



THE IMPACT OF TRANS-PACIFIC PARTNERSHIP
AGREEMENT ON MALAYSIA'S TRADE AND ACCESS
TO MEDICINE

BY

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ABSTRACT

In 2010, Malaysia announced that it will be joining the Trans-Pacific Partnership (TPP) negotiation that currently involves twelve countries from three continents namely the US, Australia, Brunei, Canada, Chile, Japan, Mexico, New Zealand, Peru, Singapore and Vietnam. 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,-enhance trade engagement with the US as well as to serve as a stepping stone in penetrating the Latin American market. Analysts are doubt on the significance of the TPPA on Malaysia's trade. In addition, 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 and expenditure. Patent linkages, patent term restoration and data exclusivity are among the subject of heated debate in the media. This study intends to analyse two most important potential impact of the TPPA. The first is to evaluate the impact on market access of Malaysian export to TPPA member countries in general and the US in particular. The research also intends to examine the impact of TPPA on Malaysia's access to medicine. To validate the critics and assess the effects of the TPPA on Malaysia's trade and access to medicine, this study is 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 Trade and Access to Medicine, regression analysis using Gravity Model of Trade and simulation exercise using Model of Impact Changes in Intellectual Property Rights have been undertaken. The study found that FTA has positive effects on Malaysia's export of beverages and tobacco (SITC-1), mineral fuels, lubricants and related materials (SITC-3), manufacturing goods classified chiefly by material (SITC- 6), machinery and transport equipment (SITC-7), miscellaneous manufactured articles (SITC-8) and commodities and transactions not classified elsewhere in the SITC (SITC-9) but negative effects on the export of food and live animals (SITC-0) export of animal and vegetable oils and fats (SITC-4). In addition, FTA is found to have caused increase in Malaysia's import for all product categories except for mineral fuels, lubricants and related materials (SITC-3). Similar effects are projected when TPPA is signed. Moreover, the study suggests that FTA has been found to have positive impacts on both the export of Malaysia and the import of the United States in some product categories namely beverages and tobacco (SITC-1), manufacturing goods classified chiefly by material (SITC-6), machinery and transport equipment (SITC-7), miscellaneous manufactured articles (SITC-8) and Commodities / transactions not classified elsewhere in the SITC (SITC-9). These exports are high and thus will have significant impact on export to the US. Apart from that, the study found that the 3 TRIPS-Plus provisions will have negative impact on Malaysia's access to medicine by causing the increase in medicine price and medicine expenditure and drop in domestic pharmaceutical industry sales. The findings of this study is hoped to provide information that may be useful for Malaysian government and other stakeholders.

