

## **Intellectual Property Rights and Pharmaceuticals: A Thai Perspective on Prices and Technological Capability\***

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### **Abstract**

The justifications in favour of pharmaceutical patenting in developing countries are that it induces foreign direct investment (FDI); it stimulates local inventive activities; it encourages transfer of new technologies into the country. The paper examines whether intellectual property protection on pharmaceuticals generates benefits to developing countries by looking at the situation in Thailand. It 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 has no impact whatsoever in promotion of the country's inventive activities, but hinders local R&D and impede inflow of technology. Patents are used by foreign drug companies as a mechanism for overpricing, transfer pricing and insertion of restrictive clauses in technology transfer agreements.

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**Key Words:** Thailand, Intellectual property, Pharmaceuticals, Technology capability

## **INTRODUCTION**

The justifications in favour of pharmaceutical patenting in developing countries are that it induces foreign direct investment (FDI); it stimulates local inventive activities; it encourages transfer of new technologies into the country. The note is aimed at examining whether intellectual property (IP) rules on pharmaceuticals 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 has also 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 paper begins with an examination of IP protection in Thailand and the new trends of IP protection under bilateral trade agreements. The second part provides a summary of the development and basic structure of the pharmaceutical industry. It then goes on examining the impact of IP protection on prices, FDI, technology transfer, and research and development (R&D) capacity. The Thai pharmaceutical industry is presented as an illustrative example.

## **INTELLECTUAL PROPERTY PROTECTION IN THAILAND**

Currently there are seven legislations protecting IP rights in Thailand, including the Patent Act B.E. 2522, the Copyright Act B.E. 2537, the Trademarks Act B.E. 2534, the Plant Variety Protection Act B.E. 2542, and the Protection of Layout-Designs of Integrated Circuits Act B.E. 2543, the Trade Secret Act B.E. 2545, and the Protection of Geographical Indications Act B.E. 2546.

Unlike Western countries, Thailand has not had a long period of legal development in the IP field. Rights over inventive ideas were recognised when the Patent Act B.E. 2522 was adopted

and entered into force in 1979.<sup>1</sup> In 1992 and 1999, Thailand, under pressure from the United States, decided to revise its patent law in order to avoid trade sanctions. The amendments significantly increased the level of patent protection, including an expansion of the scope of patentable subject-matters, an extension of the term of patent rights, the protection of petty patents or utility models, laying down conditions for the application of compulsory licensing, amending the exclusive rights and their limitations, abolishment of the pharmaceutical price review committee, etc.

The Thai patent law has an aim of providing a temporary monopoly for inventors in order to foster the development of a required technological base, and to assist the acquisition of foreign technologies. In addition, it was envisaged that the sound IP systems would create a favourable climate for foreign investment. The Patent Act B.E. 2522, as amended in 1992 and 1999, provides patent protection for inventions in almost all fields of technology for up to 20 years from the date of filing of the application in Thailand. The duration of patents is six years for a petty patent and ten years for a design patent. The term of a petty patent may be renewed twice, two years each. Patent protection in Thailand can be obtained either as a product or a process patent. The holder of a product patent has an exclusive right to make, use, sell, stock for sale, offer for sale and import the patented product. Patent law has a very strong form of monopoly rights. The patent holder may file a criminal or a civil lawsuit, or both, against those who commit an infringement of his patent rights. An intentional infringer subjects himself to imprisonment up to 2 years and a fine up to 400,000 baht or both.<sup>2</sup>

Since 2003, Thailand has negotiated a free trade agreement (FTA) with the United States. In the bilateral trade negotiations, the United States has demanded for greater trade commitments from Thailand, including demands for the enlargement of access for US exports and preferential

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<sup>1</sup> Kuanpoth, J. "Major Issues in the Thai Patent System", Thai Bar Law Journal, Vol.50 No.1, 1994, pp. 55-84. Also available at <http://www.thailawforum.com/articles/jakpat1.html>

