

Harmonisation of TRIPS-Plus IPR Policies and Potential Impacts on Technological Capability: A Case Study of the Pharmaceutical Industry in Thailand

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Executive Summary

Bilateral trade and investment agreements are increasingly used in a strategic fashion by powerful countries to incorporate TRIPS-Plus commitments that have been politically difficult to achieve in multilateral settings (notably at the World Trade Organisation). Powerful developed country economies who have been dissatisfied with the multilateral forum have resorted to bilateral agreements as a form of forum shopping to better achieve their own interests, in disregard of a more balanced approach to intellectual property right (IPR) negotiations.

The justifications in favour of pharmaceutical patenting in developing countries are that it induces foreign direct investment (FDI); it stimulates local inventive activities; and that it encourages transfer of new technologies into the country. This study is aimed at examining whether TRIPS-Plus rules on pharmaceutical patents generate benefits to developing countries by looking at the situation in Thailand. The TRIPS-Plus rules under the proposed Thailand-United States Free Trade Agreement (TUSFTA) are comprehensive, covering the following issues: restricting the grounds for exclusion of patentability; patents for any new uses or methods of using a known product; prohibiting pre-grant opposition and revocation of patents; limitations on the issuing of compulsory licenses; extension of patent term; data exclusivity; linkage of drug registration and the patent status of a drug; trade marks, and linkage of IPRs and investment.

This study finds that Thailand does not have a functional technological base and this makes the country industrially and technologically dependent on foreign interests. It consistently loses trade balance in the pharmaceutical sector to its trading partners. It is also evident that a stringent patent regime, as enshrined under TUSFTA, will have no impact whatsoever in promotion of R&D in the country. By contrast, the inherent monopoly privileges proposed in the form of TRIPS-Plus will hinder local R&D and impede inflow of technology. Patents will continue to be used by foreign drug companies as a mechanism for overpricing, transfer pricing and insertion of restrictive clauses in technology transfer agreements.

The TUSFTA provisions will have a tremendous impact on technology prices. The rules on data exclusivity, extension of patent term, and extension of the scope of patentability will increase the ability of the patent holders to maintain high prices. The rules will reduce generic competition, prohibit the use of a compulsory license to make the patented drug available, and allow the patent holder to maintain a longer monopoly position, charging a high price for its medicines. The TRIPS-Plus provisions that link drug registration and the patent status of a drug will unnecessarily restrain the entry of generic medicines, threaten the existence of the Thai generic companies, and inhibit the capacity of the Thai generic industry to expand its market. The prohibition of the pre-grant opposition will allow multinational companies to use invalid or spurious patents to increase prices and prevent the local manufacturers from producing the medicine.

Abbreviations

AFPF	Armed Forces Pharmaceutical Factory
APEC	Asia-Pacific Economic Cooperation
ARV	anti-retroviral
BOI	Board of Investment
CAFTA	Central American Countries Free Trade Agreement
DIP	Department of Intellectual Property
FDA	Food and Drug Administration
FDI	foreign direct investment
FTA	free trade agreement
GDP	gross domestic product
GPO	Government Pharmaceutical Organisation
IPR	intellectual property right
NAFTA	North American Free Trade Agreement
NGO	Non-governmental organisation
NME	new molecular entity
OTC	over the counter
R&D	research and development
TDRI	Thailand Development Research Institute
TIFA	Trade and Investment Framework Agreement
TNC	transnational corporation
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
TUSFTA	Thailand-United States Free Trade Agreement
UNAPDI	United Nations Asian and Pacific Development Institution
USTR	United States Trade Representative
WHO	World Health Organisation
WIPO	World Intellectual Property Organisation
WTO	World Trade Organisation

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Introduction

Bilateral trade and investment agreements are increasingly used in a strategic fashion by powerful countries to incorporate TRIPS-Plus commitments that have been politically difficult to achieve in multilateral settings (notably at the World Trade Organisation - WTO). Powerful developed country economies who have been dissatisfied with the multilateral forum have resorted to bilateral agreements as a way of forum shopping to better achieve their own interests in disregard of a more balanced approach to intellectual property right (IPR) protection. The issue at stake for developing countries is the loss of key 'policy space' in strategic areas such as health, agriculture, and the digital environment. TRIPS-Plus obligations may also deny developing countries benefits and flexibilities within trade agreements aimed at enhancing pro-innovation activities and technology transfer.

The justifications in favour of pharmaceutical patenting in developing countries are that it induces foreign direct investment (FDI); it stimulates local inventive activities; and that it encourages transfer of new technologies into the country. This study is aimed at examining whether TRIPS-Plus rules on pharmaceutical patents generate benefits to developing countries by looking at the situation in Thailand. Prior to the discussion, it may be appropriate to note that the study intends to provide policy arguments rather than theoretical socio-legal analysis. It also has to be pointed out that strict empirical considerations are not the yardstick for analysis. However, basic socio-economic, political and legal considerations provide the basis for the discussion on costs and benefits of pharmaceutical patents in Thailand.

The first and second parts of the paper begin with an examination of the new trends and TRIPS-Plus commitments under bilateral trade agreements. The third part summarises the development and basic structure of the Thai pharmaceutical industry. Part four then examines the impact of the TRIPS-Plus commitments on prices, FDI, technology transfer, and research and development (R&D) capacity, with reference to the Thai pharmaceutical industry.

I. The Proposed Free Trade Agreement between Thailand and the United States

1. Facts about the Thailand-US FTA

While a number of trade issues are being negotiated in multilateral settings (*i.e.* the ongoing, but stalled, Doha trade negotiations of WTO), the past decade has seen trade negotiations increase on the bilateral and regional levels. Bilateral and regional trade talks, which are typically negotiated in the form of free trade agreements (FTAs), have risen to prominence during a period in which the multilateral trade negotiations of the WTO have been the subject of great uncertainty and controversy. The developed countries that are pursuing FTA negotiations have had difficulties rapidly implementing their entire suite of trade agendas on the multilateral level. Under an FTA, the negotiators of those countries can more easily set benchmarks with respect to all their trade objectives that would have been difficult to achieve in WTO negotiations.

The Bush Administration has launched FTA negotiations with many countries. To date, the United States has signed FTAs with fourteen countries (*e.g.* Israel, Singapore, Chile, Jordan, Australia, Morocco, Central American countries and the Dominican Republic, or CAFTA-DR, and others), and is negotiating FTAs with another eleven countries (*e.g.* Colombia, South Africa, Namibia, Swaziland, Thailand, Malaysia, the Republic of Korea). The United States has been negotiating an FTA with Thailand since 2003, when George W. Bush visited Bangkok for the summit of the Asia-Pacific Economic Cooperation (APEC) forum, and initiated FTA talks. The pending Thailand-US deal will drive talks for similar agreements with other Southeast Asian nations such as Malaysia, the Philippines and Indonesia.

The United States evidently perceives bilateral and regional trade talks as a very important strategic opportunity to demand greater trade commitments from its trade partners. The US FTAs are wide in scope covering various issues, including trade, services, investment, government procurement, environmental and labour rules, and IPRs. The United States generally demands the enlargement of access for United

States exports by reducing and eliminating duties and other non-tariff barriers in those countries. The bilateral and regional trade treaties that the United States has signed with trade partners contain chapters with IPR commitments, under which the trade partners must give preferential treatment to US right holders.¹ The United States intends to achieve higher levels of IPR protection, beyond the minimum standards under the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).²

The inclusion of IPR chapters in FTAs is due to the lobbying of specific industry lobby groups. The tightening of IPR laws in foreign countries through bilateral trade negotiations, together with the use of trade leverage under US trade laws, will likely help the United States establish an acceptable framework for them within the multilateral trade negotiations. This strategy was successfully employed by the US during the Uruguay Round of trade negotiations which led to the adoption of the TRIPS Agreement.³ It should be noted that the inclusion of IPR chapters in US FTAs is a result of heavy lobbying by certain industries. US IP policy has been heavily influenced by several interest groups such as International Intellectual Property Alliance, the Biotechnology Industry Organization, and the Business Software Alliance. The Advisory Committee on Intellectual Property Rights for Trade Policy Matters (IFAC-3), which plays the most important role in advising and influencing US trade policy, comprises large multinational companies like Eli Lilly, Merck, Pfizer, Anheuser-Busch, Procter & Gamble, and others.

The obligations under the FTAs would impose IPR standards that far exceed those contained in the TRIPS provisions (this has been referred to as the ‘TRIPS-Plus’

¹ Roffe, P., *Bilateral Agreements and a TRIPS-Plus World: The Chile-USA Free Trade Agreement*, Quaker International, Ottawa, 2004; Vivas-Eugui, D., *Regional and Bilateral Agreements and a TRIPS-Plus World: The Free Trade Area of the Americas (FTAA)*, TRIPS Issues Papers 1, QUNO/QIAP/ICTSD, Geneva, 2003.

² Drahos, P. “Developing Countries and International Intellectual Property Standard-Setting”, 5 *Journal of World Intellectual Property* 765 (2002).

³ In the 1980s, the United States Trade Representative (USTR) requested consultations with a number of developing countries in Asia and Latin America on IPRs issues before and during the Uruguay Round. The United States successfully used unilateral trade sanctions against Thailand to the tune of 165 million dollars in 1989 to force the Thai government to amend and expand the coverage of patent law even before the TRIPS negotiations were concluded.

effect). Although the proposed FTAs are open to negotiation in principle, the FTAs already concluded between the United States and its trade partners are basically built on the provisions of the North American Free Trade Agreement (NAFTA) and the basic rules embodied in United States intellectual property and trade laws.

The United States' objectives in negotiating an FTA with Thailand have been clearly stated in the United States Trade Representative (USTR)'s Letter of Notification for FTA negotiations:

“The United States is concerned about intellectual property protection in Thailand. The United States has worked with Thailand on intellectual property rights issues under the Trade and Investment Framework Agreement (TIFA). While some progress has been made, bringing Thailand's intellectual property regime up to the standards set in other recent FTAs that the United States has negotiated will be a high priority of these negotiations.”⁴

On IPRs issues, the United States has also made clear statements of objectives in USTR formal notification letters to Congress:

“- Seek to establish standards to be applied in Thailand that build on the foundations established in the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights and other international intellectual property agreements, such as the World Intellectual Property Organisation (WIPO) Copyright Treaty, the WIPO Performances and Phonograms Treaty, and the Patent Cooperation Treaty.

- In areas such as patent protection and protection of undisclosed information, seek to have Thailand apply levels of protection and practices more in line with U.S. law and practices, including appropriate flexibility.

⁴ Letter of Notification of USTR to United States Congress of Intent to Initiate Free Trade Agreement Negotiations with Thailand, 12 February 2004.

- Seek to strengthen Thailand's laws and procedures to enforce intellectual property rights, such as by ensuring that Thai authorities seize suspected pirated and counterfeit goods, equipment used to make such goods or to transmit pirated goods, and documentary evidence.

- Seek to strengthen measures in Thailand that provide for compensation of right holders for infringements of intellectual property rights and to provide for criminal penalties under Thai law that are sufficient to have a deterrent effect on piracy and counterfeiting."

2. Potential Effects of the Thailand-US FTA

It is argued that the liberalisation of economic activities through bilateral and regional negotiations does not suit the need of developing nations, and generates significant economic and social costs to those countries. The prospective social costs of the bilateral trade treaties include various problems relating to monopolisation, public health, education, food security, environment, labour rights, technology transfer, biodiversity management, and others.⁵ Given that the United States is the largest investor in many countries and the biggest export market for those countries, many developing countries see FTAs as a way of opening and accessing US markets. Despite the fact that a large number of developing countries are aware of the negative effects resulting from IPR protection (as reflected in WTO negotiations, in the Doha Declaration on the TRIPS Agreement and Public Health, 2001), these same countries are often prepared to sign bilateral trade agreements which incorporate obligations higher than the WTO. It is argued that these FTAs will offer transnational corporations (TNCs) greater opportunities and even greater protection, at the expense of contracting countries, than the WTO TRIPS Agreement and other multilateral agreements.

It is important to consider what impact the Thailand-US FTA is likely to have. In part, the impacts can be determined by examining United States demands for various

⁵ Oxfam Canada "Let's Harness Trade for Development: Why Oxfam Opposes the FTAA", 2001. http://www.oxfam.ca/news/Peoples_Summit/intellectualProperty

categories of trade and investment liberalisation. While Thailand's exports to the US, currently account for a substantial US\$ 15 billion, this could increase if the Thailand-US FTA is signed. However, it is likely a range of US agricultural goods will have an advantage over Thai products including meat, milk, dairy products, vegetable, fruit, maize and soybean. Thailand could also risk losing out its sovereign control over crucial sectors of its economy such as energy, transport, finance and education. As will be discussed later, the IPR chapter of the FTA seeking to increase the level of protection would open the door for US business to seek corporate monopoly on products including seeds and drugs.

It should be noted that the actual implications of the Thailand-US free trade agreement (TUSFTA) for farmers, local communities, consumers and the general public are yet to be fully understood. This is largely because the two governments have maintained a great deal of secrecy throughout the negotiation process. Available public information on the FTA is very one-sided, coming mainly from the government and a group of large-scale industrialists who are poised to benefit. Thus, the vast majority of the public are not able to fully comprehend or participate in the content of the negotiations.⁶

3. Non-transparency of FTA negotiations

The trade liberalisation policy of the Thai government has been subject to domestic criticisms for deepening inequalities between different interest groups. FTA negotiations with the United States are generally carried out in a non-transparent manner. The secrecy of the TUSFTA has been heavily criticised by FTA Watch, a coalition of public-minded academics and non-government organisations (NGOs) that was formed in 2003. For example, there were no adequate avenues for consultation and participation of public-interest civil society groups or interest groups that would be highly affected by the FTA (*e.g.* generic drug companies, farmer organisations, labour unions, etc.). The Thai government has never allowed the participation of a

⁶ FTA Watch Thailand, Thailand's Free Trade Agreements and Human Rights Obligations, A Letter Submitted to the 84th Session of the UN Human Rights Committee, March 2005: http://www.ftawatch.org/autopage1/show_page.php?t=22&s_id=3&d_id=3 visited July 2006.

number of marginalised stakeholder groups (e.g. the Assembly of the Poor; the Coalition of People Living with HIV/Aids) in the many formal and informal meetings to which business people and trade councils were invited. As a result, the issues put up for negotiation and the decisions made by the government, tend to be biased against a range of grass-roots interests.⁷

There is also a lack of official information about what the legal effect of the FTA will be. The Thai government has not provided access to the draft negotiating texts in all relevant sectors, which creates difficulties for people to assess the potential impacts from the negotiations. Particularly during the negotiations, the United States has demanded that the Thai government keeps the process of negotiations secret. The non-transparency of trade negotiation has been reaffirmed by the Thai Senate Standing Committees on Foreign Affairs; Economic, Commercial and Industrial Affairs; Agriculture and Cooperatives; and Finance, Banking and Financial Institutions. The Senate Committees conducted studies of relevant documents and interviews with responsible government negotiators in the Ministries of Foreign Affairs and Commerce and held consultations with business organisations, NGOs and academics, and on October 10, 2003, raised the following concerns over the nature of the negotiations:⁸

The negotiation processes had been conducted in a hasty manner without any clear information on the long-term impact of trade negotiations. There was no evidence of systematic, comprehensive studies by the Thai government on the impact of the FTAs, especially from social, environmental, and cultural perspectives.

