Impact of the World Trade Organization TRIPS Agreement on the pharmaceutical industry in Thailand

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The 1994 World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) established minimum universal standards in all areas of intellectual property. It is intended to implement these standards globally through a WTO enforcement mechanism. The present article proposes a strategy for alleviating the potentially negative impact of TRIPS in Thailand in relation to the following: purchasers; prescribers and dispensers; producers; products; price control; patent-to-third-party; parallel imports; power of the customer; patentable new drugs; personnel; and prevention policies. The following TRIPS provisions are pertinent to the pharmaceutical industry in Thailand: the limited term of product and process patents; the conditions of protection; and the broad scope for compulsory licensing and enforcement procedures in the national patent system.

Keywords Drug industry; Commerce; Drug costs; Legislation, Drug; Patents; Treaties; Thailand (*source: MeSH*).

Mots clés Industrie pharmaceutique; Commerce; Coût médicament; Législation pharmaceutique; Brevet; Thaïlande (*source: INSERM*).

Palabras clave Industria farmacéutica; Comercio; Costos en drogas; Legislación de medicamentos; Patentes; Tailandia (*fuente: BIREME*).

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Introduction

In 1947, a total of 23 countries signed the General Agreement on Tariffs and Trade (GATT). The primary objective was to promote and regulate the liberalization of international trade through rounds of trade negotiations. Between 1986 and 1994 the Uruguay Round of Multilateral Trade Negotiations led to the Marrakech Agreements. These established the World Trade Organization (WTO) and extended the rules governing commercial relations between trading partners to a number of new areas, such as agriculture, services, investment measures and the protection of intellectual property rights. All of these areas had previously been excluded from trade liberalization.

Since 1994, attention has focused on the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) as the most far-reaching international instrument ever negotiated in this field. It establishes minimum universal standards in all areas of intellectual property and the intention is to implement these standards globally through a strong enforcement mechanism established in WTO. The TRIPS agreement requires universal patent protection for any invention in any field of technology. This affects pharmaceuticals, which many countries had previously excluded from patent protection in order to produce drugs at reduced prices and thereby contribute to the improvement of public health. WTO member countries that did not previously recognize pharmaceutical patents must amend their patent legislation within a limited time or transition period. Any member country failing to bring its patent law into conformity with the TRIPS agreement, if challenged by another member country, is subject to the WTO dispute settlement system. Sanctions may be established in accordance with WTO procedures. The TRIPS patent system can be expected to have a great impact on the health sector and may negatively affect national drug production, drug prices, the availability of essential medicines and

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pharmaceutical technology, and numerous other factors in developing and least developed countries. In addition, there could be a greater concentration of drug production in industrial countries rather than a transfer of technology to, or foreign direct investment (FDI) in developing countries.

No extensive review of the practical implications of the TRIPS agreement has been conducted at the global and national levels, and at the regional level only Latin America has been covered. The present paper examines the consequences of the agreement for the pharmaceutical industry in Thailand with a view to learning lessons applicable to all developing countries. Recommendations are given for alleviating the potential negative impact resulting from mandates set forth in the agreement.

In order to determine the specific implications and potential consequences accurately and meaningfully, we identified applicable and clearly defined objectives. Relevant research methods were employed, including situation and data analyses, surveys and impact assessments, and literature reviews. The situation and data analyses and the impact assessments dealt with the effect of the 1992 Thai Patent Law on the pharmaceutical industry in Thailand and on direct foreign investment and the transfer of technology in the sector. For the first time this law covered the protection of rights for both pharmaceutical processes and products.

Objectives

The objectives of the study were to review the impact of the 1992 Thai Patent Law on the pharmaceutical industry in Thailand, the FDI situation, and the transfer of technology in the sector. This involved the following steps: 1) a review of the increase in drug prices associated with patented drugs and of the increase in foreign exchange costs of imports attributable to the increased price of drugs after the Patent Act became effective in September 1992; 2) a review of the proportion of patented and generic drugs on the market and of the effectiveness of the drug price control system in Thailand; and 3) identification of those aspects of the Patent Act requiring changes in the light of findings under 1) and 2) above, and recommendations on the health sector's participation in the process of effecting improvements/changes in the Patent Act that could be considered by national and international health authorities to safeguard health interests.

Methods

The methodology used to prepare this case study consisted of a situation analysis based on a literature review of relevant research, data and statistical analyses, impact assessments, and surveys. Although there has been no extensive review of the practical implications of the TRIPS agreement on the pharmaceutical industry, there have been many studies on subcomponents of the larger issue. Several such studies specific to Thailand were used for this assessment, including key empirical studies on experience in procurement systems and drug prices. Among the data and statistical analyses were reviews of the prices, quantities and values of imported drugs, the market value of the pharmaceutical sector, and the ratio of total manufacture to imports of modern medicines registered in Thailand. Several impact assessments were conducted, comparing the import and export value of medicinal and pharmaceutical products in Thailand, the real performances of leading generic and originator pharmaceutical companies, and the nominal and real prices of selected pharmaceuticals. The market value of the pharmaceutical sector was reviewed and a comparison was made of share values of pharmaceutical trading companies with reference to the citizenship of shareholders. Surveys were conducted in order to complete the overall situation analysis. Prominent among these were surveys on the opinions of executives concerning factors influencing price policy. On the basis of the work done and previous studies it was possible to arrive at a general overview. This allowed conclusions to be drawn and strategies to be derived for dealing with the impact of the TRIPS agreement on the country's pharmaceutical industry.