<sup>2</sup> Kuanpoth, J. "Thailand" in Heath, C. (ed.), *Intellectual Property Protection in Asia*, Kluwer Publisher International, London, 2002, pp. pp.337-362.

treatment for US IP right holders.<sup>3</sup> The United States intends to achieve higher level of IP protection, beyond the minimum standards under WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).<sup>4</sup> The tightening of domestic IP legislation in foreign countries through bilateral trade negotiations, together with the use of trade leverage under US trade laws, no doubt would help the United States to produce the establishment of an acceptable framework within the multilateral trade negotiations. This strategy was successfully employed by the United States during the Uruguay Round that led to the adoption of the TRIPS Agreement.<sup>5</sup>

The inclusion of IP chapter in FTAs resulted from heavy lobbying of certain industries. The US IP policy was under great influence of 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 in advising and influencing the US trade policy, comprises large multinational companies like Eli Lilly, Merck, Pfizer, Anheuser-Busch, Procter & Gamble, etc.

When the United States Trade Representatives (USTR) submitted the draft IP text to Thailand in the sixth round of FTA negotiations in January 2006, the following new IP rules as

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<sup>3</sup> 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.

<sup>4</sup> Drahos, P. "Developing Countries and International Intellectual Property Standard-Setting", 5 *Journal of World Intellectual Property* 765 (2002).

<sup>5</sup> In the 1980s, the USTR requested consultations with some developing countries in Asia and Latin America on IP 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.

related to pharmaceuticals were proposed:<sup>6</sup> First, US draft proposal requires that an effective and adequate protection must be given to inventions in all technological fields. The products currently excluded from patentability under Thai law (*e.g.* plants, animals, biological processes, genes, gene sequences, methods of medical treatment, business methods and computer programs) must be protected in the forms of both product and process patents. Thailand must also protect second uses (*i.e.* new use of products already known or existed in the market). For example, Thailand must allow the claim to a new use of an old drug or the claim to a new therapeutic application of the known drug.<sup>7</sup>

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. Revocation cannot be undertaken in the cases of abuses of patent rights or non-working of patents which are generally the cause of high drug prices as provided by the Paris Convention for the Protection of Industrial Property.<sup>8</sup> The text also imposes stricter standards on compulsory licensing than those under TRIPS and the Paris Convention, in terms of more stringent conditions for issuing a non-voluntary license.<sup>9</sup> 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.

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<sup>6</sup> The US draft proposal submitted to Thai negotiators was leaked and posted on:

[http://www.bilaterals.org/article.php3?id\\_article=3677](http://www.bilaterals.org/article.php3?id_article=3677).

<sup>7</sup> See Savina, J. "The Patentability of the Second Therapeutic Application – Why must the Law be Changed?", *Patent World*, August 1995, pp.32-35.

<sup>8</sup> Paris Convention, Art.5 (A)(3).

<sup>9</sup> TRIPS Agreement, Art.31; Paris Convention, Art.5. See Machlup, F. and E. Penrose "The Patent Controversy in the Nineteenth Century", 10 *Journal of Economic History* 1, (1950); Vaitos, C. "Patents Revisited: Their Function in Developing Countries", *Journal of Development Studies*, Vol.9 No.1, 1972, pp.71-97.

The USTR demands Thailand to extend the term of patents in case of unreasonable delays in the patent grant. 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.<sup>10</sup> In addition, Thailand must 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 on the fact that the original product has got a marketing approval in a foreign country.<sup>11</sup>

The text the USTR has proposed to Thailand contains a provision obligating the Thai drug regulatory authority to inform the patent holder as to 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.<sup>12</sup>

The new IP rules also impose a high level of trade mark protection. 'Trade mark' is defined under the draft FTA treaty in the broadest manner, including non-visually perceptible

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<sup>10</sup> The demand is based on US law, the Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Act.

<sup>11</sup> Correa, C.M., *Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement*, South Centre, Geneva, 2002.

