United States - Thailand Free Trade Agreement Negotiations: Potential Effects on Pharmaceutical Patent Protection in Thailand

Microsoft Word 10.0.6612;

United States - Thailand Free Trade Agreement Negotiations: Potential Effects on Pharmaceutical Patent Protection in Thailand

Duangrat Laohapakakul

April 2006

This paper is submitted in satisfaction of both the course requirement and the LL.M. written work requirement

Abstract

Benefits and losses that a country would get from entering into a free trade agreement are often controversial and rise to national debate. This is especially apparent for negotiations between developed and developing countries, where there are large discrepancies between the bargaining power and the policies on national growth and development of each party. Numerous debates have dealt with the topics covered under the current U.S. – Thailand Free Trade Agreement (FTA) negotiations. One such topic is the contentious negotiations on intellectual property rights regarding pharmaceutical patents. The negotiations will affect the level of pharmaceutical patent protection in Thailand, as the U.S. tends to negotiate for TRIPS-plus protection. This paper discusses the potential impact of FTA negotiations on law and policies involving pharmaceutical patents in Thailand, an issue which has a direct effect on the Thai public heath system. By focusing the discussion on Thailand's perspective, Part I of the paper provides background information on the current status of the FTA negotiations. Part II examines the international and Thai legal regime on pharmaceutical patent protection. Part III analyzes the major potential issues that the U.S. might propose through FTA negotiations regarding pharmaceutical patent protection and their impact on Thailand. Since the FTA is currently in the negotiation phase, I discuss the issue by analyzing the TRIPS Agreement position as well as the FTA that the U.S. has entered into with Singapore, as it is the model FTA that the U.S. will use for negotiations with other member countries of the Association of Southeast Asian Nations. The conclusion then develops proposals for Thailand's negotiating position.

Introduction

Since the U.S. – Thailand Free Trade Agreement (FTA) negotiations began on June 28, 2004,[1] the Non-Governmental Organizations (NGOs), academia, media and all other relevant sectors have raised extensive debates on the benefits and losses that Thailand would face as a result of the negotiations. On June 10,

[1]Raymond J. Ahearn and Wayne M. Morrison, *U.S. – Thailand Free Trade Agreement Negotiations* (2004), `http://www.thaifta.com/english/index_eng.html` (follow "USA" hyperlink; then follow "U.S. – Thailand Free Trade Agreement Negotiations" hyperlink) (last visited Mar. 28, 2006).

2006, public concern again became apparent as nearly ten thousand protesters clashed with the police and stormed the Sheraton Hotel, Chiang Mai, Thailand, where the sixth round of negotiations took place. With a majority from the HIV/AIDS groups, protesters determined to stop the negotiations on pharmaceutical patent and other intellectual property rights issues. "We are fighting against drug patenting with our lives. I know I might get arrested or injured in clashes with police, but we are all willing to face that, because we have more to lose if the talks succeed,"[2] said of one of the protesters.[3]

On the outset, FTAs are a bilateral approach to free trade that generally aims "to eliminate tariff and non-tariff barriers (NTBs) in order to enhance market access between trading partners."[4] Countries often enter into FTA negotiations with the hope of increasing their economic growth opportunities through trade liberalization. However, there are costs incurring from free trade.[5] With the large discrepancies in the growth and development level of countries around the world, free trade negotiations tend to start off from an unequal playing field. Business sectors, industries or countries which are not well prepared may not be able to compete in the open market.

The spread of the FTA is attributed in part to the slow progress of multilateral liberalization by the World Trade Organization (WTO).[6] It is thought that the U.S. has actively utilized bilateral and regional FTA mechanisms because the Doha round of negotiations under the WTO have not reached much conclusion and issues negotiated were not main interests of the U.S.[7] A few examples of the FTAs that the U.S. have concluded are the North American Free Trade Agreement and the bilateral agreements entered with Chile,

[2]Pennapa Hongthong, *FTA TALKS: Protesters Storm Trade Negotiations*, Jan. 11, 2006, `http://www.ftawatch.org/cgi-bin/content/newse/show.pl?0282` (last visited Mar. 28, 2006).

[3]*Id.*

[4]Thailand Development Research Institute (TDRI), *Thailand-US Free Trade Agreement* 7 (2003), http://www.us-asean.org/us-thai-fta/ (last visited Mar. 28, 2006).

[5]Department of Trade Negotiations, `http://www.thaifta.com/english/index_eng.html` (last visited Mar. 29, 2006).

[6]*Id.*

[7]Jukkrit Kuanpoth, *Khwâmpçnmâ kîeowkab kânèhadtham khçtkânkhâsçrî thai-saharadamçrikâ [Background towards the Preparation for Thailand-U.S.Free Trade Area]*, `http://www.ftawatch.org/autopage1/show_page.php?t=2&s_id=7&d_id=7` (last visited Mar. 20, 2006).

Jordan and Singapore.[8]

The U.S. has also started bilateral FTA negotiations with Thailand. The U.S. – Thailand FTA, which covers a total of twenty-three trade topics, is considered the most comprehensive FTA agreement that Thailand has ever negotiated.[9] One of the most contentious topics is the issue of intellectual property rights regarding pharmaceutical patent protection, as the U.S. tends to negotiate for TRIPS-plus provisions[10]. Main concerns are drawn from the AIDS activists, as Thailand is now subsidizing access to AIDS treatment for nearly eighty thousand of an estimated one hundred and seventy thousand patients who currently need AIDS treatment. Such treatment is made possible with the low cost generic competition for first-line AIDS medicines.[11] The cost of treating patients with anti-retroviral drugs is around ten thousand Baht a month for a patented drug, while drops to just one thousand two hundred Baht for generic drugs.[12] Thus, it is crucial for Thailand to assess and understand the potential impacts that the FTA negotiations will have on Thai pharmaceutical patent protection beforehand, in order for it to reach a more appropriate negotiation position that corresponds to the level of development of the country.

This paper will discuss the potential impact of FTA negotiations on law and policies involving pharmaceutical patents in Thailand, an issue which has a direct effect on the Thai public heath system. By focusing the discussion on Thailand's perspective, Part I of the paper provides background information on the current status of the FTA negotiations. Part II examines the international and Thai legal regime on pharmaceutical patent protection. Part III analyzes the major potential issues that the U.S. might propose through FTA

[8]More details of the FTAs are available at `Office of the United States Trade Representative, Bilateral Trade Agreements, http://www` (last visited Mar. 25, 2006).

[9]Nitya Pibulsonggram, *Process and Progress of Thailand – U.S. FTA Negotiations*, Nov. 22, 2004, `http://www.thaifta.com/english/index_eng.html` (follow "USA" hyperlink; then follow "Process and Progress of Thailand-US FTA Negotiations, Banyan Tree Hotel, 22 November 2004" hyperlink) (last visited Mar. 28, 2006).

[10]Provisions that contain more stringent rules than those minimum requirements stated under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) are often called the "TRIPS-plus" provisions. *See* Hunton & Williams LLP, *Thailand –US FTA: A Roadmap to Negotiations* 61 (2003), `http://www.thaifta.com/ftaus_roadmap.pdf` (last visited Mar. 15, 2006).

[11]Bilaterals.org, *Myths and Realities: The Impact of the US-Thai FTA on Access to Medicines*, Feb. 2, 2006, `http://www.bilaterals.org/article.php3?id_article=3711` (last visited Apr. 4, 2006).