Situation analysis

Thailand's first patent law was enacted in 1979. It received little attention from government because of a misunderstanding that patent law applied only to industrialized countries and created a monopoly, and therefore that it was inappropriate for an agricultural country. As a result there were many problems and the 1979 law was therefore revised in 1992 to include the protection of rights for both pharmaceutical processes and products. In 1999 a third patent law included changes to the 1992 law and clarification of enforcement provisions. Major revisions allowed petty patents (which protect simple inventions that have industrial applicability), pipeline protection and parallel imports. The intention is to give Thai and foreign inventors an alternative to intellectual property rights protection. The process of obtaining a petty patent is shorter than that for a regular patent but the period of protection is also shorter — six years instead of twenty. Pipeline protection for patent holder countries stemmed from the controversy about the effect of the 1992 patent law on drug prices. The increase in drug prices caused difficulty for Thai pharmaceutical companies that could no longer import previously unprotected and inexpensive raw material to produce drugs. This meant that the Thai drug production market could not be developed. Outside forces compelled the government to extend patent protection to drug companies situated in other countries. The revision of the second Thai patent law stipulated that drugs granted patent rights in other

countries between 1 January 1986 and 30 September 1991 would be protected in Thailand for 5–6 years, but not for longer than the period registered in the originator country. This is termed pipeline protection for the patent holder country. The third major revision allowed parallel importation, whereby drugs belonging to a patent holder can be imported by another person, provided that the patent owner manufactures the drug or has granted a licence to manufacture it in another country.

Many people advocate that the revision of the drug patent law to coincide with TRIPS should emphasize the right of the Thai people to the benefits of patented drugs. In Thailand the TRIPS agreement could lead to an increase in the price of patented drugs and in the amount of patent royalties. There could also be a concentration of drug production in industrialized countries rather than technology transfer to, or FDI in developing countries. In addition, the new WTO patent system cannot be expected to increase research or development in developing countries. However, it has been argued that the protection of pharmaceuticals will enhance the tendency to transfer technology; that there will be an increase in FDI, benefiting developing countries; and that the increase in resources devoted to research and development by local pharmaceutical companies will lead to the development of new drugs suited to their own situations, to products of improved quality, and to an end to the brain drain in Thailand (*1*–*3*).

The potential effects of the TRIPS provisions on the pharmaceutical industry in Thailand relate to the limited terms of product and process patents, the conditions of protection, and the broad scope for compulsory licensing and enforcement procedures in the national patent system (*4*).

The findings of the present study on the implications of the TRIPS agreement for the Thai pharmaceutical industry are discussed below.

Technology transfer and FDI

There has not been much technology transfer to or FDI in the Thai pharmaceutical industry since 1992. The industry is still rather small compared with other production sectors and is concerned with domestic consumption rather than export. Moreover, 48.5% of the raw material and intermediate input for this industry was imported for domestic production. In addition, the data on Thai pharmaceutical companies registered from 1984 to 1998 indicated that there were more Thai than foreign shareholders, reflecting the fact that little FDI is flowing into the industry (see Tables 1–3).

Spending on health care

Spending on health care is mainly for curative purposes. A great deal of this expenditure is for medical technologies, including medication, the rate of which is rising faster than overall health care spending. This is because both hospitals and pharmacies provide diagnosis and a normal supply of medicines. Many drugs that require a prescription in developed countries are sold freely in Thailand. Also, there are dispensing regulations for certain drugs but they are often ignored.

Table 1. **Revealed comparative advantage of medicinal and pharmaceutical products in selected countries, 1984–95**[a]

Year	Germany	Switzerland	USA	Thailand	Singapore	Malaysia
1984	1.6481	7.6069	1.6578	0.1839	0.6625	0.1547
1985	1.5628	7.0899	1.6214	0.1738	0.7209	0.1381
1986	1.4028	6.5404	1.5582	0.1307	0.6231	0.1544
1987	1.4128	6.7897	1.3661	0.1275	0.5193	0.1432
1988	1.3565	6.0789	1.2263	0.1350	0.4153	0.1272
1989	1.3610	6.3652	1.0024	0.1020	0.4052	0.1246
1990	1.3389	6.2200	0.9677	0.1068	0.3615	0.1154
1991	1.3499	6.2582	0.9175	0.1313	0.2865	0.0848
1992	1.2739	6.3614	0.8947	0.1313	0.2865	0.0848
1993	1.4124	6.3297	0.8879	0.2411	0.3542	0.0761
1994	1.4361	6.3093	0.8472	0.1350	0.3586	0.0812
1995	1.3802	6.4269	0.7735	0.1534	0.3498	0.0748

[a] See ref. *4*.