خلاصة البحث

لقد أعلنت ماليزيا سنة ٢٠١٠ بأنها ستنتضم إلى مفاوضات الشراكة العابرة للمحيط الهادي التي تضم حاليا إثنتي عشرة دولة من ثلاثة قارات، وهي: الولايات المتحدة الأمريكية، وأستراليا، ونيروني، وكندا، وتشيلي، واليابان، والمكسيك، ونيوزيلاندا، والبيرو، وسنغافورة، وأخيرا فيتنام. ويرى بعضهم بأن اتفاقية الشراكة العابرة للمحيط الهادي التي تم اختتامها أخيرا يوم الخامس من شهر أكتوبر ٢٠١٥؛ بأنها خطوة استراتيجية نحو بلوغ درجة دولة ذات دخل عال بحلول سنة ٢٠٢٠. وتتميز هذه الاتفاقية بأنها اتفاقية تجارية طموحة وشاملة، كما أنها قضية نالت الكثير من الجدل والنقاش بسبب هذا الاتفاق التجاري الضخم. لذا فإن بعضهم يعتبر أن هذه الاتفاقية دوافع جغرافية وسياسية، وبالتالي فإنه ليس هنالك الكثير من المنافع الاقتصادية التي يمكن الحصول عليها، فيما يرى بعضهم الآخر أنه هناك مصالح محتملة يمكن للماليزيا الحصول عليها من جراء هذه الاتفاقية، والتي سوف تفوق تكاليفها. فقد ذهب المؤيدون إلى أن اتفاقية التجارة الحرة بين تلك الدول عبر القارات الثلاث؛ ستكون سببا في تحقيق اندماج أعمق وولوج لسوق أكبر للدول الأعضاء في اتفاقية الشراكة العابرة للمحيط الهادي. كما ستعمل هذه الاتفاقية على تعزيز اتفاقية التجارة مع الولايات المتحدة الأمريكية، وكذا ستكون بمثابة نقطة انطلاق لاختراق سوق أمريكا اللاتينية. أما البعض الآخر من المحللين فقد ذهب إلى التشكيك في دلالة هذه الاتفاقية على التجارة الماليزية. إضافة إلى ذلك فإن قضية تأثير الاتفاقية على إمكانية الحصول على صلاحية الأسعار المعقولة للأدوية في ماليزيا؛ تعتبر من بين أكبر القضايا الجدلية. وإذا ما تم ضم بنود الاتفاقية المعدلة للجوانب المتعلقة بتجارة حقوق الملكية الفكرية (TRIPS-plus) إلى الاتفاقية الحديثة حول الفصل الفكري، فإنه من المعتقد أن يجلب ذلك آثارا سلبية على أسعار ونفقات الأدوية. إن روابط براءات الاختراع، واستعادة مدة البراءة، والتفرد بالبيانات؛ تعتبر من بين المواضيع ذات النقاش الساخن في وسائل الإعلام. تحاول هذه الدراسة تحليل اثنين من أهم الآثار المحتملة للاتفاقية، الأول هو تقييم تأثير صلاحية الدخول في السوق على صادرات ماليزيا إلى الدول الأعضاء في اتفاقية الشراكة العابرة للمحيط الهادي، خاصة منها الولايات المتحدة الأمريكية. تخطط هذه الدراسة كذلك لأن تتحقق من تأثير الاتفاقية على صلاحية ماليزيا في استعمال الأدوية. ولأجل التحقق من صحة النقد الموجه لهذه الاتفاقية وتقييم تأثيرها على كل من التجارة الماليزية وصلاحية الحصول على الأدوية؛ فقد تم إجراء هذه الدراسة لسد الثغرات الموجودة في الدراسات السابقة؛ لأن هناك عدد محدود من الدراسات التي تناولت الموضوع حتى الآن. وفي سبيل تقييم التأثير المحتمل للاتفاقية على التجارة الماليزية والحصول على صلاحية استعمال الأدوية؛ فقد تم الاستعانة بكل من الأساليب الآتية في هذه الدراسة: تحليل الانحدار باستخدام نموذج الجاذبية في التجارة، وكذا ممارسة المحاكاة باستعمال نموذج تغيرات التأثير في حقوق الملكية الفكرية. وقد وجدت الدراسة في الأخير أن لاتفاقية التجارة الحرة آثارا إيجابية على الصادرات الماليزية من المشروبات والتبغ حسب التصنيف المعياري العالمي الأول للتجارة (SITC-1)، ومن الوقود المعدني والشحوم والمواد المشابهة لها حسب التصنيف المعياري العالمي الثالث للتجارة (SITC-3)، ومن السلع المصنعة والمقسمة خصوصا عن طريق موادها حسب التصنيف المعياري العالمي السادس للتجارة (SITC-6)، ومن الآلات ووسائل النقل، حسب التصنيف المعياري العالمي السابع للتجارة (SITC-7)، ومن المواد المصنعة الأخرى، حسب التصنيف المعياري العالمي الثامن للتجارة (SITC-8)، ومن السلع والصفقات غير المصنفة ضمن التصنيف المعياري العالمي للتجارة حسب التصنيف التاسع لها (SITC-9). كما كان لاتفاقية التجارة الحرة كذلك آثارا سلبية على كل من صادرات المأكولات والحيوانات الحية حسب التصنيف المعياري العالمي للصفر للتجارة (SITC-0)، وعلى صادرات الحيوانات والزيت النباتية والدهون، حسب التصنيف المعياري العالمي الرابع للتجارة (SITC-4). بالإضافة إلى ذلك، فإنه قد وجد أن اتفاقية التجارة الحرة كانت سببا في ارتفاع واردات ماليزيا لكل أصناف المنتجات باستثناء الوقود المعدني، والشحوم والمواد المشابهة لها (SITC-3). وستظهر هنالك آثار شبيهة لتلك التي تم عرضها بعد أن يتم التوقيع على اتفاقية الشراكة العابرة للمحيط الهادي. علاوة على ذلك؛ ثبتت فقد هذه الدراسة أن لاتفاقية التجارة الحرة آثارا إيجابية على كل من الصادرات الماليزية وواردات الولايات المتحدة الأمريكية على حد سواء، وذلك فيما يخص بعض أصناف المنتجات، وهي: المشروبات والتبغ (SITC-1)، و السلع المصنعة و المصنفة خصوصا عن طريق موادها (SITC-6)، و الآلات ووسائل النقل (SITC-7)، و المواد المصنعة الأخرى (SITC-8)، و السلع والصفقات غير المصنفة ضمن التقسيم المعياري العالمي للتجارة (SITC-9). إن كل تلك الصادرات المذكورة عالية، وبالتالي فستكون لها تأثيرات إيجابية في تصديرها إلى الولايات المتحدة. إلى جانب ذلك، فقد وجدت الدراسة بأنه ستكون لثلاثة بنود من الاتفاقية المعدلة للجوانب المتعلقة بتجارة حقوق الملكية الفكرية تأثيرات سلبية لصلاحية ماليزيا في استعمال الأدوية، وذلك يؤدي إلى ارتفاع سعر الأدوية ونفقاتها من جهة، وانحطاط مبيعات الصناعة الصيدلانية المحلية من جهة أخرى. والمأمول من وراء نتائج هذه الدراسة أن تقدم معلومات قيمة للحكومة الماليزية والمعنيين بالأمر.