[12]Reuters, *Trade Deal Won't Hit Thai Generic AIDS Drugs – U.S.*, May 4, 2005, `http://www.ftawatch.org/autopage1/show_page.php?t=22&s_id=1&d_id=1` (last visited Mar. 25, 2006).

negotiations regarding pharmaceutical patent protection and their impact on Thailand. Since the FTA is currently in the negotiation phase, I will discuss the issue by analyzing the TRIPS Agreement position as well as the FTA that the U.S. has entered into with Singapore, as it is the model FTA that the U.S. will use for negotiations with other member countries of the Association of Southeast Asian Nations (ASEAN). The conclusion then develops proposals for Thailand's negotiating position.

I.

Background of the U.S. - Thailand Free Trade Agreement Negotiations

During the tenth Asia-Pacific Economic Cooperation Leaders Meeting held in October 2002, President George W. Bush announced the Enterprise for ASEAN Initiative (EAI) as a new U.S. trade initiative with ASEAN.[13] Under the EAI, the U.S. aimed to reach a network of bilateral trade agreement negotiations that will increase trade and investment with the ASEAN countries.[14]

The U.S. – Thailand FTA negotiations were a result of the EAI.[15] President Bush and Thai Prime Minister Thaksin Shinawatra agreed on October 19, 2003 to negotiate a bilateral FTA, and subsequently on March 30, 2004 both parties announced that the negotiations would begin on June 28, 2004.[16] The FTA was intended not only to eliminate tariffs and non-tariff barriers between the parties, but also to be a comprehensive one

[13]TDRI, *supra* note 4, at i.

[14]The White House, *Fact Sheet on Free Trade and Thailand*, Oct. 20, 2003, `http://www.thaifta.com/english/index_eng.html` (follow "USA" hyperlink; then follow "Fact Sheet on Free Trade and Thailand" hyperlink) (last visited Mar. 28, 2006).

[15]TDRI, *supra* note 4, at i.

[16]Ahearn & Morrison, *supra* note 1.

that covers a wide range of topics, such as investment, trade remedies, telecommunications and intellectual property rights.[17] It is likely to be based on the U.S. – Singapore FTA model, as suggested in the EAI.[18] Before the negotiation started, Thailand was the U.S.'s nineteenth largest overall trading partner. The U.S. was Thailand's largest export market and second largest source of imports, while Thailand was the U.S.'s twenty-third largest export market and sixteenth largest supplier of imports.[19]

The U.S. Trade Representative Robert Zoellick's notification letter to the Speaker of the House and the Senate Majority Leader stated that the U.S. – Thailand FTA would benefit the U.S. agricultural producers as well as companies that export industrial goods and services by increasing export sales to Thailand. The FTA will also help U.S. investors in Thailand by preserving the preferential status (national treatment) of U.S. businesses.[20] However, the FTA itself would have limited effect on the overall U.S. economy as Thailand's economy is $1/100^{th}$ in size comparing to that of the U.S.[21] There were also benefits for the U.S. foreign policy for entering into the FTA, such as strengthening Thailand's position as its key military ally in the war of terrorism.[22]

For Thailand, incentives to negotiate an FTA with the U.S. were also centered on economic and political considerations. Thailand was concerned that it not lose its export market share in the U.S. to other countries and wanted to attract more investments into the country. It also looks forward to the transfer of skills and technologies to increase its competitiveness. A tighter relation with the U.S. would also increase its leverage among Southeast Asian countries.[23]

Currently, the U.S. and Thailand have completed six rounds of negotiations, the latest being held on January

[17] Pibulsonggram, *supra* note 9.
[18] TDRI, *supra* note 4, at i; Ahearn & Morrison, *supra* note 1.
[19] Economic Section, Royal Thai Embassy, *The United States – Thailand Free Trade Agreement: Building Blocks for a Prosperous Future*, `http://www.thaifta.com/english/index_eng.html` (follow "USA" hyperlink; then follow "The United States – Thailand Free Trade Agreement: Building Blocks for a Prosperous Future" hyperlink) (last visited Mar. 28, 2006).
[20] The White House, *supra* note 14.
[21] Ahearn & Morrison, *supra* note 1.
[22] *Id.*
[23] *Id.*

9-13, 2006.[24] The U.S. has only proposed the issue of patent protection for negotiation during the sixth round of talk.[25] The pharmaceutical patent issue is one of the more contentious issues in the negotiation, as it has long been anticipated that the U.S. will negotiate for TRIPS-plus level of intellectual property protection.[26]

II.

Legal Regime on Pharmaceutical Patent Protection

As a background for analyzing the potential impacts of the U.S. – Thailand FTA negotiations on pharmaceutical patent protection in Thailand, I will first examine the concept of patent protection as well as the current international and Thai legal regime on pharmaceutical patent protection.

A.

Patent Protection

[24]Department of Trade Negotiations, *Thailand-U.S. Free Trade Agreement*, http://www.thaifta.com/ (last visited Mar. 28, 2006).

[25]Jiraporn Limpananont, *FTA Watch pôedphœi khøsanôe lɛ̀phonkânwikhr̄ rûang sidthibad FTA thai-saharad "..." [FTA Watch Discloses the Proposals and Analysis on Thai-U.S. FTA Patent]*, `http://www.ftawatch.org/autopage1/show_page.php?t=3&s_id=10&d_id=10` (last visited Mar. 24, 2005).

[26]Pibulsonggram, *supra* note 9.

What is a patent? No definition of a patent is given under the major international conventions like the Paris Convention for the Protection of Industrial Property (Paris Convention) and TRIPS Agreement.[27] The World Intellectual Property Organization (WIPO) described a patent as "an exclusive right granted for an invention, which is a product or a process that provides, in general, a new way of doing something, or offers a new technical solution to a problem."[28] The general concept of a patent can be viewed as a bargain between the inventors and the countries in which patent is applied for. The inventors are granted the exclusive rights to their inventions for a period of time as a return for their inventions, while the countries can benefit from the disclosure of invention details.[29]

The necessity of a patent system is still debatable. In the course of history, the world has long prospered technologically and inventors have developed inventions without a patent system.[30] Concepts that justify the purpose of patents such as the reward theory or natural right theory are still refutable.[31] Nonetheless, patent grants are mainly aimed to enhance the world advancement by creating incentives for research, data disclosure, and the investment needed to assure that the invention is in fact developed and brought to the market. Whether such benefit would suffice their drawbacks primarily depends on their implication on the particular industry sector and unique condition of each country.

The merit of the invention shifts the world's justification on the extent of patent protection.[32] This is particularly significant when a patent is being applied to the pharmaceutical industry. Granting a monopoly to the pharmaceutical manufacturers may be detrimental to the public interest in some countries, while acceptable in others. For those that are not, questions are raised whether other forms of compensation can be provided

[27] Jakkrit Kuanpoth, *Kôdhmâysidthibad nżewkhwâmkhid lż botwikhr̨ [Patent Law: Idea and Analysis]* 8 (2d ed. 2001) [hereinafter Kuanpoth, *Patent Law*].

[28] Patents - Frequently Asked Questions, WIPO, `http://www.wipo.int/patentscope/en/patents_faq.html#patent` (last visited Mar. 29, 2006).

[29] Peter L. Kolker, *TRIPS Agreement: Patent Protection* 14 (2000).