Drug registration

The current drug registration system has been in place since 1992. A new feature of the system is the Safety Monitoring Programme (SMP). This requires that any new drug be used under the supervision of physicians for a minimum of 2 years, and that the licensee report any safety problems associated with its use. The SMP also stipulates that no other manufacturer is allowed to produce drugs covered by the SMP. Consequently, the SMP serves to uphold patent protection. Up to 30 December 1998, a total of 705 drug items had been registered under the new drug approval system giving the benefit of the SMP to patent holders. Of these items, 423 are still covered by the SMP, while for 282 the safety monitoring period has already elapsed.

Generic pharmaceutical companies

Before 1989, generic pharmaceutical companies did better than originator firms in terms of operational income generated from one unit of assets. Subsequently, the reverse was true, perhaps because foreign-owned companies performed better than Thai-owned firms. However, some medicines and types of health care may be luxuries rather than necessities. During the period of economic prosperity in Thailand in the late 1980s, many people could afford to purchase medicines or health services that they perceived to be of high quality, and many used imported drugs. In Thailand there is a tendency to spend more on imported drugs than on those produced in the country, and the rate of increase in expenditure on imported drugs by Thais is higher than the rate of income growth (Fig. 1, Table 4 and Table 5).

Impact of economic crisis

The impact of the economic crisis on the cost of imported drugs has caused the government to control

Table 2. **Share of foreign direct investment (FDI) in Thai industry, 1988–98**[a]

Year	Industry (*baht* × 10^6)	Chemicals (*baht* × 10^6)	Total FDI (*baht* × 10^6)	Share (%)		
				Industry/ total	Chemicals/ total	Chemicals/ industry
1988	16 162.4	1 059.7	27 963.5	57.8	3.8	6.6
1989	21 866.1	2 818.5	45 697.6	47.8	6.2	12.9
1990	29 071.4	4 293.2	62 516.3	46.5	6.9	14.8
1991	23 839.6	3 850.3	51 389.1	46.4	7.5	16.2
1992	17 467.3	1 624.3	53 764.3	32.5	3.0	9.3
1993	11 430.3	5 106.5	43 812.0	26.1	11.7	44.7
1994	5 330.0	838.0	33 241.0	16.0	2.5	15.7
1995	14 114.3	2 333.0	49 887.0	28.3	4.7	16.5
1996	17 941.8	4 631.5	57 472.0	31.2	8.1	25.8
1997	58 337.0	6 054.0	117 689.0	49.6	5.1	10.4
1998	83 505.0	8 805.0	198 266.0	42.1	4.4	10.5
1988–91	90 939.5	12 021.7	187 566.5	48.5	6.4	13.2
1992–98	208 125.7	29 392.3	554 131.3	37.6	5.3	14.1
1992–96	66 283.7	14 533.3	238 176.3	27.8	6.1	21.9
(1992–98)/ (1988–91)	2.29	2.44	2.95	—	—	—
(1992–96)/ (1988–91)	0.73	1.21	1.27	—	—	—

[a] See ref. *4*.

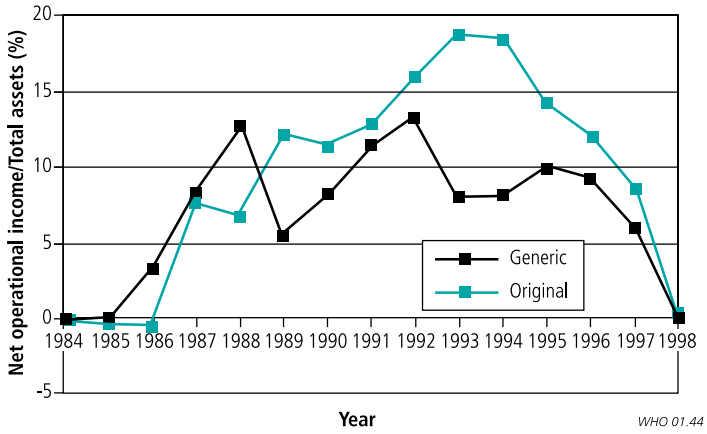
Table 3. **New registered drug foreign direct investment (FDI), Thailand, 1992–98**[a]

Year	Share value in Thai ownership (*baht*)	Share value in foreign ownership (*baht*)	Total (*baht*)
1992	16 597 800	3 002 200	19 600 000
1993	105 507 000	93 000	105 600 000
1994	150 050 020	31 049 980	181 100 000
1995	36 160 000	11 540 000	47 700 000
1996	212 182 200	129 017 800	341 200 000
1997	39 240 000	2 760 000	42 000 000
1998	138 782 870	4 359 900	143 142 770
1992–98	698 519 890 (79. 4)[b]	181 822 880 (20.7)	880 342 770
1992–96	520 497 020 (74.9)	174 702 980 (25.1)	695 200 000

[a] See ref. *4*.

[b] Figures in parentheses are % of total share value.

