Pharmaceutical Patents in the Global Arena: Thailand's Struggle Between Progress and Protectionism

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PHARMACEUTICAL PATENTS IN THE GLOBAL ARENA: THAILAND’S STRUGGLE BETWEEN PROGRESS AND PROTECTIONISM

I. Introduction

International patent protection is one of the most important trade issues affecting both developed and developing nations. Due to the high cost of product development and an increasingly competitive international market, developed nations such as the United States are under pressure from domestic industries to protect their intellectual property innovations in foreign countries. Companies within developed countries often believe that piracy of their technology is the most significant obstacle to foreign market access.

Many foreign governments, however, condone patent infringement and support domestic "copycat" companies with protectionist laws. Such is the case with Thailand and its pharmaceutical industry. The United States is engaged in an on-going debate with Thailand over the lack of comprehensive pharmaceutical patent protection within Thailand. Thailand, however, has resisted the demands of the United States for patent protection because, in Thailand's opinion, the pharmaceutical patent debate should be approached from a "social welfare" and not a purely economic perspective. Thailand claims that the protection of pharmaceutical product patents discriminates against those who cannot afford to pay for more expen-

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This is a topic of the utmost importance. Americans who engage in international trade are very concerned about the harm to United States trading interests that results from the lack of adequate and effective protection of intellectual property rights in many foreign markets. Our businesses are losing money, but more importantly, our economy is losing the competitive edge we gain from research and development, innovation and creativity. As a nation, we simply cannot afford it.

Id.


3 Id.

4 See infra part V.A.

sive patented modern technology. The use of "protectionist" provisions, such as compulsory licensing and working requirements, supports Thailand's public health justification. Thailand seeks to provide affordable medicine to the public through limiting the ability of multinational companies (MNCs) to protect their discoveries with patents. The Thai government believes that MNCs will create monopolies, thus abusing their presence in the Thai marketplace at the expense of Thai pharmaceutical needs. Beyond this public health concern, however, Thailand must face the more controversial domestic economic factor in the patent debate: granting MNCs exclusive control of their inventions may destroy Thailand's lucrative copycat drug manufacturing industry. Technological dependency is a short-term plan that cannot support Thailand's rapid integration into the world economy.

Because of its diversified export-oriented economy and free-market philosophy, Thailand is one of Southeast Asia's greatest economic success stories. Between 1987 and 1990, real economic growth averaged eleven percent; this growth, in turn, created four consecutive budget surpluses. The tourism and manufacturing industries are gradually replacing the once dominant agricultural sector. Unlike many developing nations, which carry overwhelming debts that hinder economic development, Thailand uses surplus government revenues to reduce debt obligations and build reserves. In early 1991, Thailand's economy experienced a slowdown because of the Gulf War and high domestic interest rates. This break in rapid growth, however, will actually benefit Thailand because the country can now focus on its infrastructure problems while maintaining its competitive international position.

6 Id.
7 See infra text accompanying note 62 (definition of compulsory licensing).
9 Id.
12 Id.
13 Id. at 2. In 1991, agriculture was 11.5% of the Gross Domestic Product compared to 23.2% in 1980. Id. at 4.
14 Id. at 2. In 1990, Thailand's external debt reached $11.25 billion and debt service ratio decreased 2% to 9.1%. Id. Debt service ratio is the ratio of a country's ability to meet cash requirements to satisfy annual interest and principal repayment obligations. LES SEPLAKI, ATTORNEY'S DICTIONARY AND HANDBOOK OF ECONOMICS AND STATISTICS 63 (1991).
16 Id.
While Thailand's industrial sector expands rapidly, nearly half of the country's population lives in rural areas and relies on cheap drugs for self-medication.\textsuperscript{17} The lack of pharmaceutical patent protection enables the copycat drug industry to provide rural Thai society with inexpensive drug products. Any reaction to international pressure to provide comprehensive protection to pharmaceutical products would require the Thai government to resolve the tension between the social need for pharmaceutical products and the lack of financial resources necessary for much needed research and development (R&D) projects. Nations which devote financial resources to public health realize that withholding patent protection from pharmaceuticals does not benefit public health or their economies. Developed countries typically spend five percent of their gross national product (GNP) on public health, while developing countries spend slightly over one percent of their GNP on this expense.\textsuperscript{18} By comparison, Thailand allocated approximately six percent to health expenditures in 1989.\textsuperscript{19} This high figure suggests that Thailand is undergoing a transformation from a Third World nation to a Newly Industrialized Country (NIC).\textsuperscript{20} As such, Thailand can no longer use its public health concerns to justify its reliance on safety nets such as compulsory licensing and pipeline protection.\textsuperscript{21}

Because the United States is Thailand's second largest supplier of goods and its largest export market, maintaining a conflict-free

\textsuperscript{17} See White, supra note 8, at 25.
\textsuperscript{18} See Nancy E. Pirt, Regulation of Export of Pharmaceuticals to Developing Countries, 25 DUQ. L. REV. 255, 271 (1987). In 1991 the United States spent 12.2\% of GNP on health care with under 1\% allocated to the purchase of prescription drugs. PHARMACEUTICAL MANUFACTURERS ASSOCIATION, 1992 ANNUAL REPORT 6 (1992) [hereinafter PMA ANNUAL REPORT].
\textsuperscript{20} Korea, Taiwan, and Hong Kong are among the Asian NICs. JONATHAN RIGG, SOUTHEAST ASIA: A REGION IN TRANSITION 185 (1991). Third World countries have underdeveloped but growing economies and low per capita incomes. INTERNATIONAL RELATIONS DICTIONARY OF THE DEPARTMENT OF STATE LIBRARY 69 (2d ed. 1980). NICs enjoy rapid economic growth and may be described as "middle income countries." Id. at 51. They are large importers of products from developed countries and increase their imports more rapidly than their exports. Id.

Characteristic of an NIC, Thailand has an export-oriented development strategy, diversified manufactured exports, and rapid growth. See Rigg, supra, at 203. Thailand, however, continues to face obstacles to obtaining NIC status such as its large, poor agricultural population which it must integrate into its industrial economy. Id. Thailand also suffers from a "low quality of industrial entrepreneurship and absence of a coherent government policy to promote industrialization." Id.

relationship with the United States is essential to Thailand's continued success.\textsuperscript{22} Thailand's transition to a new stage of development demands changes in its domestic laws and economic priorities. Recognizing that its economic prosperity depends on relieving trade tensions with the United States, the Thai government took steps to protect pharmaceutical patents. On February 27, 1992, despite protests from students and local drug companies, Thailand approved amendments to its Patent Act.\textsuperscript{23} The United States and especially the United States pharmaceutical industry, however, are not completely satisfied with compulsory licensing provisions and the lack of pipeline protection.\textsuperscript{24}

The 1992 amendments to the Thai Patent Act are an attempt by the Thai government to improve strained relations with the United States over this trade-related intellectual property issue. Thailand's action may represent its desire to become a more significant actor in the international arena. This result, however, is largely attributable to bilateral United States pressure tactics.\textsuperscript{25} Problematic issues still exist which may render the Thai initiative ineffective from the perspective of United States research-based pharmaceutical companies.\textsuperscript{26} Further concessions requested by the United States place the Thai government in a very undesirable position: the United States threatens trade retaliation while Thai society and local industry criticize their government for its acquiescence to United States' demands.

This Note focuses on Thailand's continued resistance to granting comprehensive patent protection to pharmaceutical products in light of Thailand's economic development and the changing global marketplace. In part II, this Note will compare the pharmaceutical industries of the United States and Thailand. Part III will highlight the scope and administration of the Thai Patent Act. Part IV will

\begin{itemize}
\item\textsuperscript{22} See 1992 FET, supra note 11, at 7–8. The United States also has close security ties with Thailand. Many United States aid programs provide Thai military personnel with International Military Education Training, which exposes them to democratic values. See HERITAGE FOUNDATION REPORTS, SIX-STEPS TO IMPROVE U.S.-THAI RELATIONS, Backgrounder No. 112, Apr. 9, 1991.
\item\textsuperscript{24} Letter from Harvey Bale, Jr., PMA Senior Vice President, International, Summary of PMA Objections to The Thai Patent Act, B.E. 2535 (1992), to M. Pascal Learedini, Juridical Counsel of European Federation of Pharmaceutical Industries' Associations (July 24, 1992). (copy on file with the Boston College Third World Law Journal) [hereinafter Summary of PMA Objections to The Thai Patent Act].
\item\textsuperscript{25} See infra part V.A.
\item\textsuperscript{26} Summary of PMA Objections to The Thai Patent Act, supra note 24.
\end{itemize}
explore whether Thailand's political and economic situation is capable of supporting Patent Act reforms without traditional safety nets. This section will also discuss the benefits of patent protection for Thailand. Part V will discuss the effectiveness of bilateral and multilateral attempts to change a developing country's domestic laws. Part VI will consider the potential effectiveness of including international patent protection discussions in the emerging trend of free trade areas. This Note concludes in part VII that although the bilateral efforts of the United States have successfully challenged Thailand to grant patent protection to pharmaceutical products by amending its Patent Act, long-term effects of this change depend on domestic forces within Thailand. Although Thailand has legitimate public health concerns, it is at a stage of development where it must accept the challenge of becoming an innovator, not an imitator.