[30] Nuno Pires de Carvalho, *The TRIPS Regime of Patent Rights* 1 (2d ed. 2005).

[31] *Id.* at 1-2; Kuanpoth, *Patent Law*, *supra* note 27, at 26-30.

[32] Carvalho, *supra* note 30, at 4.

for the inventors, such as having the government subsidizes the cost of inventions or granting rewards for innovations. As long as the world upholds the patent system, an appropriate balance between the rights of the inventors and public interests in the context of a particular society must be closely considered. This is to ensure that the system increases social welfare, and not destroy it instead.

B.

International Standards for Pharmaceutical Patent Protection

1.

International Protection of Intellectual Property Rights

As intellectual property is vulnerable to copying and spreading across borders, international protection became vital for a comprehensive intellectual property protection system.[33] Before the nineteenth century, international protection on patent rights was granted only through a reciprocity principle under bilateral agreements. The level of protection varied upon each negotiation.[34] Accordingly, countries worked towards a uniform international patent protection system and eventually agreed upon the Paris Convention, which became effective on July 7, 1884.[35]

Ideas and knowledge involving intellectual property rights later became an important comparative advantage

[33] Kuanpoth, *Patent Law*, *supra* note 27, at 219.
[34] *Id.* at 222.
[35] *Id.* at 223.

for industrial countries to compete in the world market. A uniform rule on intellectual property protection increased its importance as the countries linked the issue with international trade. The disparity in intellectual property protection standards became a source of tension in international economic relations among countries.[36]

In 1986, the industrialized countries pushed for the intellectual property rights issue to be discussed under the Uruguay round trade negotiations of General Agreement on Tariffs and Trade.[37] The results of the Uruguay round trade negotiations were set forth in "The Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations" signed in Marrakesh in 1994. The Agreement Establishing the WTO entered into force on January 1, 1995, and it incorporated the Agreement on Trade Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods, commonly known as the "TRIPS Agreement".[38]

> The TRIPS Agreement includes five broad issues, which are:
>
> "(1) how basic principles of the trading system and other international intellectual property agreements should be applied;
>
> (2) how to give adequate protection to intellectual property rights;
>
> (3) how countries should enforce those rights adequately in their own territories;
>
> (4) how to settle disputes on intellectual property between members of the WTO; and
>
> (5) special transitional arrangements during the period when the new system is being introduced."[39]

[36] WTO, *Intellectual Property: Protection and Enforcement*, http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm (last visited Mar. 29, 2006) [hereinafter WTO, *Intellectual Property*].

[37] Kuanpoth, *Patent Law*, *supra* note 27, at 21.

[38] WTO, *Legal Texts: The WTO Agreements*, http://www.wto.org/english/docs_e/legal_e/ursum_e.htm#nAgreement (last visited Mar. 29, 2006).

2.

Protection of Pharmaceutical Patents under the TRIPS Agreement

As most countries in the world are now a member of the WTO,[40] the minimum standard of intellectual property rights protection set forth by the TRIPS Agreement has become the dominant rule that member countries have to comply with. Inventions in the area of pharmaceuticals are granted patent protection under the TRIPS Agreement,[41] which attempts to achieve a balance between the long term objective of providing incentive for research and development of new pharmaceutical products, and the short term objective of making existing drugs to be available as much as possible.[42]

Under the TRIPS Agreement, patent protection must be uniformly available for any invention, whether product or process, in all fields of technology, on the condition that such inventions are new, involve an inventive step and are capable of industrial application.[43] However, the TRIPS Agreement has specified certain exceptions to the rule of patentable subject-matter which may be applicable to the pharmaceutical practice. Exceptions to such rule include: "(1) inventions the prevention of whose commercial exploitation is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health; (2) diagnostic, therapeutic and surgical methods for the treatment of humans or animals; and (3) certain plant and animal inventions."[44]

Patent protection must not expire before twenty years from the filing date of the patent application.[45] The TRIPS Agreement does not allow the extension of the patent term to compensate for the delays in the marketing of new pharmaceutical products due to the prolonged marketing approval from relevant health

[43]Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, art. 27.1, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments – Results of the Uruguay Round, *33 I.L.M. 1197 (1994)* [hereinafter TRIPS].

[44]*Id.* at art. 27.2 & 27.3; WTO, *Pharmaceutical Patents and the TRIPS Agreement*, *supra* note 41.

[45]TRIPS, *supra* note 43, at art. 33.

authorities.[46]

The area of rules most significant to the developing and least-developed countries regarding a pharmaceutical patent is the flexibility the TRIPS Agreement provided for patent protection. The flexibility, such as exceptions to the exclusive rights, compulsory licensing and parallel importation, are the channels that make it possible for countries to narrow down the level of patent protection in exchange for public health benefits. For instance, countries may allow pharmaceutical manufacturers to use patented inventions to obtain marketing approval before the patent term expires, in order to shorten the time for launching new medicines in the market.[47] The TRIPS Agreement also allows compulsory licensing and government use of a patent without the consent of the patent holder, subject to certain conditions.[48]

The concern that pharmaceutical patents may cause a negative impact on the access to affordable medicines and be detrimental to public health regime of developing and least-developed countries is shared by the world community. Due to the rigid provisions of the TRIPS Agreement, certain member countries, especially those developing and least-developed countries facing public health problems and epidemics, were uncertain about the impact of the TRIPS Agreement on public health issues. They feared that they might have to face trade retaliation if they utilized the flexibility provisions. The 2001 Doha Declaration on TRIPS Agreement and Public Health (Doha Declaration) clarified the uncertainty by stressing that the TRIPS Agreement should not deter members from taking measures to protect the public health. The interpretation and implementation of the TRIPS Agreement must be made in support of public health and promote accessibility to medicines.[49] Certain conclusions reached in the Doha Declaration include granting members freedom to determine the appropriate ground for compulsory licenses and the exhaustion of intellectual property rights, as well as emphasizing that a public health crisis may represent a national emergency or other circumstances

[46] WTO, *Pharmaceutical Patents and the TRIPS Agreement*, *supra* note 41.
[47] The example is also known as the Bolar provision. *See* WTO, *Fact Sheet*, *supra* note 42.
[48] *See* TRIPS, *supra* note 43, at art. 31.
[49] WTO, *Fact Sheet*, *supra* note 42.

of extreme urgency.[50]

Another major development on the public health issue was the resolution of the so-called "Paragraph 6" issue. On August 30, 2003, member countries agreed to allow countries to import cheaper generics made under compulsory licensing if they are unable to manufacture medicines themselves. The obligation under Article 31(f) of the TRIPS Agreement that requires medicines produced under compulsory licensing be supplied only in the domestic market were waived.[51]

C.

Pharmaceutical Patent Law in Thailand

1.

Background of Pharmaceutical Patent Protection in Thailand

Requests from domestic industries and the national policy in promoting industrial development and international trade were the early forces that drove Thailand to turn towards patent protection.[52] As a civil law country, Thailand must enact an Act in order to legitimately recognize patent rights. The Thai government had first proposed a draft patent act for consideration by the legislature in 1965, but it was refused because of the fear that patent law would result in trade monopoly and an increased burden on consumers. The lack

[50]WTO, Declaration on the TRIPS Agreement and Public Health, Nov. 14, 2001, WT/MIN(01)/DEC/2 (2001), http://www.wto.org/english/tratop_e/trips_e/pharmpatent_e.htm (last visited Mar. 28, 2006); *Id.*

[51]WTO, *Fact Sheet*, *supra* note 42.

