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Original Research Article

'Patent Linkage: Possible Impact on Malaysia's Access to Medicine'

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Abstract: Free Trade Agreement (FTA) is an agreement which being argued as to bring many economic benefits to signatory countries. FTA generally aims at removing trade barriers and this lead to the free movement of goods and services between member countries. Indeed, FTA will give greater access to member countries economy. Despite the potential benefits that it may bring, analysts have cautioned on the negative effect that FTA may produce. The areas of coverage in recent FTAs which include chapter on intellectual property have become subject of heated debate. Among the issues being highlighted is the introduction of many new provisions in recent FTAs involving developed nations which are not in the Trade Related Aspect of Intellectual Property Rights (TRIPS) Agreement. Provisions like data exclusivity, patent term restoration and patent linkage are debated to bring adverse effects on a country's access to medicines. In relation to Malaysia's recent participation in FTA which involves developed country such as the Trans Pacific Partnership Agreement (TPPA), this study attempts to examine the impact of patent linkage only on access to medicine in Malaysia. The impact of this provision on medicine price and medicine expenditure in Malaysia is estimated using Model of Impact Changes in Intellectual Property Rights. This paper attempts to systematically examine the impact of Patent Linkage on Medicine Access and fill in the research gap on this area of study.
Keywords: Free Trade Agreement (FTA), Patent Linkage, Access to Medicine, TRIPS-Plus.

INTRODUCTION

Free Trade Agreement (FTA) is a degree of economic integration on which signatory countries agree to allow freer movement of goods and services between them. Many countries have signed FTA in the past 2 decades to integrate economy of member countries and for other benefits that it would gain. On this regard, Malaysia is not an exception. Malaysia has signed more than 12 trade agreements both bilateral and regional FTA. Indeed, FTA gives greater access to partner countries' economy.

Despite the benefits that FTA may bring many have cautioned on the possible effects of FTA. Recent FTA negotiations involving developed nation are reported to be more comprehensive and includes many areas. New potential areas such as government procurement and intellectual property are also reported as to be in the FTA.

In February 2016, Malaysia announced that together with eleven other negotiating members, they have signed the Trans Pacific Partnership Agreement (TPPA). Malaysia's involvement in the TPPA has become a subject of heated debate in the media. There are many issues being highlighted. One of them is on intellectual property chapter.

Under intellectual property chapter, it is alleged that there are many new potential provisions such as data exclusivity; patent term restoration and patent linkage are to be introduced. This paper intends to investigate on the possible impact of patent linkage regardless to be introduced in TPPA or not on access to medicine.

Patent linkage refers to a provision under intellectual property chapter of a Free Trade Agreement (FTA) on which it requires drug control authority to inform patent holder if there's any attempt to apply for marketing approval by generic manufacturer. Some recent FTAs involving developed nations have this provision in their FTA. Patent linkage is a provision which is not found under the Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement. It is known to be an element in the so called TRIPS-Plus.

The provision gives an extra burden to drug control authority to inform patent holder if there's any such attempt. This implies that patent linkage prohibits the earlier marketing approval application and hence it can only be made once normal patent term expires. In Malaysia both product registration and marketing approval takes about less than a year.

The followings give out the details on the time taken to register medicine in MalaysiaSource: BPFK Website [15]

- Prescription drugs: 210 days
- Non-Prescription drugs: 210 days
- New drugs and biological: 245 days

Therefore, it is assumed that generic drugs entry will have to delay for about one year after normal patent term expires.

In relation to this, there is a developing body of literature that discuss the impact of TRIPS-Plus on access to medicines. Various studies have attempted to assess the impact of Trips-Plus provisions on medicine access. Many studies have shown that these provisions produce negative impact on medicine access (Pan-American Health Organization, 2005;Peru's Ministry of Health, 2005;Health Ministry of Peru, 2005 [2];Gamba, 2006 [3]; Serna, 2006 [4]; Akaleephan*et al.;*[5] 2009;IFARMA, 2009 [6]; and Shaffer and Brenner, 2009 [7]; Kessomboon *et al.;*2010 [8]; Moir *et al.;*2014 [9]; Gleeson *et al.;*2015 [10]; Rafiq Idris, 2015) [11]. In addition, there is limited amount of empirical study which attempt to assess the impact of patent linkage on access to medicine. This study intends to fill in the research gap at least on assessing the impact of patent linkage for Malaysia's case. The next section explains the study methodology. The following section reports the findings. The subsequent section is the discussion section and the final section gives a concluding remark.

