

POTENTIAL IMPACT OF TRIPS-PLUS PROVISIONS ON MALAYSIA'S DOMESTIC PHARMACEUTICAL INDUSTRY

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ABSTRACT: *Trans-Pacific Partnership Agreement (TPPA) which is now known as the Comprehensive and Progressive Agreement on Trans Pacific Partnership (CP-TPP) opens door of opportunities as well as challenges to Malaysia. The agreement has become subject of heated debate in Malaysia as well as other countries due to the reason that it may bring some new elements which are not in the other earlier Free Trade Agreements (FTA) on which Malaysia has signed. One of the key concern is the possibility of including WTO-Plus commitments in the agreement which is TRIPS-Plus element which may affect access to medicine and the local pharmaceutical industry. This study focuses on one issue that is on the potential impact of TRIPS-Plus provisions in the intellectual property chapter on Malaysia's pharmaceutical domestic industry sales. In assessing the potential impact of the TPPA on Malaysia's pharmaceutical industry, simulation exercise using Model of Impact Changes in Intellectual Property Rights have been undertaken. The finding of the study indicates that domestic pharmaceutical industry sales may drop if data exclusivity, patent term restoration and patent linkage is being implemented.*

Keywords: TRIPS-Plus, TPPA, data exclusivity, patent linkage, patent term restoration, Malaysia, Pharmaceutical Industry

1. INTRODUCTION

The Trans-Pacific Partnership Agreement (TPPA) that was finally concluded on 5th October 2015 is viewed by some as a strategic step towards achieving high income nation status by 2020. TPPA is ambitious and comprehensive trade agreement and there has been a lot of controversy and debate on this mega-trade deal. Some argue that the TPPA is more geopolitically motivated and that there is no much economic advantage that can be gained from the deal while some other suggest the potential benefits that Malaysia would gain from TPPA will outweighs its costs. The proponents argue that the free trade agreement between countries across the three continents would create a deeper integration and obtain greater market access in the TPPA member nations, as well as to serve as a stepping stone in penetrating the Latin American market.

The issue on the effect of the TPPA on access to affordable medicines in Malaysia is among the most contentious one. The TRIPS-plus elements if included in the recent agreement on intellectual chapter are believed to bring adverse effects to medicine prices, medicine expenditure and domestic pharmaceutical industry sales. Patent linkages, patent term restoration and data exclusivity are among the subject of heated debate in the media.

This study intends to analyze one of the sector that might be affected which is the pharmaceutical industry. In addition, this study is being conducted to fill in the gaps in the literature as there is limited study has been undertaken to date. In assessing the potential impact of the TPPA on Malaysia's domestic pharmaceutical industry, simulation exercise using Model of Impact Changes in Intellectual Property Rights have been undertaken.

2. LITERATURE REVIEW

The reform in intellectual property chapter of the FTA is expected to cause innovation due to the protection given to inventors. The TRIPS-Plus elements in the FTA agreements lead to the strengthening of intellectual property protection. TRIPS-Plus Agreement is a higher level of protection than the TRIPS Agreement normally negotiated by developed nations in their recent FTA negotiation. In TRIPS-Plus agreement, signatory countries are normally required to sign nine international treaties related to intellectual property, to implement provisions like data exclusivity, extension of copyright term of protection, patent term restoration, patenting of diagnostic, therapeutic and surgical methods, patent linkage, compulsory licensing and certain other copyright provisions in the intellectual property chapter. These provisions are not found in the existing TRIPS agreement. Strengthening intellectual property protection is expected to benefit drug innovators.

Elements in TRIPS-Plus such as drug exclusivity, would give assurance to the manufacturer of originator's product that they will be granted protection period for their effort in inventing or drug testing. Patent linkages will prevent the entry of infringing medicines during the patent term. Patent term restoration will give compensation to the patent holder for any unnecessary delay in patent or drug registration. All this consequently is expected to cause an increase in research and development specifically in the development of medicines for diseases which might be crucial in developing country, makes the availability of new medicines even faster, rise in foreign direct investment and technology transfer [1 and 2].

