IMPACT ON ACCESS TO MEDICINES FROM TRIPS-PLUS: A CASE STUDY OF THAI-US FTA

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Abstract. This study assessed the impact of the Thai-US Free Trade Agreement (FTA) on access to medicines in Thailand. We first interpreted the text of the sixth round of Thai-US negotiations in 2006 on intellectual property rights (IPR). The impact was estimated using a macroeconomic model of the impact of changes in IPR. The estimated impact is based on a comparison between the current IPR situation and the proposed changes to IPR. The FTA text involves the period of patent extension from the Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS Agreement). The provisions involve the period of patent extension, which have to do with compensation for delays in patent registration and/or drug registration, data exclusivity that would result in a delay in generic drug entry, and the enforcing role of the Thai Food and Drug Administration of patent linkages. As a worst case scenario for this single provision, a 10 year patent extension would be given to compensate for delays in patent registration and/or drug registration. The impact on access to medicine, in the year 2027, would be: 1) A 32% increase in the medicine price index, 2) spending on medicines would increase to approximately USD 11,191 million, (USD1= THB 33.9 on September 2, 2009), and 3) the domestic industry could loss USD 3.3 million. These results suggest there would be a severe restriction on the access to medicines under the TRIPS-Plus proposal. IPR protection of pharmaceuticals per the TRIPS-Plus proposal should be excluded from FTA negotiations.

Key words: free trade agreement, impact, access to medicines

INTRODUCTION

Trade liberalization is one of the manifestations of globalization. It includes multilateral, regional and bilateral agreements. Both its positive and negative effects are discussed in the literature (Bacchetta and Jansen, 2003; Taylor *et al*, 2007). An important point is reduction of barriers to trade will benefit some sectors in a country, but will be a financial detriment to others. Trade liberalization should lead to an increase in income, especially in developing countries (World Bank, 2002). Some sectors may have negative consequences, such as the area of public health (McMillan *et al*, 2002; Baker, 2004).

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Simultaneous participation by several countries in trade agreements results in increasingly complex agreements. From 1948 to 1994, the General Agreement on Tariffs and Trade (GATT) received 124 notifications of Regional Trade Agreements relating to trade in general products. Since the creation of the World Trade Organization (WTO) in 1948, until 2008 over 400 other arrangements covering trade in goods or services have been notified to the WTO (World Trade Organization, 2010). Developing countries have been confronted with the complex challenges of performing effective management of national development objectives, regional initiatives within the multilateral trading environment. Policy makers need to be aware of cross-cutting issues, such as protection of the environment, public health, the promotion of competition and technology transfer. These require the development of coherent trade, health and other public policies to ensure sustainable development.

The Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS Agreement), signed April, 1994 in Marrakesh, came into force in January, 1995 (World Trade Organization, 1995). The TRIPS Agreement outlines the minimum standards for protection and enforcement of Intellectual Property Rights (IPR) among member countries of the WTO. The agreement allows member nations to develop their own IPR laws to promote national interests. The IPR laws of each country must remain within the spirit of the agreement to balance the interests of the private producer with those of the public consumer. The areas covered by the TRIPS Agreement are: 1) copyright and related rights; 2) trademarks, including service marks; 3) geographical indications; 4) industrial designs; 5) patents; 6) layout-designs (topographies) of integrated circuits; and 7) undisclosed information, including trade secrets.

It should be noted that under the TRIPS Agreement, life-saving products, such as pharmaceuticals, are treated in the same way as other commodities. Numerous studies have shown the TRIPS Agreement can create problems with access to medicines (Supakankunti *et al*, 2001; Commission on Intellectual Property Rights, 2002; T'Hoen, 2002). While granting pharmaceutical patents encourages innovation, it also provides as monopoly for the patent owner that allows the pharmaceutical companies to maintain high pharmaceutical prices for a minimum of 20 years. The patents delay entry of lower cost generic drugs, which are needed by patients in developing countries (Bailey and Mayne, 2001).