Fig. 1. **Real performance of the leaders of generic versus originator pharmaceutical companies, Thailand, 1984–98** (see ref. *1*).



spending on health more stringently. This has involved the introduction of an essential drugs policy and the more common use of generic drugs, as happened in 1998. It is worth considering whether such a policy would be sound following economic recovery. Policy-makers will have to determine the grounds on which government control of spending is warranted and whether such control is effective when people can afford to buy higher-priced products. The reduction in the import value of finished drugs, mostly originals, in 1998, can be explained by at least three factors: the price effect, attributable to the depreciation of the *baht*; the income effect; and government policy favouring domestically produced drugs. These factors are interconnected and difficult to separate.

The 1992 Patent Act

Since the 1992 Patent Act went into effect, the share of original drugs in the Thai market increased by 1–6% per year, reaching a peak in 1997, when the shares of generic and original products were 33% and 67%, respectively. Until 1997 the growth rate of the originator market was two to three times that of gross domestic product (GDP). It seemed that the originator sector was not affected by the financial crisis in mid-1997, when the *baht* was floated. However, when the effect of the exchange rate was taken into account, the market value of the originator sector began shrinking in 1997: the total volume in US$ decreased by 17% and 24% in 1997 and 1998, respectively. In 1998, original drugs lost 13.3% of their share; nonetheless, they still dominated the market with more than 50% of the total. Generally, the Thai market continues to be segmented between original and generic drugs, with the substitution effect, to

some degree, depending on purchasing power and drug dispensing regulations (Table 6, Fig. 2).

Patented drugs

Pharmaceutical products in six therapeutic categories were chosen to represent the market situation in respect of patented drugs: antidepressants; antihistamines and antiallergics; antihyperlipidaemic agents; antiulcerants; broad-spectrum antibiotics; and gastrointestinal tract regulators. There was no obvious price reduction after the point at which a competitor entered the market. The gap of equivalent prices between original and generic products was varied and unpredictable (Table 7, Fig. 3).

Market prices of drugs

Market prices of drugs in Thailand are regulated by legal means as well as non-legal mechanisms. Price control is under the jurisdiction of the Ministry of Commerce, which specifies categories of drugs whose prices are to be controlled (Table 8). During the 1997–98 economic crisis it set across-the-board percentage limits on price increases (Table 9). The implementation of price control laws generally targets the list prices of manufacturers and importers and the retail prices charged by pharmacies. The prices of drugs sold through hospitals and clinics are not subjected to legal control. Although private hospitals set their prices independently, retail drug prices in public hospitals are normally no greater than 15% of hospital purchase prices. Since self-medication is common, retail prices of drugs distributed through pharmacies directly affect the affordability of drugs. However, there is no systematic evaluation of the effectiveness of government price regulation of the influence of drug prices on affordability.

Wholesale drug prices are influenced by the rules governing public sector procurement and by provincial group purchasing. Collective procurement is effective in price bargaining. In addition, competition among suppliers helps to hold drug prices in check. Because of a lack of overall coordination, however, drug companies charge different prices for the same product procured by different Thai purchasers.

Table 4. **Value of manufactured and imported modern medical drugs, Thailand, 1987–98**[a]

Year	Manufactured (*baht* × 10^6)	Imported (*baht* × 10^6)	Total (*baht* × 10^6)	Imported (%)
1987	5 145.75	2 325.43	7 471.18	31.13
1988	6 708.85	2 570.98	9 279.83	27.71
1989	8 372.85	3 307.60	11 680.45	28.32
1990	8 886.02	3 449.08	13 873.95	30.39
1992	10 696.54	4 682.61	15 379.15	30.45
1993	11 831.03	5 075.31	16 906.34	30.02
1994	12 969.68	6 086.63	19 056.31	31.94
1995	15 820.87	9 276.47	25 097.34	36.96
1996	18 120.41	10 676.01	28 796.42	37.07
1997[b]	20 221.00	11 255.00	31 476.00	35.76
1998[b]	20 012.00	11 676.00	31 688.00	36.85
Total	**148 442.54**	**74 597.53**	**223 040.07**	**33.45**

[a] See ref. *4*.

[b] Preliminary data.

Potential effects of TRIPS provisions on pharmaceuticals

The following are main problem areas for developing countries with respect to pharmaceuticals as affected by the TRIPS agreement: the limited terms of product and process patents; the short terms of protection; and the broad scope for compulsory licensing and enforcement procedures in national patent systems. The provisions of the TRIPS agreement may need further review in the following areas.

Patentability

The TRIPS agreement requires WTO members to grant patent protection for a minimum of 20 years for

Table 5. **Comparison of total drug supply and gross national product (GNP) per capita, Thailand, 1987–96**[a]

Year	Domestic drugs manufactured (*baht* × 10^6)	Imported drugs (*baht* × 10^6)	Total drug supply (Q) (*baht* × 10^6)	GNP per capita (*baht*)	Relative rate of change of Q to income	Relative rate of change of domestic manufactured drugs to income	Relative rate of change of imported drugs to income
1987	5 145.75	2 325.43	7 471.18	22 960.00	—	—	—
1988	6 708.85	2 570.98	9 279.83	27 179.00	1.28	1.57	0.60
1989	8 372.85	3 307.60	11 680.45	33 204.00	1.15	1.11	1.26
1990	8 886.02	3 449.08	12 335.10	38 582.00	0.36	0.40	0.28
1991	9 657.54	4 216.41	13 873.95	43 335.00	1.01	0.72	1.73
1992	10 696.54	4 682.61	15 379.15	48 359.00	0.94	0.93	0.96
1993	11 831.03	5 075.31	16 906.34	53 593.00	0.92	0.98	0.78
1994	12 969.68	6 086.63	19 056.31	60 612.00	0.97	0.75	1.47
1995	15 820.87	9 276.47	25 097.34	69 047.00	2.10	1.52	3.19
1996	18 120.41	10 676.01	28 796.42	74 585.00	1.78	1.76	1.82

[a] See ref. *4*.