There was a lack of participation by all stakeholders in determining the country's position in negotiations; consultation was limited to private businesses. Negotiating positions had been determined on the basis of an assessment of levels of competitiveness in the private sector alone without regard to the overall social, cultural and environmental impacts.

⁷ Interviews with Buntoon Srethasirote and Witoon Lianchamroon, FTA Watch, Bangkok June 2006.

⁸ Senate Committee on Foreign Affairs, Report on Free Trade Agreement: An Analysis of Its Impact on Thailand, Presented and Distributed at National Dialogue on FTA held at Chulalongkorn University, 9-10 February 2004, Bangkok (in Thai).

Many commitments under the signed framework agreements with foreign trade partners were made in violation of Article 224 of the constitution, which requires prior approval of Parliament.

There was no preparation from the government to mitigate the impact of the FTAs. The only response made by the government official on this issue was for those affected to change occupation (*i.e.* farmers to change crops).

II. Protection of Pharmaceutical Inventions under the Proposed Thailand-US Free Trade Agreement

IPR rules proposed by the United States are comprehensive, covering almost all areas including patents, copyright, trade marks, geographical indications, and others. When the USTR submitted the draft IPR text to Thailand in the sixth round of FTA negotiations in January 2006, the following TRIPS-Plus provisions were included:⁹

- Restricting the grounds for exclusion of patentability
- Patents for any new uses or methods of using a known product
- Prohibition of pre-grant opposition and revocation of patents
- Limitations on the issuing of compulsory licenses
- Extension of patent term
- Data exclusivity
- Linkage of drug registration and the patent status of a drug
- Trade marks
- Linkage of IPRs and investment

The details of those TRIPS-Plus IPR rules are now highlighted.

(a) Restricting the grounds for exclusion of patentability

The US draft proposal maintains principally that an effective and adequate protection must be given to inventions in all technological fields. According to the proposal, the products currently excluded from patentability (*e.g.* plants, animals, biological

⁹ The United States draft proposal submitted to Thai negotiators was leaked and posted on: http://www.bilaterals.org/article.php?id_article=3677.

processes, genes, gene sequences, methods of medical treatment, business methods and computer programs) must be protected under the patent law of Thailand in the forms of both product and process patents. In light of the current Thai prohibition of patents on living organisms, therapeutic, surgical and diagnostic methods, mathematical algorithms and object code; Thailand would no longer be able to take advantage from the exemption clauses under TRIPS. This removes safeguards preventing foreign interests from exerting monopolistic power over these essential subjects and related knowledge.¹⁰

(b) Patents for any new uses or methods of using a known product

The text proposed by the USTR to Thailand requires it to protect second uses, and new use of products already known or existing in the market. For example, Thailand must allow claims to a new use of an old drug or claims to a new therapeutic application of a known drug.¹¹ Given that a single medical product can have multiple uses and formulations, providing patents for the subsequent uses or the new composition of a known drug would allow ‘evergreening’ (*i.e.* trivial inventions which allow for the extension of patent protection). This unnecessarily prolongs the monopolistic market enjoyed by the patent holder and deprives consumers of the right to affordable essential medicines.

(c) Prohibition of pre-grant opposition and revocation of patents

The USTR text requires Thailand to abolish the pre-granting opposition which provides proceedings for the invalidation or amendment of patents before the patent office. It also prevents Thailand from revoking patents on grounds other than those that would have justified a refusal to grant the patent (*e.g.* lack of patentability, insufficiency of or unauthorised amendments to the patent specification, non-

¹⁰ See Correa, C.M., *Implications of the Doha Declaration on the TRIPS Agreement and Public Health*, World Health Organisation, Geneva, 2002; Kuanpoth, J. “Closing in on Biopiracy: Legal Dilemmas and Opportunities for the South” in Ricardo Melendez-Ortiz and Vicente Sanchez, *Trading in Genes: Development Perspectives on Biotechnology, Trade and Sustainability*, Earthscan, London, 2006, pp.139-152.

¹¹ See Savina, J. “The Patentability of the Second Therapeutic Application – Why must the Law be Changed?”, *Patent World*, August 1995, pp.32-35.

disclosure or misrepresentation of prescribed, material particulars, fraud, or misrepresentation). Revocation cannot be undertaken where there has been abuse of patent rights or non-working of patents which are generally the cause of high drug prices, as has been provided by the Paris Convention.¹²

(d) Limitations on the issuing of compulsory licenses

The USTR text imposes stricter standards on compulsory licensing than those under TRIPS and the Paris Convention; namely, more stringent conditions for issuing a non-voluntary license.¹³ The proposed text permits Thailand to issue compulsory licenses in the following three circumstances only: (i) to remedy a practice determined by a judicial or administrative body as anti-competitive according to competition law of the country, (ii) in the case of public non-commercial use, or (iii) in the case of national emergency or other circumstances of extreme urgency.

In cases of public non-commercial use, national emergency or other circumstances of extreme urgency, a compulsory license can be granted only in accordance with these conditions:

A compulsory license can be issued only to the public sector or third parties authorised by the government. The contracting party cannot apply the compulsory license provisions to authorise private companies to manufacture or import cheaper drugs.

Full compensation, with reference to the TRIPS provisions, in the event of compulsory license must be provided to the patent owner.

There must be no requirement for the transfer of undisclosed information or for the disclosure of know-how without the consent of the right holder.

(e) Extension of patent term

¹² Paris Convention, Art.5 (A)(3).

¹³ TRIPS Agreement, Art.31; Paris Convention, Art.5. See Machlup, F. and E. Penrose “The Patent Controversy in the Nineteenth Century”, 10 J. Econ. Hist. 1, (1950); Vaitos, C. “Patents Revisited: Their Function in Developing Countries”, Journal of Development Studies, Vol.9 No.1, 1972, pp.71-97; Abbott, F.M. “First Report (Final) to the Committee on International Trade Law of the International Law Association on the Subject of Parallel Importation”, Journal of International Economic Law, Vol.1, 1998, pp.607-636.

The USTR has demanded that Thailand extend the term of patents in cases of unreasonable delays in the grant of patents. Such delays occur when there is a delay in the issuance of a patent of more than five years from the filing date or three years after a request for examination of the application has been made, whichever is later.¹⁴

(f) Data exclusivity

The USTR text requires Thailand to enforce data exclusivity, which prevents the national drug regulatory authority from using the originator's clinical test data for a period of five years (in the case of pharmaceutical products) and ten years (for agricultural chemical products) from initial regulatory approval of the original product. The drug regulatory authority is prevented from granting market approval to generic drugs on the basis of bio-equivalence or based on marketing approval of the original product in a foreign country.¹⁵

(g) Linkage of drug registration and the patent status of a drug

The text the USTR has proposed to Thailand contains a provision obliging the Thai drug regulatory authority to inform the patent holder when there is any attempt to register a generic drug. The authority is barred from approving registration for a generic medicine unless it is certain that the manufacturing, importing and selling of the generic will not infringe the patent rights of other companies. The linkage of drug registration with the patent status will impose an unnecessary burden on the drug authority and unnecessarily restrains the entry of generic products.¹⁶

(h) Trade marks

¹⁴ The demand is based on United States law, the Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Act.

¹⁵ Correa, C.M., Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement, South Centre, Geneva, 2002.

¹⁶ As an example, the US-Vietnam Bilateral Trade Agreement that Vietnam signed with the United States in 2001 requires Vietnam to provide data exclusivity. Vietnamese law requires a manufacturer to prove that the use of the generic drugs it seeks to register will not lead to infringement of patent rights of other companies. This in effect prevents generic medicines from entering the market as it is almost impossible for the generic company to prove the patent status of the drug. See Kuanpoth, J. and L.H. Duong, Legal and Trade Issues Related to Access to Affordable Anti-retroviral Drugs for People Living with HIV/AIDS in Vietnam, Ford Foundation, Hanoi, 2004.

TRIPS-Plus provisions introduced by the United States also impose a high level of trade mark protection. 'Trade mark' is defined in the broadest manner, including non-visually perceptible trade marks, such as scent marks. Sound, texture and smell could be registered as trade marks. This requirement is an obvious attempt to bring other countries' trade mark laws up to the level of US legislation.

The USTR text also requires Thailand to give effect to Articles 1 to 6 of the Joint Recommendation Concerning Provisions on the Protection of Well-Known Marks (1999), which is an international standard adopted by the Assembly of the Paris Union for the Protection of Industrial Property and the General Assembly of WIPO, as well as the WIPO Trade mark Law Treaty. This requirement offers unregistered well-known marks wider protection, as a framework for determination of well-known marks under the Joint Recommendation apparently discriminates against local trade marks in favour of foreign well-known marks.

(i) Linkage of intellectual property and investment

TRIPS-Plus rules introduced by the United States advance the liberalisation of investment measures by restricting the sovereign right of states to regulate foreign investments. The USTR text includes IPRs in the definition of investment. It also prohibits Thailand from imposing performance requirements. Expropriation or other measures tantamount to expropriation are prohibited except when such measures are taken in the public interest, on a non-discriminatory basis, against payment of prompt, adequate and effective compensation, and in accordance with due process of law. Compensation would have to be paid without delay, equal the fair market value of the investment before the expropriation occurred, and be fully conceivable and freely transferable. The text proposed to Thailand by the USTR also incorporates provisions for investor-to-state dispute settlement that allows private investors to sue the host state directly in international dispute tribunals for monetary compensation for government policies or actions judged by the tribunal to undermine an investor's future profits.

The aforementioned TRIPS-Plus provisions will have a devastating impact on Thailand, particularly on its attempt to build technological capability in the pharmaceutical sector. The impact of the TRIPS-Plus rules on the Thai pharmaceutical industry will be analysed and discussed in the final section. The next section will turn to examine the structure and characteristics of the pharmaceutical industry to provide background for analysis of TRIPS-Plus implications.

III. Structure and Characteristics of the Pharmaceutical Industry

1. Pharmaceutical Production and Supply

Box 1
Pharmaceutical Production

The production of pharmaceuticals can be referred to as the process of developing chemical or non-chemical substances into medicinal products, which can be consumed by humans or animals for recovery from or avoidance of ailments. There are two major stages of pharmaceutical manufacture: the production of raw materials, and the combination of these raw materials into a finished product form.

The production of raw materials involves R&D activities to search for new physiologically active ingredients having certain therapeutic effects, and their preparation. Raw materials for the production of a drug can be divided into two types: active therapeutic ingredients, and intermediates. The active ingredients of a drug, sometimes called new molecular entities (NME), are the most important element for drug manufacture. They can be produced from synthetic or semi-synthetic chemicals, natural substances (*e.g.* extracts of animals or plants), or fermentation (*e.g.* by micro-organisms). The intermediate ingredients used for pharmaceutical manufacture are those that do not have therapeutic effects, but are necessary for formulation, such as distilled water, solvency, sugar, and starch. The active and inactive ingredients must be purified and made suitable for consumption in order to avoid the risk of unacceptable hazards. The final stage of production, called the formulation process, involves combination of the raw materials into pharmaceutical products. There are various dosage forms of medicines, including tablet, capsule, liquid, ointment, etc. In every stage of production, appropriate technical and quality control measures are required so that the purpose for which the product is intended can be safely and rapidly achieved.

R&D carried out in the pharmaceutical industry has the aim of creating new knowledge which can be further developed into a new product, a new use or a new less costly production process. Medicinal research generally requires considerable capital investment and high technical input. A large company, therefore, can meet such high costs more easily than a smaller one. The high degree of investment required makes it difficult for companies with limited access to investment funds to engage in pharmaceutical research. Instead, these companies tend to buy the active ingredients from the large firms.

Like R&D, the preparation of the raw materials, particularly the active pharmaceutical ingredients, normally is quite technically complex and requires high technology and considerable capital investment. On the contrary, the formulation and packaging of active ingredients and intermediates into finished product forms are relatively simple and technically straightforward, and capital investment needed in this process is low.

Since R&D is an activity that requires a high level of skill and training, it is usually carried out at the main centres located in countries with a proven record of success in innovation, mainly in a small number of developed countries. Pharmaceutical companies tend to concentrate on the production of pharmaceutical raw materials at one site, and decentralise the later stages of production at other locations.¹⁷ From the perspective of the drug companies, developed countries are generally preferable to developing countries due to a number of factors, including the availability of well-trained researchers and technicians, an extensive university network, an advanced manufacturing sector and mass-production to supply necessary equipment and machines, and large high-income consumer markets which generate the demand to buy new drugs.

Pharmaceutical raw materials are generally produced by the large companies themselves or by their affiliates. The guaranteed access to raw materials is the main reason for their vertically integrated operations. If the firm is large enough, it can

¹⁷ Gereffi, G., *The Pharmaceutical Industry and Dependency in the Third World*, Princeton University Press, New Jersey, 1983, p.203; Hancher, L., *Regulating for Competition: Government, Law, and the Pharmaceutical Industry in the United Kingdom and France*, Clarendon Press, Oxford, 1990, p.43.

perform all functions of drug-making. However, large firms may subcontract the formulation and packaging processes to independent firms in the local market. This usually occurs when the industrial infrastructure of the host country is sufficiently developed.

If one looks at the world's suppliers of pharmaceuticals, one may categorise countries involved in production into three groups, according to the stages of their manufacturing capability:

- (1) The major producers are industrialised countries: *e.g.* Belgium, France, Germany, Italy, Japan, the Netherlands, Sweden, Switzerland, the United Kingdom and the US. Some developing countries, such as Argentina, Brazil, Egypt, India, Mexico, South Korea, and China, may also be included in this group. Each country mentioned has been able to develop a substantial pharmaceutical industry and is capable of manufacturing NMEs and other raw materials, and even engages in the R&D of new drugs.¹⁸
- (2) A group of middle level producer states, include Colombia, Kenya, Thailand, and others. These are mainly developing countries with an intermediate stage of manufacturing capability. These countries can produce some pharmaceutical intermediates from raw materials available in the country, and indigenous firms are able to carry out particular types of manufacturing such as formulation and packaging. However, the production of NMEs does not occur. The therapeutic ingredients are mainly imported from countries from the first group above.
- (3) The countries which have the lowest level of manufacturing capability are heavily dependent on imports of finished drugs to satisfy their health care requirements. Since there is no local formulation or packaging industry, the market shares of foreign firms are very high. A large number of countries belong to this group, including Vietnam, Laos, Costa Rica, and many African states.

