

V. CONCLUSION

International standards for the legal protection of drugs should focus on protecting the ability of drug makers to sell their patented drugs at premium prices in developed countries, rather than on preventing developing countries from making affordable generic copies of patented drugs in national emergencies. The high prices charged for patented drugs are intended to support the research efforts of drug companies to find treatments for diseases affecting people in developed countries, who can afford these prices. Thus, it is fair that these people should pay for this research. The Thai people, however, cannot afford the high cost of promising new AIDS therapies. It does not follow that they should be denied the benefit of these drugs in order to eliminate any possibility that the markets in developed countries might be threatened. A better legal solution would focus on enforcing existing law that forbids parallel importing in developed countries. Thailand should be given the opportunity to provide drugs for its HIV-infected citizens at the lowest possible prices without suffering U.S. trade sanctions.

\textsuperscript{237} See supra note 194 and accompanying text.

\textsuperscript{238} See Bosley, supra note 30.