Table 6. **Market value of pharmaceutical sectors, Thailand, 1992–98**[a]

	1992	1993	1994	1995	1996	1997	1998
Market composition							
Original (*baht* × 10^6)	7 352	9 063	10 558	12 073	14 603	16 728	13 389
Total (*baht* × 10^6)	15 464	17 087	18 555	21 036	24 238	25 000[b]	25 000[b]
Original (US$ × 10^6)	289	358	420	484	576	533	324
Total (US$ × 10^6)	609	675	738	844	957	797	604
Original/total (%)	47.5	53.0	56.9	57.4	60.2	66.9	53.6
Exchange rate (*baht*/$US)	25.40	25.32	25.15	24.92	25.34	31.37	41.37
Comparison of originator growth with other key parameters							
% GDP growth (*baht*)	8.1	8.5	8.9	8.8	5.5	–0.4	–8.0[c]
Population[c] (× 10^6)	57.79	58.34	59.1	59.46	60.12	60.82	61.47
% originator growth (US$)	NA[d]	24	17	15	19	–7	–39
% GODEPC[e] (US$)	NA	22	16	15	18	–9	–40

[a] See ref. *4*. These data were mostly obtained from Pharmaceutical Products Association (PPA) and from direct contact with its president. There were other sources such as the Drug Control Division, Thai Federal Drug Administration. The latter data, however, were not grouped as close to our objectives as those of the PPA. Other key parameters were obtained from the National Accounts Division and the Office of the National Economic and Social Development Board. Monthly reports were obtained from the Bank of Thailand.

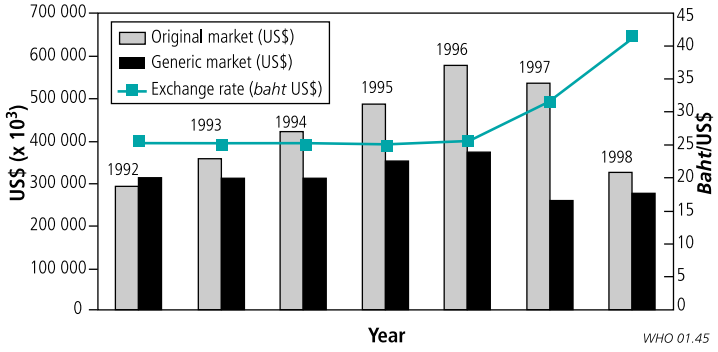
[b] Estimate.

[c] Probably underestimated. There may be unregistered persons in remote areas as well as illegal immigrants.

[d] NA = not available.

[e] GODEPC = growth of original drug expenses per capita.

Fig. 2. **Market value of pharmaceutical sectors in Thailand, 1992–98** (see ref. *1*).



any invention in any branch of technology. This provision is expressly aimed at pharmaceutical products and processes, which most developing countries, as well as some developed countries, do not yet cover in their national patent laws. Because of the high prices of patented drugs and the high costs of research and development in the pharmaceutical field, some countries grant patents only for processes. Through reverse engineering, often used to copy original drugs in countries that do not grant patents for pharmaceutical products, many countries meet their national requirements for drugs at reduced cost and are able to develop their technology at the same time. Other countries with no pharmaceutical industry can buy these drugs at competitive prices but this ability is limited by licence agreements.

The TRIPS agreement authorizes certain exclusions from patentability, depending on public ethics, especially in connection with the protection of human, animal or plant life, or with the prevention of serious damage to the environment. Member countries may exclude diagnostic, therapeutic and surgical methods for the treatment of humans and animals.

Effects of protection or term of patent

In many countries, patent protection that lasts 20 years can be expected to result in an increased duration of the patent owner's monopoly. In the case of pharmaceuticals, the logical consequence of this provision is that drugs can be sold at a relatively high price for longer periods of time. The manufacturers of generic products thus have to wait longer before they can produce the same drugs and sell them at more reasonable prices.

Transitional period arrangements

The TRIPS agreement provides for transitional periods during which countries can bring their national legislation and practices into conformity with the terms of the agreement. As far as the substantive rules on patent protection are concerned, a distinction was made between least developed countries and developing countries and also between countries with and countries without a system of patent protection for pharmaceuticals when WTO was established. As a result, the dates of effectivity of TRIPS are as follows: developed countries, in 1996; developing countries, in 2000 or 2005; and for least developed countries, in 2006.