II. COMPARISON OF THE UNITED STATES AND THAI PHARMACEUTICAL INDUSTRIES

A. The United States Research-Based Pharmaceutical Industry

The United States research-based pharmaceutical industry boasts a healthy and competitive track record, as it is the world's largest producer of drugs.27 Because foreign sales of United States-based companies comprise 43.8% of total sales,28 the continued growth of this industry depends on overseas sales performance.29 In 1990, twenty Pharmaceutical Manufacturers Association (PMA)30 companies directly invested in the local economy and accounted for fourteen percent of the $540 million Thai pharmaceutical market.31

27 See 1992 PMA ANNUAL REPORT, supra note 18, at 18; Pirt, supra note 18, at 266.
30 "PMA is a non-profit trade association of over 100 research-based pharmaceutical companies. These firms produce most of the ethical pharmaceuticals sold in the U.S. and a substantial portion of the world supply." 1989–1991 PMA ANNUAL SURVEY REPORT 3 (1991) [hereinafter 1989–1991 PMA ANNUAL SURVEY].
The structure of the United States pharmaceutical industry explains MNCs' small share of the lucrative Thai pharmaceutical market.

PMA's current president, Gerald J. Mossinghoff, explains that "[t]here are two kinds of pharmaceutical companies: research-based companies and imitators that do not carry out substantial research on their own but profit from the fruits of the research of others." Patent protection is necessary to provide the incentive for the enormous financial investment in the R&D of new drugs. Only a fraction of the expended resources results in commercially successful products because "[m]ost compounds . . . ultimately are shelved and reap no profits whatsoever for the inventors." Thus, original investors assume the initial risk of marketing an unsuccessful product and of losing revenues from otherwise profitable technological developments. Thai imitator companies, which have operations only within Thailand, take advantage of this situation by producing only successful drugs—those with low risk and with extremely low production cost. The United States pharmaceutical industry is in the

\[32 \text{ See Gerald J. Mossinghoff, Research-Based Pharmaceutical Companies: The Need for Improved Patent Protection Worldwide 2 J.L. & TECH. 307 (1987).} \]

\[33 \text{ Id. at 307–308. A "product" patent provides the highest level of protection because it "protect[s] a generic or specific chemical structure defining either a group of related chemical compounds or a specific chemical compound." Id. at 311. A "process" patent is the least desirable for pharmaceutical products because it protects only the steps used to create the final product. Id. Proving infringement of a patented process is almost impossible because many different processes can result in the same product. Id. A "composition" patent protects a chemical formula with one or more active ingredients and at least one surface active agent carrier. Id. Preparation or sale of the formula constitutes infringement; mere manufacture of the active ingredient does not. Id.} \]

\[34 \text{ 1991 PMA Petition, supra note 29, at 9. The large amount of R&D expenses is primarily attributable to the expensive and lengthy New Drug Approval Process (NDA). The average drug company spends approximately $231 million over ten to twelve years on researching, testing, and developing a pharmaceutical product for public consumption. See id. at 8. A NDA submitted to the United States Food and Drug Administration (FDA) requires scientific data showing the results of safety tests and demonstrating substantial evidence of the new drug's effectiveness. 21 C.F.R. § 314.50 (1992). A 1991 study by the Special Work Group of the President's Council on Competitiveness reveals that the NDA required 5.7 years of human clinical trials and 2.8 years of regulatory review per new product at the FDA. See Mossinghoff Speech, supra note 28, at 37. This time expenditure intensifies competition in the international arena because other countries are able to approve new products more quickly. For example, the same study indicates that medically sophisticated countries, on average, require only 3.9 years for clinical trials and 1.1 years for regulatory review. Id.} \]

\[35 \text{ Charles P. Wallace, The Frustrating Campaign to Stop Thai Drug Copying, L.A. TIMES, Dec. 3, 1990, at D1. The Thai Pharmaceutical Manufacturers Association estimates that there are 111 local manufacturers producing drugs without a license. Id. at D3. This scenario has plagued Smith, Kline & French (Thailand) Ltd., the local subsidiary of the United States drug maker. The company claims that it has lost four-fifths of the market for ulcer drugs because of manufacturers imitating its patented chemical ingredient, cimetidine, which is in the popular drug "tagamet." Id.} \]

\[36 \text{ See Mossinghoff, supra note 32, at 308.} \]
difficult position of balancing the need to be competitive in a global market with the adverse effects of rising drug costs. Infringement upon United States drug patents leads to a decrease in the benefits flowing from new technology to the public.

B. Thailand's Pharmaceutical Industry

The government-run Government Pharmaceutical Organization (GPO) dominates the local Thai pharmaceutical industry, including private companies. The Thai government maintains its position in the pharmaceutical market in order to implement protectionist policies. For example, not only does the GPO control the supply of medicines on the Ministry of Health's essential drugs list for government facilities such as hospitals run by the Ministry, but it also purchases fifty percent of the pharmaceutical products on the essential drugs list from private companies. Drugs produced

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37 Development and marketing expenses contribute to why pharmaceuticals from the United States sell at approximately thirty times the price of pharmaceuticals produced by Thai copycats. See Wallace, supra note 35, at D3. Thailand, however, claims that it pays extremely high prices for drugs such as penicillin, developed many years ago. Arup Banerji, Bush Takes on Third World Piracies, N.Y. TIMES, May 16, 1991, § 3, at 11.

38 See Marshall A. Leafer, Protecting United States Intellectual Property Abroad: Toward a New Multilateralism, 76 IOWA L. REV. 273, 277 (1991). Without the incentive of pharmaceutical patent protection, a study estimated that "sixty-five percent of drugs would not have been introduced and sixty percent would not have been developed." See 1991 PMA Petition, supra note 29, at 9 n.14. The possible health impact of nonprotection is substantial: a 1989 study by Battelle estimated that pharmaceuticals saved 1.6 million lives and eliminated $141 billion in costs associated with society's management of disease related expenses. See Richard J. Kogan, Public Policy and Pharmaceutical Progress: Understanding Innovation's Value, Address before the Pharmaceutical Manufacturers Association Annual Meeting (Apr. 29–30, 1991), in AMERICA'S PHARMACEUTICAL RESEARCH INDUSTRY: AN ASSESSMENT BY ITS LEADERSHIP 21 (1992). The Battelle study focused on four diseases (tuberculosis, polio, coronary heart disease, and cerebrovascular disease) from 1940 to 1990. Although the study does not address Thailand's health situation, it can be inferred that Thailand would benefit similarly from protecting pharmaceutical patents. Thailand currently faces a rapid expansion in the heterosexual acquisition and transmission of the HIV virus. Marsha F. Goldstein, Rapid Spread of Pandemic in Asia Dismays Experts, Spurs Efforts to Fight Transmission, 266 JAMA 1048 (1991). In 1991 seventy-seven medicines and vaccines to treat AIDS and related disorders were in the developmental pipeline. PHARMACEUTICAL MANUFACTURERS ASSOCIATION, 1991 ANNUAL REPORT 5 (1991). A potentially devastating effect of Thailand's patent policy is that life saving medication will not be available to the public because of MNCs' fear of imitators.

39 Attachment to Mar. 6, 1992 letter from Roger Brooks, Assistant Vice President of PMA International Division, to David Walters, Chief Economist, Office of the U.S. Trade Representative, THE THAI PHARMACEUTICAL MARKET 1 (Background Paper, undated) [hereinafter THAI PHARMACEUTICAL MARKET]. In 1990 there were 290 private firms registered in Thailand, of which ten percent were subsidiaries of MNCs. Id. Of the 261 domestically-owned companies, 190 had local manufacturing facilities which produced seventy percent of Thailand's pharmaceutical needs. Id.