Since the 2000s, some developed countries, particularly the United States and countries of the European Union, have tended to enforce higher-level intellectual property in developing countries, in what is called TRIPS-Plus. The Unites Sates has conducted FTA negotiations with several countries, including Australia, Bahrain, Chile, Morocco, the Southern Africa Customs Union countries and Singapore (Office of the United States Trade Representative, 2010). Developing countries are facing pressure regarding IPR protection from the FTA which could restrict access to essential medicines.

With a population of 66.25 million in 2008 (Bank of Thailand, 2010), Thailand has aggressively moved to globalization and international trade. The value of exports amounted to 30% of the GDP in 1997 and to 60% of the GDP in 2006. In 2006-2007, more than three-fourths of GDP growth came from net exports. In general, the health of the Thai economy has been

increasingly tied to the performance of the export sector (Thaicharoen and Ananchotikul, 2009). This large proportion of the economy relying on exports puts Thailand at risk for pressure from international, regional and bilateral trade agreements.

The Thai-US FTA negotiations began in June 2004. It encompasses 22 issues, covering trade in goods and services and investment. The latest round of talks (6th round) took place in Chiang Mai, Thailand, in January 2006; the discussion focused mainly on the issue of intellectual property. The negotiations are now currently on hold (Pratruangkrai, 2009).

Research regarding the potential implications of TRIPS-Plus on accessibility to essential medicines and the cost of medication in Thailand was performed by Akaleephan *et al* (2009). It aimed to estimate the magnitude of the impact of market exclusivity on medicine expenditures under the TRIPS-Plus model and to estimate the current potential cost savings and accessibility to medicines. The calculation was based on deriving the price differentials for 74 innovative drugs and their generics in a competitive market. They found in 2003, the availability of generics would help save 104.5% of actual costs and accessibility would increase 53.6%. Using market exclusivity, assuming 60 new drugs would be approved annually, the cumulative potential cost was projected to be USD 6.2 million for the first year and USD 5,215.8 million by the tenth year. (Akaleephan *et al*, 2009) However, only the top 74 international non-proprietary names accounting for 49.9% of sales were included in the study.

This study addressed the issue of intellectual property from a public health point of view in order to assist in drafting the text for Thai-US FTA negotiations and to assess the possible impact on pharmaceutical spending and the local drug industry caused by the proposal put forth by the US government during the sixth round of FTA negotiations in January 2006, particularly in regard to intellectual property and made public on the website Bilaterals.org (2006).

A principal concern for Thai policy makers is what type of impact the new IPR provisions could have on the price of medicines and pharmaceutical expenditures that could provide a barrier to access to medicines. Therefore, an objective of this study was to calculate the impact of the US trade proposals on Thailand's access to medicine based on the negotiations of the Thai-US FTA. Another objective of this paper was to explore a negotiation strategy to be used in the Thai-US FTA negotions by presenting the negative consequences of the US proposal on access to medicines in Thailand.

MATERIALS AND METHODS

This study calculated the impact on access to medicines under the specific conditions, including extension of patent rights for 2, 5, and 10 years and data exclusivity for 5 and 10 years. The extension of the patent period could result from a delay in patent approval, drug registration and/or a link between the patent and drug registration (Table 1).

Scenario modeling of the impact of the TRIPS-Plus provisions was based on the Model of Impact of Changes in Intellectual Property Rights (MICIPR) developed by Joan Rovira and jointly produced by the World Health Organization and the Pan-American Health Organization (WHO/PAHO Region) (Rovira J, 2007, personal communication). The MICIPR has been applied in different contexts to various

Table 1
TRIPS-Plus provisions of Thai-US FTA.

A principal concern is agreement to the new IPR provisions could increase the price of medicines, thereby reducing access to medicines. This could happen through the TRIPS-Plus patent provisions of the Thai-US FTA. When the United States trade representative (USTR) submitted the draft IPR text to Thailand during the sixth round of FTA negotiations in January 2006, TRIPS-plus provisions appeared in the US proposed text. (http://www.bilaterals.org/article.php3?id_article=3677)

Patent term extension

Article 7 requires Thailand to extend the patent term to offset unreasonable delays in either granting the patent or delays in approval for marketing the drug.