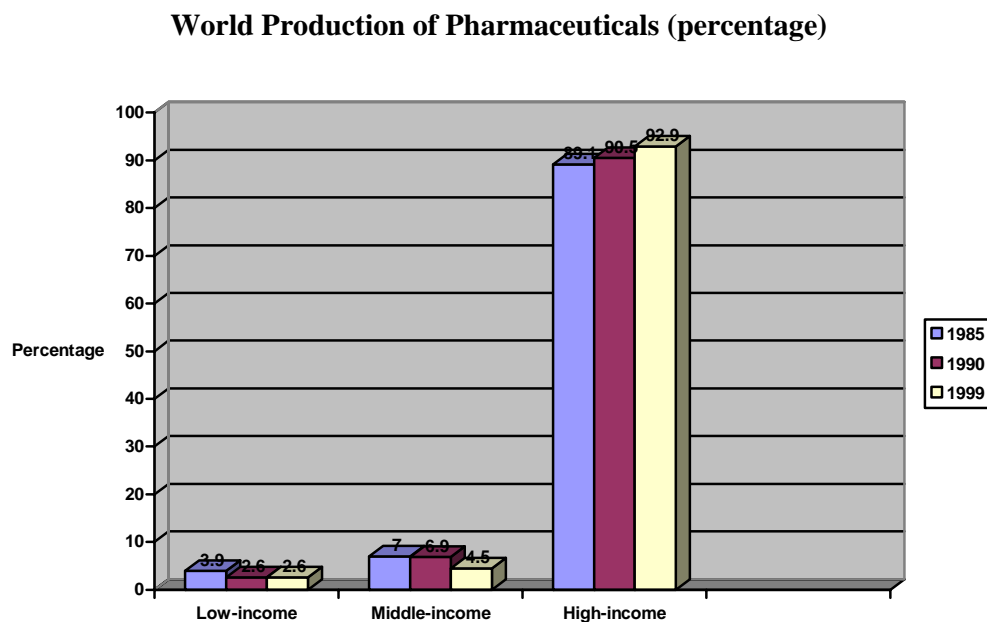
¹⁸ Tarabusi, C.C. and G. Vickery "Globalization in the Pharmaceutical Industry", *International Journal of Health Services*, Vol.28 No.1, 1998, pp.67-105.

Between 1985 and 1999, almost 90 percent of the total value of world pharmaceutical production was accounted for by high income countries (see Figure 1).¹⁹ The figure shows that high-income developed countries dominate world pharmaceutical production, and the share of those countries in the value of world pharmaceutical output continued to increase gradually from 89.1 percent in 1985 to 92.9 percent in 1999. By contrast, the figures of the world drug production in countries from middle- and low-income countries dropped from 7 and 3.9 percent in 1985, to 4.5 and 2.6 percent in 1999 respectively (Figure 1).

Among the high-income countries, the majority of world pharmaceutical production is accounted for by 5 major countries. The United States is the biggest producer, accounting for almost one-third of total production (31 percent) in 1999, following by Japan (16 percent), France (8 percent), Germany (6 percent) and the United Kingdom (6 percent) (Figure 2).

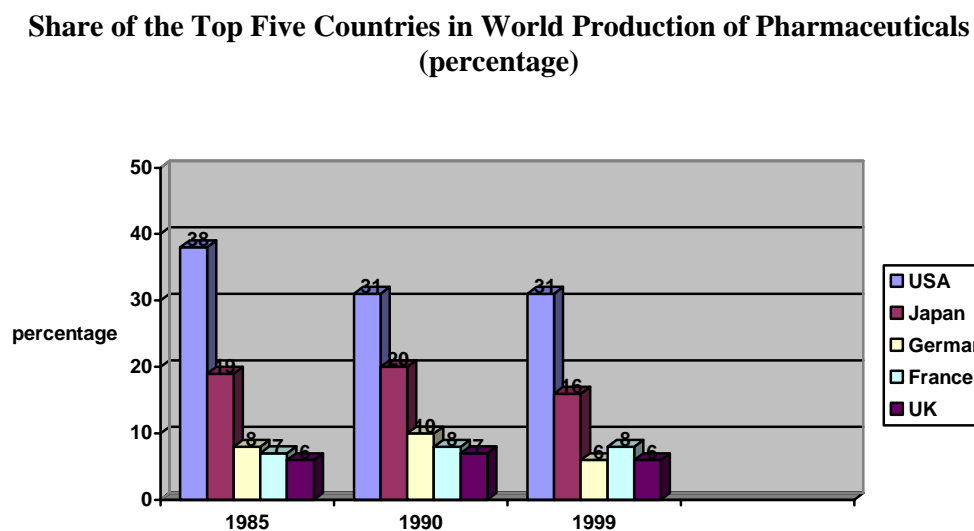
¹⁹ This is based on the World Bank classification of countries according to the level of income as follow: (i) High-income: GNP per capita of US\$ 9,361 or more, (ii) Middle-income: GNP per capita of US\$ 761- US\$ 9,360, and (iii) Low-income GNP per capita of US\$ 76 or less in 1999.

Figure 1



Source: WHO, The World Medicines Situation, WHO/EDM/PAR/2004.5, 2004

Figure 2



Source: WHO, The World Medicines Situation, WHO/EDM/PAR/2004.5, 2004

2. International Trade in Pharmaceuticals

One of the main features of the pharmaceutical industry is its international operation. Pharmaceutical products can be exported worldwide in various forms: bulk pharmaceuticals for dosage formulations, tablets or capsules in bulk for packaging, or finished packed products ready for use. Many drug companies establish manufacturing subsidiaries, or sales agencies, or both in foreign countries in order to enlarge their market and increase profitability. This characteristic, however, is generally exclusive to large companies. Small firms are inclined to limit their operations within a domestic market. However, in recent years more innovative firms from developing countries have appeared. Generic companies in India and China can now produce active ingredients, and have become the world's most important suppliers of some active ingredients and finished products.²⁰

Despite the emergence of India and China, the world exports of pharmaceutical have been dominated by a few large exporting countries. For instance, Germany, Switzerland, the United States, the United Kingdom, and France together accounted for more than half of world exports during the last decade (Table 1).

Box 2
Types of Pharmaceutical Producers

Typically, there are two types of companies operating in the pharmaceutical business: research-based and non-research-based companies. The former are large companies, mainly transnational corporations (TNCs). These large companies carry out their own research programmes. Medicines sold by these companies are often newly invented products arising from successful R&D. Applications for worldwide patents will usually be applied for as soon as an NME is discovered. Non-research-based companies, generally known as generic companies, are typically small in size. These firms have limited engagement in R&D, and focus on selling cheaply-priced drugs - generics, which are unable to enjoy patent protection or whose legal protection has expired. Generic firms used to operate within their country of residence, but the situation has been changing in recent years. Indian and Chinese firms have now expanded their operations and become multinational, taking advantage of the economies of scale available to them.

²⁰ Dhar, B. and C. Rao, Transfer of Technology for Successful Integration in the Global Economy: A Case Study of Pharmaceutical Industry in India, UNCTAD Investment Policy and Capacity-Building Branch, UNCTAD/ITE/IPRC/Misc.22, 2002.

Table 1
Value of World Exports of Pharmaceutical Products
(US\$ billion)

Country	1990	1999	Rank
Germany	5.6812 (15.6%)	14.978 (14.5%)	1
Switzerland	4.3595 (12.1%)	11.452 (11.1%)	2
US	4.1032 (11.4%)	11.071 (10.7%)	3
UK	4.0404 (11.2%)	10.053 (9.7%)	4
France	3.6652 (10.2%)	10.043 (9.7%)	5
Belgium	1.6329 (4.5%)	6.438 (6.2%)	6
Italy	1.5169 (4.2%)	5.607 (5.4%)	7
Ireland		5.122 (4.9%)	8
Sweden		4.010 (3.9%)	9
Netherlands	1.3771 (3.8%)	3.852 (3.7%)	10
Ten top countries	26.554 (73.7%)	82.626 (79.8%)	
World export	36.037 (100%)	103.619 (100%)	

Source: WHO, The World Medicines Situation, WHO/EDM/PAR/2004.5, 2004

Table 2
World's Largest Pharmaceutical Companies by Value of Sales 1977-2001

Company	Country	Rank 1977	Rank 1985	Rank 1998	Rank 2001
Pfizer	US	8	6	5	1
GlaxoSmithKline	UK/US	-	12	12	2
Merck	US	2	1	1	3
Astra/Zeneca	Sweden/UK	-	-	4	4
Aventis	France/Germany	-	-	2	5
Bristol-Myers Squibb	US	14-13	10	6	6
Johnson & Johnson	US	-	-	9	7
Novartis	Switzerland	-	-	7	8
Upjohn/Pharmacia	US	11	13	-	9
Wyeth	US	6	2	11	10
Eli Lilly	US	10	9	8	11
Roche	Switzerland	5	15	10	12
Bayer	Germany	3	5	3	13
Schering-Plough	US	-	-	14	14
Abbott	US	-	8	13	15
Takeda	Japan	15	-	-	16

Source: WHO, The World Medicines Situation, WHO/EDM/PAR/2004.5, 2004

The world pharmaceutical industry has been dominated by a small number of large TNCs. Although there are many pharmaceutical companies around the world, less than one hundred of them make up for the bulk of global drug production and international marketing participation. For instance, more than 90 percent of 2,000 NMEs launched to the market between 1960 and 1988 were produced by developed country-based TNCs.²¹ By contrast, pharmaceutical firms in developing countries are small and currently account for less than twenty percent of world production.²²

TNCs have dominated the world trade in pharmaceuticals for a long time, and the list of the world's largest pharmaceutical companies has not changed much over the past few decades (Table 2). This is due to the range of barriers for new firms aspiring to venture into this field. The barriers to entry derive not only from the peculiarity of the pharmaceutical industry which requires a high degree of investment, but also from the employment of patent rights and other marketing practices by the existing firms which have created obstacles to the entry of new companies. The impact of marketing practices of the pharmaceutical companies is examined in section 3.2.

3. Characteristics of the Thai Pharmaceutical Industry

3.1 Production of Medicines

The pharmaceutical industry in Thailand primarily consists of non-research based manufacturers. In 2005, there were 162 firms involved in manufacturing modern medicines in the country.²³ The Thai government established two state enterprises to manufacture drugs to fulfil the requirements of the Thai market: the Government Pharmaceutical Organisation (GPO) and the Armed Forces Pharmaceutical Factory (AFPF).

²¹ UNIDO, *The World's Pharmaceutical Industries: An International Perspective on Innovation, Competition and Policy*, Edward Elgar, Hants, 1992, p.12.

²² Kaplan, W. and R. Laing, *Local Production of Pharmaceuticals: Industrial Policy and Access to Medicines*, HNP Discussion Paper, Washington D.C., 2005, p.7.

²³ TDRI, *Intellectual Property and Impacts of Trade Agreements on Thai SMEs*, Thailand Development Research Institute, Bangkok, 2006 (in Thai).

GPO, which was established in 1964 under the Ministry of Public Health, is the most important public enterprise in the pharmaceutical field. The major roles of GPO are to support government health practices and plans as well as to be a source of cheap drugs for institutions and retailers.²⁴ Its activities include: producing basic pharmaceuticals; procuring medicines from other sources; conducting quality control; and distributing all pharmaceutical supplies to public hospitals.²⁵ GPO has proven its ability to create a competitive force in the generics market. For example, it has recently produced an anti-retroviral compound called GPO-vir - a fixed-dose combination of three drugs (*i.e.* stavudine, lamivudine and nevirapine) - that has become the first cheap and affordable ARV treatment in Thailand and other developing countries. GPO currently exports medicines to other developing countries such as Malaysia, Myanmar, Nepal, Vietnam, Laos, and Cambodia.²⁶ In 2002 it agreed to form a joint venture to supply anti-retroviral drugs (*i.e.* GPO-vir and didanosine - ddI) to thirteen African countries.²⁷

The private sector represents almost 90 percent of the pharmaceutical manufacturers in Thailand. Thai-owned private companies are mostly small in size and are involved in packaging or formulating drugs. Domestic firms are characterised by low production capacity and simple technology. These companies generally acquire chemical ingredients and technologies from foreign sources.

The affiliates of drug multinationals have played important roles in Thailand in terms of production, importation, and distribution. Foreign investment in the Thai pharmaceutical industry appears in the forms of joint ventures and wholly-owned subsidiaries, most of which come from Switzerland, Germany, the United Kingdom, the United States, Japan, Luxembourg and Italy.²⁸ Most affiliates of foreign companies supply the Thai market by importing finished products from abroad. A small number of foreign companies formulate drugs from imported active ingredients.

²⁴ Hutangura, P and C. Sepulveda, *The Pharmaceutical Industry in ASEAN Countries: Thailand*, UNAPDI, Bangkok, 1979, p.209.

²⁵ *Ibid.*, p.184.

²⁶ Ministry of Industry, *Master Plan for the Development of Pharmaceutical Industry*, Bangkok, September 2002.

²⁷ Kaplan and Laing, *op.cit.*, at p.27.

²⁸ Hutangura and Sepulveda, *op.cit.*, p.211.

There are currently only ten companies engaged in local pharmaceutical formulation.²⁹ Foreign companies have many formulation and packaging factories, but they have not established local plants for the production of basic active ingredients in Thailand.

No firms, whether foreign or local, are engaged in R&D activity in the search for new drugs in Thailand. Some basic and applied research programmes have been carried out in state universities, but the achievement of these research programmes is still uncertain. The researchers in the public sector generally lack financial resources and management skill to convert their research outcomes into large scale commercial ventures. Successful research outcomes are generally sold to foreign companies.

Foreign companies view Thailand as an inappropriate location of research units³⁰ due to several factors, including the scarcity of well-trained personnel, equipment and resources, the lack of a chemical industrial base, the low level of technological capability, and the deficiencies of the registration system for new medicines.³¹

Less than ten companies in Thailand, including GPO and AFPP, are involved in the production of raw materials that can be used as inputs for the production of medicines. Almost all the raw materials produced by those companies are confined to intermediate ingredients such as alcohol, solvent, and sodium chloride. Only a few active ingredients that possess therapeutic effects (*e.g.* chloramphenicol and ferrous sulphate) are manufactured in Thailand.³² Like R&D, the absence of the production of active ingredients in Thailand can be explained by two factors: (i) the lack of capacity

²⁹ International Trade Centre: UNCTAD/WTO, Thai Pharmaceutical Industry Study, Bangkok, 1999.

³⁰ Supakankunti, S. et al, Study of the Implications of the WTO TRIPS Agreement for the Pharmaceutical Industry in Thailand, WHO Regional Office for South-East Asia, 1999, Bangkok.

³¹ Interviews with an official at B.L.H. Trading Ltd. (a distribution company of an American drug company), Bangkok, June 2006, and with an official at Takada Ltd. (a subsidiary of a Japanese pharmaceutical company), Bangkok, July 2006.

³² Bumrungruech, P., The Role of European Pharmaceutical Transnational Corporations in ASEAN Countries, ESCAP, Bangkok, 1981, p. 27; Hutangura and Sepulveda, *op.cit.*, at p.317; GPO, Annual Report, Government Pharmaceutical Organisation, Bangkok, 2004.

of domestic companies, and (ii) the limited size of the market, making it unappealing to the multinationals.