<sup>12</sup> As an example, US-Vietnam Bilateral Trade Agreement that Vietnam signed with the US in 2001 requires Vietnam to provide data exclusivity. Vietnamese law requires a manufacturer to prove that the use of the generic drug it seeks registration will not lead to infringe patent rights of other companies. This in effect prevents generic medicines to enter 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.

trade marks, such as scent marks. Sound, texture and smell could be registered as trade marks. 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, and the WIPO Trade mark Law Treaty.

The USTR text links IP and investment rules by including IP rights in the definition of investment. The trade parties may not impose 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. The text 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 new IP regime proposed by the United States may have a devastating impact on Thailand, particularly on its attempt to build technological capability in the pharmaceutical sector. The impact of the new IP rules on the Thai pharmaceutical industry will be analysed and discussed in the final section. Next, we will turn to examine the structure and characteristics of the pharmaceutical industry to provide background for analysis of IP implications.

## **STRUCTURE AND CHARACTERISTICS OF THE PHARMACEUTICAL INDUSTRY**

### **Pharmaceutical Production and Supply**

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 the preparation of raw materials. The active ingredients of a drug, or sometimes called new molecular entity (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. micro-organisms). The final stage of production, called the formulation process, is the process for the 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 inventing new knowledge which can be developed further into a new product, a new use or a new less costly process of production. 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, is normally 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 are low.

The pharmaceutical companies tend to concentrate on R&D and the production of raw materials at one site, and decentralise the later stages of production at other locations.<sup>13</sup> As regards to R&D and production of raw materials, developed countries are generally preferable, from the perspective of the drug companies, 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

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<sup>13</sup> 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.

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 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 United States. 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.<sup>14</sup>
- (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.

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<sup>14</sup> Tarabusi, C.C. and G. Vickery "Globalization in the Pharmaceutical Industry", *International Journal of Health Services*, Vol.28 No.1, 1998, pp.67-105.

- (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 Laos, Cambodia, Costa Rica, and many African states.

Almost 90 percent of the total value of world pharmaceutical production was accounted for by high income countries.<sup>15</sup> The figure shows that the high-income developed countries dominate in world pharmaceutical production. The share of those countries in the value of world pharmaceutical output increased 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.<sup>16</sup>

Among the high-income countries, the majority of world pharmaceutical production is accounted for by 5 major countries. The United States has been the biggest producer, accounting for almost one-third of total production (31 percent), following by Japan (16 percent), France (8 percent), Germany (6 percent) and the United Kingdom (6 percent).<sup>17</sup>

### **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,

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<sup>15</sup> 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.

<sup>16</sup> World Health Organisation, The World Medicines Situation, WHO/EDM/PAR/2004.5, 2004.

<sup>17</sup> Ibid.

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.<sup>18</sup>

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.<sup>19</sup>

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<sup>18</sup> 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.

<sup>19</sup> World Health Organisation, *The World Medicines Situation*, op.cit.

**Table 1**  
**World's Largest Pharmaceutical Companies by Value of Sales 1977-2001**

| <b>Company</b>       | <b>Country</b> | <b>Rank<br/>1977</b> | <b>Rank<br/>1985</b> | <b>Rank<br/>1998</b> | <b>Rank<br/>2001</b> |
|----------------------|----------------|----------------------|----------------------|----------------------|----------------------|
| 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

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). The large companies are carrying out research programmes. Medicines sold by these companies are largely newly invented products arising from successful R&D. Patents will be applied for worldwide as soon as an NME is discovered. Unlike the multinationals, the non-research-based companies, or generally known as generic companies, have a small size. These firms are normally not engaged in R&D, but selling cheaply-priced drugs, so-called generics, which are unable to enjoy patent protection or whose legal protection has expired. Generic firms used to operate within the country of residence, but situation is recently changing. Indian and Chinese has now expanded their operation and become multinational to take advantage of economies of scale.

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.<sup>20</sup> By contrast, pharmaceutical firms in developing countries are small and currently account for less than twenty percent of world production.<sup>21</sup>

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 1). 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

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<sup>20</sup> UNIDO, *The World's Pharmaceutical Industries: An International Perspective on Innovation, Competition and Policy*, Edward Elgar, Hants, 1992, p.12.