Patent Article 7

a. Each Party, at the request of the patent owner, shall adjust the term of a patent to compensate for unreasonable delays that occur in granting the patent. For purposes of this paragraph, an unreasonable delay shall at least include, a delay in the issuance of the patent of more than four years from the date of filing, of the application in the territory of the Party, or two years after a request for examination of the application, whichever is later. Periods attributable to actions of the patent applicant need not be included in the determination of such delays.

b. With respect to patents covering pharmaceutical products or methods of using pharmaceutical products;

i. each Party shall make available, an adjustment of the patent term to compensate the patent owner for unreasonable curtailment of the effective patent term as a result of the marketing approval process related to the first commercial use of a new pharmaceutical product in that Party; and

ii. where a Party approves the marketing of a new pharmaceutical product based on evidence of prior approval in another territory, including information on safety and efficacy submitted in connection with that approval, the Party shall make available an adjustment of the patent term to compensate the patent owner for unreasonable curtailment of the effective patent-term in the Party as a result of the marketing approval process in the other territory and in the Party.

Linkage of marketing approval process and the patent status of a drug

Article 4 obliges the drug regulatory authority in Thailand to notify the patent holder and inform the patentee when there is any attempt to register a generic drug. Therefore, the provisions would prevent or delay marketing approval of a generic drug and would impose an unnecessary burden on the drug regulatory authority in Thailand.

Measures Related to Certain Regulated Products in Article 4

Where a Party permits, as a condition of approving the marketing of a pharmaceutical product, persons, other than the person originally submitting safety or efficacy information, to rely on that information or on evidence of safety or efficacy information of a product that was previously approved, such as evidence of prior marketing approval in the territory of the Party or in another territory, that Party shall:

a. implement measures in its marketing approval process to prevent such other persons from marketing a product covered by a patent claiming the product or its approved method of use during the term of that patent without the consent or acquiescence of the patent owner; and

b. provide that the patent owner shall be notified of the identity of any such other person that requests marketing approval to enter the market during the term of a patent notified to the approving authority as claiming that product or any approved method of use.

Data exclusivity

The text has demanded Thailand to allow a period of data exclusivity for 5 years in pharmaceuticals and 10 years in agricultural chemicals. It means the regulatory authority cannot use the test data submitted by the originator during the period. Therefore, the regulatory authority cannot grant market approval to a generic on the basis of bio-equivalence or based on marketing approval of the original product in a foreign country.

Measures Related to Certain Regulated Products in Article 1

a. If a Party requires or permits, as a condition of granting marketing approval for a new pharmaceutical or new agricultural chemical product, the submission of information concerning safety or efficacy of the product, the Party shall not, without the consent of a person that previously submitted such safety or efficacy information to obtain marketing approval in the Party, authorize another to market a same or a similar product based on: i. the safety or efficacy information submitted in support of the marketing approval; or ii. evidence of the marketing approval; for at least five years for pharmaceutical products and ten years for agricultural chemical products from the date of marketing approval in the territory of the Party.

b. If a Party requires or permits, in connection with granting marketing approval for a new pharmaceutical or new agricultural chemical product, the submission of evidence concerning the safety or efficacy of a product that was previously approved in another territory, such as evidence of prior marketing approval in the other territory, the Party shall not, without the consent of a person that previously submitted the safety or efficacy information to obtain marketing approval in the other territory, authorize another to market a same or a similar product based on: i. the safety or efficacy information submitted in support of the prior marketing approval in the other territory; or ii. evidence of prior marketing approval in the other territory; for at least five year for pharmaceutical products and ten years for agricultural chemical products from the date of marketing approval of the new product in the territory of the Party.