METHODOLOGY

This study uses Model of Impact Changes of Intellectual Property Rights (MICIPR) introduced by Rovira (2008) [12] to assess the impact of patent linkage on access to medicine. Impact on access to medicine here means the effect of patent linkage on medicine price and medicine expenditure.

MICIPR is a scenario modelling which compare present intellectual property rights (IPR) regime and the new IPR condition with patent linkage. The principle underlying the model is to compare two scenarios which are namely the baseline and alternative scenario. The baseline scenario or current scenario indicates the IPR condition in Malaysia under TRIPS regime while alternative scenario is the possible/expected IPR provision with the inclusion of patent linkage. Hence, the simulation exercise is basically trying to examine the impact of patent linkage which means one year delay in generic medicine entry on medicine access. The model has several assumptions. The model assumptions are as follows:

1. Price difference between medicine under exclusivity and under competition is constant.
2. Price elasticity demand function is constant.
3. In the whole product life, medicine has the same market share.
4. Market share of the domestic and the innovative industry are not equal and is the same over time.

The first year of the simulation exercise is 2006 while final year is 2030. The year assumed on which the patent linkage provision is implemented is 2015. The methodology applied here and type of data used is similar to the model being discussed in Rovira (2008) [12] and being applied in the work of Kessomboon *et al.;*(2010) [8]. The data being used in the simulation exercise is based on assumptions and data obtained from various sources such as from BPFK Annual Report (various year annual reports), Malaysia Pharmaceuticals & Healthcare Report, Q4 2010 (Business Monitor International, 2010) [13] andBPFK website [14, 15].

The simulation is conducted in 5 different scenarios. The difference between scenarios is the percentage of expiring medicine patent product assumes to be affected by patent linkage provision. Below are the alternative scenarios assumed on this study?

Scenario 1: All expiring medicine patent to be affected by patent linkage provision
Scenario 2: 50% of expiring medicine patent to be affected by patent linkage provision
Scenario 3: 20% of expiring medicine patent to be affected by patent linkage provision
Scenario 4: 10% of expiring medicine patent to be affected by patent linkage provision
Scenario 5: 1% of expiring medicine patent to be affected by patent linkage provision

RESULTS

The effect of patent linkage on medicine price in all the five scenarios is not that severe. The results based on the simulation exercise conducted indicates that the effect of this provision on price is less than 3percent even after 15 years of implementation in 2030 assuming other factors to be constant. As expected, the impact on medicine price is greater when all expiring medicines' patentis subject to patent linkage (scenario 1). Table 1 shows the findings.

Table 1: Impact on Medicine Price Index (% change)

Year	Impact on Medicine Price Index (%)				
	Scenario 1 (100%)	Scenario 2 (50%)	Scenario3 (25%)	Scenario 4 (10%)	Scenario 5 (1%)
2007	0.00%	0.00%	0.00%	0.00%	0.00%
2014	0.00%	0.00%	0.00%	0.00%	0.00%
2015	0.66%	0.33%	0.17%	0.07%	0.01%
2020	1.74%	0.87%	0.44%	0.17%	0.02%
2021	1.55%	0.77%	0.39%	0.15%	0.02%
2022	1.10%	0.55%	0.27%	0.11%	0.01%
2023	1.12%	0.56%	0.28%	0.11%	0.01%
2024	1.07%	0.53%	0.27%	0.11%	0.01%
2025	1.14%	0.57%	0.28%	0.11%	0.01%
2026	2.20%	1.10%	0.55%	0.22%	0.02%
2027	1.52%	0.76%	0.38%	0.15%	0.02%
2028	1.17%	0.59%	0.29%	0.12%	0.01%
2029	1.22%	0.61%	0.31%	0.12%	0.01%
2030	1.11%	0.56%	0.28%	0.11%	0.01%

Table 1indicates that under worst case scenario that is when the study assume that all expiring medicine patent are subject to patent linkage provision, price of medicine increase to as high as 2.2% more in 2026 than the price in baseline scenario, assuming other factors to be constant. This results imply that the inability of generic manufacturer to apply for marketing approval before normal patent period expires which results the late entry of generic medicines for about one year does not affect price that much.