[52]Kuanpoth, *Patent Law*, *supra* note 27, at 21.

of readiness in terms of manpower and facilities to accommodate the patent system was another concern of the legislature.[53]

Patent protection in Thailand was eventually recognized through the enactment of the Patent Act B.E. 2522 (A.D. 1979) (1979 Act), which came into effect on September 12, 1979.[54] It was clearly specified under this 1979 Act that pharmaceutical products were not patentable.[55] Only pharmaceutical processes were eligible for patent protection, which corresponded to the level of pharmaceutical development of the country at that time.[56]

During the 1980s-1990s, the U.S. government pressured Thailand to amend the patent protection granted under the 1979 Act by tying trade retaliation measures to the protection of intellectual property rights.[57] For instance, it cut Thailand's Generalized System of Preferences for certain goods in January 1989 for the reason that Thailand did not provide sufficient intellectual property protection to U.S. nationals, especially on the protection of computer programs and pharmaceutical products.[58] It also threatened to use Section 301 of the Omnibus Trade and Competitiveness Act of 1988 as a trade retaliation measure.[59]

As a result, Thailand amended the 1979 Act in 1992 on various important issues, including making pharmaceutical products patentable[60]. The amendment also set up mechanisms to monitor the price and availability

[53] *Id.* at 22.

[54] *Id.* at 22.

[55] Section 9 of the 1979 Act states that "The following inventions are not patentable: (1) food, beverage or pharmaceutical products." *See* Pharâtchabanyat sidthibad pho so 2522 [Patent Act B.E. 2522 (A.D. 1979)], available at http://www.krisdika.go.th/lawHeadPDF.jsp?formatFile=pdf&hID=4 (last visited Apr. 4, 2006).

[56] Jiraporn Limpananont, *Khţoklông kânkhâsçrî thai-saharadamçrikâ kânkhumkhţng sabsinthângpanyâ kab phonkrathob t̨ rabobyâ lż rabobsukkhaphâb khţng prathçtthai [Thailand – U.S. FTA Agreement: Intellectual Property Protection and the Effects on Pharmaceutical and Health System in Thailand]*, http://www.ftawatch.org/autopage1/show_page.php?t=3&s_id=8&d_id=8. (last visited Mar. 28, 2006).

[57] Kuanpoth, *Patent Law*, *supra* note 27, at 22.

[58] Farnsworth (1989) "US Curbs Thai Goods", New York Times, b.1, as cited in *id.* at 268.

[59] Kuanpoth, *Patent Law*, *supra* note 27, at 275-276.

[60] Section 4 of the Patent Act (No. 2) B.E. 2535 (A.D. 1992) amended Section 9 of the 1979 Act by removing pharmaceutical products from one of the items that are not patentable. *See* Pharâtchabanyat sidthibad (chababthî 2) pho so 2535 [Patent Act (No. 2) B.E. 2535 (A.D. 1992)], available at http://www.krisdika.go.th/lawHeadPDF.jsp?formatFile=pdf&hID=3 (last visited Apr. 4, 2006).

of drugs in the market,[61] in order to prevent pharmaceutical patent holders from abusing their rights. However, such mechanisms were later revoked by the second amendment to the 1979 Act in 1999.[62]

2.

Current Pharmaceutical Patent Protection

On the international level, Thailand is not a party to any international treaty or convention regarding patent protection, except for the TRIPS Agreement.[63] The 1979 Act, which was amended twice respectively in 1992 and 1999,[64] is the domestic law governing pharmaceutical patent protection in Thailand. Currently, the Patent Act recognizes protection of inventions, which include pharmaceutical products and processes. An invention is patentable if: (1) it is a new invention; (2) it involved in higher inventive step; and (3) it is capable of industrial application.[65] The inventor might also choose to apply for a petty patent if criteria (1) and (3) are met.[66] However, the law does not allow the application for both a patent and a petty patent for the same invention.[67]

In order to obtain patent protection under the law, applicants have to file applications with the relevant authority in accordance with the formalities specified in the Patent Act. Generally, the patent lasts for a

[61] *Id.* at Part 7 of Title II.

[62] Section 25 of the Patent Act (No. 3) B.E. 2542 (A.D. 1999) revoked Part 7 of Title II of the Patent Act (No. 2) B.E. 2535 (A.D. 1992) on pharmaceutical patent measures. *See* Pharâtchabanyat sidthibad (chababthî 3) pho so 2542 [Patent Act (No. 3) B.E. 2542 (A.D. 1999)], available at http://www.krisdika.go.th/lawHeadPDF.jsp?formatFile=pdf&hID=1 (last visited Apr. 4, 2006).

[63] Kuanpoth, *Patent Law*, *supra* note 27, at 22.

[64] The updated 1979 Act, which incorporates all subsequent amendments, shall hereinafter refer to as the "**Patent Act**". The Patent Act is available at `http://www.krisdika.go.th/lawHeadPDF.jsp?formatFile=pdf&hID=0` (last visited Apr. 4, 2006).

[65] *Id.* at sec. 5.

[66] *Id.* at sec. 65 bis.

[67] *Id.* at sec. 65 ter.

term of twenty years from the filing date of the patent application within the country.[68]

As in the TRIPS Agreement, the Patent Act has also specified some flexibility for patent protection. The Patent Act recognizes compulsory licensing as a remedy to the abuse of a monopoly right.[69] There are also two exceptions to the exclusive rights that directly concern the pharmaceutical industry. First, professional pharmacists or medical practitioners may compound drugs to fill a doctor's prescription as well as use pharmaceutical products without the consent of, or remuneration paid to, the patent holder.[70] This exception is aimed at protecting the public against a monopoly by the patent holders and preventing the medical practitioners from infringing pharmaceutical patent in treating patients.[71]

The second exception is similar to the Bolar exception under the TRIPS Agreement. The Patent Act allows applicants to file for drug registration if they intend to produce, distribute or import patented pharmaceutical products after the expiration of the existing patent term.[72] Such exception allows pharmaceutical companies to file a drug application during the patented term and enable them to release the products immediately after the expiration of the patent term. The provision is meant to promote competition among pharmaceutical companies and lessen time for generic drugs to be available to the market, which will enhance public benefit.[73]

---

[68] *Id.* at sec. 35.

[69] Jakkrit Kuanpoth, *Major issues in the Thai patent system*, `http://www.thailawforum.com/articles/jakpat6.html` (last visited Feb. 12, 2006).

[70] Kuanpoth, *Patent Law*, *supra* note 27, at 312; Patent Act, *supra* note 64, at sec. 36 para. 2(3).

[71] Kuanpoth, *Patent Law*, *supra* note 27, at 312.

[72] Patent Act, *supra* note 64, at sec. 36 para. 2(4).

[73] Kuanpoth, *Patent Law*, *supra* note 27, at 314.

III.