Compulsory licensing

The provision in TRIPS for the use of a patented product without authorization of the patent holder

Table 7. **Pharmaceutical profiles of selected items**[a]

Generic or chemical name (dose in mg)	Therapeutic categories	No. of forms[b]	Original brand	Imported generics	Generic copies	Other original substitutes[c]
Amoxycillin + clavulanic acid (375 mg)	Broad-spectrum antibiotics	4	1	2	4	7
Ciprofloxacin (250 mg)	Broad-spectrum antibiotics	2	1	6	40	7
Cisapride (5 mg)	GIT regulators	2	1	0	15[d]	3
Fluoxetine (20 mg)	Antidepressants	3	1	1	18	3
Gemfibrozil (300 mg)	Antihyperlipidaemic agents	3	1	1	42[d]	2
Loratadine (10 mg)	Antihistamines and antiallergics	3	1	1	13	2
Omeprazole (20 mg)	Antiulcerants	3	1	2	19	1
Roxithromycin (150 mg)	Broad-spectrum antibiotics	2	1	2	36	5

[a] See ref. *4*. The data were last updated on 20 April 1999 from Thai Federal Drug Administration.

[b] Different forms. In any one form there may be different concentrations, different sizes and different packaging.

[c] Other originals in the same drug class that are used in a rather loose clinical meaning.

[d] One generic firm was contracted to produce the original brand for the originator company.

might be understood as equivalent to the compulsory licence rules used by countries to prevent the abuse of exclusive rights conferred by the patent. However, there are differences between the traditional provisions of compulsory licensing and the TRIPS provision: the former are principally intended to serve the public interest, whereas the purpose of the latter is to protect the interests of the rights holder.

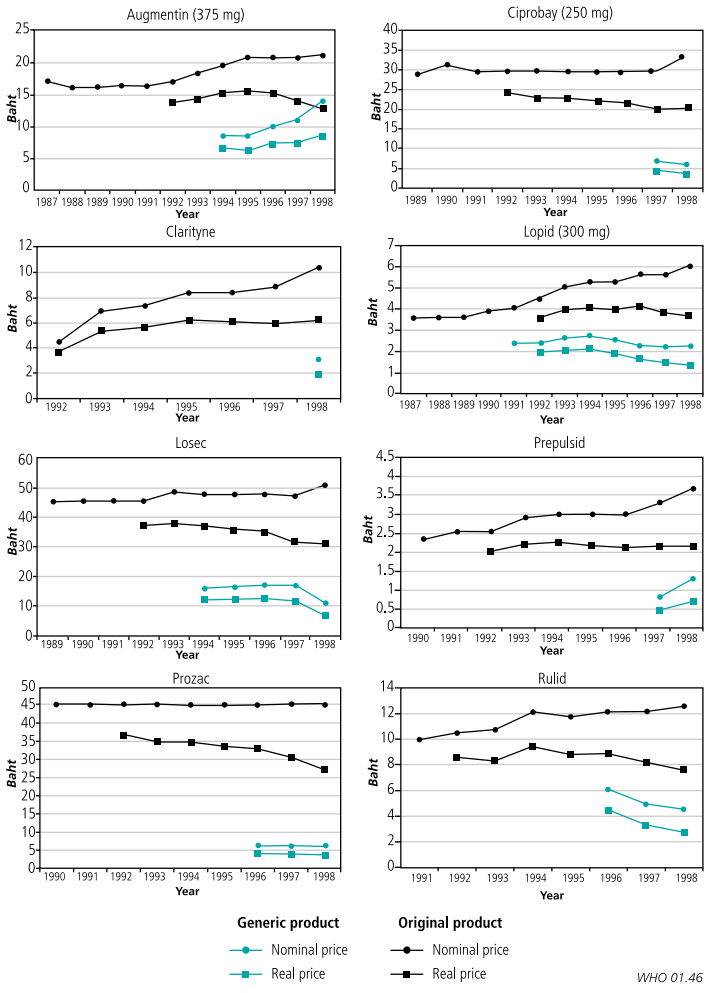
Exclusive marketing rights

Exclusive marketing rights have to be provided by WTO member countries to the applicant for a pharmaceutical patent for at least 5 years during the transitional period. If the application for such a patent was filed after 1995 in a developing country, exclusive marketing rights could be provided before the expiry of the transitional period. This would enable the patent holder to enjoy monopoly rights even if proper patent protection were not granted until after the expiry of the interim period.

Burden of proof

A new TRIPS agreement rule, relating to the burden of proof in the case of process patents, is also important for member countries. According to the rule, member countries must provide for a reversal of the burden of proof in their legislation. This stipulates that if the holder of a process patent suspects someone of having used the process to obtain an identical product, the person suspected must prove deviations from the patented process. The position of patent holders is thereby strengthened in relation to persons who try to obtain given products through alternative technological routes. Furthermore, the traditional "innocent until proven guilty" maxim is reversed in this instance.

Fig. 3. **Nominal and real price of selected pharmaceutical items, Thailand, 1987–98** (see ref. *1*).