On the effect of patent linkage on medicine expenditure, the studyfinds that under worst scenario that is when the study assumes that all patent expiry medicine are subject to this provision, medicine expenditure is expected to increase by about RM 334 million than the projected medicine expenditure in year 2026. The impact is substantial when all expiring patented medicines are subject to patent linkage.

Table 2: Effect Projection of Patent Linkage on Medicine Expenditure (increase in Malaysian Ringgit-RM)

Year	Impact on Medicine Expenditure (increase in RM)				
	Scenario 1 (100%)	Scenario 2 (50%)	Scenario 3 (25%)	Scenario 4 (10%)	Scenario 5 (1%)
2007	-	-	-	-	-
2014	-	-	-	-	-
2015	44,044,466	22,022,596	11,011,389	4,404,577	440,459
2020	169,056,364	84,531,832	42,266,833	16,906,954	1,690,709
2025	160,837,384	80,420,968	40,211,055	16,084,559	1,608,464
2026	334,726,249	167,372,223	83,688,399	33,475,910	3,347,624
2030	228,838,089	114,422,210	57,211,899	22,884,950	2,288,506

Table 2 suggests that when more medicines are subject to this provision the more severe the effect is. It extends monopoly power to patent holder, causes a budgetary pressure on the government as well as private consumers and narrowpolicy space on the part of government. It eventually affects the access to medicine in Malaysia.

DISCUSSION

This study assesses the impact of patent linkages on medicine expenditure assuming it is implemented in 2015. The impact of patent linkage on price in general can be seen as small in terms of percentage. However, in terms of increase in medicine expenditure, the effect is estimated to be big. If this provision is to be implemented under TPPA, it will affect medicine access in Malaysia. This paper suggests few policy recommendations to cushion the impact.

Firstly, increase in manpower if necessary is required to maintain or improve the efficiency of drug control authority due to the additional tasks and responsibilities imposed on them. Patent linkage provision in the TPPA may require drug control authority to inform patent holder if there is any attempt to apply for product registration or obtain marketing authorization. This gives extra burden to the drug control authority and hence may affect its efficiency. In addition, additional manpower for other government department from different ministry may be needed since the implementation process involves other ministry. For instance, staff from Custom's Department and Ministry

of Domestic Trade, Cooperative and Consumerism (KPDNKK) will involve in the enforcement aspect of the implementation. Therefore, increasing manpower is needed if additional tasks/responsibilities affect its efficiency.

Secondly, drug control authority, KPDNKK's and Custom's manpower need to be equipped with the necessary knowledge and training before the implementation of this provision. This provision requires the understanding of how it is going to be implemented since it is a new provision to the country.

Thirdly, good and an up to date database need to be created and made available for various stakeholders such as pharmacists, officers in Custom's and KPDNKK's and generic producers. Without an up to date database it may affect Malaysia's access to medicine. The work of Zarocostas J. (2010) [16] found that 19 shipments of legal generic medicines from other countries were mistakenly seized while in transit in Europe. This has affected the supply chain of legal generic versions of important medicines. The creation of this database is extremely important to minimize similar problem.

CONCLUSION

Assuming patent linkage provision implemented in 2015, the study estimated it produces negative impact on Malaysia's medicine access. The impact ranges from 0.02% to 2.2% increase across different scenarios in this study. In terms of its impact on medicine expenditure, the impact are estimated to increase from a range of RM2.3 million to RM228.8 million across different scenarios compared to the projected expenditure without patent linkage in 2030. The findings of this study indicate that patent linkage affect medicine access by increasing price and expenditure, delaying the entry of generic medicines and narrowing policy space. Additional supporting policy need to be introduced to cushion the impact of change in intellectual property regime in Malaysia.

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