40 Id. Public hospitals must spend eighty percent of their pharmaceutical budget on
by foreign manufacturers cannot compete with the low prices offered by local manufacturers who pirate foreign products. Although there is no official government control of drug prices, the internal structure of the Thai government places a ceiling on drug prices which discourages foreign manufacturers from entering the Thai market.41

Another example of protectionism is the Thai government's control over import procedures. Foreign importers of pharmaceuticals must apply to the Thai Food and Drug Administration (FDA) for import licenses.42 Pharmaceutical MNCs must provide the Thai FDA with pharmalogical and toxilogical data, clinical studies, or a certified statement that the drug has been accepted for sale in a developed country.43 In contrast, Thai generic producers have no requirement to submit this additional data.44 Pharmaceutical MNCs oppose this regulatory procedure because "th[e] formula often leaks out to Thai producers before marketing approval is granted to the foreign firm," thereby allowing copycats the opportunity to exploit a new drug.45 Moreover, there is a thirty-three percent duty on all imported pharmaceuticals.46 The registration process requires at least three months and can take up to one year to complete.47 These requirements effectively reduce the incentives for foreign manufacturers to export pharmaceutical products to Thailand.

III. Thailand's Patent Law

A. Scope and Administration of the Thai Patent Act

The newly amended Thai Patent Act provides a twenty-year patent term to pharmaceutical products.48 As in the United States,
Thailand has a "first-to-invent" patent system. Any invention which is publicized outside Thailand by the inventor or displayed at an exhibition within twelve months before its application for patent is eligible for protection. The amended Patent Act, however, does not provide retroactive protection for products that have been patented elsewhere. Pipeline protection—protecting pharmaceuticals which are invented, but not yet on the market—is also lacking. Pipeline protection is very important to the United States pharmaceutical industry because the licensing procedure in Thailand can take years.

Section 55 of the newly amended Patent Act contains one of the most significant changes. Section 55 creates a Board of Pharmaceutical Patents (Board) which has three main functions: (1) to compare prices of patented to non-patented pharmaceutical products; (2) to advise the Cabinet on policy issues affecting pharmaceutical patents; and (3) to formulate the structure for financial support of R&D of pharmaceutical products. Applicants granted patents must provide specific information about pricing, production and distribution costs, and licensees of the pharmaceutical patent or pharmaceutical processes or ingredients. The Board also has the "power to summon the patentee, the licensee, or any other person to present facts or opinions, or deliver any additional doc-


49 Compare Thai Patent Act, supra note 23, § 5 (a patentable invention must be new, useful, and constitute an inventive step), with 35 U.S.C. § 101 (1988) ("whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent . . .").

50 Thai Patent Act, supra note 23, §§ 19, 19 bis. The 1979 Thai Patent Act, supra note 48, § 6(5), previously gave inventors only 180 days to file a patent application if they desired to have the filing date as the opening date of the exhibition.

51 Thai Patent Act, supra note 23, § 6(3) provides:

An invention is new if it does not form part of the state of the art. The state of the art also includes any of the following inventions:

. . . .

(3) an invention patented in this or a foreign country prior to the date of the patent application.

52 See infra part II.B.


54 Id. § 55 quartre (3).

55 Id. § 55 quartre (4).

56 Id. § 55 bis (1).

57 Id. § 55 bis (2).

58 Id. § 55 bis (3).
uments or items." Those who do not provide this specific information may be required to pay a fine, face incarceration, or both.

The Board provisions, however, do not refer to any schedule for price monitoring. Presumably, the Board has unlimited discretion to solicit information from companies. This arrangement can only foster hostility between MNCs and the Thai government. These provisions, therefore, do not create incentives to file patent applications for pharmaceutical products in Thailand.

B. Compulsory Licensing

Like other developing countries, Thailand significantly curbs patent protection with broad compulsory licensing provisions. A compulsory license authorizes a person to use the patented product without obtaining the patentee's approval. Developing countries use compulsory licensing to assure that their citizens benefit from foreign patented products.

Compulsory licensing is one of the most significant obstacles to comprehensive patent protection in Thailand. A license may be granted if the patented product has not been produced or sold in Thailand, or is sold at an unreasonably high price or in insufficient quantities to meet public demand. Therefore, a person may infringe upon an existing patented invention if it can be shown that the use of the invention does not seriously harm the rights of the original patentee and that the product is important to commerce in Thailand. Even if no one applies for a license, the Director-General has the authority to order an investigation regarding the disuse or high prices of the patented product. Upon the publication of a violation, any person may apply for a license. The compulsory licensing provisions in the Thai Patent Act are, in essence, a loop-
hole around the exclusivity of a patent. These provisions, theoretically, could be used to withdraw patent protection at any time.

In order to avoid compulsory licensing, the manufacturer of the patented product must “work” the invention to infuse capital into the host country.68 “Working” means commercially exploiting an invention so that the public has access to the patented product; importing a product is not working.69 If the patentee does not comply with the “working” requirement within three years of the patent grant or four years after the date of the patent application, compulsory licensing becomes available to imitator companies.70 Two years of non-working results in a revocation of the patent.71 Pharmaceutical MNCs often object to working requirements because it is “technically and economically impractical to build a sophisticated chemical manufacturing plant in each nation in which a manufacturer markets a product.”72 Because the pharmaceutical industry requires technical expertise and a highly educated work force, the working requirement significantly hinders the twenty year grant of patent exclusivity, as it may not be feasible to introduce this type of operation in Thailand within a short period of time.

C. Enforcement Mechanisms

The newly amended Thai Patent Act significantly changes the enforcement mechanisms provided in the 1979 Patent Act. Under the 1979 Patent Act, the patentee did not have a right to initiate a civil action in court.73 MNCs were in the uncomfortable position of relying on the Thai government to institute an action against a patent infringer.74 A patent holder had to make a motion to a Thai court to join the public prosecutor as a joint prosecutor before the court could make a judgment.75 This restriction no longer applies as Section 10 of the Thai Patent Act now provides that where the name of the inventor is registered, the patentee may sue a violator

68 See id. § 46.
69 See Mossinghoff, supra note 32, at 312 n.17.
71 Id. § 55. Section 55 of the 1979 Patent Act, supra note 48, previously allowed six years before the patent could be cancelled on grounds of nonworking.
72 Mossinghoff, supra note 32, at 312.
74 See Champon, supra note 21, at 321.
75 Id.
of a patent right.\textsuperscript{76} If the patentee has proof that the defendant’s product shares similar characteristics as the patentee’s, the amended law presumes that the defendant stole the patentee’s idea.\textsuperscript{77} The defendant must rebut the presumption.

Another change is that once there is clear evidence of a violation, the patentee can request the court to grant a restraining order against the offender.\textsuperscript{78} The court also has the power to order damages paid to the infringed patentee.\textsuperscript{79} Unlike United States patent law, which is a civil statute in its entirety with civil penalties, the Thai Patent Act is a civil code with both civil and criminal penalty provisions.\textsuperscript{80} A person who infringes upon a patentee’s exclusive rights faces imprisonment, fines, or both.\textsuperscript{81}

These enforcement mechanisms appear at first to provide strong incentives for pharmaceutical MNCs to apply for patent protection in Thailand. The effectiveness of these provisions, however, is not self-evident. First, there is no statutorily defined amount of damages. It may be, as before, that the cost of pursuing damages outweighs any nominal benefits achieved. Second, foreign patent holders remain at the mercy of a Thai court, which may be partial to domestic interests. Because of political sensitivity of pharmaceutical patents, it is unlikely that pharmaceutical MNCs can rely on Thailand’s system to protect foreign inventions.

IV. THAILAND’S ABILITY TO SUPPORT PHARMACEUTICAL PATENT PROTECTION

Because patent protection involves seemingly incompatible economic and public health issues, an inquiry into Thailand’s ability to support stronger patent legislation is necessary. Legal protection afforded by the Thai Patent Act is merely one aspect regarding the feasibility of persuading Thailand to protect foreign patents.\textsuperscript{82} Political stability as related to economic conditions is a significant factor.\textsuperscript{83} If Thailand wants to attract investors and increase trade ties

\textsuperscript{76} Thai Patent Act, supra note 23, § 10.
\textsuperscript{77} Id. § 77.
\textsuperscript{78} Id. § 77 bis.
\textsuperscript{79} Id. § 77 tri.
\textsuperscript{80} See id. §§ 77, 85.
\textsuperscript{81} Id. § 85.
\textsuperscript{83} See id.
with developed nations, it cannot continue its history of political turbulence. Intellectual property is an area where the disciplines of law and economics intersect. As such, economic conditions in Thailand play an important role in whether the Thai Patent Act will successfully protect foreign MNCs' R&D expenditures. The amendments do not require the Thai domestic industry to significantly decrease their dependence on foreign technology. The patent issue, therefore, continues to challenge Thailand to stimulate its own social, economic, and technological progress in order to become a stronger, more industrialized nation.