Since the domestic production of active ingredients is almost non-existent, most chemical compounds required for transformation into finished drugs (*i.e.* about 95 percent of compounds used in the country)³³ are imported. The local manufacturers import chemicals from foreign countries such as the United States, the United Kingdom, Germany, Switzerland, France, Japan, Italy, Eastern European countries and China, but the affiliates of foreign companies import from their central plant.³⁴

Table 3
Thailand's Pharmaceutical Exports and Imports
(million baht)

Year	Exports	Imports	Balance of trade
2001	4,338 (\$ 114.1 m)	17,185 (\$ 452.2 m)	-12,847 (\$ 338 m)
2002	4,126 (\$ 108.5 m)	17,077 (\$ 449.3 m)	-12,951 (\$ 340 m)
2003	4,834 (\$ 127.2 m)	20,788 (\$ 547 m)	-15,954 (\$ 419.8 m)
2004	4,949 (\$ 130.2 m)	22,183 (\$ 583.7 m)	-17,234 (\$ 453.5 m)

Source: Ministry of Commerce, Bangkok, 2005

Overall, Thailand is unable to achieve self-reliant pharmaceutical production. This is evident from the growing trade deficit in this area. The statistics show that Thailand's trade balance of payments in the pharmaceutical sector has always been in deficit, and this deficit seems to be continually widening. For example, the value of trade deficit in pharmaceutical products substantially rose from 12,847 million baht (US\$ 338 million) in 2001 to 17,234 million baht (US\$ 453.5 million) in 2004 (see Table 3).

The lack of domestic pharmaceutical production leads to high dependency on other countries regarding technology, finished drugs, and medicinal active ingredients. This

³³ GPO, *ibid.*

³⁴ Thai Drug Control Division, *Pharmaceutical Manufacture in Thailand*, Bangkok, 2003.
Available on: <http://www.fda.moph.go.th>

means that the healthcare service in Thailand will face difficulties, especially when situations of crisis occur, such as during conflict or war, in cases of epidemic, or following natural disasters like earthquakes or tsunamis. The heavy import dependence of the economy also means substantial outflows of foreign exchange resources. Therefore, domestic industrialisation and greater self-sufficiency in the supply of drugs is necessary for the country to achieve sustained economic growth in this sector and meet social development objectives (*i.e.* improved public health). However, there are major problems, achieving this in practice.

3.2 Generic and Branded Drugs

A common marketing technique widely employed in the pharmaceutical industry is to launch a product in different packaged forms, and to use more than one brand name for one therapeutic drug.³⁵ So-called ‘me-too’ drugs, that are molecularly distinct but therapeutically identical to an existing medicine, are widespread in the market.³⁶ In Britain, for example, there were 3,550 different brand names used on about 1,200 medical substances.³⁷ The Patented Medicine Prices Review Board evaluated 1147 newly patented drugs in Canada between 1990 and 2003, and found only 142 to be breakthrough drugs. The remaining 1,005 were classified as ‘me-too’ drugs, which did not provide any ‘substantial improvement over existing drug products.’³⁸ In the United States, the Food and Drug Administration (FDA) approved 415 new drugs between 1998 and 2002. It was found that 14 percent of the approved drugs were truly innovative, 9 percent were regarded as significant improvements, and 77 percent were not more effective than the drugs already on the market.³⁹

³⁵ British Medical Association, *The British National Formulary*, London, 1988.

³⁶ Braithwaite, J., *Corporate Crime in the Pharmaceutical Industry*, Routledge & Kegan Paul, London, 1986, p.164.

³⁷ British Medical Association, *op.cit.*

³⁸ Morgan, S.G. et al “‘Breakthrough’ Drugs and Growth in Expenditure on Prescription Drugs in Canada”, *BMJ*, 8 October 2005, pp.815-816. Available on: <http://bmj.bmjournals.com/cgi/content/full/331/7520/815>

³⁹ Angell, M., *The Truth about the Drug Companies*, Random House, New York, 2005, p.75.

As a result of this practice, WHO observes that the number of brand-name drugs throughout the world is over 100,000.⁴⁰ The proliferation of brands has recouped large profits for the original companies. The total sale of the top ten brands in 2004, for example, is as high as US\$ 53,500 million (Table 4).

Box 3

Marketing Practices and Creation of Brand Loyalty in the Pharmaceutical Industry

Each drug has a single generic name, which is the generally accepted name of a drug and reflects the therapeutic class to which the drug belongs. No one can hold a monopoly over the generic name. Unlike the generic name, the brand name is a proprietary name which belongs to one owner only. To the extent that a brand name is used to proclaim ownership, a drug company is able to have its brand name displace the generic name, and the drug will be popularly known by the name that is the property of the firm. The brand name is advertised to consumers, or in the case of prescription drugs to doctors, in order to build up brand loyalty. When a particular branded drug is fixed in a doctor's mind, his decision to prescribe is likely to be influenced by the brand loyalty of the promoted drug. The drugs that are heavily promoted tend to be heavily prescribed.

The commercial and marketing strength of the drug maker created by the brand name seems to be indefinite. Since the legal rights under trade marks can exist forever, the doctors influenced by brand loyalty will continue to prescribe the drug, even though such a product no longer enjoys patent protection. The multiplicity of brands causes confusion in consumers' minds. Consumers and doctors tend to believe that the branded drug is different from, and cannot be substituted by, another lower-priced generic. The proliferation of branded products, together with intense advertisement, enables large companies to create and sustain a good impression of their product by name. This helps create and maintain leading market positions and can protect their disproportionate market share against small generic firms.

⁴⁰ WHO, *The World Drug Situation*, Geneva, 1988, p.43.

Table 4
Top Ten Brands, Global Sales, 2004
(US\$ million)

Brands	Company	Sale volume
Lipitor (cholesterol-lowering)	Pfizer	12,000
Zocor (cholesterol-lowering)	Merck	5,900
Plavix (anti-clotting)	BMS	5,000
Nexium (anti-ulcerant)	AstraZeneca	4,800
Zyprexa (anti-psychotic)	Eli Lilly	4,800
Norvasc (anti-hypertensive)	Pfizer	4,800
Seretide/Advair (anti-asthma)	GlaxoSmithKline	4,700
Erypo (blood-cell booster)	Johnson & Johnson	4,000
Prevacid (anti-ulcerant)	TAP Pharmaceutical Products	3,800
Effexor (anti-depressant)	Wyeth	3,700
Total		53,500

Source: IMS Health cited in the Economist, 16 June 2005

The marketing technique of product differentiation (using several brand names for one drug) is widely used in Thailand. For example, there are 88 different brand names for paracetamol.⁴¹ Ampicillin is sold in the ‘over the counter’ (OTC) market under 35 brand names.⁴²

In 1981, the Thai government established an ‘Essential Drug List’ as part of the National Drug Policy. The National Drug Policy requires state hospitals and health centres to buy essential drugs from GPO which sells the drugs under generic names. The use of generic names is designed to limit the number of drugs and to control the proliferation of branded drugs. Despite this attempt, branded drugs still play a leading role in the market. This is because the drugs on the Essential Drug List represents

⁴¹ Food and Drug Administration, Thai Medical Directory, Ministry of Public Health, Bangkok, 2002.

⁴² Ibid.

only 5 percent of the total drug consumption in Thailand.⁴³ In addition, state hospitals and health centres are not obliged to buy generic drugs from GPO if the purchase fund comes from their income budget.⁴⁴ As a result, generic drugs are unable to totally replace branded drugs in the public health sector.

In Thailand, medicines can be advertised under brand names, which are protected by the Trade Marks Act B.E. 2534 (1991). The advertisement of prescription drugs are regulated under the Drugs Act 1967. While non-dangerous OTC drugs may be advertised directly to the general public, the advertisement of potentially dangerous drugs (or prescription medicines) cannot be directed to the consuming public. It is restricted to professionals such as doctors, veterinarians, nurses and pharmacists. The absence of advertising control in the public market allows the pharmaceutical companies to run intensive promotional campaigns to influence doctors' prescribing practices.

With regard to OTC drugs, pharmaceutical companies in Thailand normally promote their products to customers through different mass media, including radio, television, and newspapers. Discounted drug prices for pharmacists and drugstores are also a common promotional practice. Although several methods of advertisement (*e.g.* exhibitions, symposiums, drug samples and gifts) are found in Thailand, the most popular means is the use of sales-representatives. Pharmaceutical companies, both locally-owned and foreign-controlled, employ a large number of pharmacists as salespersons to doctors.⁴⁵

The expenditures on drug advertisement incurred by the pharmaceutical companies in Thailand have been declared at between 0.43 and 20.81 percent of the total sales. Of the total promotional expenditure, it is estimated that 45 percent goes to sale

⁴³ Kanavos & Paganelli, *Emerging Pharmaceutical Markets - Potential & Problems*, URCH Pharmaceutical Publications, London, September 2000.

⁴⁴ Rattanarojsakul, K., *The Pharmaceutical Industry in Thailand*, Unpublished Master of Economics Thesis, Thammasat University, Bangkok, 1986, p.138.

⁴⁵ Interviews with Dr. Jiraporn Limpananont, Social Pharmacy Research Unit, Faculty of Pharmaceutical Sciences, Chulalongkorn University, Bangkok, June 2006

representatives.⁴⁶ However, since pharmaceutical firms are not required by law to provide the state authorities with specific information relating to promotional costs, the real expenditures may be much higher than these figures.

As previously noted, the advertisement of drugs can influence the pattern of consumption. In Thailand, the problem is more acute. The Thai population, who mostly live in rural areas, generally medicate themselves without knowing how to use drugs properly. The advertisements of pharmaceutical companies seem to be the most important source of information concerning medicines. A survey on the use of medicines in Thailand reveals that drug promotion exerts a significant influence on medicine consumption. Consumers tend to buy a branded drug, which is heavily promoted, rather than non-promoted or less promoted drugs with identical therapeutic effects. In order to remind himself, a consumer usually brings a package of the branded drug to a drugstore or tells the seller about the brand name of the drug.⁴⁷

The study of the United Nations Asian and Pacific Development Institution (UNAPDI), which was based on an analysis of morbidity patterns in Thailand, found an asymmetry between drug consumption and requirements. The level of consumption in some drugs such as antibiotics was seven times higher than the requirement for the drugs. This was in contrast to the level of consumption in other drugs dealing with specific health priorities in the country, such as tuberculosis and malaria. Anti-tuberculosis drugs were found to be under-consumed, equivalent to only 5 percent of estimated drug requirements.⁴⁸ This data confirms that the pharmaceutical companies tend to market and promote drugs according to their own specific product lines, rather than the products suitable to the medical needs in developing countries.

The marketing strategies of drug companies plus the character of the Thai market, based mainly on self-medication, causes several negative effects. These include: (i) unnecessarily high consumption of non-essential drugs; (ii) strong brand-name

⁴⁶ Information supplied to the author by an official of Food and Drug Administration, Ministry of Public Health, Bangkok, June 2006.

⁴⁷ Rattanaojasakul, op.cit., at p.147.

⁴⁸ Cited in Ibid, at p.167.

preferences; and (iii) high drug prices. There is no doubt that the brand loyalty built up by intense brand-name promotion can maintain a high demand for such drugs and results in high profitability for the drug companies. The TRIPS-Plus rules that demand a higher level of protection for trade marks will allow the pharmaceutical companies to prolong marketing practices. The IPR and investment rule under TUSFTA that allows foreign companies to directly sue the Thai government for compensation will most likely discourage Thailand from taking measures to control the promotion and advertising activities adopted by the pharmaceutical companies.

IV. Impact of Patents on Pharmaceutical Prices and Technological Capability

This part examines the implications of patents on technological development. It is divided into three separate issues: (i) patents and pharmaceutical prices; (ii) patents and FDI; and (iii) patents, R&D and technology transfer.

1. Patents and Pharmaceutical Prices

The pharmaceutical industry has been widely criticised for its high prices and excessive profits. The peculiarity of the market and the use of marketing techniques, creates an oligopolistic situation. This allows drug companies to exercise market power and charge whatever prices the market will bear. The highly oligopolistic situation in the prescription drug market means the normal economic conditions of supply and demand are artificially skewed, and consequently there is no price competition among pharmaceutical companies.⁴⁹

There is a great deal of polemics surrounding the pricing of drugs. Ideally, a medicine should be priced in the market at the cost of production plus a reasonable level of profit. But it remains unclear what that reasonable profit would be. It is very difficult to arrive at a comprehensive financial picture of the industry, due to corporate

⁴⁹ Oligopoly is defined as a “market where some degree of competition remains but where there is still a mere handful of competitive undertakings ... and the nature of the rivalry between them is substantially affected by this fact.” Goyder, D.G., *EC Competition Law*, Clarendon Press, Oxford, 1993, p.10. See also Scherer, F.M. “Pricing, Profits, and Technological Progress in the Pharmaceutical Industry”, 7 *J. Econ. Persp.* 97 (1993).

financing and accounting techniques used by the firms operating in this area. The following are the main factors responsible for high drug price:

- the absence of price competition;
- the unavailability of raw materials and active ingredients from alternative sources;
- high import and other taxes on pharmaceuticals;
- the prices of branded drugs are normally quoted several times higher than the prices of generic products;
- drugs with intense promotional campaigns are generally sold at a higher price than the generics.

No doubt, the lack of generic competition and government control on prices provide ample opportunity for drug suppliers to set excessive prices; being the main factors for the high prices of medicines. Any attempt to tackle this problem has to be mindful of these factors. Unlike other goods, identical medicinal products are usually quoted at different prices in different markets.

The price differentials mainly stem from the pricing policy of drug multinationals that typically charge ‘whatever price the market can bear’. The price level of medicines generally depends on the situation in the market.⁵⁰ Patents seem to be the most important factor for determining drug prices. Before TRIPS was adopted as part of the WTO agreements, it was evident that countries with no pharmaceutical product patents, whether developed or developing countries, showed lower price levels than countries that provided a high degree of patent protection. Moreover, in countries with no patents on medicinal products and also price control measures, such as India and Italy, the price levels of pharmaceuticals were very low.⁵¹

⁵⁰ A multiple-country analysis based on price packages of medicines conducted by Schut and Van Bergeijk shows that the main factors that cause price differentials in the pharmaceutical industry are: (i) per capita gross domestic product (GDP), (ii) government policies on price controls, and (iii) patent protection for pharmaceutical products. Schut, F.T. and P.A.G. Van Bergeijk “International Price Discrimination: the Pharmaceutical Industry”, World Development, Vol.14 No.9, 1986, pp.1141-1150.

⁵¹ Ibid., at pp.1146-1147.