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countries, including Colombia (2005, 2006, 2007), Guatemala (2005), Costa Rica (2005), Bolivia (2006), Costa Rica (2008), the Dominican Republic (2008) and Uruguay and Argentina (Ernesto *et al*, 2009). The basic principle underlying the model was to compare two specific scenarios. The first scenario, which is a baseline scenario, reflects the pharmaceutical market conditions in Thailand under given IPR conditions during a specific baseline year. This baseline scenario is then compared with

alternative scenarios that simulate market evolution due to changes in IPR. The model is a relatively simple EXCEL spreadsheet, the results are calculated based on the values of important variables.

In this study, the TRIPs Agreement was considered as the basic scenario. The alternative scenarios were constructed by introducing TRIPs-Plus provisions set out by the Thai-US FTA proposal.

Model assumptions

The key assumptions of the model are:

1. A constant price differential between an active ingredient (AI) under exclusivity and an AI under competition. The price of an AI would be higher under exclusivity than under competition.

2. The price of the AI immediately falls from the average exclusivity price to the average competitive price when the period of exclusivity expires. It is assumed this assumption would not dramatically affect the results of the model.

3. A constant price elasticity demand function is assumed.

4. The AI has the same market share throughout the entire product life.

5. The market share of the domestic and the innovative industry remains constant over time. Therefore, the variation in the share of the total market held by the domestic industry is directly related to variations in the relative size of these two markets.

Model operation

Defining the time horizon of the application. The initial year in this study was 1992, when the IPR for Thailand was changed from process patent to product patent. The final year was 2042, which was long enough to capture the full effect of the changes and reach a point where stabilization takes place.

Calculating the proportion of AI under market exclusivity. MICIPR calculates the number of existing AI on the market each year starting from the number of AI in 1992. For 1993 and other years, the number of AI was calculated by adding the number of AI entering the market and subtracting the number of AI leaving the market.

MICIPR calculated the number of AI with patent-protection exclusivity on the market. The number of AI with patent-protection exclusivity was computed by adding the number of those entering the market with patent protection and subtracting the number of AI that lose exclusivity protection each year. MICIPR assumes that if the product patent is introduced in year i, the first AI to enter the market with patent exclusivity will do so in year i plus the average time period between patent filing and market entry.

The exclusivity period was computed by adding the period required for the TRIPS-Plus provisions of the FTA to the original period of effective patent protection. The TRIPS-Plus provisions of the FTA that required patent term extensions beyond the 20 years of TRIPs Agreement were translated in terms of IPR changes as follows:

1) Provisions which require Thailand to provide extension of a patent term from 20 years, plus 2, 5, or 10 years, due to compensation for "unreasonable" delays in the granting of a patent or approval for marketing of the drug (patent term extensions).

2) Provisions which prevent or delay marketing approval of generics for 2, or 5 years due to a link between drug registration and patent status that would impose an unnecessary burden on the Thai drug regulatory authority and an unnecessar-

ily restraint on the entry of generic medicines.

3) Provisions which allow a period of "data exclusivity". This means the Thai drug regulatory authority cannot approve for marketing a generic equivalent of another drug by relying on the test data submitted by the innovative drug company. The additional period required for generics to enter the market would be 5, or 10 years due to data exclusivity. Therefore, the generic company would have to complete the registration trials before marketing approval. The provision may also limit the effectiveness of the compulsory licensing system for preventing the drug regulatory authority from registering a generic drug produced under a compulsory licence.

MICIPR calculated the periods of exclusivity for different AI groups that enter the market each year and the number of AI that would be under patent exclusivity each year.

MICIPR calculated the total number of AI in the situation of exclusivity. It also calculated the proportion of AI in exclusivity versus the total AI on the market. It was assumed the patent term extension under TRIPS-Plus did not increase the market power of each AI.

The previous procedures were repeated for all scenarios.

Calculating the impacts on expenditure and domestic production. The expenditure or value of the market (in real terms) in the baseline scenario was calculated using a constant growth rate of 12% for expenditure during the initial year.

Calculation of the expenditure for each of the alternative scenarios was performed as follows:

1) MICIPR calculated a price index for the alternative scenario for each year. The price index for the baseline scenario of each year was equal to one. The index for an alternative scenario in year(i) reflects the weighted price differentials between: AI with and without exclusivity, and between AI sold as branded generics and international non-proprietary name (INN) generics.