A. Thailand's Political Instability

Thailand's military has dominated the country's history of political turbulence. In 1932, a group of young intellectuals and the military overthrew the absolute monarchy, then known as Siam, and established a constitutional monarchy. King Bhumibol Adulyadej is the Head of State and the symbolic Head of the Armed Forces. As such, the King is the most respected figure in Thailand and provides a unifying influence. Despite this factor, military dominance in Thai politics continues to threaten political stability.

On February 23, 1991, the Royal Thai army peacefully overthrew the democratically-elected Chatichai Choonhaven administration in Thailand's seventeenth military coup since 1932. The first

86 Id. at 58.
87 Id. at 122.
88 After Thailand's Coup, It's Business as Usual for Most Projects, BUS. ASIA, Mar. 4, 1991, at 69 [hereinafter Business as Usual]. Government corruption triggered the downfall of Chatichai's administration and is a constant threat to MNCs that desire to import or manufacture drugs in Thailand. Requesting the Thai government to protect foreign patents is a difficult task, as many Thai legislators hold stakes in local drug companies. White, supra note 8, at 25.

The coup leaders quickly installed the National Peacekeeping Council (NPC) which appointed Anand Panyarachun as the interim Prime Minister and drafted an interim constitution. THAI INTERIM CONST. art. 18 (Mar. 1, 1991) (copy on file with the Boston College Third World Law Journal). Despite protests by students, academics, and other pro-democracy groups, the King promulgated a new constitution into law on December 9, 1991. THAI CONST. (Dec. 9, 1991) (copy on file with the Boston College Third World Law Journal). The new constitution provides that military leaders are prohibited from concurrently holding future cabinet posts. Id. ch.7, art. 162.
general elections since the coup were held on March 22, 1992. Three pro-military parties won 190, or fifty-three percent, of the 360 seats in the Lower House of Parliament. On April 7, 1992, five pro-military parties appointed General Suchinda Kraprayoon, Thailand's top military commander, as Thailand's Prime Minister. Suchinda's appointment ignited the bloodiest civilian upheaval in Thailand's history. On May 19, 1992, the Thai army began the "four nights of fury" against unarmed pro-democracy demonstrators, killing and wounding many of those voicing their dissatisfaction with military rule.

On May 21, 1992, the King intervened in the unrest. Suchinda resigned on May 24, 1992, after losing his political support. The King then re-appointed Anand Panyarachun as an interim Prime Minister to restore balance until the September elections.

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89 Philip Shenon, Elections in Thailand Help Raise Military's Power in Government, N.Y. TIMES, Mar. 23, 1992, at A9. The Lower House of Parliament is an elected body. THAI CONST., supra note 88, ch.6, pt.3, art. 99. The Senate has 270 members who are appointed by the King. Id. ch.6, pt.2, art. 94.


91 Philip Shenon, Deaths Mount as Troops Fire on Thais, N.Y. TIMES, May 19, 1992, at A1, A4. Unlike anti-government protests in 1973, these demonstrators had broad support from students, laborers, and businessmen. Id.


93 Philip Shenon, Thailand's Premier Quits Over Unrest, N.Y. TIMES, May 25, 1992, at 1. At the time of Suchinda's resignation, over 400 persons were reported as missing. Id. The King issued a royal pardon preventing the prosecution of Suchinda and others involved in the military intervention. Id. at 5. On July 22, 1992, a Thai constitutional tribunal upheld the royal pardon. Thai Tribunal Backs Amnesty Decree Covering May Unrest, UPI, July 22, 1992, available in LEXIS, Nexis Library, UPST90 File.

tember 11, 1992, the King responded to the pro-democracy demonstrators' demand and signed a constitutional amendment into law that requires future prime ministers to be elected representatives. Despite prediction of strong public sentiment to repudiate military dominance in politics, the September 13, 1992 general election did not yield an overwhelming victory for anti-military parties, as pro-democracy parties won only fifty-one percent of the contested parliamentary seats. On September 23, 1992, Chuan Leekpai of the Democratic Party was named Thailand's twentieth prime minister.

Political stability and a dedicated effort by the Thai government to protect pharmaceuticals are paramount to foreign investment in Thailand. Tensions between pro-democracy and traditional military rule create a sensitive political situation for potential foreign investors. Revising the Thai Patent Act to exclude compulsory licensing and other onerous provisions depends on whether the future Thai government can withstand public pressure long enough to realize the long-term benefits of patent protection. The pro-

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95 Pranee Srithongnoy, Law Passed to Ensure Thai Prime Ministers are Elected, UPI, Sept. 11, 1992, available in LEXIS, Nexis Library, UPST90 File.
98 Dr. Valvudhi, manager of a local drug company has summarized the political process: First we have to have a committee to draft a law, then it has to be reviewed by many more committees, then the cabinet has to look at it, then it has to go to Parliament for them to think about, and then maybe Parliament gets dissolved and we start all over again.

White, supra note 8, at 25. Thailand's past attempts at reforming the Patent Act have been mere stalling tactics. In May 1989, Thailand proposed a two-year monitoring system as an interim measure which would have prohibited the marketing of generic copies of pharmaceuticals from the day a new drug is registered on the Thai market until the Thai FDA approved its sale. Compromise Hoped for on Drug Patent Regulations, PHARMACEUTICAL BUS. NEWS, May 12, 1989, available in LEXIS, Nexis Library, Pbnws File. This measure which would have protected a foreign drug manufacturer's position during the specified period should have been effective by October 1, 1989, but had not even been introduced to the National Assembly by that date. Thai Pharmaceutical Patent Problem Reaches Impasse, PHARMACEUTICAL BUS. NEWS, Feb. 16, 1990, available in LEXIS, Nexis Library, Pbnws File. Another instance of stalling occurred when a patent protection bill was pushed through the National Assembly on July 12, 1990. Transformation for Thailand's Pharmaceutical Industry, PHARMACEUTICAL BUS. NEWS, Aug. 17, 1990, available in LEXIS, Nexis Library, Pbnws File. This bill would have allowed foreign companies to bypass the Thai FDA, to establish majority controlled joint venture companies involved in R&D, and to receive tax breaks for ten years. Id. This policy change, however, was never implemented, as opposition ministers who had been "tricked" into voting for this bill dismantled the legislation. PMA Slams Thai Government's Patent Protection, PHARMACEUTICAL BUS. NEWS, Feb. 15, 1991, available in LEXIS, Nexis Library, Pbnws File.
democracy Prime Minister will hopefully recognize Thailand’s need to “play a role in the world economic structure commensurate with its industrial diversification and growing economic importance.”

B. Economic Considerations of Pharmaceutical Patent Protection in Thailand

1. Arguments Against Implementing Patent Protection in Developing Countries

Calculations concerning the value of protecting an intellectual property right utilize a cost/benefit analysis. Developing nations are concerned primarily with development. Therefore, those who oppose patent protection in these nations often assume that imitating products without an inventor’s permission is a necessary first stage of development.

Opponents argue that the costs of implementing a patent system are too prohibitive for a developing country to grant patent protection because the country does not necessarily receive economic benefits. Developing countries fear a form of “technological colonialism” where their economic development is dependent on monopolistic MNCs. Critics argue that past efforts to transfer technology to developing countries have done little to advance technological capacity. While developing countries may have greater access to inventions, they do not possess the technical or human resource capacities necessary to implement the new technology.

Opponents argue that there is no correlation between R&D expen-

101 Oddi, supra note 100, at 843.
102 SHERWOOD, supra note 84, at 166.
104 Id. at 213, 218. Technology transfers include licensing technology, patent disclosures, publications or technical meetings, the hiring employees of innovating firms, the reverse engineering of a product, and independent R&D. RAPP & ROZEK, supra note 100, at 4. These programs traditionally have been implemented through private party contracts with minimal governmental interference. Haug, supra note 103, at 222-23.
105 Oddi, supra note 100, at 851-52.
ditures and the need for patent protection in developing countries because these costs are recovered largely in the markets of developed countries. From a developing country's perspective, administrative costs, which are already burdensome, would also place barriers to an efficient patent system. The consumer in the developing country would therefore bear the inequities of a patent system through higher prices.

2. Arguments Favoring the Implementation of Patent Protection in Developing Countries

Proponents of patent protection in developing countries believe that legal protection of patents is directly related to improved economic growth. In the area of pharmaceutical patents, the overall benefits are improved public health and increased technological capacity.