Potential Issues from the U.S. -Thailand FTA Negotiations Regarding Pharmaceutical Patent Protection and Their Assessment

No official public disclosure on the details of the U.S.'s proposals regarding pharmaceutical patent protection is now available to the public. However, as suggested in the EAI, the U.S. - Thailand FTA will be based on the U.S. – Singapore FTA model and the U.S. made its stance clear that it will negotiate for TRIPS-plus protection. Therefore, I will evaluate the major potential issues based on the terms agreed to in the U.S. – Singapore FTA, which was begun on November 16, 2000 and concluded on January 15, 2003. The U.S. – Singapore FTA was the first FTA the U.S. entered with an ASEAN country under the EAI.[74]

Since both the U.S. and Thailand have to comply with the minimum standards of patent protection stipulated under the TRIPS Agreement, the main potential issues of the negotiation focus on around the flexibility provisions of the TRIPS Agreement, such as compulsory licensing provisions and parallel importation mechanism. The TRIPS Agreement leaves room for countries to adjust the level of compliance to their own needs.[75]

[74]Office of the United States Trade Representative, *Quick Facts: U.S. – Singapore Free Trade Agreement*, May 6, 2003, `http://www.ustr.gov/Document_Library/Fact_Sheets/2003/Quick_Facts_US-Singapore_Free_Trade_Agreement.html` (last visited Mar. 28, 2006).

[75]Rahul Rajkumar, *The Central American Free Trade Agreement: An End Run Around the Doha Declaration on TRIPS and Public Health*, 15 Alb. L.J. Sci. & Tech. 433 (2005).

A.

Extension of the Term of Patent Protection

1.

Changes to the Rules

The first major issue that is likely to be proposed by the U.S. under the FTA is the indirect extension of patent protection term. The term of patent protection under Thai law corresponds with that of the TRIPS Agreement, which is not less than twenty years. No extension is possible under both bodies of rules.

Under the U.S. – Singapore FTA, however, a patent term may be extended beyond the presumed twenty year period in many cases.[76] First, the patent holder may request for a three or five year extension of the patent term, as the case may be, to compensate for unreasonable delays in granting the patent.[77] The second case is where patent is to be granted based on the examination of the invention conducted in another country. If such other country experiences delay in issuing the patent and extends the patent term, the patent holder may also request for up to five years of extension in the filing country.[78] Last, an extension of the patent term for a pharmaceutical product is also possible for unreasonable curtailment of the patent term due to the marketing approval process.[79]

[76] The U.S. – Singapore FTA does not specify the patent term, but it was presumed to be twenty years as the provision bases on the TRIPS Agreement. *See* Oxfam International, *Oxfam Briefing Note: Undermining Access to Medicines: Comparison of Five US FTAs* 4 (2004), http://www.oxfamamerica.org/newsandpublications/publications/briefing_papers/art7360.html (last visited Mar. 12, 2006).

[77] United States – Singapore Free Trade Agreement, U.S.-Sing., Jan. 15, 2003, art. 16.7(7), http://www.ustr.gov/Trade_Agreements/Bilateral/Singapore_FTA/Final_Texts/Section_Index.html (last visited Mar. 16, 2006) [hereinafter U.S. – Singapore FTA].

[78] *Id.* at art. 16.7(8).

[79] *Id.* at art. 16.8(4)(a).

2.

Assessment

As mentioned in Part II, the basic underlying principle of patent protection is the balance between the benefit of the inventors and the general public. The "inventors" who gain the benefit of patent protection in the pharmaceutical industry are the pharmaceutical manufacturers. The temporary monopoly granted to these manufacturers is meant for them to earn benefits in compensation for the high research and development costs incurred in developing new drugs. The companies are expected to invest more in pharmaceutical research and development with the high benefits they earn during the monopoly.

Accordingly, the question arises on how long is appropriate for these pharmaceutical manufacturers to have a monopoly. For developing countries, the longer pharmaceutical patent protection is granted to the patent holders, the slower the cheaper generic versions of patented drugs will be made available to the market. A prolonged time might result in unnecessary suffering or death especially to those countries that cannot afford expensive drugs.[80]

From Thailand's standpoint, the objective of patent protection in encouraging more research and development will not be achieved with a long monopoly period, as most of the parties gaining benefit from patent protection are foreigners. A study basing on two thousand four hundred and forty-four patent applications filed from 1992-2002 in Thailand shows that most patent applicants are foreigners, comprised mostly of Americans, Germans, Japanese, Swiss and Swedish, with only one point three one percent of Thais. Ninety-eight points zero eight percent are applications first filed in other country. The figures reflect that the

[80] Oxfam International, *supra* note 76, at 6.

research and development that leads to patent registration does not occur in Thailand, nor is it conducted by Thais.[81] Longer patent protection will instead be an obstacle for Thais to access to data necessary for creating new inventions.

Moreover, pharmaceutical sales in Thailand contributed only a small portion of the total global sales. The U.S. pharmaceutical companies make eighty-eight point five percent of their sales from markets of North America, Europe and Japan. The trivial profit gained from the Thai market does not contribute much to the research and development of these companies.[82] Major companies in the pharmaceutical industry also spend nearly three times as much on marketing and administration as on research and development. They usually profit twice more than what they have invested in the tax-deductible research and development.[83] Thus, the argument that pharmaceutical companies need long patent protection in gaining profit and encouraging research and development of new drugs has no weight when applied to the developing countries' context.

Each pharmaceutical manufacturer will also have the best knowledge on the products it developed. If they are able to further improve the technology into new invention, new patent with a new term of protection may be granted.[84] In many cases, delays on patent issuance also result from the applicants themselves in not proceeding with the patent examination filings.[85] Therefore, the extension of patent term is deemed unnecessary.

Taking into account the idea that all property rights have duration, property rights in tangible goods last with the physical toleration of the subject matter, while intangible property like a patent lasts according to the average length of time society frames for such property, which may vary by the different areas of innovation.[86] Most patent laws, however, use a uniform average term of patent protection they deem appropriate

[81] Limpananont, *supra* note 56.
[82] Bilaterals.org, *supra* note 11.
[83] *Id.*
[84] Kuanpoth, *Patent Law*, *supra* note 27, at 217.
[85] Limpananont, *supra* note 56.
[86] Carvalho, *supra* note 30, at 378.

for all areas of technology for practical purpose.[87] Thus, since the WTO member countries have negotiated and agreed upon the twenty year term of patent protection under the TRIPS Agreement, such term should be used as the base line for pharmaceutical patent protection without any direct or indirection extension.

B.

Restrictions on Compulsory Licensing and Data Exclusivity

1.

Changes to the Rules

Compulsory licensing is the situation where the government allows a third party to produce the patented product or utilize the patented process without the patent holder's consent.[88] The TRIPS Agreement and the Doha Declaration allow each member country to determine the grounds for compulsory licensing, in support of public health benefits. For Thailand, compulsory licensing under Thai law may be applied when the patented process is not being used in the country or the patented product is not produced or sold, or is sold at an unreasonably high price, or the supply does not meet public demand within the country without any legitimate reason.[89] The latest amendment to the Patent Act in 1999 also allows the government to exercise compulsory licensing in case of severe drug shortage or for other public interest protection, which is

[87] *Id.* at 378.
[88] WTO, *Fact Sheet*, *supra* note 42.
[89] Patent Act, *supra* note 64, at art. 46.

a broad ground for utilizing compulsory licensing.[90]

On the contrary, the proposals of the U.S. through the FTA set more rigid grounds and conditions to use compulsory licensing. The U.S. – Singapore FTA limits compulsory licensing application only to cases where there are anti-competition practices; public, non-commercial use; or national emergency or circumstances of extreme urgency.[91] Besides the limited grounds, the compensation standard for the use of compulsory licensing set under the FTA, being "reasonable and entire compensation", is also higher than that of the TRIPS Agreement, where "adequate remuneration" must be paid to the patent holders.[92] Parties to the FTA also cannot request for the transfer of relevant undisclosed information or technical know-how from the patent holder.[93]