<sup>21</sup> Kaplan, W. and R. Laing, "Local Production of Pharmaceuticals: Industrial Policy and Access to Medicines", *HNP Discussion Paper*, Washington D.C., 2005, p.7.

marketing practices by the existing firms which have created obstacles to the entry of new companies. The practices of the pharmaceutical companies are examined in depth below.

## **Characteristics of the Thai Pharmaceutical Industry**

### **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.<sup>22</sup> 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).

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.<sup>23</sup> Its activities include: producing basic pharmaceuticals; procuring medicines from other sources; conducting quality control; and distributing all pharmaceutical supplies to public hospitals.<sup>24</sup> 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,

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<sup>22</sup> TDRI, "Intellectual Property and Impacts of Trade Agreements on Thai SMEs", Thailand Development Research Institute, Bangkok, 2006 (in Thai).

<sup>23</sup> Hutangura, P and C. Sepulveda, *The Pharmaceutical Industry in ASEAN Countries: Thailand*, UNAPDI, Bangkok, 1979, p.209.

<sup>24</sup> *Ibid.*, p.184.

Laos, and Cambodia.<sup>25</sup> 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.<sup>26</sup>

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 affiliates of foreign companies supply the Thai market by importing finished products from abroad. Some foreign companies have formulation and packaging factories, but they have not established local plants for the production of basic active ingredients in Thailand.<sup>27</sup>

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 units<sup>28</sup> due to several factors, including the scarcity of well-trained personnel, equipment and resources, the lack

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<sup>25</sup> Ministry of Industry, Master Plan for the Development of Pharmaceutical Industry, Bangkok, September 2002.

<sup>26</sup> Kaplan and Laing, *op.cit.*, at p.27.

<sup>27</sup> International Trade Centre: UNCTAD/WTO, "Thai Pharmaceutical Industry Study", Bangkok, 1999.

<sup>28</sup> 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.

of a chemical industrial base, the low level of technological capability, and the deficiencies of the registration system for new medicines.

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.<sup>29</sup> Like R&D, the absence of the production of active ingredients in Thailand can be explained by two factors: (i) the lack of capacity 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)<sup>30</sup> are imported, mainly from the United States, the United Kingdom, Germany, Switzerland, France, Japan, Italy, Eastern European countries and China.<sup>31</sup>

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<sup>29</sup> Bumrungcheep, 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.

<sup>30</sup> GPO, *ibid.*

<sup>31</sup> Thai Drug Control Division, *Pharmaceutical Manufacture in Thailand*, Bangkok, 2003. Available on: <http://www.fda.moph.go.th>

**Table 2**  
**Thailand's Pharmaceutical Exports and Imports**  
(million baht)

| <b>Year</b> | <b>Exports</b>     | <b>Imports</b>      | <b>Balance of trade</b> |
|-------------|--------------------|---------------------|-------------------------|
| 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 (Table 2).

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

### 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.<sup>32</sup> So-called ‘me-too’ drugs, that are molecularly distinct but therapeutically identical to an existing medicine, are widespread in the market.<sup>33</sup> In Britain, for example, there were 3,550 different brand names used on about 1,200 medical substances.<sup>34</sup> The Patented Medicine Prices Review Board evaluated 1,147 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.’<sup>35</sup> 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.<sup>36</sup>

As a result of this practice, WHO observes that the number of brand-name drugs throughout the world is over 100,000.<sup>37</sup> 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 3).

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<sup>32</sup> British Medical Association, *The British National Formulary*, London, 1988.

<sup>33</sup> Braithwaite, J., *Corporate Crime in the Pharmaceutical Industry*, Routledge & Kegan Paul, London, 1986, p.164.

<sup>34</sup> British Medical Association, op.cit.

<sup>35</sup> 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>

<sup>36</sup> Angell, M., *The Truth about the Drug Companies*, Random House, New York, 2005, p.75.

<sup>37</sup> WHO, *The World Drug Situation*, Geneva, 1988, p.43.