Proponents argue that patent protection provides an economic incentive to MNCs to participate in technology transfers. Exchanging the grant of an exclusive right in return for the disclosure of details of an invention satisfies mutual needs: MNCs reap financial rewards which in turn fund future R&D, and developing countries gain access to new technology. Proponents argue that the disclosure of advance technical information forces domestic industries in developing countries to generate their own improved products instead of imitating foreign inventions. Growth of R&D facilities abroad also benefits the developing country's economy by creating employment opportunities. These developments therefore will result in lessened economic dependence, that is, a stronger human resource and technological infrastructure. Proponents of

106 See 1991 UNCTAD REPORT, supra note 82, at 192.
107 Oddi, supra note 100, at 846-48.
108 See RAPP & ROZEK, supra note 100, at 39.
109 Id.
110 Id. at 14-17; Champon, supra note 21, at 330.
111 See RAPP & ROZEK, supra note 100, at 15-16.
112 Id. at 15. As evidenced by western European countries, a significant benefit of stronger patent laws is increased economic development through the infusion of foreign capital. Id. at 7. In 1989, pharmaceutical companies spent 67.7% of their total foreign R&D expenditures in Western Europe, compared to only 0.5% in the Far East and Pacific regions. See 1989-1991 PMA ANNUAL SURVEY, supra note 30, at 24. Between 1969 and 1989 R&D efforts in the European Community have yielded the discovery of 122 new drugs. PMA MEMBER COMPANIES' EC SURVEY 4 (1989) (copy on file with the Boston College Third World Law Journal).
113 See SHERWOOD, supra note 84, at 173-75.
114 Id. at 173, 191.
patent protection also argue that anticipated high prices should not result, as the grant of a patent right does not necessarily guarantee market share. Costs should actually decrease, as an expanding market creates competition through the availability of a choice of drugs at various prices. Newly patented drugs also compete with many drugs from the World Health Organization's (WHO) Essential Drug List, many of whose patent lives have expired. A developing country that does not provide patent protection chooses a short-term approach to economic development that leads to a pattern of dependency.


Economic conditions in Thailand are conducive to granting patent protection to pharmaceuticals without the safety nets of compulsory licensing or working requirements. As discussed earlier, Thailand is in the enviable position of soon graduating from Third World status to become a NIC, and has the modern economy to support this upward shift in its global status. Despite this economic success, however, Thailand's copycat drug industry claims that Thailand is not "mature enough for patents." Local Thai drug manufacturers fear that opening the import market to patent owners will result in elevated costs to consumers. Thus, the Thai pharmaceutical industry erroneously believes that it must steal technology of developed countries and discourage the protection of

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115 See Rapp & Rozek, supra note 100, at 39–40.
116 Sherwood, supra note 84, at 161; Rapp & Rozek, supra note 100, at 24–25.
117 Rapp & Rozek, supra note 100, at 24. The WHO is a 166-member international health agency of the United Nations which seeks to obtain the highest level of health care for all people. Some of its many projects include: emphasizing health needs of developing countries, working towards developing new techniques to effectuate solutions, and establishing standards for pharmaceutical needs. Encyclopedia of Association—International Organizations 876 (26th ed. 1992).
118 As one scholar has noted, "in its pursuit of this cost reduction objective, the country has savaged its indigenous technology infrastructure and foregone opportunities to build tacit knowledge, human resources and its research base." Sherwood, supra note 84, at 166.
119 See 1992 FET, supra note 11, at 3; Jansen, supra note 10, at 13. In contrast to developing countries such as India, Thailand has successfully attracted a large amount of foreign investment. In 1991, United States companies invested one billion dollars in Thailand while between $150 to $200 million was invested in India. Greater U.S. Investment in South Asia Depends on Reform Process, Daily Rep. for Exec. (BNA), July 29, 1992, at 146.
120 See White, supra note 8, at 25.
121 See Oddi, supra note 100, at 847; Williams, supra note 5, § 4, at 9.
pharmaceutical patents in order to maintain its rapid economic development.

Pharmaceutical patent protection will force Thailand to emerge from its mode of dependency without destroying its domestic drug industry. Comprehensive legislation would enable Thailand to benefit from modern drug research. Patent protection will enable safer drugs to reach the Thai market because pharmaceutical products imported into Thailand from the United States have already met the strict United States FDA standard. Thailand currently has limited means for monitoring safety and, as a result, quality-control problems at local drug producers are common. The grant of exclusivity accompanied by government enforcement would enable pharmaceutical MNCs to feel more secure about marketing their safer inventions in Thailand. Future benefits to Thai society through the introduction of safe, new, patentable drugs by foreign MNCs therefore would respect Thailand's public health concern.

Another benefit to Thailand will be in the area of technology advancement. Advancements in the growing industrial sector are in the areas of processing natural resources and import-dependent cheap labor products, and not in technology. Thailand is also heavily dependent on foreign technology in most fields. Because Thailand has the technical ability to drive a strong export-oriented economy, it should strive to incorporate technological advances. Thailand has a lucrative pharmaceutical industry that already has assembled financing, resources, and manpower. Granting patent protection would not put the Thai pharmaceutical industry out of business; it would provide an incentive to do more than just imitate. Technology transfer through a grant of patent protection will benefit Thailand by propelling it to a new level of economic independence.

Effective patent protection will also result in increased foreign investment in Thailand. The attempt of MNCs to establish manufacturing bases in Thailand, however, will not be without obstacles.

122 See Williams, supra note 5, at 9.
123 See Mossinghoff, supra note 32, at 307.
124 See Jansen, supra note 10, at 13.
125 Id. at 26. A survey of manufacturing firms in Thailand suggests that companies spend only 0.1% of annual sales on R&D. Id. (figure reflects multi-industry manufacturing, not only the pharmaceutical industry).
126 Contrary Oddi, supra note 100, at 843.
127 See Sherwood, supra note 84, at 167.
128 Id. at 192–93.
Cheap labor is a motivating factor to MNCs, but Thailand’s insufficiently skilled workforce creates a barrier for pharmaceutical companies to begin large-scale production in a short time period.\textsuperscript{129} Even if the Thai government offers business investment incentives and an effective patent system, foreign firms must address Thailand’s problematic infrastructure, which is developmentally lagging behind the needs of its modern exporting ventures.\textsuperscript{130}

Within Thailand’s domestic situation, political stability would enhance Thailand’s ability to create and implement an effective physical and technological infrastructure plan which is necessary to support new industries drawn to Thailand’s multinational, business-oriented environment.\textsuperscript{131} Tensions from the high administrative cost of a patent system must also be resolved in favor of patent protection. Legal protection alone will not offset the current lack of trained personnel and other cost intensive improvements.\textsuperscript{132} These challenges, however, should be met to provide better products for consumers and promote economic development. In short, a government free from military dominance and instability is necessary for Thailand’s continued economic health.\textsuperscript{133} As to Thailand’s patent protection policies, the key to positive change in the present patent law is to effectively change the Thai copycat mindset to one of innovation.

V. U.S.-THAI RELATIONS REGARDING PHARMACEUTICAL PATENT PROTECTION: THE EXISTING FRAMEWORK

This section provides a brief overview of United States efforts to “encourage” Thailand to enact a more aggressive patent law. The issue of patent protection in the international arena traditionally has been addressed through instruments providing voluntary prescribed standards and concepts. The Paris Convention for the Protection of Industrial Property, for example, is the governing inter-

\textsuperscript{129} 1992 FET, \textit{supra} note 11, at 6.
\textsuperscript{132} 1991 \textit{UNCTAD REPORT}, \textit{supra} note 82, at 191.
\textsuperscript{133} Nicolas D. Kristof, \textit{Thai Unrest Does Harm to Economy}, \textit{N.Y. Times}, May 26, 1992, at D1, D9.
national treaty for patent protection. The principle multilateral intellectual property organization is the World Intellectual Property Organization (WIPO), which encourages developing nations to participate in the international patent system and performs administrative tasks for the Paris Convention.

The United States no longer considers the Paris Convention to be the relevant body to address the modern needs of intellectual property owners. The Convention's most significant deficiency is that it does not provide a minimum level of protection for member nations. The lack of effective procedures regarding treaty enforcement and dispute settlement are also problematic areas. Thailand is not a member nation of the Convention. Thus, the Convention principles cannot be applied to Thailand. Developing countries prefer WIPO as the forum to discuss intellectual property rights because they view the issue as a social, not trade, concern. From the perspective of the United States, however, WIPO is not competent enough or an important enough actor in the international arena to effectuate broad changes in international patent laws.