On the other hand, there are many studies which highlight the adverse effects that TRIPS-Plus provisions may bring. This section highlights some past studies which are related to the studies which attempted to assess to the impact of TRIPS-Plus provision on medicinal or pharmaceutical related areas. Table 1 gives the summary of studies being reviewed.

Table 1: Studies which attempted to assess to the impact of TRIPS-Plus provision on medicinal or pharmaceutical related areas.

| Study | Author | Results |
|--|--------|---|
| The effect of new possible patent systems under TPPA on the cost of health care with specific reference to HIV treatment in Vietnam. | [3] | with TRIPS flexibility, 82% of HIV patients can have antiretroviral (ARV) therapy. Under TPPA (TRIPS-Plus) it is expected only 30% of HIV patients who can have access to ARVs. |
| The effects of patent in Australia. | [4] | patent term restoration is estimated to increase the expenditure for: Pharmaceutical Benefit Scheme from about AUS\$6 million in 2001 to 2002 period to AUS\$160 million in 2005 to 2006 period. The cost further increase in 2012-2013 period where it is about AUS\$240 million. |
| Impact of having data exclusivity provision on a drug called colchicine | [5] | after data exclusivity being enacted: price of colchicine have increased by more than 5 times in the US. |
| Effects of TRIPS-Plus on access to medicines based on the proposed US-Thai FTA | [6] | there will be an increase in medicine price index by 32%, medicines spending and domestic industry would incur loss more than USD 3 million |
| Potential implications of TRIPS-Plus on the cost of medication and accessibility to essential medicines in Thailand. | [7] | in 2003, the availability of generics is expected to save 104.5% of actual costs and 53.6% increase in accessibility and it is forecasted that cumulative potential cost is USD 6.2 million for the first year and USD 5,215.8 million by the tenth year under market exclusivity |
| The impact of Central America Free Trade Agreement on access to generic drugs in Guatemala. | [8] | CAFTA intellectual property rules reduced access to some generic drugs already on the market and create barrier for the new entry of generics medicine, several protected drugs are available as generics in the United States before generic versions are legal in Guatemala. Data exclusivity caused several medicine prices to increase up to 846 %. |
| How TRIPS-Plus intellectual property rules in the US-Jordan FTA affect access to medicines. | [9] | Since 2001, medicine prices increased by 20%. Data exclusivity has created barrier for 79% of generic medicines newly launched by 21 multinational pharmaceutical companies between 2002 and mid-2006 and additional |

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|--|------|---|
| | | expenditures for medicines worth between USD6.3 million and USD 22.04 million without generic alternative, due to data exclusivity by multinational companies. |
| Possible impact of the US-Peru FTA on access to medicines due to data exclusivity provision | [10] | it is expected that 700,000 to 900,000 people cannot afford to buy medicines in the first five years to sustain the access to medicines, the Peruvians need to spend an extra of US\$34.4 million in the first year and household and Ministry of Health would have to increase their expenditure by US\$28.9 million and US\$1.6 million respectively. |
| Impact of the EU-Andean trade agreement on access to medicines in Colombia | [11] | In 2025, data exclusivity and supplementary patent protection (SPC) policies would cause total pharmaceutical expenditure to rise by US\$ 756 million, price is also estimated to increase by 16 % and aggregate medicinal consumption is projected to drop by 10 %. |
| Effects of patent term extensions on research and development and drug expenditures in Canada. | [12] | Extension of patent terms combined with other price controls and the retrenchment of public prescription drug subsidy programs have caused spending on research and development to increase by US\$4.4 billion and medicine spending to rise by \$3.9 billion. |

The literature review shows that, TRIPS-Plus has affected the access to medicine in some countries. In addition, specifically in Thailand, the work of Kessomboon [6] shows that domestic industry would incur loss more than USD 3 million.

In sum, there is limited study to date which attempted to assess the potential impact of TRIPS-Plus on pharmaceutical industry in developing country. This study shall fill in the gap in the literature.

3. OBJECTIVE OF STUDY

The objective of the study is:

>To analyze the potential effects of three TRIPS-Plus provisions (i.e. patent term restoration, patent linkages and data exclusivity) on Malaysia's domestic pharmaceutical industry sales.