2) A constant price-elasticity demand of -0.01 was determined to calculate the impact of increasing the price index would have on the quantity consumed and on expenditure.

MICIPR calculated the value of sales for the domestic industry on the market, assuming the domestic industry had a fixed market share in the segments under exclusivity of 0% and under competition of 85%. These market shares were assumed constant over time.

RESULTS

The findings for all 35 scenarios demonstrated a negative impact on the pharmaceutical market, particularly for increasing drug expenditures, reducing access to medicines, and shrinking of the domestic pharmaceutical industry.

Impact of the worst scenarios of the US proposal

Comparison of the single provisions of the US proposal revealed the scenario that resulted in a 10 year patent extension would have the greatest negative impact.

The study found if a 10 year patent extension were given in compensation for delays in patent registration and/or drug registration, it would cause the following negative consequences over the next 20 years (in 2027): a 32% increase in the price index for medicines; spending on medicines would increase from baseline to

approximately USD 11,191 million; the domestic industry would lose USD 3,370 million.

Regarding the triple provisions of the US proposal: a 10 year patent extension due to compensation for delays caused by regulatory approval processes or by the granting of a patent, a 5 years delay in generic entry due to a link between drug registration and patent status, and a 10 year delay in generic entry due to data exclusivity, the following results over the next 20 years (in 2027) would be seen: 67% of medicine prices would increase from the baseline scenario; pharmaceutical expenditures would increase to USD 23,595 million; the domestic industry could lose USD 9,000 million.

Impact on pharmaceutical expenditures by individual provisions of the US proposal

Comparing the negative impact of extension of the patent term with data exclusivity, the results varied depending on the time frame. In the next 5 years (in 2013), the economic impact would be USD 2,400 million, which is greater than the impact for a 5 year extension of the patent term, resulting in an impact of USD 821 million. Over 15 years (in 2023) the economic impact of the 5 year extension of data exclusivity would be USD 3,713 million, less than the impact of a 5 year extension in the patent term, which would be USD 4,039 million (Fig 1).

Data exclusivity had a more negative impact than a situation where a new drug had no patent or the existing patent term was shorter than the data exclusivity period.

To assess the impact of data exclusivity MICIPR was conducted based on the following assumptions:

1) The patent term for newly patented drugs remains at 14 years, which is longer than a market exclusivity period of 5 years and 10 years for data exclusivity.

2) The number of new drugs (new originals and new generics) coming to the market annually is constant.

3) A new patented drug is marketed once every 3 years.

4) This model does not include the parameter of government use of a drug patent.

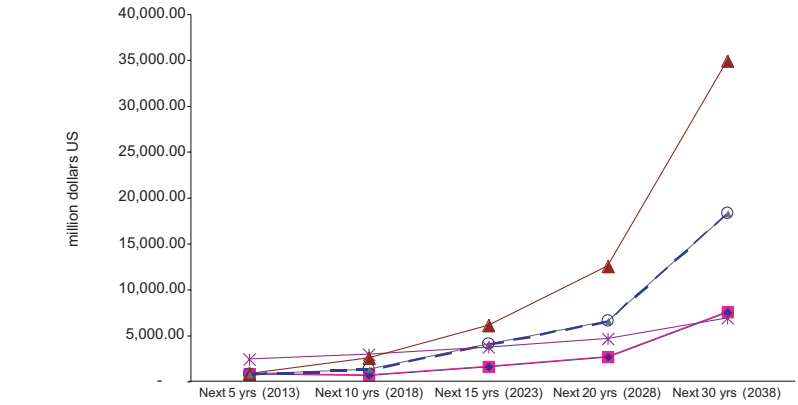
From these assumptions, the data exclusivity will not extend a market monopoly after 2054, 50 years from now. This will occur because all new drugs would be patented.

In cases of extension of patent term by 2, 5, or 10 years, the extension periods resulted in a monopoly. The extension of patent terms can also affect the IPR and the drug system, which would then have be balanced and checked by the system administration. The study did not cover other consequences from this factor.