A further hurdle to the use of compulsory licensing laid down as the U.S. - Singapore FTA requires stringent test data exclusivity and prevents generic manufacturers from obtaining market approval prior to the expiration of the patent term. Under the FTA, parties must provide a five year period of protection for information concerning the safety and efficacy of a pharmaceutical product submitted for marketing approval anywhere in the world. They shall not allow third parties to market the same or similar products during the specified period of time without the consent of the information provider.[94] Article 16.8(3) of the FTA also specifies that the test data protection must be upheld even if the patent protection is already terminated. Thai law does not have such restriction and it complies with the minimum TRIPS Agreement standard. Article 39.3 of the TRIPS Agreement only requires the member countries to protect data against unfair commercial use, which is not interpreted extensively to include data exclusivity.[95] The government can still use such data in

[90] *Id.* at art. 51.
[91] U.S. – Singapore FTA, *supra* note 77, at art. 16.7(6); *See* Oxfam International , *supra* note 76, at 10.
[92] U.S. – Singapore FTA, *supra* note 77, at art. 16.7(6); TRIPS, *supra* note 43, at art. 31(h); *See* Oxfam International, *supra* note 76, at 10-11.
[93] U.S. – Singapore FTA, *supra* note 77, at art. 16.7(6).
[94] More details in U.S. – Singapore FTA, *supra* note 77, at art. 16.8.
[95] Rajkumar, *supra* note 75.

considering the marketing approval for the same product for other companies.[96]

2.

Assessment

The proposal of the U.S. for harder implementation of compulsory licensing and strict data exclusivity protection are much criticized by the global community. Compulsory licensing is one of the key flexibility provisions that developing and least-developed countries depend upon to protect its public health system, especially when there is a high demand for a drug. For instance, Brazil was able to negotiate with multi-national pharmaceutical companies for affordable anti-retroviral drugs through the threat of compulsory licensing.[97]

The more stringent grounds for compulsory licensing and higher compensation paid to the patent holders under the U.S. – Singapore FTA are restrictions which undeniably benefit pharmaceutical manufacturers in developed countries. Data from the World Health Organization (WHO) shows that of the ten largest pharmaceutical companies that control over one-third of the three hundred billion dollars market, six of them are based in the U.S. and four in Europe. It is also anticipated that North America, South America, Europe and Japan will continue to dominate eighty-five percent of the world pharmaceutical market in the twenty first century.[98] Thailand does not have a share of any advantage of such proposals.

[96] Jukkrit Kuanpoth, *Khṭoklông kânkhâsçrî thai-saharad "..." panhâ wâdûay "TRIPS phanûak" [Thailand-U.S. Free Trade Agreement: Issue on "TRIPS-plus"]*, `http://www.ftawatch.org/autopage1/show_page.php?t=3&s_id=3&d_id=3` (last visited Mar. 24, 2006) [hereinafter Kuanpoth, *Issue on "TRIPS-plus"*].

[97] Paul J. Heald, *Mowing the Playing Field: Addressing Information Distortion and Asymmetry in the TRIPS Game*, 88 Minn. L. Rev. 249, 252 (2003), as cited in Rajkumar, *supra* note 75.

[98] *See* WHO, *Pharmaceutical Industry*, available at `http://www.who.int/trade/glossary/story073/en/index.html` (last vis-

Moreover, the U.S.'s proposal on data exclusivity and compulsory licensing provisions bars other manufacturers from entering the market, which are disadvantageous to the Thai public health system. With the data exclusivity provision, generic drug companies would have to repeat the long and costly tests of the product in obtaining marketing approval. The repetition of the tests is restrictive during emergencies and is economically impossible as it is often too expensive to invest and gain access to a considerably small market like Thailand.[99] With the lack of competition from generic drug companies, patent holders tend to have a monopoly period beyond the patented term and can maintain a high drug price.[100] The restriction on data exclusivity also makes it unfeasible to use compulsory licensing even if the grounds to utilize it are met.[101] Generally, data exclusivity should be used in countries where a pharmaceutical patent is not properly enforced. Thailand has implemented a considerable pharmaceutical patenting system and the Food and Drug Administration of Thailand has also enforced data protection during the marketing approval process for drugs under the Trade Secret Act B.E. 2545 (A.D. 2002), which is in accordance with the requirements of the TRIPS Agreement.[102]

Nonetheless, it is argued from the pharmaceutical manufacturers' perspective that the use of compulsory licensing and the weak data exclusivity provisions tend to deprive them from their monopoly rights and reduce the incentive to invest in research and development, especially on diseases threatening developing countries.[103] However, to a large extent, pharmaceutical companies do not innovate only because of strong patent protection. They often gain additional incentives, such as government subsidy for the cost of research or favorable tax incentives, to conduct their useful inventions. The companies will basically develop new

ited Mar. 1, 2006).

[99] Bilaterals.org, *supra* note 11.

[100] *Id.*

[101] Oxfam International, *supra* note 76, at 14.

[102] FTA Watch Group, *Khṭoklông kânkhâsçrî thai-saharad "..." phonkrathob ṭ kânkhaothýngyâ khṇng prachâchôn [Thailand-U.S. Free Trade Agreement: Effect on Citizens' Access to Medicines]*, `http://www.ftawatch.org/autopage1/show_page.php?t=6&s_id=8&d_id=8` (last visited Mar. 10, 2006).

[103] Rajkumar, *supra* note 75.

drugs in which there is a market demand for the drugs to stay in business.[104] The pharmaceutical industry already gains substantial profits under the current patent protection regime. Most importantly, compulsory licensing only come into use when there are special circumstances, such as public health emergencies, and certain conditions protecting the patent holders are met. Thus, Thailand need not raise its patent protection by making compulsory licensing harder to utilize. It needs only to conform to the minimum compulsory licensing and data protection rules stipulated by the TRIPS Agreement and to uphold the Doha Declaration, which emphasizes that member countries may use compulsory licensing mechanism for public health purposes without the fear of trade retaliation. By complying with the TRIPS Agreement standards, pharmaceutical companies are granted with the level of protection agreed multilaterally.

C.

Blockage of Parallel Importation

1.

Changes to the Rules

Parallel importation is a result of free trade. As the pharmaceutical industry tends to manufacture drugs with various quality and prices to different parts of the world,[105] parallel import generally allows countries

[104] John Doulamis, *Getting Back in the Path to Life: Negotiating the International Patent Regime to Provide Access to HIV Medicines to Africa* 33-36 (2004), `http://www.law.harvard.edu/faculty/hutt/table_of_contents_2002.html` (last visited Apr. 1, 2006).