**Table 3**  
**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<br>Products | 3,800         |
| Effexor (anti-depressant)      | Wyeth                          | 3,700         |
| <b>Total</b>                   |                                | <b>53,500</b> |

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.<sup>38</sup> Ampicillin is sold in the 'over the counter' (OTC) market under 35 brand names.<sup>39</sup>

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<sup>38</sup> Food and Drug Administration, "Thai Medical Directory", Ministry of Public Health, Bangkok, 2002.

<sup>39</sup> Ibid.

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 only 5 percent of the total drug consumption in Thailand.<sup>40</sup> 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.<sup>41</sup> 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. The advertisement of prescription drugs are regulated under the Drugs Act B.E. 2510. 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 sales-persons to doctors.

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<sup>40</sup> Kanavos & Paganelli, *Emerging Pharmaceutical Markets - Potential & Problems*, URCH Pharmaceutical Publications, London, September 2000.

<sup>41</sup> Rattanarojsakul, K., "The Pharmaceutical Industry in Thailand", Unpublished Master of Economics Thesis, Thammasat University, Bangkok, 1986, p.138.

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 representatives.<sup>42</sup> 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.<sup>43</sup>

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.<sup>44</sup> This data confirms that the pharmaceutical

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<sup>42</sup> Food and Drug Administration, "Thai Medical Directory", Ministry of Public Health, Bangkok, 2006.

<sup>43</sup> Rattanaojksakul, op.cit., at p.147.

<sup>44</sup> Cited in Ibid, at p.167.

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 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 new IP rules that demand a higher level of protection for trade marks will allow the pharmaceutical companies to prolong marketing practices. The IP and investment rules under the proposed FTA 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.

## **IMPACT OF PATENS 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.

### **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.<sup>45</sup>

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 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

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<sup>45</sup> 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).

medicines generally depends on the situation in the market.<sup>46</sup> 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.<sup>47</sup>

**Table 4**  
**Comparison of Prices of Selected Anti-retroviral Drugs in Thailand,**  
**2001**

| <b>Drugs</b>              | <b>Brand name price (US\$)</b> | <b>Generic price (US\$)</b> | <b>Price difference from minimum (%)</b> |
|---------------------------|--------------------------------|-----------------------------|--|
| Fluconazole (200 mg caps) | 6.20                           | 0.30                        | 1966.67                                  |
| Stavudine (40 mg caps)    | 2.60                           | 0.10                        | 2500                                     |
| Zidovudine (100 mg caps)  | 0.50                           | 0.15                        | 233                                      |
| 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.

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<sup>46</sup> 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.

<sup>47</sup> *Ibid.*, at pp.1146-1147.

**Table 5**  
**Comparison Anti-retroviral Prices in Thailand, January 2005**

| <b>ARV</b>                          | <b>Patent status in Thailand</b> | <b>Originator (baht/units)</b> | <b>Generic (baht/units)</b> |
|-------------------------------------|----------------------------------|--------------------------------|-----------------------------|
| <b>1<sup>st</sup> line ARVs</b>     |                                  |                                |                             |
| 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)                |
| <b>2<sup>nd</sup> line ARVs</b>     |                                  |                                |                             |
| 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)/<br>Ritonavir (RTV)<br>(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 show high price variations in the Thai pharmaceutical market. Identical products are generally sold by different companies at disparate prices.<sup>48</sup> 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 5 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

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<sup>48</sup> Hiranrath, W. *et al*, *The Survey of Selling Prices of TNCs and Local GMP Manufacturers*, Chulalongkorn University Press, Bangkok, 1990, pp.43-44.

countries whose patent legislation was not stringent (such as India).<sup>49</sup> 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.

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.<sup>50</sup> 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.<sup>51</sup> 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

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<sup>49</sup> 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.

<sup>50</sup> Chaiseri, N. and C. Hongladarom (eds.), *The Role of Multinational Corporations in Thailand*, Conference at Thammasat University, Bangkok, 1984, p.175.