Conclusion

This analysis of the implications of the TRIPS agreement for the pharmaceutical industry in Thai-

Table 8. **Drug categories subject to Thai Ministry of Commerce price control**[a]

Category	Active ingredient
Antiflatulents	Sodium bicarbonate
	Phenyl salicylate
	Asafoetida
Antacids	Aluminium hydroxide
Antidiarrhoeals	Oral rehydration salt
	Loperamide
	Diplenoxylate + atropine
Antitussives/expectorants/mucolytics	Glycyrrhiza fluid extract
	Dextromethorphan
	Bromhexine salt
	Acetylcysteine
	Glyceryl guaiacolate
Cold preparations	Paracetamol and chlorpheniramine maleate and phenylpropanolamine
Analgesics/antipyretics	Aspirin (acetylsalicylic acid)
	Paracetamol
Anthelmintics	Albendazole
	Mebendazole
	Niclosamide
Antibacterials	Gentamicin
Topical preparations	Sulfanilamide
	Tetracycline and derivatives
Oral preparations	Ampicillin
	Amoxicillin
	Co-trimoxazole
	Penicillin V
	Tetracycline and/or derivatives
Antifungals	Clotrimazole
Topical preparations	Isoconazole
	Miconazole
	Salicylic acid
	Tolnaftate
Antiallergics/antipruritics	Betamethasone
Topical preparations	Calamine
	Prednisolone
	Triamcinolone
Antiinflammatories	Diclofenac
Topical preparations	Methyl salicylate
	Piroxicam
	Mucopolysaccharide polysulfate
Inhalers	Menthol
	Eucalyptus oil
Lozenges	Cetylpyrdinium chloride
	Dequalinium chloride
	Dichlorobenzyl alcohol
	Tyrothricin
	Neomycin and/or bacitracin
	Menthol and/or eucalyptol

[a] See ref. *5*.

land is merely the starting point for a continuing process. Ongoing changes in the structure of the economy, regulations, patent laws and a myriad of other factors mean that further study and action will be needed. The TRIPS provisions relating to patentability, the effects of protection or term of patents, transitional period arrangements, compulsory licensing, exclusive marketing rights, and the burden of proof will require further review.

The Thai government, the private sector and the population in general should prepare themselves for the consequences of the country's Patent Drug Act. In both the short and the long term, some economic disadvantages are expected for the Thai pharmaceutical industry.

Each country has specific, sometimes unique, characteristics and needs. Domestic laws and regulations therefore have to be changed in order to match national conditions and help to orientate the pharmaceutical industry in a desirable way, while allowing compatibility with international agreements. The present study does not reveal any price change due to the patent protection act and does not provide strong evidence of FDI and technology transfer. In anticipation of price movement or low-grade technology transfer, the study proposes that some aspects of the existing Patent Act be changed — in particular, that attention be given to the following: the term or duration of patent protection; non-patentable subject matter; the rights and privileges of patentees; import monopoly; non-voluntary licences unrelated to non-working patents; the definition of working and non-working patent; actions against non-working patents (e.g. provision for revocation or forfeiture of patent); stipulation on conditions promoting technology transfer; the repeal of any disadvantageous interim measures; and regulatory mechanisms. Bolar provision (early working) is an another exception specifically applicable to pharmaceutical patents — it relates to using an invention without the patentee's authorization for the purpose of obtaining approval of a generic product before the patent expiration date (*6*).

An appropriate time frame for effective action and the extent to which patent laws are implemented and practised would undoubtedly help to alleviate the economic burden of buying more expensive drugs. In the long run, Thailand should endeavour to learn more from other countries before fully committing itself to new aspects of more progressive intellectual property protection, e.g. patent term extension. Above all, the involvement of the government is extremely important if progressive development is to be ensured. The pharmaceutical industry has not received enough consideration and national authorities should have a clear vision for this industry and should understand the implications for health if they do nothing. Lessons learnt from other countries and continuing study can be expected to lead to solutions appropriate to conditions in Thailand. The provision and revision of pharmaceutical policies should not only conform to present standards in the industry and to international commitments but should also ensure an improved quality of life for the Thai people as a whole.

Recommendations

In the long run, only the strongest companies are likely to survive in the Thai pharmaceutical market. However, it is doubtful whether many of them will

be Thai-owned. In anticipation of future market conditions, therefore, Thai companies should focus on those areas where they are most skilful. Many chemicals are still not covered by patent law, and the development of drugs from these chemicals is therefore potentially profitable for local pharmaceutical industries. Full drug development is expensive and currently unrealistic, not only for Thai companies but also for those in many other countries that are not research-based. Thailand would gain by investing in areas where it is relatively competent and where benefits are likely to be obtained for society as a whole. At the same time, key players in the health sector have to prepare themselves for a new era of competition.

As a Member of WTO, Thailand has to comply with the mandates set forth in the TRIPS Agreement. With a view to alleviating the potentially negative impact of such compliance we propose a strategy with the following components.