Table 5
Comparison of Prices of Selected Anti-retroviral Drugs in Thailand, 2001

Drugs	Brand name price (US\$)	Generic price (US\$)	Price difference from minimum (%)
Fluconazole (200 mg caps)	6.20	0.30	1966.67
Stavudine (40 mg caps)	2.60	0.10	2500
Zidovudine (100 mg caps)	1.20	0.62	93.55

Source: GPO, Production of HIV-AIDS-Related Drugs in Government Pharmaceutical Organisation, Research and Development Institute, Government Pharmaceutical Organisation, Bangkok, 2001

Table 6
Comparison ARV Prices in Thailand, January 2005

ARV	Patent status in Thailand	Originator (baht/units)	Generic (baht/units)
1st line ARVs			
Zidovudine (AZT) (100mg)	Non-patent	4644/100 (GSK)	600/100 (GPO)
Lamivudine (3TC) (150mg)	Non-patent	6046/60 (GSK)	600/60 (GPO)
Nevirapine (NVP) (200mg)	Non-patent	1659/60 (BI)	900/60 (GPO)
Efavirenz (EFV) (200mg)	Patented	3192/100 (Merck)	1292/100 (Cipla)
Stavudine (d4T) (40mg)	Non-patent	5660/60 (BMS)	270/60 (GPO)
2nd line ARVs			
Tenofovir (TDF) (300mg)	Unconfirmed	3131/100 (Gilead)	n/a
Didanosine (ddI) (250mg or 125x2mg)	Patented	7384/60 (BMS)	1380/60 (GPO)
Abacavir (ABC) (300mg)	Non-patent	4617/100 (GSK)	3040/100 (Cipla)
Ritonavir (RTV) (100mg)	Non-patent	418/100 (Abbott)	1022/100 (Hetero)
Lopinavir (LPV)	Patented	n/a	n/a
Saquinavir (SQV) (200mg)	Unconfirmed	5515/180 (Roche)	1900/180 (Hetero)
Lopinavir (LPV)/ Ritonavir (RTV) (113.3+33.3mg)	Patented	17762/180 (Abbott)	5930/180 (Hetero)

Source: Department of Intellectual Property; Ministry of Public Health; MSF: Untangling the Web of Price Reductions: A Pricing Guide for the Purchase of ARVs for Developing Countries, June 2005

The figures in Table 5 show high price variations in the Thai pharmaceutical market. Identical products are generally sold by different companies at disparate prices.⁵² The price margins for each drug are relatively wide, ranging from 93.55 to 1,966.67 percent. Drugs sold by Thai-owned companies are generally much cheaper than those offered by TNCs. For example, Pfizer's Fluconazole (200 mg caps) is sold under the brand name of 'Diflucan' at US\$ 6.20 – much more expensive than that sold by GPO at US\$ 0.30. Table 6 also reveals price differentiation of various anti-retroviral medicines in Thailand. This confirms that the prices of branded drugs are quoted several times higher than those of the generics.

Three factors are responsible for the price differences. First, the original companies often sell their products under brand names, while GPO offers its products under generic names instead. This enables GPO's drugs to remain the lowest-priced products in the market. Second, the cost of heavy promotion is normally included in the prices charged for the products sold. This causes prices of branded drugs with intense promotional campaigns to be higher than that of GPO. GPO basically operates as a non-profit-making organisation, choosing not to spend its financial resources to attract customers and create positive associations with the brand. Third, local companies and GPO could maintain low prices because they were free to import cheap raw materials and active ingredients from many alternative sources. These particularly include countries whose patent legislation was not stringent (such as India).⁵³ By contrast, subsidiaries of multinationals or joint ventures procure raw materials from their overseas affiliates. The prices of intra-group sales of raw materials are generally set in accordance with the standard accounting policy relating to transfer pricing. This leads to over-invoicing of imports and high prices for finished products sold by the foreign firms.

⁵² Hiranrath, W. *et al*, The Survey of Selling Prices of TNCs and Local GMP Manufacturers, Chulalongkorn University Press, Bangkok, 1990, pp.43-44.

⁵³ However, the situation might change after 2005 when all WTO Members (except least developed countries) have to protect pharmaceutical patents as required by the TRIPS Agreement. The supply of cheap raw materials and active ingredients might be limited as a result. See Karandikar, S.M., Indian Drug Industry after GATT, World Trade Centre, Bombay, 1994.

In Thailand, apart from customs and tariffs law, there is no specific legislation regarding arm's length price or other mechanisms dealing with the transfer pricing practices of TNCs.⁵⁴ As a result, the transfer pricing techniques have been widely utilised by foreign companies operating in Thailand. A study on pharmaceutical prices indicates that prices of sales by parent companies to subsidiaries located in Thailand are often artificially raised and usually higher than prices charged between other unrelated parties. For example, in 1981 the prices of imported aspirin, dexamethasone, and ampicillin paid by subsidiaries of multinationals to their parent or overseas affiliates were respectively 23, 15 and 5 percent higher than the prices of the same drugs charged between independent enterprises.⁵⁵ The lack of any specific legislation to check transfer pricing renders the pharmaceutical market in Thailand vulnerable to foreign price distortions. Prices of drugs can therefore be artificially inflated or deflated by pharmaceutical firms depending on what they feel about the market.

Despite being more costly, it seems paradoxical that branded products of the multinationals still have a relatively large market share (about 35 percent). The ability of foreign affiliates to maintain prices of certain drugs at levels higher than those of local companies may partly be explained by the fact that the consumers are generally ignorant of price differences due to the strong persuasion of the pharmacist or drug seller. It can also stem from the fact that consumers influenced by heavy promotion or the drug seller, often tie quality of drugs with prices. It is found that in Thailand the consuming public always believes that drugs with high prices are different from and superior in quality to cheaper products.⁵⁶

While exclusion of patents on pharmaceutical products is now less feasible due to TRIPS obligations, it is suggested that a country seeking to improve access to medicines should adopt a policy of strict control on prices. Direct and indirect price controls by the State will inhibit the overpricing of drugs by firms.

⁵⁴ Chaiseri, N. and C. Hongladarom (eds.), *The Role of Multinational Corporations in Thailand*, Conference at Thammasat University, Bangkok, 1984, p.175.

⁵⁵ Kaosa-ad, M. "Transfer Pricing in the Pharmaceutical Industry", *Thammasat Economic Journal*, Vol.3 No.1, 1985, p.15.

⁵⁶ Rattanarojsakul, op.cit., at p.130.

Under the National Drug Policy, the Thai government indirectly controls prices of medicines to be sold to public hospitals by requiring public hospitals to purchase drugs on the essential drug list from GPO. But no such intervention exists in the private market. Where the role of the government in controlling drug prices is minimal, it is strongly argued that unnecessary over-pricing of products by private and foreign firms helps in giving a distorted picture of pharmaceutical prices thus casting unnecessary expenditure on the ordinary consumers in Thailand.

2. Patents and Foreign Direct Investment

For a long time, transnational corporations have played a key role in FDI and cross-border transactions. TNCs hold a unique and privileged position whereby they possess considerable economic resources, technology, and managerial skills. This offers them unlimited opportunities to influence the process of socio-economic development in the countries in which they invest.⁵⁷ The roles and objectives of TNCs in host developing countries have been widely criticised and have been a subject of continuing political controversy and academic critique.

Currently, foreign TNCs are widely regarded as major driving forces behind the rapid development of many business sectors in Thailand. To fulfill their industrial development plan, the government has recognised the importance of foreign investment by establishing, in 1966, the Board of Investment (BOI). The Board is envisaged as a centre for planning, and drawing up of policy guide-lines in relation to foreign investment. It also helps in the attraction of FDI by direct promotion; providing foreign investors with assistance and promotional privileges in establishing business in Thailand.⁵⁸

⁵⁷ Miljan, T. (ed.), *The Political Economy of North-South Relations*, Broadview Press Ltd., Peterborough, 1987, p.252. See also Carsten Fink, *How Stronger Patent Protection in India Might Affect the Behaviour of Transnational Pharmaceutical Industries*, World Bank Group, Policy Research Working Paper No. 2352, 2000.

⁵⁸ Panupong, C., *MNCs and the Role of the Thai government*, in Chaiseri and Hongladarom (eds.), *op.cit.*, at p..6.

One of the main purposes for the enactment of the Thai patent law (and the consequent amendment of the Act) was to offer protection to pharmaceuticals and therefore to create a favourable climate for foreign investment.⁵⁹ It is expected that strong patent protection that guarantees satisfactory returns on investment plus other privileges provided by the BOI will encourage TNCs to establish manufacturing activities in Thailand.

In an attempt to attract the interests of multinationals, it is necessary for each country to establish a suitable 'investment climate'. Nevertheless, this climate cannot be created solely by the mere promulgation of investment promotion policy and various incentives. The creation of such a climate needs to be matched with the availability of several interrelated factors, including economic, political and legal conditions in the host country.⁶⁰ Anderfelt points out that, among the three factors, economic and political conditions within the host country are more influential on the investor's decision to invest in a particular country than the legal conditions.⁶¹ He further observes that

“... only in cases in which neither economic nor political conditions pose any significant non-business risks for the venture would the legal conditions be of primary importance.”⁶²

In other words, politico-economic factors, such as local market size, low-waged labour force, available raw materials, advantages for export-oriented production, and political stability, are far more important than legal frameworks such as patent legislation. There is a range of evidence suggesting that the availability of patent

⁵⁹ The arguments in favour of the patent system in this respect are found in Sell, A. and M. Mundkowski, *Patent Protection and Economic Development - Some Results of an Empirical Analysis in the Pharmaceutical Industry in Latin America*, 10 IIC 566 (1979); Mangalo, N., *Patent Protection and Technology Transfer in the North-South Conflict*, 9 IIC 109 (1978).

It is even argued that weak patent protection will push foreign investments out of the country. See Behrman, J. and A. Deolakikar, *Of the Fittest?, Duration of Survival of Manufacturing Establishments in a Developing Country*, *Journal of Industrial Economics*, Vol.38, 1989, p.215.

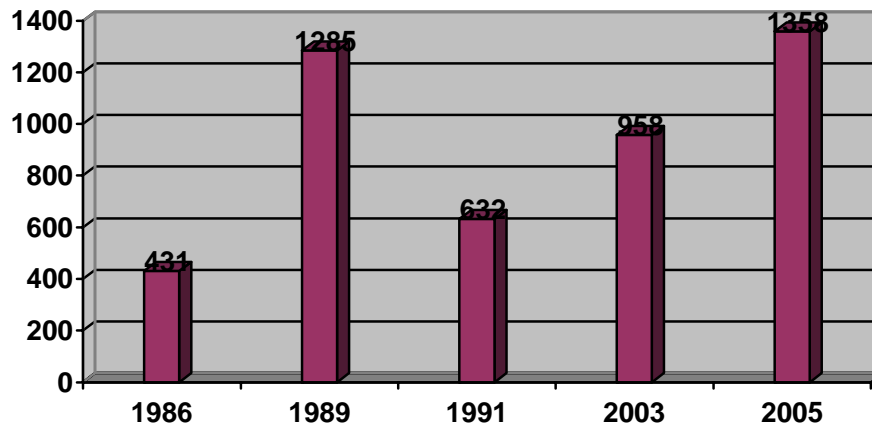
⁶⁰ Anderfelt, U., *International Patent-legislation and Developing Countries*, Martinus Nijhoff, The Hague, 1971, pp.139-141.

⁶¹ *Ibid.*, at p.140.

⁶² *Ibid.* See also Maskus, K.E., *Encouraging International Technology Transfer*, UNCTAD-ICTAD Project on IPRs and Sustainable Development, Issue Paper No.7, 2004, pp.18-20.

protection alone does not guarantee the inflow of FDI. According to Bangs, the majority of the firms in his survey felt that industrial property protection was not a decisive factor in their decision to undertake foreign investment.⁶³ This view is shared by prominent science and technology expert, Carlos Correa, who contends that there are several factors affecting the relationship between FDI and IPRs. Those factors include the type of IPRs, purpose of the investment, and the degree of industrial and technological development of the country in question.⁶⁴

Figure 3
Number of Applications for BOI Promotion, 1986-2005



Source: Board of Investment, Bangkok, 2006

Thailand's experiences have demonstrated that economic and political conditions in the country are significant factors in inducing foreign investments. Statistics reveal that the level of foreign investment increased significantly during the late 1980s (Figure 6.3). The growth was spurred by both external and internal factors, such as favourable global economic conditions including low oil prices; the Thai government's foreign exchange policy maintaining the value of the baht at an appropriate level; and policies stimulating trade with neighbouring countries (*i.e.*

⁶³ Bangs, R.B., *Use of Industrial Property in Foreign Countries: A Further Report*, IDEA - The Journal of Law and Technology, Vol.13, 1969-70, p.557.

⁶⁴ Correa, C.M. "Intellectual Property Rights and Foreign Direct Investment", *International Journal of Technology Management*, Vol.10, 1995, pp.173-199.

Vietnam, Cambodia, Laos and Myanmar). Due to its geographical location, this regional trade has led Thailand to become a manufacturing base for many companies intending to market their products in Indo-china.⁶⁵

After considerable success in the inducement of foreign investment in the late 1980s, the flow of FDI declined in the 1990s (Figure 3). The drop in FDI was attributed to several factors, including the Gulf war in the early 1990s, the Asian financial crisis and economic recession between 1997 and 2000. The sharp decline in FDI was also attributed to Thailand's domestic situation, which saw a military coup in February 1991; a saturation of investment in some manufacturing sectors; high land prices; infrastructure inadequacies and shortages in skilled personnel. From 2003 to 2005, the amount of FDI in Thailand increased again after its economy had recovered from the economic crisis (Figure 3).

This reveals that growth and decline in FDI in Thailand depend on a number of positive and negative conditions.⁶⁶ There is no conclusive evidence to suggest that the level of patent protection is the major determinative factor encouraging foreign investment.⁶⁷ When Thailand amended its patent law in 1992, the expansion of patents to pharmaceutical inventions has not made Thailand more attractive to foreign investors. So far, multinational pharmaceutical companies have not established the potential full range of operations in Thailand. The investments of multinationals are still limited to the final stage of medicine production. Those companies have continued to supply the Thai market by importing products from overseas plants and by formulating and packaging products in Thailand, regardless of the level of IPR protection in the country. Therefore, the introduction of TRIPS-Plus rules under the TUSFTA would not be likely to significantly influence the desire of foreign companies to set up an R&D unit or a factory for the production of active ingredients in Thailand. Potential pharmaceutical FDI is limited due to a number of the country's inadequacies for these sorts of activities mentioned earlier.

⁶⁵ Bangkok Post: Economic Review, Spins Ahead despite Hurdles, 30 December 1989, p.18.

⁶⁶ See Maskus, K.E., Intellectual Property Rights in the Global Economy, Institute for International Economics, Washington D.C., 2000, pp.199-232.

⁶⁷ The view is shared by Professor Edith Penrose. See Penrose, E.T., International Patenting and the Less-Developed Countries, Economic Journal, Vol.83, 1973, p.775.