<sup>51</sup> Kaosa-ad, M. "Transfer Pricing in the Pharmaceutical Industry", *Thammasat Economic Journal*, Vol.3 No.1, 1985, p.15.

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.<sup>52</sup>

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.

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.

### **Patents and Foreign Direct Investment**

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.<sup>53</sup>

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<sup>52</sup> Rattanaojksakul, op.cit., at p.130.

<sup>53</sup> 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.<sup>54</sup> 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.<sup>55</sup> 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.<sup>56</sup> 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.”<sup>57</sup>

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<sup>54</sup> 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.

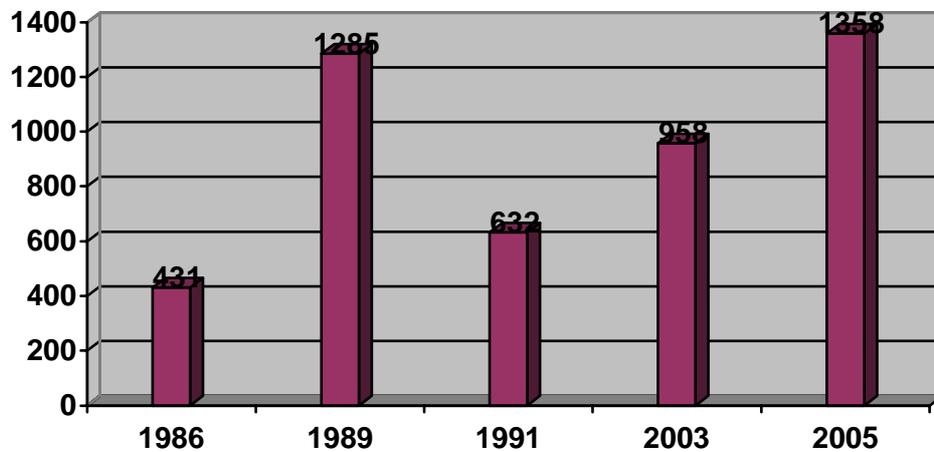
<sup>55</sup> Anderfelt, U., *International Patent-legislation and Developing Countries*, Martinus Nijhoff, The Hague, 1971, pp.139-141.

<sup>56</sup> *Ibid.*, at p.140.

<sup>57</sup> *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.

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 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.<sup>58</sup> 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 IP protection. Those factors include the type of IP rights, purpose of the investment, and the degree of industrial and technological development of the country in question.<sup>59</sup>

**Figure 1**  
**Number of Applications for BOI Promotion, 1986-2005**



Source: Board of Investment, Bangkok, 2006

<sup>58</sup> 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.

<sup>59</sup> Correa, C.M. "Intellectual Property Rights and Foreign Direct Investment", *International Journal of Technology Management*, Vol.10, 1995, pp.173-199.

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. 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.* 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.<sup>60</sup>

After considerable success in the inducement of foreign investment in the late 1980s, the flow of FDI declined in the 1990s. 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 1).

This reveals that growth and decline in FDI in Thailand depend on a number of positive and negative conditions.<sup>61</sup> There is no conclusive evidence to suggest that the level of patent protection is the major determinative factor encouraging foreign investment.<sup>62</sup> 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

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<sup>60</sup> Bangkok Post: Economic Review, Spins Ahead despite Hurdles, 30 December 1989, p.18.

<sup>61</sup> See Maskus, K.E., *Intellectual Property Rights in the Global Economy*, Institute for International Economics, Washington D.C., 2000, pp.199-232.

<sup>62</sup> 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.

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 IP protection in the country. Therefore, the introduction of the new IP regime under the proposed FTA with the United States 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.

Excessive IP 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.<sup>63</sup> 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

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<sup>63</sup> Oddi, A.S. "The International Patent System and Third World Development: Reality or Myth?", *Duke Law Journal*, 1987, p.849.

pharmaceutical patenting.<sup>64</sup> This view is shared by Lall and Bibile, who conclude 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.<sup>65</sup>

### **Patents and Technological Development**

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.<sup>66</sup> The current 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.<sup>67</sup>

### **Research and Development**

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

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<sup>64</sup> See Correa, C.M. "Reforming the Intellectual Property Rights System in Latin America", *World Economy*, 2000, pp.851-872.