In cases of market monopoly due to data exclusivity, the study shows the results may vary. If the patented drugs came to market faster, the period of market monopoly due to data exclusivity may not extend the life of the patent. However, if the government decides to implement government use, data exclusivity will limit the Thai Food and Drug Administration's ability to register such generic drugs.

DISCUSSION

The MICIPR must be considered as a guide to anticipate what might happen with the introduction of new IPR provisions. Though it is not an accurate prediction of the future, the relatively simple nature of the model makes it more easily understood by policy makers, allows for several specific scenarios and the assump-



	Next 5 yrs (2013)	Next 10 yrs (2018)	Next 15 yrs (2023)	Next 20 yrs (2028)	Next 30 yrs (2038)
Delay 2 yrs	822.51	708.02	1,629.38	2,691.71	7,531.68
Linkage 2 yrs	822.51	708.02	1,629.38	2,691.71	7,531.68
Delay 5 yrs	822.51	1,371.50	4,039.00	6,533.98	18,282.39
Linkage 5 yrs	822.51	1,371.50	4,039.00	6,533.98	18,282.39
Data exclusivity 5 yrs	2,399.88	2,874.40	3,713.51	4,613.27	6,886.34
Delay 10 yrs	822.51	2,476.70	6,056.25	12,483.19	34,820.03

The first year of the impact calculation is 2008

Fig 1– Estimated trend in pharmaceutical expenditures, by individual provisions of the US proposal.

tions employed are reasonable, putting the data in the hands of decision makers. A disadvantage of the simplicity of the model is that it makes assumptions that fail to mirror the complexities of the relationships between variables in the real world, for example, the price differential of a product before and after going off patent, and the constant price elasticity of demand. In the aggregate model, which combines a multiplicity of products and a multiplicity of distribution channels, it is usually difficult to estimate realistic values for key variables. Accordingly the results need to be considered as indicative rather than precise.

Many countries signed or are engaged in negotiations to extend trade agreements, including bilateral agreements, economic partnership agreements (EPAs), etc. Such agreements have extensive implications for pharmaceutical patent protection, which can directly impact access to medicines. The TRIPS-Plus provisions in the FTA undermine important safeguards and required flexibilities that developing countries seek to preserve under the TRIPS Agreement. This study indicates TRIPS-Plus proposals of the Thai-US FTA will increase medicine prices, since they delay or restrict the introduction of generic competition, they extend patent terms, they introduce data exclusivity, they incorporate patent linkages between drug registration and patent approval, and create new enforcement mechanisms for IPR.

The negotiation strategies used in the Thai-US FTA include: informing interested organizations about the impact of the FTA, preparing negotiators from Thailand who have knowledge regarding the impact on access to medicine, and preparing a patent database containing the completeness of patent status. Additional strategies include establishing cooperation between the Intellectual Property Department and the FDA. The negotiation process must be transparent and open to the public. Strong evidence should be used for FTA negotiations with the USA.

The strategies associated with a drug patent include: (1) measures to improve the mechanism of monitoring patent status, and examing the correctness, reliability and appropriateness of the patent; (2) the development of guidelines for IPR staff for examining patent applications; (3) improvement of the drug patent database to identify patent status more easily, rapidly and completely; and (4) amendment of the patent act to expedite access to medicine.

The strategies to address the negative consequences of the FTA that affect the access to medicines are based on the four elements of the drug system: drug selection, drug procurement, drug distribution, and drug use. The impact on patients and their participation should be considered and included in the following 6 strategies, which are: (1) a strategy of pharmaceutical research and development; (2) a strategy of drug pricing; (3) a strategy of local drug manufacturing; (4) a strategy of rational drug use; (5) a strategy to support the gathering of patients who have the same illness; and (6) a strategy to network with advocacy groups for access to medicine.

ACKNOWLEDGEMENTS

This study was funded by the Food and Drug Administration, Ministry of Health, Thailand. The authors would like to thank Joan Rovilar for providing the program and suggestions.

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