Excessive patent protection does not necessarily mean an inflow of FDI, and low levels of protection do not necessarily keep away foreign investment either. This is evident through the entrance of many foreign pharmaceutical companies into Thailand before the first patent law was adopted in 1979. The fact that a number of multinational drug companies had established investment activities in Thailand while their home country governments were calling for improvement of patent protection worldwide seems to contradict the argument that insufficiency in patent protection leads to a decline in foreign investment.

Oddi argued in the late 1980s that the absence of patent protection in a developing country might actually be a significant factor in attracting foreign investment.⁶⁸ He refers to the situation in Argentina as an example. A large number of foreign pharmaceutical companies entered Argentina to invest in the manufacture of generic products. It is believed that the weak patent protection on pharmaceuticals was the main factor in making the country a manufacturing base of the pharmaceutical companies. This is consistent with the more recent work of Professor Carlos Correa who found a significant flow of FDI into the country despite the absences of pharmaceutical patenting.⁶⁹ This view is shared by Lall and Bibile, who conclude that that the exclusion of pharmaceuticals from patent protection was a significant factor leading Italy to become a base for export-oriented production of generic medicines.⁷⁰

This section has examined the roles of patents in inducing foreign investment into the patent-granting country. The next section, evaluates the contribution of the patent system to technological development with special emphasis on the experiences of Thailand.

⁶⁸ Oddi, A.S. "The International Patent System and Third World Development: Reality or Myth?", *Duke Law Journal*, 1987, p.849.

⁶⁹ See Correa, C.M. "Reforming the Intellectual Property Rights System in Latin America, *World Economy*, 2000, pp.851-872.

⁷⁰ Lall, S. and S. Bibile "The Political Economy of Controlling Transnationals: The Pharmaceutical Industry in Sri Lanka (1972-76)", *World Development*, Vol.5 No.8., 1977, at p.688. See also Scherer, F.M. and S. Weiburst "Economic Effects of Strengthening Pharmaceutical Patent Protection in Italy", 26 *IIC* 1009-1024 (1995).

3. Patents and Technological Development

There are divergent views held by different authors and authorities on what the term ‘technology’ should really mean.⁷¹ In sum, technology can be referred to as ‘the knowledge to produce and use tools to satisfy human needs either directly or indirectly.’⁷² In other words, knowledge that can be considered technology must be used and applied for the production and provision of goods and services for the benefit of mankind.

Technology is a basic requirement for the industrial growth and economic development of developing countries. While the acquisition of modern technology in developed countries may be through locally undertaken R&D, developing countries generally acquire technology through two channels: domestic R&D and import of technology from abroad.⁷³ The following section considers whether or not patent protection for pharmaceuticals would stimulate local R&D and encourage foreign technology owners to transfer technology to developing countries.⁷⁴

3.1 Research and Development

⁷¹ For definitions and concepts of technology see Santikarn, M., *Technology Transfer: A Case Study*, Singapore University Press, Singapore, 1981, pp.3-6; UNCTC, *Technology Acquisition under Alternative Arrangements with Transnational Corporations: Selected Industrial Case Studies in Thailand*, UN Pub. Sale No.E.87.II.A.14, 1987, p.2; Strassmann, W.P., *Technological Change and Economic Development: The Manufacturing Experience of Mexico and Puerto Rico*, Cornell University Press, New York, 1968, p.2; Hayden, E.W., *Technology Transfer to East Europe: U.S. Corporate Experience*, Praeger Publishers, New York, 1976, p.23; and Vincent, D., *The Role and Functions of Patents as Tools of Technology Transfer*, *Industrial Property*, No.7/8, 1984, p.256.

⁷² Yankey, G.S., *International Patents and Technology Transfer to Less Developed Countries*, Gower, Aldershot, 1987, p.4.

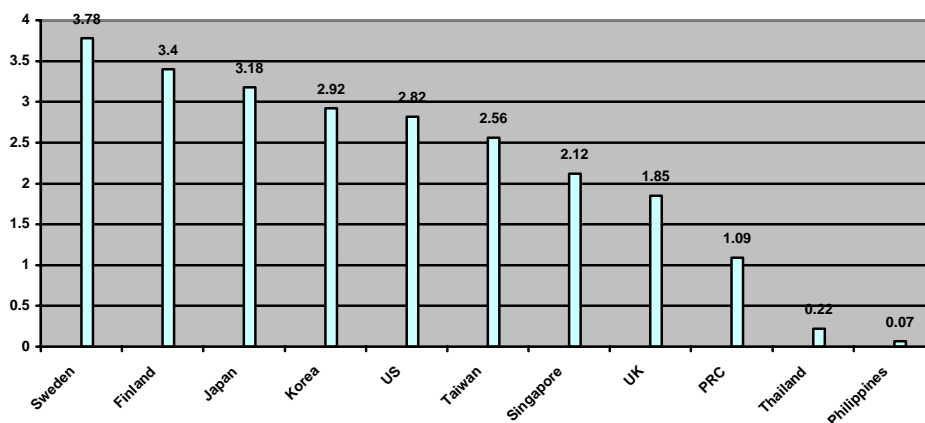
⁷³ For analysis of the TRIPS Agreement in regard to the transfer of technology in developing countries see Verma, S.K. “TRIPS – Development and Transfer of Technology”, 27 *IIC* 3 (1996).

⁷⁴ The benefit of the patent system in encouraging R&D and transfer of technology is emphasised by Rapp, R.T. and R.P. Rozex, *Benefits and Costs of Intellectual Property Protection in Developing Countries*, *J.W.T.*, Vol.24 No.5, 1990, p.95; and Kunz-Hallstein, H.P., *The Revision of the International System of Patent Protection in the Interest of the Developing Countries*, 10 *IIC* 652 (1979). For policy discussion on the transfer of technology in Thailand see TDRI, *The Barriers to and Strategies for Technology Acquisition*, Thailand Development Research Institute, Bangkok, 1991.

Modern technologies are mostly developed in a small number of industrialised countries. In general, developed country governments are not directly involved in R&D, but may encourage private research by providing various incentives. In order to stimulate local R&D, many countries provide privileges to research-oriented firms. The privileges include, direct government funding, investment tax credit, patent protection and legal protection of trade secrets, amongst others.

In Thailand, the government has recognised the importance of modern technology and has encouraged the development of local technology by financing a number of research programmes in various universities and public research institutes. It also provides financial support for research to private firms. Moreover, the profitability guaranteed by the patent system is designed to be another significant incentive for the development of indigenous technologies in the country.⁷⁵

Figure 4
Comparison of Total Expenditure on R&D in Various Countries, 2002
(Percentage of GDP)



Source: IMD World Competitiveness Yearbook 2004

⁷⁵ TDRI, *ibid.*, at p.14.

Table 7
Comparison of Total Expenditure on R&D by Private Sectors in Various Countries, 2002

Countries	Private sector R&D expenditure (US\$ million)	Private sector R&D expenditure (% of total R&D expenditure)
Developed countries		
US	200,525	73.06
Japan	94,246	73.67
Germany	34,426	69.11
UK	18,246	67.40
NICs		
South Korea	10,152	73.30
Taiwan	3,965	61.09
Singapore	1,168	61.44
Developing Countries		
PRC	9,518	61.19
India	860	22.98
Mexico	645	24.53
Malaysia	443	65.63
Thailand	138	42.07
Philippines	21	41.18

Source: IMD World Competitiveness Yearbook 2004

Table 8
Comparison of Total Research Personnel, 2000-2001
(per 10,000 population)

Year	Country	Researchers
2000	Japan	136.0
2000	Singapore	83.5
2000	USA	74.0
2001	PRC	60
2000	Korea	40.9
2000	Taiwan	39.3
2000	Malaysia	15.6
2001	Thailand	7.4

Source: National Research Council, National Survey on R&D Expenditure and Personnel of Thailand, Bangkok, 2004

In spite of several incentives, Thai government policies designed to stimulate local R&D have proved unsuccessful. Thailand spends a smaller share of Gross Domestic Product (GDP) on R&D than many other countries. While R&D expenditures of industrialised countries are generally more than two percent of GDP, the amount of research spending in Thailand in 2002 was US\$ 277 million,⁷⁶ or 0.22 percent of GDP (Figure 4). This amount was smaller than those spent by newly industrialised countries including the Republic of Korea, Taiwan and Singapore, which were at 2.92, 2.56 and 2.12 percent of GDP respectively.

Regarding R&D in the private sector, Thai companies spent US\$ 138 million on R&D in 2002.⁷⁷ The Thai private sector accounted for 42.07% of the total R&D cost of the country. This is relatively low by international standards, compared to approximate private sector R&D spending of 70 and 61 percent in developed countries and newly industrialised countries respectively (Table 7).

⁷⁶ APEC Industrial Science & Technology Internationalization Database Trendsetters, 2005.

<http://www.apec-isti.org/isti/abridge/cic/cicrde00.htm>

⁷⁷ Ibid.

Statistics also reveal that Thailand has a smaller number of full-time research personnel than other countries. While the number of researchers in Thailand in 2001 was at 7.4 per 10,000 population, the number of research personnel in Taiwan, Korea, China, the United States, and Singapore were in the range of 40-80 per 10,000 population (Table 8).

R&D activities are not significant in view of the number of companies operating in Thailand. Private firms, both local and foreign, rely largely on imported technology for all production activities. Although R&D is carried out in some private firms, these research projects are confined to the development of low standard technology such as product and process improvement.⁷⁸ The lack of R&D can be explained by three factors: (i) most firms produced standardised products which require only simple technology; (ii) Thai companies consider the development of technological inventions to be costlier and slower than the import of ready-made technologies; (iii) the country's acute shortage of scientists and engineers.

Table 9
Number of Patent Applications and Grants in Thailand, 1996-2005

Year	Application (Foreign)	Application (Thai)	Application Total	Grant (Foreign)	Grant (Thai)	Grant Total
2005	6,627	4,258	10,885	817	505	1,322
2004	5,514	3,428	8,942	1,177	867	2,044
2003	5,148	3,426	8,574	1,529	797	2,326
2002	4,696	3,030	7,726	1,831	635	2,466
2001	5,490	2,504	7,994	1,098	418	1,516
2000	5,246	2,500	7,746	580	164	744
1999	5,011	1,886	6,897	488	110	598
1998	5,141	1,268	6,409	914	261	1,175
1997	5,849	769	6,618	933	198	1,131
1996	4,896	622	5,518	1,169	186	1,355
Total	53,618 (69.36%)	23,691 (30.64%)	77,309 (100%)	10,536 (71.79%)	4,141 (28.21%)	14,677 (100%)

⁷⁸ TDRI, Intellectual Property and Impacts of Trade Agreements on Thai SMEs op.cit.

Source: Department of Intellectual Property, Ministry of Commerce, Bangkok, 2006
<http://www.ipthailand.org/Thai/Default.aspx>

Table 10
Number of Granted Patents in Thailand Classified by Types, 1996-2005

Year	Invention (Foreign)	Invention (Thai)	Invention Total	Design (Foreign)	Design (Thai)	Design Total
2005	491	62	553	326	443	769
2004	659	57	716	518	810	1,328
2003	950	56	1,006	579	741	1,320
2002	1,063	39	1,102	768	596	1,364
2001	738	58	796	360	360	720
2000	371	45	416	209	119	328
1999	363	29	392	125	81	206
1998	680	43	723	234	218	452
1997	684	22	706	249	176	425
1996	866	18	884	303	168	471
Total	6,865 (94.12%)	429 (5.88%)	7,294 (100%)	3,671 (49.72%)	3,712 (50.28%)	7,383 (100%)

Source: Department of Intellectual Property, Ministry of Commerce, Bangkok, 2006
<http://www.ipthailand.org/Thai/Default.aspx>

The country's lack of innovation is reflected in the number of patents granted by the Department of Intellectual Property (DIP). Between 1996 and 2005, DIP received 77,309 applications for patents. In the period, 14,677 patents were issued (Table 9).

A closer examination reveals that Thai nationals substantially fewer less patents than foreigners. Out of 14,677 patents, Thai-owned patents represent only a small proportion. While 10,536 patents or 71.79 percent were granted to foreigners, 4,141 patents or 28.21 percent went to Thai nationals (Table 9). The situation is even worse when the number of patents for inventions alone is considered. From 7,294 patents granted for inventions, 6,865 patents or 94.12 percent were given to foreigners, only 429 patents or 5.88 percent of all patents were accounted for by local inventions (Table 10).

So far, the patent system has been utilised by foreigners more than Thai nationals. Moreover, the number of patents issued to local scientists each year does not show any sign of substantial increase. The high degree of foreign domination implies that local inventors have low technological capability to develop inventions that meet the basic requirements of novelty, inventive step and industrial application. While Thailand's technological capabilities are still in the embryonic stage, the main purpose of the patent system – the encouragement of local R&D – seems unlikely to be fulfilled. The foreign control of patents in Thailand seems likely to increase in line with the higher level of patent protection, especially if Thailand adopts the TRIPS-Plus patent rules that protect high-tech inventions.⁷⁹

Although there are no official records, a survey by the Thailand Development Research Institute (TDRI) found that only a small number of patents granted by DIP are being used for production in the country.⁸⁰ The non-working of patents means that foreign patent-owners have deliberately and effectively used Thailand as an export market. It also means that foreign patent owners have not modified patented inventions that were initially conceived to satisfy markets in developed countries, to suit Thai conditions. The possibility to use compulsory licensing and other mechanisms to force local working of patents would be limited if Thailand adopts the TRIPS-Plus rules under the TUSFTA, which prohibits the use of compulsory licensing and patent revocations.

3.2 Transfer of Technology

International transfer of technology refers to the transfer of technical knowledge such as production processes or management techniques from an industrial enterprise in one country to another enterprise located in another country.⁸¹ It is claimed that the system of patent protection contributes to technology transfer in several ways,

⁷⁹ The extent of the discussion on the relationship between protection of IPRs and R&D capability in developing countries see Kang, M., Trade Policy Mix under the WTO: Protection of TRIPS and R&D Subsidies, Korea Institute for International Economic Policy, Seoul, 2000.

⁸⁰ TDRI, The Barriers to and Strategies for Technology Acquisition, op.cit., at p.20.

⁸¹ Marton, K. "Technology Transfer to Developing Countries via Multinationals", World Economy, Vol.9 No.4, 1986, pp.409-426.

including through patent documents and licensing agreements.⁸² We now examine the roles of patents in technology licensing in Thailand to find out if adoption of strong IPR rules like those contained in TUSFTA would enhance technology transfer to developing countries.

Technology transfer by means of purchasing technology from abroad is acknowledged as being important and may be the most efficient method for enterprises in developing countries to acquire technology.⁸³ It is argued by some that without a sound patent system, the technology owners are not willing to license their technology and this will impede the technology acquisition process of the developing country.⁸⁴

But from a practical point of view, it can be argued that patents do not actually promote technology transfer.⁸⁵ The value of patent protection is that it allows the patentee to earn profits from the invention, whether in the form of direct production or licensing agreements. The patent holder will license his patented or proprietary information only when the level of profits obtainable through direct exploitation of the invention is not higher than royalties.⁸⁶ Where the foreign patent holder (*e.g.* a multinational pharmaceutical company) can effectively use patent rights to monopolise the developing country's market and earns high profits there, one can

⁸² Blakeney, M., *Legal Aspects of the Transfer of Technology to Developing Countries*, ESC Publishing Ltd, Oxford, 1989, p.87.