134 Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, 21 U.S.T. 1630, 828 U.N.T.S. 305. This Convention embodies four main concepts. First, national treatment requires member states to grant all the advantages of their domestic law to nationals of other countries subscribing to the Convention. Id. art. 2. Second, the right of priority provides that a patent holder may file a patent in one member country and wait up to one year from the first filing to file in the remaining member countries. Id. art. 4 (A)(1). Third, patents have legal independence—the existence of a patentable item is dependent upon the laws of the granting state. Id. art. 4 bis (1). Fourth, member states are limited in their ability to forfeit patents and may grant compulsory licenses if a foreign manufacturer does not "work" the invention. Id. art. 5A.


138 Sherwood, supra note 84, at 25.


140 See Kunz-Hallstein, supra note 137, at 79–80. Another criticism of WIPO is that agreements can be manipulated by nations with little involvement in the global economy, as many nations have a greater voting power than their size justifies. See Christopher M.
The United States therefore has looked towards other mechanisms to effectuate changes in Thailand's intellectual property policies.

A. Special 301

The United States' most effective bilateral initiative to gain patent reforms in foreign countries is the Special 301 action which is part of the Omnibus Trade and Competitiveness Act of 1988 (hereinafter 1988 Trade Act). The goal of Special 301 is to negotiate improvements in foreign countries' intellectual property systems through bilateral and/or multilateral initiatives. The United States seeks to ensure adequate and effective intellectual property protection and equal market access.

Thirty days after submitting the National Trade Estimate to congressional committees, the United States Trade Representative (USTR) identifies foreign countries and priority foreign countries that violate United States intellectual property policies. Within thirty days of designating a priority foreign country, the USTR must initiate a Section 301 investigation. An investigation can also be triggered by a petition filed on behalf of any


146 A designated foreign country denies adequate and effective means under the law of the foreign country for persons who are not citizens or nationals of such foreign country to secure, exercise, and enforce rights relating to patents. 19 U.S.C. § 2242(d)(2) (1988).

147 A priority foreign country has the most egregious practices that deny adequate intellectual property protection and have the greatest adverse effect on the relevant products of the United States. 19 U.S.C. § 2242(b)(1)(A)–(B). These countries are also not participating in good faith negotiations to remedy the inadequate practices. 19 U.S.C. § 2242(b)(1)(C).


interested person. The USTR must make a determination of whether violations have occurred within twelve to eighteen months for a regular investigation, or within six months for a priority country, while the USTR is required to take action in certain circumstances, the United States has yet to retaliate against any priority country.

After several failed attempts by the United States to force Thailand to amend its Patent Act, the Pharmaceutical Manufacturers Association (PMA) filed a petition to initiate an investigation of Thailand's pharmaceutical patent protection. The USTR initiated

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153 The USTR is required to take action if an act, policy, or practice of a foreign country:
   (1) violates the provisions of or denies benefits to the United States under any trade agreement, or
   (2) is unjustifiable and burdens or restricts United States commerce. 19 U.S.C. § 2411(a)(1)(B) (1988). The USTR, however, is not required to take in certain circumstances such as when the foreign country has agreed to eliminate the disputed practice or the action would have an adverse impact on the United States economy substantially out of proportion to the benefits of the action. 19 U.S.C. § 2411(a)(2)(B). The USTR has discretion to take action upon a determination that "an act, policy, or practice of a foreign country is unreasonable or discriminatory and burdens or restricts United States commerce . . . ." 19 U.S.C. § 2411(b)(1). The USTR has the authority to:
   (A) suspend, withdraw, or prevent the application of, benefits of trade agreement concessions . . . ; (B) impose duties or other import restrictions on the goods of . . . such foreign country for such time as the Trade Representative determines appropriate; or (C) enter into binding agreements with such foreign country that commit such foreign country to (i) eliminate, or phase out, the act, policy, or practice that is the subject of the action . . . . (ii) eliminate any burden or restriction on United States commerce resulting from such act, policy, or practice, or . . . . (iii) provide the United States with compensatory trade benefits . . . .
19 U.S.C. § 2411(c).
an investigation of Thailand’s intellectual property system on March 15, 1991. 155 Thailand became the focus of the USTR a second time on April 26, 1991 when, in response to Congressional pressure, the USTR upgraded Thailand to the status of a “priority country.” 156 Thailand initiated its Patent Act amendments in October 1991, and by February 1992 the King had promulgated the Patent Act into law. 157 On March 13, 1992, the USTR announced that Thailand failed to protect United States patents, but delayed action until after the general election on March 22, 1992. 158 On April 29, 1992, the USTR once again designated Thailand as a priority foreign country. 159 Because of recent political turbulence in Thailand, the USTR has delayed trade sanctions until the formation of a new Thai government. 160

of revoking GSP benefits does not have a substantial impact on Thailand, as only twenty-two percent of Thailand’s total exports enter the United States with GSP privileges. Thailand Stands Firm on Pharmaceutical Patent Rights, PHARMACEUTICAL BUS. NEWS, Jan. 20, 1989, available in LEXIS, Nexis Library, Pbnws File. By contrast, the denial of GSP benefits would probably have a greater effect on a lesser-developed country such as Indonesia, which depends more heavily on foreign concessions.

156 Office of the United States Trade Representative, Fact Sheet: “Special 301” on Intellectual Property (Apr. 26, 1991). The USTR cited areas of deficiencies such as lack of patent protection for pharmaceuticals, overly broad compulsory licensing provisions, and insufficient term of protection. Id. China and India also were designated as priority foreign countries; this was the first time the USTR had designated a priority country. Id. Thailand had been on the “priority watch list” in previous years. Office of the United States Trade Representative, Fact Sheet: “Special 301” on Intellectual Property (Apr. 27, 1990); 1989 Special 301 Fact Sheet, reprinted in 38 Pat. Trademark & Copyright J. (BNA) No. 933, at 131 (June 1, 1989). The “priority watch list” designation is not provided by statute, but is the USTR’s broadly interpreted “escape clause” to retaliation against priority countries. See Davis, supra note 143, at 524 (arguing that Special 301 should be amended to provide for the USTR’s discretionary approach).

159 Office of the United States Trade Representative, Fact Sheet: “Special 301” on Intellectual Property 1 (Apr. 29, 1992) [hereinafter 1992 Special 301 Fact Sheet]. India and Taiwan also were named as priority foreign countries. Id. The United States subsequently suspended $60 million of Indian products from the GSP scheme. Nancy Dunne, U.S. Hits India’s Trade Status in Patent Dispute, FIN. TIMES, Apr. 30, 1992, at 7. On June 5, 1992, Taiwan agreed to amend its patent law in conformance with the current GATT text. U.S., Taiwan Reach Agreement on Patents, Trademarks, Copyrights, 9 Int’l Trade Rep. (BNA) 1001 (June 10, 1992). Those on the priority watch list include: Australia, Brazil, Egypt, European Community, Hungary, Korea, Philippines, Poland, and Turkey. 1992 Special 301 Fact Sheet, supra, at 2. Those on the watch list include: Argentina, Canada, Chile, China, Colombia, Cyprus, Ecuador, El Salvador, Germany, Greece, Guatemala, Indonesia, Italy, Japan, New Zealand, Pakistan, Paraguay, Peru, Spain, Saudi Arabia, UAE, and Venezuela. Id. at 5.
160 Id. at 2.
The newly amended Thai Patent Act, although not entirely acceptable to the United States, indicates the effectiveness of the Special 301 provisions to stimulate change. The central issue facing the United States is whether Special 301 retaliation should be used to force Thailand to further amend its Patent Act and omit compulsory licensing provisions. The United States has refrained from using Special 301 retaliation because intellectual property protection is on the agenda in the General Agreement on Tariffs and Trade (GATT) talks. The United States, however, should continue to press Thailand for patent protection commensurate with Thailand’s stage of economic development. In return, the United States should remove Thailand from the priority country list. Thailand’s strained trade relationship with the United States can be rebuilt if Thailand significantly improves its Patent Act.

B. General Agreement on Tariffs and Trade

Because Special 301 is solely a retaliatory measure and does not provide dispute negotiation mechanisms, the United States places great importance on the success of the GATT talks. Since its enactment, GATT continues to be the principle instrument of international law regulating trade discussion, negotiation, and settlement. GATT is based on the assumption that individual nations benefit from a combined effort to increase global trade.