[105] Liew Woon Yin, *Intellectual Property Rights*, *in* The United States-Singapore Free Trade Agreement: Highlights and Insights 123, 130 (Tommy Koh & Chang Li Lin eds., 2004).

where drugs are more expensive to import cheaper drugs from another country. This import would normally lower the price of the drugs as there is competition between the importer and the distributor of the drugs who bought them from the manufacturer, often at a higher price.[106]

The legal basis for parallel importation lies on the exhaustion doctrine, whereby the exclusive rights relating to commercialization over a product will be exhausted "by the first act of introduction into the commercial circuit of the product incorporating the claimed invention."[107] The universal concept is that once a product is sold in a country with consent, the patent holder will lose its exclusive right to control the sale of such product within the country. This is known as national exhaustion.[108] However, if a country applies the concept of international exhaustion, the patent holder will lost its right to control further sale or importation of the product once the patent holder sold the product anywhere in the world with consent.[109] The exhaustion doctrine aims to protect public interest and promote the use of intellectual property.[110]

Under Article 6 of the TRIPS Agreement, members have the free choice of adopting either the national or the international exhaustion doctrine, meaning they can decide whether parallel imports are allowable.[111] The Thai Patent Act adopts the international exhaustion doctrine to promote parallel importation and competition in drug prices.[112] On the contrary, the U.S. – Singapore FTA concluded to grant patent holders with the right to bring an action against a person who, without their consent, procures patented pharmaceutical product knowing or having reason to know that such product has been distributed in breach of a licensing agreement. This is regardless whether such breach takes place inside or outside the country,[113] which deters

[106] Doulamis, *supra* note 104, at 40.
[107] Carvalho, *supra* note 30, at 108.
[108] Doulamis, *supra* note 104, at 40-41.
[109] *Id.* at 40-41.
[110] Kuanpoth, *Patent Law*, *supra* note 27, at 324.
[111] Krithpaka Boonfueng, *Parallel Imports in Pharmaceuticals: Increase Access to HIV Drugs*, http://www.thailawforum.com/articles/hivdrugs1.html (last visited Feb. 23, 2006).
[112] *Id.*; Kuanpoth, *Issue on "TRIPS-plus"*, *supra* note 96.
[113] U.S. – Singapore FTA, *supra* note 77, at art. 16.7(2); Liew, *supra* note 105, at 123, 130.

the use of the international exhaustion doctrine.[114]

2.

Assessment

Similar to the case of compulsory licensing, parallel importation is another flexibility that allows developing and least-developed countries access to cheaper drugs, despite patent protection. There is no doubt that pharmaceutical manufacturers will push hard for restrictions on parallel importation as it reduces their profit.

There are several arguments for Thailand to uphold parallel importation. For countries with low technological advancement like Thailand, parallel importation is an important alternative for access to a cheaper drug supply from other countries in case of a public health crisis. Compulsory licensing might be meaningless as Thailand has limited capacity and capability to manufacture drugs.[115] Parallel importation can also be carried out flexibly, as there is not much government intervention or approval in the process.[116] Its use is justified because the patent holders have already received the benefit from the first sale of their products.[117] The mechanism is also viewed as a help to reduce the trade of counterfeit drugs as consumers will buy genuine parallel imported drugs rather than fake ones.[118] Thus, the benefits of parallel importation are still significant for the protection of the Thai public health system.

[114]Kuanpoth, *Issue on "TRIPS-plus"*, *supra* note 96.
[115]Boonfueng, *supra* note 111.
[116]*Id.*
[117]*Id.*
[118]*Id.*

D.

Other Accompanying Issues

1.

Finding the Right Balance

From the few main issues discussed above, it is apparent that the core debate on pharmaceutical patent protection lies between arguments protecting the benefits of the pharmaceutical manufacturers, which mostly are from the developed countries, and those arguing in favor of "purchasers" of the products, comprised largely of the developing and least-developed countries. Having a strong and influential pharmaceutical manufacturing industry, there is no doubt that the U.S. will and should propose provisions that will support its growing industry.

Numerous other proposals of the U.S. under the FTA clearly reflect the above notion. For instance, the U.S. – Singapore FTA requires the parties to ratify or accede to the Patent Cooperation Treaty of 1984 (PCT),[119] which aims to enable patent application and information search more convenient worldwide.[120] The PCT states its purpose as "cooperation in the filing, searching, and examining, of applications for the protection of inventions, and for rendering special technical services."[121] Patent offices of developed countries may accept and review patent applications on behalf of the developing countries. However, the non-manufacturing countries believe that the main benefit of the PCT only falls on multinational companies in having to file an application once for protection in the contracting countries,[122] and there is no mechanism

[119] U.S. – Singapore FTA, *supra* note 77, at art. 16.1(2).
[120] Kuanpoth, *Issue on "TRIPS-plus"*, *supra* note 96.
[121] Markus Nolff, *TRIPS, PCT and Global Patent Procurement* 45 (2001).
[122] Kuanpoth, *Issue on "TRIPS-plus"*, *supra* note 96.

to guarantee that the benefit of such countries will be taken into account in implementing the system.[123]

Other proposals include Article 16.7(4) of the U.S. – Singapore FTA, which makes it more difficult to revoke patents, most of which are held by companies in developed countries. The U.S. also proposes stricter enforcement of intellectual property violations by imposing harsher punishments and penalties.[124] Thus, the consideration is to what extent Thailand should and would be able to accept those proposals considering the status quo and development trend of the country's pharmaceutical industry.

2.

Negotiating for TRIPS-plus Position

As discussed, most of the U.S.'s proposals are TRIPS-plus provisions. How legitimate and appropriate it is for countries to negotiate TRIPS-plus provisions remain controversial since the standpoint and benefits of different countries often move in different directions.

Looking back on the U.S. history, in August 2002, President Bush signed the Trade Promotion Authority into law, granting the U.S. government the power to negotiate "Fast Track" trade agreements and present them to the Congress for approval without any amendment made to the agreements.[125] The Bush administration accordingly moved to engage in bilateral and regional trade agreements for a higher level of intellectual property protection than is stipulated under the TRIPS Agreement. The U.S. Trade Representative, Robert

[123] *Id.*
[124] *Id.*
[125] Western Hemisphere Department, U.S. Chamber of Commerce, *An Insider's Guide to Trade Promotion Authority and the Trade Act of 2002* (2002), `http://www.summit-americas.org/Quebec-Trade/Insider's%20Guide%20to%20TPA%20(English).doc` (last visited Mar. 23, 2006).

Zoellick, justified the approach from the failures of the WTO process, such as the unsuccessful rounds of Cancun negotiations.[126]

Having more direct leverage in terms of market size as well as economic and political power over their trading parties in bilateral and regional negotiations, the U.S. has successfully negotiated TRIPS-plus protection through these agreements, which became new standards of protection for latter negotiations.[127] It is left to the counter parties of these FTAs to accept or compromise for TRIP-plus provisions.

3.

Legitimacy of the Thai FTA Negotiation Practice

Another broader aspect of the FTA negotiation that I would like to discuss concerns the practice of the Thai authority in negotiating FTAs. Under the current practice, the FTA negotiating process in Thailand is determined by the government,[128] with the Department of Trade Negotiations, Ministry of Commerce as the lead agency responsible for conducting studies and taking action involving FTA negotiations. The Thai government does not have to obtain approval from the Parliament to enter into an FTA, nor does it have to disclose the details of the negotiation to the public.

Entering into multilateral and bilateral agreements directly affects the sovereignty of a country in determining appropriate policies. A comprehensive FTA such as this between the U.S. and Thailand will no doubt have a

[126] Rajkumar, *supra* note 75.
[127] *Id.*
[128] Limpananont, *supra* note 56.

widespread effect on national interests in trade, economic and social structure as well as the legal framework of Thailand. The question is raised whether the Thai legal regime grants such a broad decision making power to the government.