4. METHODOLOGY OF STUDY

It is expected that strengthening intellectual property rights protection under the TPPA would have 3 key impacts which are namely medicine price, pharmaceutical/medicine expenditure and domestic pharmaceutical industry sales. Only the impact on domestic pharmaceutical industry sales is estimated in this study using a scenario model method based on the Macroeconomic Model of Impact Changes in

Intellectual Property Rights (MICIPR) developed by Rovira [1, 2, 6 and 13]. The MICIPR has been used in different contexts to various countries like Colombia, Guatemala, Costa Rica, Bolivia, Costa Rica, the Dominican Republic [6], Uruguay and Argentina [15] and Thailand [6].

Changes in IPR may cause changes in the degree of competition. As monopoly power increases, the price may also change. Hence, if stronger IP protection is implemented, it may cause price to rise. Increase in price will eventually lead to the increase in pharmaceutical expenditure.

The estimated impact using MICIPR is based on comparison between the present intellectual property rights (IPR) regime and the possible IPR regime under the TPPA. The principle underlying the model is to compare baseline and alternative scenarios. The baseline scenario or current scenario indicates the IPR condition in Malaysia under TRIPS regime while alternative scenario is the possible/expected IPR provision under the TPPA.

It is important to note that the possible/expected IPR provisions assumed here are not necessarily the true IPR provisions under actual TPPA or CP-TPP since there are provisions or elements that might be suspended. The study takes into account 3 provisions of the IP chapter that are directly related to pharmaceutical industry. Considering that in the model, given both the current and alternative scenario, the model simulates the effect of TRIPS-plus on domestic pharmaceutical industry.

In this study, MICIPR computes the number of medicines registered in the market each year starting from the number of medicine registered in 2006. For 2007 onwards, the number of medicine is computed by adding the number of medicine entering the market and subtracting the number of medicine exiting the market. The model also calculates the number of medicine with patent-protection exclusivity in the market by summing the number of those entering the market with patent protection and subtracting the number of medicine that lose exclusivity protection every year. The exclusivity period is computed by summing the original period of patent protection with the additional period granted by the three TRIPS-Plus provisions of the FTA.

Under market exclusivity, total number of medicines under exclusivity is the sum of those under patent protection and those under new provisions' protection. It is necessary to express and quantify the amendment in the provisions of IPR and other pharmaceutical policies in mathematical forms. Hence, the quantitative form of expression is used and the mathematical equation are not shown here but using the one as depicted in Rafiq [2].

The three TRIPS-Plus provisions of the FTA that results patent term extensions more than 20 years of TRIPS' Agreement are:

- 1) plus 10 years compensation as a result of delays in the granting of a patent or approval for marketing of the medicine [6]
- 2) prevent or delay marketing approval of generics for 1 year due patent linkages.
- 3) additional period of 5 years due to data exclusivity [6]

The model attempts to assess the impact on domestic pharmaceutical industry sales by computing the difference in domestic industry market sales under alternative scenario and baseline scenario. The equations take into account the proportion of market under exclusivity and competition for

both the baseline and the potential TPPA scenario.

The bigger the proportion of market under competition in current scenario, the larger will be the impact on total domestic industry sales as a result of alternative scenario.

This happens because larger number of people is dependent on generics medicine in baseline scenario. As prices increase and generics manufacturer are not allowed to sell new generics products, people becomes less afford to purchase expensive medicines. Hence, sales of domestic pharmaceutical industry will drop.

Seven scenarios are being simulate in this study and they are [2]:

- a. Scenario 1: Have patent term restoration provision
- b. Scenario 2: Have patent linkages provision
- c.. Scenario 3: Have data exclusivity provision
- d. Scenario 4: Have patent term restoration and patent linkages provision
- e. Scenario 5: Have patent term restoration and data exclusivity provision
- f. Scenario 6: Have patent linkages and data exclusivity provision
- g. Scenario 7: Worst case scenario (having all 3 provisions)

To sum up, changes in IPR are expected to cause changes on the welfare of society. The effects on welfare can happen in a different ways such as changes in price level, expenditure and gain/loss to domestic pharmaceutical industry. However, the estimated changes in domestic pharmaceutical industry sales here take into account only three TRIPS-Plus provisions. Other factors not in the model such as changes in energy price which may affect price are not taken into account. The details of the complete methodology is as depicted in [1, 2].