161 See Bello, 1989–1990 Special 301, supra note 143, at 275.
162 Special 301 has been successful in securing changes in the laws of foreign countries. After placement on the priority list in 1985, South Korea agreed to provide better protection for United States pharmaceutical patents. See Thomas N. O'Neill, III, Note, Intellectual Property Protection in Thailand: Asia's Young Tiger and America’s "Growing" Concern, 11 U. Pa. J. Int'l Bus. L. 603, 614 (1990). South Korea was subsequently transferred to the priority watch list. Id. The placement of Mexico on the priority watch list in 1989 encouraged Mexico to improve its patent protection for pharmaceuticals. Removal from all lists occurred when Mexico passed the Law for the Promotion and Protection of Industrial Property in June of 1991. Manuel Gomez-Maqueo, Analysis of Mexico's New Industrial Property Law, 42 Pat., Trademark & Copyright J. (BNA) 381 (Aug. 15, 1991). The Mexican law not only provides a twenty-year term for pharmaceutical patents, but also has compulsory licensing and working requirements. Id.
165 Id. The two principles of Most-Favored-Nations Treatment (MFN) and National Treatment comprise the basic GATT structure. MFN Treatment requires a GATT-contracting party to extend the same treatment given to its most favored trading partner regarding trade relations with all other GATT-contracting parties. GATT, supra note 163, art. 1. National Treatment prevents discrimination against foreign goods by requiring that con-
The most recent round of the 107-nation GATT talks, the Uruguay Round, began in April, 1986. The addition of the Trade-Related Intellectual Property Rights (TRIPS) negotiating group is a significant departure from the traditional agenda of tariff reduction. The inclusion of intellectual property in the GATT format, as advocated by industrialized nations, is a difficult social issue for developing nations. Progress in the area of international patent protection through the GATT framework is questionable because combining different legal systems and economic theories to provide a patent system may not be universally fair. There remains much debate over whether the exclusive grant of an intellectual property right in the international arena is a desirable goal. The United States argues that an agreement providing developing nations with a greater opportunity to sell their agricultural exports will encourage them to respect other countries' patent laws in exchange. Developing countries, however, fear that the acceptance of GATT-protected patents will adversely affect other areas of their trade if developed nations do not believe that developing nations are working fast enough to change their patent laws. Because of the perceived negative impact of intellectual property on domestic development, developing countries favor a provision with public interest exceptions that would balance the strength of a patent law against the level of development.

Another problematic issue related to the successful inclusion of intellectual property is that the GATT system addresses sovereign states and not the citizens of the contracting parties. Thus, a

tracting parties treat foreign imported goods in the same manner as national goods. Id. art. 2.

166 O'Neill, supra note 162, at 615.
170 See GACEK, supra note 140, at 5.
172 Kostecki, supra note 168, at 272.
173 1991 UNCTAD REPORT, supra note 82, at 193.
United States pharmaceutical company would have to rely on the United States government to take up its cause. Under the GATT rules, an arbitration panel of five individuals settles disputes between contracting parties. After this panel submits a written opinion, the GATT council makes a final decision as to whether there is a violation of international law. The power to authorize retaliation is not granted often, as the GATT procedure requires consensus.

The lack of consensus in diverse subject areas and the subsequent slow pace of the GATT negotiations indicate that it is not an effective approach to the global commercial domain. After four years of difficult deliberations, the Uruguay Round talks broke down in Brussels on December 7, 1990, over the reduction of agricultural subsidies. Progress in intellectual property matters came to a halt because the TRIPS negotiations are tied to the success of all negotiating groups.

Negotiations were later revived and in December 1991, Arthur Dunkel, Director General of GATT, submitted a “final act” draft treaty for member countries to review. Under this draft treaty, contracting parties must determine the appropriate methods of implementing the TRIPS agreement. Patents must be available whether products are imported or locally produced. This provision would require Thailand to change the compulsory licensing provisions in the Thai Patent Act. The term of protection is twenty years from the filing date. Developing countries, however, can delay the transi-

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175 Fikentscher, supra note 174, at 109. By contrast, a Convention system uses the court system of its member states.
176 Gacek, supra note 140, at 5.
177 Id.
178 Id.
179 See Ruggeri, supra note 167, at 6.
183 Id. art. 27.
184 Id. art. 33.
185 Id. art. 65 § 1.
tion into GATT compliance for four years.\textsuperscript{186} In areas of technology that are not protected as of the date of the TRIPS agreement, developing countries have an additional five years to change their domestic laws.\textsuperscript{187} Least-developed countries have ten years from the date of the TRIPS agreement to comply, because of their need for flexibility to create a viable technological base.\textsuperscript{188} Developed countries are also required to provide incentives to promote technology transfers into developing countries.\textsuperscript{189} A TRIPS Council, separate from GATT, will monitor the agreement under the newly formed Multilateral Trade Organization (MTO).\textsuperscript{190}

From the perspective of the United States, the lengthy transitional period is the major flaw of the TRIPS agreement.\textsuperscript{191} The United States pharmaceutical industry also criticizes the lack of pipeline protection. Thailand, as part of the Association of Southeast Asian Nations (ASEAN),\textsuperscript{192} supports the adoption of the compromise draft treaty for intellectual property.\textsuperscript{193} Thailand prefers the proposed delayed transitional periods over potential trade sanctions under Special 301.\textsuperscript{194}

The Uruguay Round is currently stalled because of continuing disagreements between the European Community and the United States on farm-subsidy cuts.\textsuperscript{195} Dunkel hopes to conclude the talks by December 1992.\textsuperscript{196} The draft treaty calls for the developed world to be very patient, a very different approach from the United States’

\textsuperscript{186} Id. art. 65 § 2.
\textsuperscript{187} Id. art. 65 § 4.
\textsuperscript{188} Id. art. 66 § 1.
\textsuperscript{189} Id. art. 66 § 2.
\textsuperscript{190} Id. Annex IV, art. 5 § 4. MTO is the institutional framework which will administer an Integrated Dispute Settlement System, thus eliminating the ability of the United States to use Special 301 provisions. \textit{See id.} art. III § 4.
\textsuperscript{192} Founded in 1967 to foster intra-regional economic development, promote social progress, and ensure intra-regional peace, ASEAN is comprised of the nations of Brunei, Indonesia, Malaysia, Philippines, Singapore, and Thailand. \textit{Antonia Hussey, Regional Development and Cooperation through ASEAN}, 81 GEOG. REV. 87 (1991).
fast-paced bilateral efforts. Consequently, the goal of establishing a GATT-regulated intellectual property system, which requires countries with diverse needs to subscribe to uniform standards, may not be achieved.

VI. REGIONAL FREE TRADING AREAS: PROGRESS?

Difficulties in negotiating a successful GATT agreement has created disillusionment over GATT's ability to regulate the global trading system. The decline of United States leadership in the global trading arena has undermined support for a multilateral system of trade, thus encouraging a trend towards regionalism. If the membership does not agree on the recent GATT proposals, nations will be free to adhere to the guidelines of trading blocs or to unilaterally implement their own trade rules. In the absence of a multinational framework, countries with the most protective statutes will be able to satisfy their trade policy objectives. The United States may “get tough” and harm Thailand's export economy by imposing Special 301 trade sanctions in retaliation to Thailand's refusal to grant “acceptable” pharmaceutical patent protection. Regional trading zones such as the European Community (EC) and the emerging North American Free Trade Agreement (NAFTA), however, are also very significant long-term concerns of Asian nations such as Thailand which fear a potential shift of jobs and investment to preferred trading partners within these blocs.
The GATT system is open to all who agree to abide by membership rules. GATT principles support free trade based upon nondiscrimination and comparative advantage. By contrast, regional trading blocs are not open to nations willing to follow the rules. These groups are based upon the principles of discrimination, economic nationalism, and managed trade. This strategic trade vision utilizes trade policies, investment strategies, and government activities to create economic advantages. As the attractiveness of regional trading blocs, whose smaller forums allow more expansive economic ties, gains momentum, the cumbersome nature of a multilateral intellectual property system linked to free trade principles will lose support. The current debate is whether these groupings will be vehicles for protectionism or alliances for free global trade. Countries could utilize these regional agreements to adjust their economies and laws to address modern technological aspects of international trade such as intellectual property concerns.

These regional groupings may result in the breakdown of the multilateral system. Inward-focused alliances could slow down world trade and effectuate a decrease in worldwide prosperity. It may be difficult for Asia to accomplish its goals in this new world order because the divergent economic statuses of Asian countries cannot be articulated through a uniform response.

three nations benefit, as Canada and Mexico are heavily dependent on ensured access to United States markets. Id. at 133–40. A long congressional battle is anticipated and the earliest approval will not occur until 1993. Bradsher, supra, at C3.