<sup>65</sup> 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).

<sup>66</sup> 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).

<sup>67</sup> 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.

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.<sup>68</sup>

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,<sup>69</sup> or 0.22 percent of GDP.<sup>70</sup> 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.<sup>71</sup>

Regarding R&D in the private sector, Thai companies spent US\$ 138 million on R&D in 2002.<sup>72</sup> 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.<sup>73</sup>

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<sup>68</sup> TDRI, *ibid.*, at p.14.

<sup>69</sup> APEC Industrial Science & Technology Internationalization Database Trendsetters, 2005.

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

<sup>70</sup> IMD World Competitiveness Yearbook 2004.

<sup>71</sup> *Ibid.*

<sup>72</sup> APEC Industrial Science & Technology Internationalization Database Trendsetters, *op.cit.*

<sup>73</sup> IMD World Competitiveness Yearbook 2004.

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.<sup>74</sup>

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.<sup>75</sup> 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.

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.<sup>76</sup> 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.<sup>77</sup> 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.<sup>78</sup>

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<sup>74</sup> National Research Council, National Survey on R&D Expenditure and Personnel of Thailand, Bangkok, 2004.

<sup>75</sup> TDRI, "Intellectual Property and Impacts of Trade Agreements on Thai SMEs", op.cit.

<sup>76</sup> Department of Intellectual Property, Ministry of Commerce, Bangkok, 2006

<http://www.ipthailand.org/Thai/Default.aspx>

<sup>77</sup> Ibid.

<sup>78</sup> Ibid.

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 new patent rules that protect high-tech inventions.<sup>79</sup>

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.<sup>80</sup> 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 new IP rules under the proposed US FTA, which prohibits the use of compulsory licensing and patent revocations.

### **Transfer of Technology**

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

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<sup>79</sup> The extent of the discussion on the relationship between protection of IP 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.

<sup>80</sup> TDRI, *The Barriers to and Strategies for Technology Acquisition*, op.cit., at p.20.

acquire technology.<sup>81</sup> 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.<sup>82</sup>

But from a practical point of view, it can be argued that patents do not actually promote technology transfer.<sup>83</sup> The value of patent protection is that it allows the patent holder 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.<sup>84</sup> 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 safely assume that the patentee is not going to transfer the valuable technology to anyone.<sup>85</sup>

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<sup>81</sup> 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.

<sup>82</sup> 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.

<sup>83</sup> 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.

<sup>84</sup> Cabanellas, G., *Antitrust and Direct Regulation of International Transfer of Technology Transactions*, VCH, Weinheim, 1984 p.60.

<sup>85</sup> 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.

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.<sup>86</sup> 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.<sup>87</sup> 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.<sup>88</sup>

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.<sup>89</sup>

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 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

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<sup>86</sup> Supakankunti et al, op.cit., at pp.29-35.

<sup>87</sup> See Yankey, G.S., *International Patents and Technology Transfer to Less Developed Countries*, Gower, Aldershot, 1987.

<sup>88</sup> 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.

<sup>89</sup> Rattakul, A., *Pharmaceutical Patents and National Interest*, A Thesis Submitted to the National Security College, Bangkok, 1990, p.68 (in Thai).

and paid 28 percent of annual sales revenue for anaesthetics.<sup>90</sup> 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.<sup>91</sup> 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.<sup>92</sup> 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 Santikarn<sup>93</sup> found that 'export prohibition'<sup>94</sup> and 'tie-ins'<sup>95</sup> 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'<sup>96</sup> and 'grant-back'<sup>97</sup> clauses were also found. A

<sup>90</sup> United Nations, *Costs and Conditions of Technology Transfer through Transnational Corporations*, ESCAP/UNCTC, Pub. Series B, No.3, 1984, p.210.

<sup>91</sup> OECD, *Transfer of technology for Pharmaceutical Chemicals*, Paris, 1975, p.56.