Paragraph 2 of Section 224 of the Constitution of the Kingdom of Thailand (Constitution) requires that "A treaty which provides for a change in the Thai territories or the jurisdiction of the State or requires the enactment of an Act for its implementation must be approved by the National Assembly."[129] Accordingly, academia and relevant parties argue that FTA negotiations should fall within the scope of such Section where approval from the Parliament is required.

Through rigid interpretation, there are ways to get around Section 224. The Constitution states that the "treaty" which needs approval must be one that requires the enactment of an Act to implement it. Therefore, if current laws are amended to be in compliance with the terms of FTA to be negotiated beforehand, or if it is interpreted that current law is not contrary to the FTA provisions, no law needs to be enacted and, thus, the requirement of Section 224 is not met.[130] There are also attempts to interpret "a change in the Thai territories" to cover only the geographical change of Thai territory. This means that the effect of the FTA on the administrative, judiciary and legislative sovereignty of the country does not falls under Section 224 and no approval from the Parliament is required to enter into the FTA.[131]

Some also argue that since Thailand is a dualist country, implementation of the FTA can only be done by amending or issuing laws and regulations under the consideration of Parliament.[132] Parliament does not

[129]Translation of the Constitution enacted on Oct. 11, B.E. 2540 (A.D. 1997) is available at http://www.krisdika.go.th/pdfPage.jsp?page=eng&type=laws&lawType=law1&lawCode=%25c306&lawID=%25c306-10-2540-A0001 (last visited Mar. 20, 2006).

[130]Charoen Kumpephab, *Amnâdathipatai kab kânthamkhçtkânkhâsçrî (FTA) [Sovereignty and the Creation of Free Trade Area (FTA)]*, http://www.ftawatch.org/autopage1/show_page.php?t=5&s_id=3&d_id=3 (last visited Apr. 7, 2006).

[131]*Id.*

[132]Somkiat Tangkitvanich, *Khsangkçd bângprakân t kânèhçrâèhâ FTA thai-saharad "..." l è hôdfâkkhid samhrab radthabân*

have to enact or amend a law if they conclude that the FTA will have a detrimental effect on the country. Nonetheless, this proposed argument does not have much weight as it is an ex post review and Thailand will have to face sanctions from the international arena if it does not upheld provisions of the agreements it enters with other countries.[133]

I share the view that FTA negotiations must be subject to the approval of Parliament. Parliament, which is the direct representative of the people, must have the authority to scrutinize FTA provisions to uphold the interests of different groups of people, especially on issues that deal with the public health such as pharmaceutical patent protection. Parliament can also help cross check the stance of the negotiators and share responsibility with the government if FTAs cause any unforeseeable negative impact on the country.[134]

Concluding Proposals for Thailand Negotiation Position

FTA negotiations between the U.S. and Thailand on pharmaceutical patent protection are contentious because the two countries have a direct conflict of interests on the issue. The proposals from the U.S. to uphold benefits for its pharmaceutical manufacturing industry are certainly in conflict with the interests of Thais, who are mainly purchasers of the drugs. The more stringent pharmaceutical patent protection proposed by the U.S., such as the longer patent term protection or blockage of parallel importation, results in a stronger monopoly power of the manufacturers. Without competition, the cost of medicine increases and Thais have less access to medicines. The sociological and economical impact of the FTA on the Thai public health regime is large. Thus, Thailand must ready itself before stepping into the negotiation arena.

---

l¿ prachâchonthai [Certain Remarks on the Thailand-U.S. FTA Negotiations and Considerations for the Thai Government and People], Jan. 13, 2006, `http://www.ftadigest.com/articleTUSFTAremark.html` (last visited Mar. 20, 2006).

[133] *Id.*

[134] *Id.*

The critical step towards negotiation is good preparation. In order to achieve the purpose of FTA in trading on a country's comparative advantage, Thailand has to analyze the aspects of the FTA and prepare a comprehensive strategy prior to the negotiation.[135] FTAs are often long, complex and filled with complicated matters. Thailand should develop professional expertise and relevant resources in preparing to negotiate with a repeated player like the U.S. Technical issues like pharmaceutical patent protection require extensive study and empirical data in support of any proposed changes to be made to the rules.

Transparency of the FTA negotiation is another major point that the Thai government should encourage. No law requires the government to disclose details of the negotiations to the public. However, the public voice can be a good reflection of the issues and can help increase leverage on the negotiation. NGOs are viewed as one of the main driving forces that helps highlight the impact of intellectual property protection issues on public health.[136] Many countries have also used public disapproval as an excuse for declining FTA proposals. For instance, when India was pressured to amend its drug patent law, it conducted public hearing and coordinated with the academia and NGOs to debate the effect of such an amendment on the country's public health and pharmaceutical system. It then used public disapproval as an excuse not to follow the proposals.[137] Thus, information disclosure is among the key factors that may help to improve the efficiency of FTA negotiations.

Concurrently, in order to compete with the world and open up the market, Thailand must strengthen its pharmaceutical industry. The government may use tax incentives to motivate pharmaceutical research and development, and encourage more training and education to help develop technical skills of personnel in the area.[138] Since the industry is not yet technologically developed, applying the TRIPS-plus provisions will deprive the country of the flexibility to design its intellectual property system in its early stages of

[135]Limpananont, *supra* note 56.
[136]Rajkumar, *supra* note 75.
[137]Limpananont, *supra* note 56.
[138]Siripen Supakankunti et al., *Impact of the World Trade Organization TRIPS Agreement on the Pharmaceutical Industry in Thailand*, 79 Bulletin of the WHO 461, 469 (2001).

development.[139] Thailand should maintain as much flexibility as is available under the TRIPS Agreement and utilize existing exceptions for the benefit of the Thai public health system.

While it is necessary to provide patent protection for the pharmaceutical companies, the minimum protection required under the TRIPS Agreement is already a good compromise for all parties involved. As of the status quo, Thailand may either request that TRIPS-plus provisions be negotiated multilaterally by refusing to include them as one of the topics in the FTA negotiations,[140] or request for an extended implementation period. The latter option might be a good driving force for the government and all relevant parties concerned with reform of the Thai pharmaceutical industry.

The short term cost for complying with the FTA negotiations on pharmaceutical patent comprises mainly of the cost in amending relevant laws and adjusting the administration to implement them.[141] Nonetheless, the long term cost of having more stringent patent protection that does not correspond with the Thai pharmaceutical industry growth is very detrimental. Racing for increase in trade and investment is undeniably important; however, it should not be exchanged for national interests like the Thai citizens' public health guarantee, the basic right of which is assured under the Constitution.[142] Thailand faced trade retaliation pressures during the Uruguay round of negotiations to amend the patent protection and now history repeats itself in the form of an FTA. Lessons should be learned and the government should show its willingness to uphold the interests of the country. Singapore took four years to conclude the FTA with the U.S. and about thirteen years for Australia.[143] Thus, Thailand must not rush in making crucial decisions that deal with fundamental aspects of the economy and society.

[139]TDRI, *supra* note 4, at 100.
[140]Limpananont, *supra* note 56.
[141]TDRI, *supra* note 4, at 101.
[142]Limpananont, *supra* note 56.
[143]Supara Janchitfah, *Free Trade Could Cost Plenty*, Bangkok Post, Feb. 12, 2006, at Perspective.