⁸³ Technology contracts may appear in various forms including licensing agreements, technical assistance contracts, management contracts, trade mark contracts and turn-key contracts involving the construction and installation of industrial plants.

⁸⁴ Taylor, C.T. and Z.A. Silberston, *The Economic Impact of the Patent System: A Study of the British Experience*, Cambridge University Press, Cambridge, 1973, p.214; Albrechtskirchinger, G., *Characteristics of a Patent Policy Aimed at Industrial and Economic Development*, in WIPO, *The Importance of the Patent System to Developing Countries*, World Symposium at Colombo, Sri Lanka, 1977; Maskus, K.E., *Intellectual Property Rights in the Global Economy*, op.cit., at pp.143-160.

⁸⁵ See Penrose, *International Patenting and the Less-Developed Countries*, op.cit., at pp.773-774; and Lall, S. *The Patent System and the Transfer of Technology to Less-Developed Countries*, J.W.T.L., Vol.10, 1976, p.9.

⁸⁶ Cabanellas, op.cit., at p.60.

safely assume that the patentee is not going to transfer the valuable technology to anyone.⁸⁷

A 1999 survey reveals that the majority of top executives in Thailand were of the opinion that there has been no transfer of technology to the Thai pharmaceutical industry since the Thai patent law was amended in 1992 to comply with the TRIPS Agreement.⁸⁸ This is consistent with the experiences of many other developing countries. Countries like Nigeria and Ghana have operated a strong patent system since the colonial period but to date these countries have been unable to establish a self-reliant domestic pharmaceutical industry.⁸⁹ By contrast, the developing nations that have no pharmaceutical patents or have weak patent protection such as Argentina, Brazil, China, India and Turkey, have been able to set up relatively large local pharmaceutical industries and all these countries have successfully transformed themselves into strong contenders in the world pharmaceutical market.⁹⁰

Although FDI could contribute to the host country's economy in acquiring technology, the foreign investment policy of the Thai government has only emphasised the inflow of capital funds. No attempts have been made and no concrete measures have been adopted to absorb modern technologies from investing firms.⁹¹

With regard to licensing contracts, it was found that the drug companies in Thailand pay high prices for technology, despite the fact that the technologies purchased are relatively simple and unsophisticated for formulating and packaging drugs. A joint study of the Economic and Social Commission for Asia and the Pacific, and the

⁸⁷ North-South technology transfers do occasionally take place, but this situation is still an exception rather than the norm. A success case on North-South technology transfer is a partnership arrangement between Eli Lilly and WHO and the Gates Foundation whereby the former agreed to transfer technology to help companies in China, India, South Africa and Russia to produce two off-patent TB medicines. Wall Street Journal, HIV/AIDS Report, 5 June 2003.

⁸⁸ Supakankunti et al, op.cit., at pp.29-35.

⁸⁹ See Yankey, op.cit.

⁹⁰ See Gereffi, op.cit., at p.182 and Table 6.5; and UNIDO, *The World's Pharmaceutical Industries: An International Perspective on Innovation, Competition and Policy*, Edward Elgar, Hants, 1992, pp.24-25.

⁹¹ Rattakul, A., *Pharmaceutical Patents and National Interest*, A Thesis Submitted to the National Security College, Bangkok, 1990, p.68 (in Thai).

United Nations Centre on Transnational Corporations, reveals that in 1981 the Thai pharmaceutical industry paid as much as 20 percent of the industry's gross sales for technology on the formulation of a simple and well-known analgesic and paid 28 percent of annual sales revenue for anaesthetics.⁹² These exorbitant royalty payments provide a clear insight into the problems of transfer pricing in Thailand.

It should be noted that technology transfers are a kind of commercial transaction in which terms and conditions are subject to bargaining between the parties concerned.⁹³ In addition, the technology market is generally regarded as having market imperfections, in which the technology owners are in a 'quasi-monopolistic' position and have more bargaining powers than the buyers.⁹⁴ The dominant position of TNCs and the high demand for technology enable the global firms to impose a variety of restrictions when dealing with the recipients from developing countries.

Restrictive terms and conditions relating to price, quantity, territory, duration, field of use and so on are found in licensing contracts. A study carried out by Santikarn⁹⁵ found that 'export prohibition'⁹⁶ and 'tie-ins'⁹⁷ were the most common restrictive clauses in transfer of technology transactions in Thailand. Other conditions which affect technological development and pricing policies of the recipients such as 'price-fixing'⁹⁸ and 'grant-back'⁹⁹ clauses were also found. A later study, which examined 275 licensing contracts concluded during the 1980s, revealed that numerous limiting conditions, including export bans, tie-ins, and grant-backs, were imposed by foreign TNCs on Thai licensees.¹⁰⁰

⁹² United Nations, Costs and Conditions of Technology Transfer through Transnational Corporations, ESCAP/UNCTC, Pub. Series B, No.3, 1984, p.210.

⁹³ OECD, Transfer of technology for Pharmaceutical Chemicals, Paris, 1975, p.56.

⁹⁴ Ibid; and see also Helleiner, G.K., Transnational Enterprises in the Manufacturing Sector of the Less Developed Countries, World Development, Vol.3 No.9, 1975, p.648.

⁹⁵ Santikarn, op.cit., at pp.131-135 and Table 29.

⁹⁶ 'Export prohibition' clause prohibits the licensee to produce and export to territory and country specified.

⁹⁷ 'Tie-in' is the clause that requires the licensee to buy raw materials or other non-patented goods from the licensor only.

⁹⁸ 'Price-fixing' clause is included in order to allow the licensor to set the sale price of products produced by the licensed technology.

⁹⁹ 'Grant-back' is a clause that obliges the licensee to transfer to the licensor the right over any improvement developed from the licensed technology by the licensee.

¹⁰⁰ United Nations, op.cit., at pp.217-226 and Tables 20-24.

These restrictive business practices have negative effects on the Thai economy. The clauses prevent the recipient from having full access to technology, debase the value of the technology purchased, inhibit industrial growth, and restrain the export ability of the licensee. Although this paper does not intend to examine the restrictive business practices in patent licensing, the implications of tie-in clauses, one of the most common clauses in the licensing of patented technology, are briefly discussed as an example.¹⁰¹

While tie-in clauses allow the technology seller to maximise profits by controlling the supply of raw materials, the economic effects on the licensee and the recipient country are enormous. First, the licensor can charge unreasonably high prices on the tied products. Although substitutable goods are available from alternate sources at cheaper prices, the licensee cannot turn to buy such products. Second, the use of the over-priced products as inputs will no doubt affect production costs of the licensee.¹⁰² Third, in cases of licensing agreement with related parties, tie-in arrangement can be exploited as a conduit for transfer-pricing from subsidiary to parent company.¹⁰³

In Thailand there are no regulations dealing with transfer of technology transactions, and there is no anti-trust law as a means of preventing restrictive business practices. The Thai government has used a liberal licensing policy and does not intervene in the technology market. The parties are free to conclude terms and conditions of the agreements according to the rule of freedom of contract.

The only measure that has been passed which indirectly deals with international licensing agreements is a requirement for Central Bank approval before the technology payments can be remitted abroad. But the Bank has no authority to screen

¹⁰¹ For further discussions see Yankey, op.cit., at pp.24-38; Cabanellas, op.cit.; Adikibi, O.T., *The Multinational Corporation and Monopoly of Patents in Nigeria*, World Development, Vol.16 No.4, 1988, pp.518-520; Otten, A. "The Implications of the TRIPS Agreement for the Protection of Pharmaceutical Inventions", Presentation at the International Conference of Drug Regulatory Authorities, World Drug Information, Bahrain: 10-13 November 1997.

¹⁰² UNCTAD, *Major Issues Arising from the Transfer of Technology to Developing Countries*, TD/B/AC.11/10, 1972, p.29 cited in Yankey, ibid, at p.31; Maskus, K.E., *Price Effects and Competition Aspects of Intellectual Property Rights in Developing Countries*, World Development Report, World Bank, Washington D.C., 1998.

¹⁰³ UNCTAD, ibid, at p.27.

the licensing contracts.¹⁰⁴ In practice, once an application is submitted to the Bank; the remittance is approved almost automatically.¹⁰⁵ Clearly the measure aimed at regulating foreign exchange remittances, is ineffective at minimising the negative effects of the onerous terms and conditions in licensing contracts and of the transfer-pricing practices aforementioned.

The Thai government policy increasing levels of patent protection so as to enhance transfer of technology is misguided. The earlier discussion shows that Thai generic companies were able to acquire technology, despite the unavailability of pharmaceutical product patents. The existing problems for Thailand instead relate to: the inability of domestic industries to apply technology rapidly and successfully; issues of transfer pricing; and restrictive business practices. Increased patent protection is not well suited to economic development goals, and industrial policies building domestic technological capability and adapting imported technology to the local environment. The new TRIPS-Plus patent rules, if adopted, would operate against the national interest by representing an obstacle to the transfer of technology and to the development of local technology.

V. Concluding remarks

1. Appraisal

Compared with other countries, Thailand lacks a functional technological base and this makes the country industrially and technologically dependent on foreign interests. It constantly loses trade balance in the pharmaceutical sector to its trading partners. Thailand has only acted as a host for foreign pharmaceutical companies. Those companies have entered the country to operate the final stage of medicine production solely for the purpose of penetrating the locally protected market. The perceived role of patents in Thailand's industrial and economic development should be markedly different to that portrayed in technologically advanced countries like the United States. It would be illogical for Thailand to adopt the high standards of TRIPS-Plus

¹⁰⁴ Kuanpoth, J. "Technology Transfer in Thailand" in Christopher Heath (ed.), *Legal Rules of Technology Transfer in Asia*, Kluwer Publisher International, London, 2002.

¹⁰⁵ Ibid.

IPR protection. While a stringent patent regime as enshrined under TUSFTA may be designed to foster research, the high degree of patent protection in Thailand would promote R&D and protect research results developed *elsewhere*. The inherent monopoly privileges proposed in the form of TRIPS-Plus will hinder local R&D and impede inflow of technology. Patents will continue to be used by foreign drug companies as a mechanism for overpricing, transfer pricing and insertion of restrictive clauses in technology transfer agreements.

On medicine prices, Thailand explicitly recognized its problems of access to vital medicines. As a response to high prices, in 2001 it jointly proposed a draft text for a ministerial declaration on IPRs and public health.¹⁰⁶ The collective effort of Thailand and other developing countries led to the adoption of the Doha Declaration on the TRIPS Agreement and Public Health, which reinforces the importance of access to medicines and re-affirms the right of WTO Members to use the flexibilities available under TRIPS to increase the affordability of medicines.¹⁰⁷ Thailand has currently switched its policy direction to bilateral trade negotiations and given very little attention to its negotiating positions in the WTO. It would be a sad irony then for Thailand to adopt the TRIPS-Plus rules that may further restrict its accessibility to essential products.

The TUSFTA provisions will have a tremendous impact on prices. The TRIPS-Plus rules that are intended to broaden the scope and prolong the period of monopoly (*i.e.* data exclusivity, extension of patent term, extending the scope of patentability, etc.) will enhance the ability of the patent holders to maintain high prices.

Granting exclusive rights over test data will reduce generic competition. Thai generic manufacturers would have to conduct their own clinical trials, which they do not have the capacity to do. Since the trial process is too costly and time consuming, the only option for the local companies would be to wait until the exclusivity period expired,

¹⁰⁶ See the Submission by the African Group, Barbados, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand and Venezuela (IPR/C/W/296).

¹⁰⁷ Declaration on the TRIPS Agreement and Public Health, adopted on 14 November 2001, WT/MIN(01)/DEC/2.

which would delay the entry of generic medicines into the market. Consumers would then be forced to pay monopoly prices for the branded drugs for an extra ten years. Data exclusivity will allow multinational pharmaceutical companies to dominate the market even if there is no patent on the medicines they sell. When a patent is granted for the medicine, Thailand would have little or no chance to grant a compulsory license or allow government use to make the patented drug available. This is because the medicine produced under the government license would still be unable to secure market approval during the exclusivity period due to the lack of the clinical test data required for registration.

The TRIPS-Plus provisions that link drug registration and the patent status of a drug will unnecessarily restrain the entry of generic medicines. The provisions require the national drug regulatory body, before approving registration for a generic version, to ensure that the manufacturing, importing and selling of the generic medicine will not infringe the original company's patent rights. The practice of linking patent status to registration is not easy to implement in view of the fact that the national drug regulatory body in Thailand has no patent expertise to determine whether the generic medicine sought for registration is the same or different from the medicine that another company has patented. This would cause considerable delays to the introduction of the generic product.

The TRIPS-Plus provisions that require an extension of patent term would threaten the existence of the Thai generic companies by preventing them from making use of patented technology for the duration of the extended period. This would effectively increase the patent life for a pharmaceutical, thus blocking the introduction of generic products. The patent holder can then maintain a longer monopoly position and charge high prices for its medicines.

Considering the significance of this for the well-being of society, the extended term of pharmaceutical patents proposed by the United States is too long. No matter how much investment involving drug development is claimed by the pharmaceutical companies, it would still be imprudent for Thailand and other developing countries to offer protection periods for longer than twenty years. The logic is that

pharmaceuticals generate a high rate of turnover, and therefore maximum profits need to be recouped to their owners by selling drugs at high prices around the world. Due to the urgent need for technological acquisition, the developing country will be denying itself the benefits from newly developed modern technology by granting an unnecessarily lengthy protection period which will discourage competitive innovation. Modern scientific innovation has continued to yield evermore rapid technological change, and therefore new products are developed rapidly. No technology, no matter how beneficial it is, should be accorded more than a twenty-year term for protection as required by TRIPS.

The provisions that require Thailand to extend the scope of patentability to new uses and new formulations of the known drugs will allow multinational companies to claim exclusive rights over formulations that do not generate a truly new and inventive product. A great many drugs, although therapeutically effective, have other far from perfect properties and potential side-effects. Companies that hold a drug patent can come up with secondary improvements that can then also be patented.¹⁰⁸ This would protect the original patent holder against generic competition, even in situations where a generic company is prepared to challenge what it perceives as bad patents. Costly and time-consuming litigation can keep the matter locked up in the courts for many years, thereby unnecessarily restraining the entry of generic medicines.

As regards technological capability, TRIPS-Plus rules will drastically curtail the ability of the Thai government to enforce transfer of technology, reduce the effectiveness of compulsory licensing as a means of ensuring access to medicines, and inhibit the capacity of the Thai generic drugs industry to expand its market.

In principle, patents are granted on condition that the holder must work the patented invention or license it within a certain period of time from the date of granting the patent.¹⁰⁹ Thailand incorporates several measures into its law so as to bolster the local working of patents. The current patent law contains not only compulsory licensing but

¹⁰⁸ Hutchins, M. "Extending the Monopoly — How 'Secondary Patents' can be Used to Delay or Prevent Generic Competition upon Expiry of the Basic Product Patent", *Journal of Generic Medicines*, Vol.1 No.1, 2003, pp.57-71.