The EC comprises three distinct communities: the European Coal and Steel Community, the European Economic Community, and the European Atomic Energy Community. WILLIAM RAWLINSON & MALACHY P. CORNWALL-KELLY, EUROPEAN COMMUNITY LAW 1 (1990). The ultimate goal of the EC is European unity and the main principle is nondiscrimination among nations of member states. Id. at 2. The creation of an internal market for the movement of goods, services, persons, and capital occurred on January 1, 1991. Id. The EC is a protectionist trading bloc due to its product standards and import barriers. See Peter Morici, Regionalism: Motivations and Risks, in The Growth of Regional Trading Blocs in the Global Economy 135 (Richard S. Belous & Rebecca S. Hartley eds., 1990) [hereinafter Regional Trading Blocs].

Belous & Hartley, supra note 198, at 3.

Id. at 2–3.

Id.

Id. at 4.

See Blustein & Auerbach, supra note 197, at H4.

Id.

Richard V.L. Cooper, Blocs: Making the Best of a “Second-Best” Solution, in Regional Trading Blocs, supra note 202, at 32–33.

Id.

Dick K. Nanto, Asian Responses to the Growth of Trading Blocs, in Regional Trading Blocs, supra note 202, at 93.
Southeast Asia's Response to the Potential Breakdown of the Existing World Trading System

The fear of being "left out" of the new world order and the emergence of stronger regional economic identities have encouraged Thailand and other Southeast Asian nations to assert a newfound sense of economic unity and confidence through proposals of different types of trade-based Pacific Rim groupings. Although not an immediately available option to possible Section 301 retaliation by the United States, Thailand could eventually focus its efforts on redistributing its export market throughout ASEAN and Japan. Pacific Rim nations, however, fear that their traditional markets in the United States may be usurped by preferred trading partners in trading blocs, even if they comply with United States intellectual property policy demands. The potential ramifications of a successful Asian grouping are significant: Asia accounts for fifty percent of the world's population, and this consumer base and work force is rapidly expanding.

At the January 1992 ASEAN summit meeting, leaders announced a resolution of two recent proposals regarding ASEAN economic cooperation. First, ASEAN agreed to move slowly on the East Asian Economic Caucus (EAEC). The EAEC, formerly the East Asian Economic Group, was first proposed by Malaysia's Prime Minister Mahathir Mohamad after the breakdown of the Uruguay Round in December of 1990. The EAEC, an intra-

\[\text{RAWTEXT}\]
ASEAN trading bloc, would operate as a loose body within the existing Asia-Pacific Economic Cooperation (APEC)\(^{219}\) to discuss ways to promote trade.\(^{220}\)

Second, ASEAN leaders also agreed to implement an ASEAN Free Trade Area (AFTA)—Thailand's proposal for a free-trade zone—that would encompass 300 million people and create an ASEAN common market.\(^{221}\) The six-nation association will attempt to integrate its economies by reducing or eliminating tariffs on non-agricultural goods within fifteen years beginning January 1, 1993.\(^{222}\) AFTA will use the Common Effective Preferential Tariff (CEPT) scheme in hopes of reducing tariffs to a range of zero to five percent.\(^{223}\) The fifteen groups of products subject to the first round of tariff cuts include pharmaceuticals.\(^{224}\) With Central and South America offering low cost labor and better strategic access to the North American market, this free trade accord is an important move towards attracting investment to Southeast Asia.\(^{225}\) Unlike its disapproval of the EAEC proposal, the United States does not oppose AFTA because its scope is smaller than the EAEC's.\(^{226}\) AFTA, however, is not a match for the EC or NAFTA. Because AFTA's

\(^{219}\) APEC includes the United States, Australia, Brunei, Canada, Indonesia, Japan, South Korea, Malaysia, New Zealand, Philippines, Singapore, Thailand, Hong Kong, China, and Taiwan. While APEC has not accomplished substantive changes, it agreed recently to create a permanent secretariat and budget for ten projects to promote regional cooperation and growth. James Sterngold, A Wary Step Toward Regional Cooperation, N.Y. TIMES, Nov. 17, 1991, § 4, at 5; RICHARD D. FISHER, HOW BUSH CAN PREVENT CREATION OF AN ASIAN ANTI-U.S. TRADE BLOC I (Heritage Foundation Backgrounder No. 169, Oct. 31, 1991, updating AMERICA'S ROLE IN PROMOTING PACIFIC ECONOMIC COOPERATION, Asian Studies Center Backgrounder No. 100).

\(^{220}\) See Sheila Tefft, Southeast Asians Inch Towards Developing Regional Trading Blocs, CHRISTIAN SCI. MONITOR, July 25, 1991, at 4. EAEC would include Indochina, Taiwan, Hong Kong, China, South Korea, and Japan. Id. Slow movement towards complete reliance on intra-ASEAN trade is wise because the general reaction was that it is a political, not economic tool. Japan did not endorse the EAEC for fear of protectionist complaints from the United States. See Wallace, supra note 214, at A3.

\(^{221}\) See SINGAPORE DECLARATION, supra note 216, at 5.

\(^{222}\) Id.

\(^{223}\) Id. The CEPT scheme allows countries to selectively delay cutting tariffs on products they consider too sensitive or products that are produced by an established domestic industry. Id.

\(^{224}\) Id. at 5–6. The other groups are vegetable oils, cement, chemicals, fertilizer, rubber products, leather products, pulp, textiles, ceramic and glass products, gems and jewelry, copper cathodes, electronics, and wooden and rattan furniture. Id.


scope is very narrow, ASEAN countries remain economically dependent on the United States export market for the majority of their goods. Potential problems related to intra-ASEAN trade will be more easily addressed in this smaller forum. This limited regional alliance, however, will not hinder the United States' efforts to effectuate change in Thailand's patent laws as long as the United States remains Thailand's largest export market. Frustrations with currently available methods to initiate dialogue between countries over intellectual property protection have challenged United States leaders to propose alternative systems.

B. United States Initiative: H.R. 2569

On June 6, 1991 Representative Philip M. Crane (R-Ill.) introduced H.R. 2569. This bill encourages the establishment of bilateral free trade areas between the United States and certain Pacific Rim countries. H.R. 2569 attempts to resolve Asian fears of a potential "fortress America" resulting from a successful NAFTA. In addition to the goals of eliminating tariff and non-tariff barriers, H.R. 2569's objective is to negotiate effective mechanisms for developing rules in the nontraditional area of intellectual property protection. This bill provides that "bilateral disputes between the United States and Pacific Rim countries could be more effectively resolved in the context of mutually agreed-upon disciplines and dispute settlement mechanisms rather than by issue-by-issue confrontations under Special 301 or other trade remedy laws."

This proposal to achieve foreign intellectual property protections through a bilateral forum is a more comprehensive solution than past efforts that merely threatened developing countries with trade retaliation. The United States and Thailand may be able to reach an understanding of their mutual concerns, and create a system that is acceptable to the particular needs of each country. The hope is that free trade would result in increased competition, the elimination of inefficiencies, and lower cost to consumers. H.R. 2569 died in the House Ways and Means Committee at the close of

227 See Blustein & Auerbach, supra note 197, at H1.
229 These countries include ASEAN, Australia, New Zealand, Taiwan, South Korea, Japan, and Hong Kong. H.R. 2569, 102d Cong., 1st Sess. § 4 (1991).
230 Id. § 3(2)–(3).
231 Id. § 1(3).
the 102d Congress, but Representative Crane plans to re-introduce it in the upcoming term.232

VII. Conclusion

The success of pharmaceutical patent legislation in Thailand depends on political stability and the country's long-term commitment to economic and technological development. This transformation cannot be sustained by imitating technology; Thailand must invest financial and intellectual resources in its future. Improved patent laws will encourage more MNCs to invest in Thailand and will build a stronger trade relationship with the United States. Significant changes in Thailand's position, necessary to protect United States companies in the Thai pharmaceutical market, cannot be addressed effectively through the multilateral efforts of GATT. Bilateral action through Special 301 presently appears to be the most effective tool to protect MNCs until an alternative solution, such as a bilateral forum suggested by H.R. 2569, can be implemented. The threat of trade retaliation, however, does not aid mutual long-term goals. Increased patent protection safeguards United States R&D investments and will enable Thailand to benefit from more sophisticated and safer pharmaceutical products. Achieving these goals requires an understanding of the economic, political, and social considerations of intellectual property protection within a global arena. While becoming competitive in the international market is costly, Thailand has the potential for great economic rewards and social progress. By revising its Patent Act to protect pharmaceuticals—absent fallbacks such as compulsory licensing or the Board of Pharmaceutical Patents—Thailand can promote better public health and economic growth. Thailand is able to take this next step; the United States, however, should not expect this to be an easy or even rapid transition for Thailand to achieve.

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