5. FINDINGS

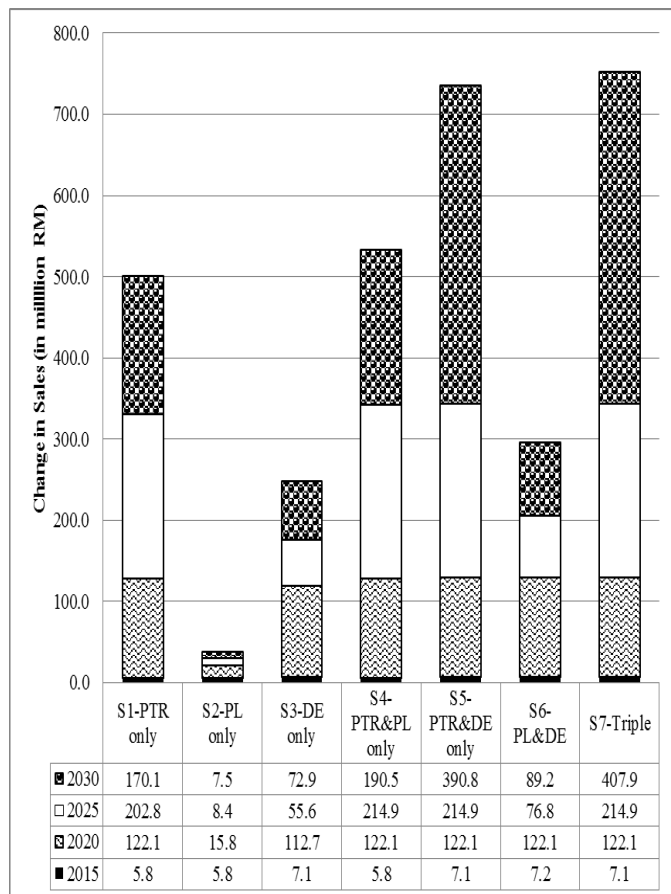
For the impact on domestic pharmaceutical industry, the effect differs across various combination of provisions imposed and it depends on period of compensation given to patent holder. In terms of single provision, it is evident that patent term restoration produces the biggest impact on domestic medicinal industry as compared to other single provision. This is followed by data exclusivity and patent linkages.

By comparing all possible provisions combination, as expected, triple provisions (scenario 7) or implementing all three provisions produce the most severe impact on domestic pharmaceutical industry. This is followed by the combination of patent term restoration and data exclusivity (scenario 5), the combination of patent term restoration and patent linkages (scenario 4), patent term restoration provision only (scenario 1), the combination of patent linkages and data exclusivity (scenario 6), data exclusivity provision only (scenario 1) and patent linkages only (scenario 2).

Figure 1 compares the different potential impacts produced by different IP provisions on Malaysia's domestic medicine industry sales. The drop in domestic medicine sales is forecasted to continue even after 15 years of implementation. Consequently, it results to potential budgetary burden on both government and private consumers who have to consume some patented originators medicine due to delay in the entry of generic medicines.

Local generic medicines manufacturers have to wait until extra period of protection expires. Additional funds will have to be allocated by the government or taken out of consumers' pocket then to meet future needs. The value in figure below shows a decline even though a negative sign is not shown in the figure.

Figure: Impact on Malaysia's 5.11 Domestic Pharmaceutical Industry in 7 different scenarios



6. DISCUSSION

All the scenarios are expected to affect medicine access adversely. However, it is to be noted many medicines are not affected to these possible provisions. This is due to the fact that many medicines used widely in the hospitals are off patent medicines, hence not affected by those provisions. Many medicines which the general public consume have no patent protection

7. CONCLUSIONS

The implementation of TRIPS-Plus may cause domestic pharmaceutical industry sales to drop in the future. The severity of the impact depends on the years of extra protection due to new provisions given to patent holder. The longer the compensation period the severe would be the impact. The estimation in this study is based on its assumption and those mention in the work of Rafiq [13]. The idea is to estimate the direction of sales, increase or decrease and not really how much on the actual drop.

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