¹⁰⁹ See Paris Convention, Article 5.

also a system of forfeiture and revocation of patents. The TRIPS-Plus provisions on compulsory licensing will limit flexibilities that Thailand can issue, such as non-voluntary licenses to ensure the health of its citizens and to enable development of local industries. It will also prevent Thailand from exporting compulsorily licensed drugs to countries that have insufficient or no medicine production capacity. The Thai government also will not be able to force the patent holder to disclose the know-how needed to manufacture the medicine.

There is no reason why Thailand should not continue to use these mechanisms in order to meet public interest objectives. Regardless of the position of developed countries, Thailand would benefit by adopting compulsory licensing and other provisions for compulsory working in its law. These mechanisms when appropriately implemented would guarantee maximum control over effective working of patented inventions.

The USTR text prohibits Thailand from adopting pre-grant oppositions. This straightforward administrative procedure is necessary for Thailand because it allows local generic companies to challenge the validity of a patent at relatively low cost, prior to an infringement action. Generic producers that work in the same field are often in a position to challenge patents before they are granted. This system reduces excessive burdens on the courts and contributes to speedy proceedings of patent invalidation. The prohibition of the pre-grant opposition will allow multinational companies to block challenges on invalid patents, increase prices and prevent local medicine manufacture.

The TRIPS-Plus provisions that link IPRs and investment, if adopted by Thailand, will have an adverse impact on technology transfer and on the development of the country's pharmaceutical industry. For example, the USTR text specifies that when a compulsory license is issued in compliance with the FTA provisions (which are generally more restrictive than the TRIPS Agreement), it does not violate the investment chapter's limitation on expropriation. But if the issuance of the compulsory license does not comply with the FTA IPR chapter (even though it is in compliance with TRIPS), the patent holder can directly sue the host government in a

special trade tribunal for compensation. The patent holder can claim much higher compensation than reasonable royalties in cases of compulsory licensing under TRIPS, as the investment chapter under the TUSFTA requires compensation to be the full market value of a patent. The prospect of paying high compensation to the patent holder will undoubtedly discourage the Thai government from issuing compulsory licenses to protect public health, or from taking measures that facilitate transfer of technology and development of the local pharmaceutical industry.

As discussed earlier, the new trade mark rule under the TUSFTA would allow the pharmaceutical companies, to create ‘brand loyalty’ by using intense advertisement and sophisticated marketing techniques. It will create indefinite commercial and marketing strength for the company even after the expiration of the patent. It will also limit the possibility for the Thai government to control the use of trade marks for the promotion of medicines.

2. Feasible options

This study has indicated that pharmaceutical product patenting seems likely to generate severely negative impacts on Thailand in terms of high drug prices and balance-of-payment difficulties. It is also suggested that a strong patent system, on the one hand, would have no relation whatsoever to the rate of R&D and foreign investment, but, on the other hand, is likely to impede the industrial development process of the country. The costs of pharmaceutical patents in Thailand will therefore outweigh the benefits. This consequently calls for a re-examination of the TRIPS-Plus IPR rules being negotiated under the TUSFTA. This final section offers recommendations to the Thai government as well as the governments of other developing countries, in the hope of improving the current patent protection, pharmaceutical production and distribution regimes.

(a) Appropriate policy on international trade negotiations

The existing system for the international protection of industrial property rights under the framework of the Paris Convention, WTO/TRIPS, and recently FTA/TRIPS-Plus,

have failed to accommodate and protect the interests of developing countries. The present norms and standards clearly do not assist developing countries in their attempt to achieve self-reliance in the field of science and technology.

It seems as if it were inevitable that developing countries would submit to some of the developed countries' demands as reflected in the successful conclusion of the Uruguay Round and the adoption of the TRIPS Agreement. However, in the near future concerted efforts in the multilateral fora must be made by the developing countries with the aim of eliminating the use of regional or bilateral coercion through trade sanctions such as the extension of domestic trade law and TRIPS-Plus rules under FTAs. Multilateral talks are more appropriate in dealing with the problems of conflicting interests between the North and the South, when compared with bilateralism. Developing countries should increase their role in the negotiations at the relevant international fora such as WTO and WIPO so as to influence the world trade agenda. Concerted multilateralism will help to reduce bilateral pressure from the more powerful countries.

So far, the trade policy of some developing countries including Thailand has yielded too much to the developed countries' demands, especially in bilateral negotiations. As an international trading institution, the WTO has played a key role in global business transactions. It has also played a significant role in dispute settlement among Contracting Parties. Developing countries, therefore, should take full advantage of the current round of WTO trade talks. Strategic alignment and closer economic co-operation among developing countries need to be set up in negotiations at the WTO and WIPO. A more united stand will help Thailand and its counterparts by strengthening their bargaining power.

Strategies/Options on policy on international trade negotiations

Apply flexibility, and introduce a public health perspective, into national IPR laws and trade policy
Adopt a common and united stand towards improving the multilateral trading system, as well as reducing the use of regional and bilateral trade pressure
Adopt a common and united stance on improving the IPR system, technology transfer and access to medicines
Adopt a common and united stance against any proposal to limit flexibilities under TRIPS
Seek inter-country collaboration in areas such as price negotiation, import/export of essential medicines, reducing regulatory barriers, assuring quality

(b) Appropriate policy on transfer of technology

Since the current system of patent granting in Thailand and in many developing countries is still at an elementary level, efforts have to be made by the government of those countries to step up the efficiency of the national patent office. The patent office should have two roles: (i) to carry out the various activities relating to patent granting, and (ii) to administer transfer of technology issues. Since the function of the office is essentially related to several fields, it is necessary to ensure the availability of personnel in legal, technical and economic areas.

Although developing countries may find it hard to recruit qualified local staff, participation in training programmes organised by international organisations like WIPO, UNCTAD, UNIDO, etc., as well as the assistance from other developed countries' patent offices, could be very helpful in upgrading the capacity of the national patent office. Apart from the recruitment and training of specialised personnel, a modern database system should be developed. This, when accomplished,

should assist towards the use of patent documentation as a source of technical information.

In addition to carrying out local scrutiny of patent applications, the patent office should play a key role in adopting and implementing a technology transfer policy. The major policy objective would be for the rapid absorption and acquisition of appropriate technologies, which are suitable to domestic human and capital resources, at reasonable cost. This can be done by assisting local recipients to draft technology transfer contracts and by providing advisory services and vital information to local firms willing to negotiate licensing agreements with foreign counterparts.

Developing countries should realise that their entrepreneurs are always the unequal partners when they come to foreign technology acquisition. These difficulties are particularly pronounced in relation to pharmaceutical technologies. In order to achieve the most favourable commercial conditions and the inflow of appropriate industrial technology at affordable cost, it is also necessary to require registration of all licensing agreements concluded between local entrepreneurs and foreign parties with the patent office. The office will then carry out examination to make sure that discriminatory and restrictive clauses are not inserted in the contracts. Failure to register will make the contracts null and void.

Strategies/Options on policy on transfer of technology

- Improve efficiency of the national patent office in patent granting and administering technology transfer
- Adopt and implement policy on technology transfer and regulate licensing agreements
- Encourage wide use of patent documentation as a source of technical information
- Review the process for patent granting and repealing, particularly incorporating pre-grant opposition into national patent law

(c) Foster generic competition and regulate drug promotion

Product competition and promotion can be reduced by the increased use of generic names and the government control of drug advertisements. Creation of a competitive market will make the medicine prices more competitive as competition from other companies forces the dominant firm to reduce price. Generic firms can play a significant role in market competition. Since a large number of off-patent medicines are now available in world markets, developing countries should consider implementing policies encouraging generic substitution.

Although most countries now have regulations strictly controlling the ways in which drugs are promoted, it is evident that the regulation has not been implemented and that prosecution for false or misleading advertising rarely occurs. The following options may be taken:

First, developing countries should introduce the required use of generic names on pharmaceuticals along with trade marks. The drugs then will be identified and marketed under their generic names. This, when accomplished, will reduce the proliferation of branded drugs in the market. In addition, the government ought to start a re-education programme for doctors with the aims of ensuring the exclusive use of generic names and supply of the cheapest available version of drugs.

Second, the government should formulate a major policy aimed at controlling drug promotion. This may be done by requiring drug manufacturers to submit all advertising materials of medicines for official approval to guarantee the accuracy and sufficiency of information before they can be circulated to doctors, drug-sellers and the public. Furthermore, the distribution of samples and gifts, as well as the provision of other financial advantages, to physicians should be regarded as a criminal offence. When the regulation is enacted, the government must ensure that the law is seriously implemented and rigorously enforced.

Strategies/Options on generic competition and regulate drug promotion

Apply all feasible means to make available generic version of branded drugs by encouraging generic production and/or procuring affordable products wherever available in the world market

Encourage generic substitution and the use of generic names to ensure that prices of drug are not artificially raised under brand names

Adopt a centralised procurement system which will give the government agency ample opportunities to select appropriate quality and price

Vigorously implement legal controls and closely monitor the advertisement of medicines

Control excessive spending on drug promotion by suppliers and do not allow direct-to-consumer advertising of prescription drugs

(d) Price controls

An adoption of a direct price control always leads to a substantial reduction of the medicine prices in the market. Lowering the price of medicines will not only save consumers and public money, but enhance competitiveness of the local generic industry. The government of Thailand and other developing countries should initiate a policy of drug price control which can appear in various forms. One possibility would be the appointment of a medicine price review board to monitor pharmaceutical prices. The board should be composed of experts in the areas of medicine, law and economics, coming from government offices, non-governmental organisations and academia.

The establishment of the board may be of significance in checking high drug prices, but it seems unlikely to be effective in checking the complexity of transfer pricing and over-invoicing of pharmaceuticals, which are usually standard practices in intra-firm transactions among pharmaceutical TNCs. To curtail such abuses, it may be possible to suggest that financial services laws, which require business enterprises to disclose their financial information to a government agency, should be promulgated to complement patent law in this regard.

Strategies/Options on price controls

Establish global and regional databases on drug prices for purpose of price controls
Regulate the prices of individual drugs
Voluntary discount agreements between drug suppliers and the government
International tendering among pre-qualified suppliers
Direct profit control: for example curbing high prices by limiting the profitability of selling companies
Reimbursement controls: such as establishing different levels of reimbursement, increasing the proportion of the cost paid by the consumers for certain medicines, and adopting positive lists of (generic) medicines that will be reimbursed
Indicative prescribing: such as the government agency closely monitoring the level of prescribing by general practitioners, and then comparing the number of prescriptions with the estimated figure previously set by the government
Negative lists: namely specifying some particular drugs that doctors must prescribe on generic names only
Comparative price information distributed to health providers and consumers
Adopt regulation specifically dealing with issues of transfer pricing

(e) Appropriate policy to increase access to medicines

For the attainment of the goal of industrial and economic development, self-sufficiency in pharmaceutical production is crucial in facilitating a strong and healthy labour-force that is not reliant upon foreign interests. However, in practice self-sufficiency is rare. Few developing countries can claim to be self-sufficient in drug supply (e.g. China, India, and Brazil). Most developing countries including those that provide the final formulations or packaging require significant imports of pharmaceuticals and intermediates. In order to achieve the goal of accessibility to medicines, a developing country must adopt and implement appropriate policies

relating to technology, health, and IPRs to ensure effective, safe and affordable medicines. The details of those policies are now highlighted.

First, on the technology policy, the developing countries should aim at increasing national technological capabilities including:

- monitoring technological change in international markets;
- obtaining technical assistance from other countries and relevant international organisations;
- increasing financial support for industrial R&D to public research institutes and private enterprises;
- supporting research activities in the private sector by providing soft loans for industrial research and tax credit on R&D expenditure;
- providing an effective service in technological consultancy to private firms;
- improving national education in the long term and developing the personal skill of scientists and engineers in the short term;
- fostering production and commercialisation of research results;
- encouraging efficient co-operation among researchers in universities and the industries, supporting technological co-operation among domestic firms, etc.

In order to achieve key policy goals of self-sufficiency in pharmaceutical supply, the developing countries have to come up with rational and coherent national pharmaceutical policies as part of their overall development strategies. The pharmaceutical industry is vital to a nation's well-being and therefore it should not be left solely in the hands of free enterprise or foreign interests. This is the stark reality. No country, no matter how developed it is, does not subsidise its national pharmaceutical sector. The locally-owned drug firms in developing countries should benefit from the government's supported subsidy for raw material procurements and R&D activities.

Second, with regards to health policy, apart from the continuous use of the essential drug list and the operation of a central procurement system, the developing countries' government should establish a scheme for co-operative health action with other

developing countries, especially those developing countries with a higher technological level. International co-operation among developing countries may include: R&D projects of drug development, production of medical substances, procurement of drugs suitable to the needs of the developing countries, and clinical testing for the quality and efficacy of drugs.

For centuries, developing countries like Thailand have also used traditional medical practices and indigenous medicines for preventive and curative treatment of ailments before turning to Western drugs. Many developing countries possess extensive tropical natural resources such as herbs and other botanical products which have tremendous potential for use as raw materials in industrial pharmaceutical production. Most of these natural resources have not been fully explored or appreciated in modern, science-based therapy. The government of developing countries must initiate research projects aimed at discovering the therapeutic value of these indigenous resources and developing these materials into medically useful compounds. In addition, the government must give value to customary knowledge and the traditional methods of treatment must be incorporated into the national health-care plan. In essence, there should be a co-existence between research in traditional and modern medicine.

Third, on IPR policy, developing countries' governments should take measures to facilitate the availability of patented products. While it is advisable to adopt the system of compulsory licensing, it has to be borne in mind that the compulsory licensing alone cannot help a country to address all the problems related to public health. This is because limiting access to pharmaceuticals can result from several structural problems as has been elaborated earlier. A country can be well advised to use other public policy measures, within and outside IPR law to address these problems.

Strategies/Options on access to medicines

Apply compulsory licensing in the most flexible manner as permitted by TRIPS

Incorporate various grounds for the grant of compulsory licence in national legislation, including non-working, anti-competitive practices, refusal to deal, and protection of public interest

Take full advantage of the TRIPS provisions and the Doha Declaration by using the compulsory licence, but ensuring that TRIPS rules are respected

Implement expeditious licensing procedures such as establishing clear and transparent procedures for issuing the licence, setting up an administrative body to review the decisions taken by the licensing authority, etc.

Apply all other possible means, including parallel import, broad exceptions to patent rights such as research exemptions (*i.e.* the use of the patented invention in the course of study, research or experimentation), private use (*i.e.* the use for private and non-commercial purposes), and Bolar provision (*i.e.* the use of patented information for registration of drugs which facilitates prompt marketing of generic drugs), etc.

Find ways to harmonise national safety and health regulations in order to remove barriers to international trade in generic drugs

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