<sup>92</sup> 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.

<sup>93</sup> Santikarn, M., *Technology Transfer: A Case Study*, Singapore University Press, Singapore, 1981, pp.131-135 and Table 29.

<sup>94</sup> 'Export prohibition' clause prohibits the licensee to produce and export to territory and country specified.

<sup>95</sup> 'Tie-in' is the clause that requires the licensee to buy raw materials or other non-patented goods from the licensor only.

<sup>96</sup> 'Price-fixing' clause is included in order to allow the licensor to set the sale price of products produced by the licensed technology.

<sup>97</sup> '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.

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.<sup>98</sup>

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.<sup>99</sup>

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.<sup>100</sup> 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.<sup>101</sup>

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<sup>98</sup> United Nations, op.cit., at pp.217-226 and Tables 20-24.

<sup>99</sup> 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.

<sup>100</sup> 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.

<sup>101</sup> UNCTAD, *ibid*, at p.27.

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 the licensing contracts.<sup>102</sup> In practice, once an application is submitted to the Bank; the remittance is approved almost automatically.<sup>103</sup> 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.

## **APPRIASAL**

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 IP protection. While a stringent patent regime as enshrined under the proposed FTA may be

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<sup>102</sup> Kuanpoth, J. "Technology Transfer in Thailand" in Christopher Heath (ed.), *Legal Rules of Technology Transfer in Asia*, Kluwer Publisher International, London, 2002, pp.171-192.

<sup>103</sup> Ibid.

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 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 IP rights and public health.<sup>104</sup> 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.<sup>105</sup> 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 new IP rules that may further restrict its accessibility to essential products.

The FTA provisions will have a tremendous impact on prices. The new patent 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

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<sup>104</sup> 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).

<sup>105</sup> Declaration on the TRIPS Agreement and Public Health, adopted on 14 November 2001, WT/MIN(01)/DEC/2.

local companies would be to wait until the exclusivity period expired, 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 USTR text that links 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 FTA 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.<sup>106</sup> This would protect the original patent holder against generic competition.

As regards technological capability, the new IP 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.<sup>107</sup> 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 also a system of forfeiture and revocation of patents. The provisions on compulsory licensing will limit flexibilities that Thailand

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<sup>106</sup> 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.

<sup>107</sup> See Paris Convention, Article 5.

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.

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 FTA provisions that link IP 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 IP 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 proposed FTA 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 proposed FTA 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.

## **CONCLUSION AND FEASIBLE OPTIONS**

Product competition and promotion can be reduced by the increasing use of generic name and the government control of drug advertisement. Creation of a competition 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 the competition. Since the large number of off-patent medicines are now available in the world markets, Thailand and other developing countries should considering implementing the policy of encouraging generic substitution.

Developing countries may 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 dispensing the cheapest available version of drugs.

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 medicine for official approval to guarantee the accuracy and sufficiency of information before they can be circulated to doctors, drug-sellers and the public. Further, 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 rigorously and seriously implemented.

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 developing countries should initiate a policy of drug price control which can appear in various forms. One possibility would be an appointment of medicine price review board to monitor pharmaceutical prices.

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, that require business enterprises to disclose their financial information to a government agency, should be promulgated to complement the patent law in this regard.

For the attainment of the goal of industrial and economic development, self-sufficiency in pharmaceutical production is necessary in order to facilitate a strong and healthy labour-force without co-operation of foreign interests. However, in practice self sufficiency is rare. Few developing countries can claim to be self sufficiency 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 achieve the goal of accessibility to medicines, a developing country must adopt and implement appropriate policies relating to technology, health, and IP rights to ensure effective, safe and affordable medicines. The following options may be taken: (i) increasing financial support for industrial R&D to public research institutes and private enterprises; (ii) improving national education in the long term and developing the personal skill of scientists and engineers in the short term; (iii) fostering production and commercialisation of research results; (iv) encouraging efficient co-operation among researchers in universities and the industries, supporting technological co-operation among domestic firms, etc.