- An innovative purchaser strategy to establish rational cost-effective drug selection procedures for public and private health care facilities and to create a government financing system for drugs and other aspects of health care.
- A prescriber and dispenser strategy to promote the rational use of drugs in health facilities and encourage the prescribing of generic drugs. Both national and multinational firms should be urged to develop an agreed set of business practices to ensure maximum benefit for the public and punish the unethical promotion of medicine.
- A producer strategy to support and encourage technical transfers of drug development processes to Thailand, to provide truthful information allowing doctors and patients to make the best and most efficient use of medicine, and to bridge the gap between developing and developed countries through "pharmacophilanthropy".
- A product strategy promoting research into and the development of traditional medicines so as to reduce dependence on modern drugs and strengthen the country's capacity for innovation. This would also facilitate participation in the modern drug development process, with accompanying enhancement of indigenous technical, personnel, financing, patenting, research and related capabilities, and would help to streamline and simplify patent registration of potential compounds.
- An effective price control system taking global drug prices into consideration. Prices for new drugs protected under patents should be set on a reasonable basis and subsidized where necessary in order to make essential drugs accessible to all segments of the population. Direct legal control of drug prices might be necessary if standard means of price regulation were ineffective.
- A patent-to-third-party strategy. The TRIPS Agreement permits compulsory licensing. For example, in order to protect public health and nutrition the government could grant a patent to a third party without the consent of the original patent holder.
- Parallel imports could theoretically be used in a national strategy for restoring price competition for patented products, including pharmaceuticals, by allowing the importation of identical patented products at reduced prices.
- A power-of-the-customer strategy, recognizing the need for countries to accept that, as world citizens, all people share the price burden of drug research and discovery. However, governments can play a key role in educating people on how to avoid illness by reducing risks, adopting preventive health care, and avoiding the irrational and unnecessary use of drugs.
- Research and development. It is proposed that the Thai Government use a tax on drug sales to build capacity for developing patentable new drugs and strengthen price and patent management and monitoring systems.
- Personnel strategy. The Thai Government should provide better education, training, development and support in highly technical skills to ensure adequate human resources in the area of research and development. It should also create a fair incentive system in order to maintain these scarce human resources, stop the brain drain and encourage Thai scientists and experts living abroad to return home.
- Prevention strategy. Primary care and preventive medicine should form the keystones of national health policy. Preventive measures and healthy lifestyles can be expected to diminish the demand for medical care and improve the quality of life in a relatively cost-effective fashion. ■

Table 9. **Permitted percentage price increases from present level for three categories of pharmaceutical product in response to Thai currency devaluation**[a]

Drug categories	% increase	
	1 October 1997	25 March 1998
Imported finished products	18.89	7.75
Repackaged products	17.15	6.91
Locally manufactured products	17.15	6.95

[a] Data from: Ministry of Commerce, Department of Internal Trade, Division of Industrial Goods 1, Bangkok, 1999.

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Résumé

Impact de l'Accord de l'Organisation mondiale du Commerce sur les ADPIC sur l'industrie pharmaceutique en Thaïlande

L'Accord sur les aspects des droits de propriété intellectuelle qui touchent au commerce (ADPIC) adopté en 1994 par l'Organisation mondiale du Commerce (OMC) a établi des normes minimales universelles dans tous les domaines de la propriété intellectuelle. Il est prévu de faire appliquer ces normes partout dans le monde par le biais d'un mécanisme approprié. Le présent article propose une stratégie pour atténuer les effets potentiellement négatifs de l'Accord sur les ADPIC en Thaïlande concernant les acheteurs, les prescripteurs et dispensateurs, les producteurs, les produits, le contrôle des prix, la délivrance de brevets à des tiers, les importations parallèles, le pouvoir des consommateurs, les nouveaux médicaments brevetables, le personnel et les politiques de prévention. Les dispositions ci-après de l'Accord sur les ADPIC intéressent tout particulièrement l'industrie pharmaceutique en Thaïlande : la durée limitée des brevets de produit et de procédé ; les conditions de la protection, et la large place donnée à l'octroi de licences obligatoires et aux procédures visant à faire respecter les droits dans le système national de brevets.

Resumen

Repercusión del Acuerdo sobre los ADPIC de la Organización Mundial del Comercio en la industria farmacéutica de Tailandia

En el Acuerdo de la Organización Mundial del Comercio de 1994 sobre los Aspectos de los Derechos de Propiedad Intelectual relacionados con el Comercio (ADPIC) se establecieron normas universales mínimas en todas las áreas de la propiedad intelectual. El acuerdo aspira a aplicar esas normas a nivel mundial mediante un mecanismo coercitivo de la OMC. En el presente artículo se propone una estrategia para paliar las repercusiones potencialmente negativas de los ADPIC en Tailandia en relación con lo siguiente: compradores; prescriptores y dispensadores; productores; productos; control de precios; patentes a terceros; importaciones paralelas; poder del cliente; medicamentos nuevos patentables; personal, y políticas de prevención. Las siguientes disposiciones de los ADPIC son pertinentes para la industria farmacéutica en Tailandia: la duración limitada de las patentes de productos y procesos; las condiciones de protección; y el amplio margen para el régimen vinculante de concesión de licencias y los procedimientos de vigilancia del cumplimiento en el sistema nacional de patentes.

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