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DECLARATION

I hereby declare that this thesis is the result of my own investigations, except where otherwise stated. I also declare that it has not been previously or concurrently submitted as a whole for any other degree at IIUM or other institutions.

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My Father (Idris Hashim), My Mother (Soran Kaur D/O Harnam Singh), My Brother (Rizal Zamani Idris), My Wife (Dr. Siti Fatmah Suahid), the big family of the late Pengiran Daud Bin Pengiran Momin and Sayangan of Kg Tanjung Aru Lama and Sembulan, the big family of the late Osman Bin Otu and Ria Binti Sumbah (Yang Mok) of Kg Mengkabung, Berungis, Sembulan, the big family of the late Harnam Singh and Pritam Kaur, my late niece Nur Fatilah Syafinah Jamil and her lovely daughter Nur Rizqillah Syafina, Malaysian government and stakeholders.

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LIST OF ABBREVIATIONS

AANZFTA	ASEAN - Australia and New Zealand Free Trade Agreement
ACFTA	ASEAN-China Free Trade Agreement
AFTA	ASEAN Free Trade Agreement
AIFTA TIG	ASEAN – India Free Trade Agreement (Trade In Goods)
AJCEPA	ASEAN-Japan Closer Economic Partnership Agreement
AKFTA	ASEAN-Korea Free Trade Agreement
ASEAN	Association of Southeast Asian Nations
DE	Data Exclusivity
et al.	(et alia): and others
FTA	Free Trade Agreement
GDP	Gross Domestic Product
ISDS	Investor-State Dispute Settlement
MAFTA	Malaysia-Australia Free Trade Agreement
MCFTA	Malaysia-Chile Free Trade Agreement
MICECA	Malaysia-India Comprehensive Economic Cooperation Agreement
MICIPR	Model of Impact Changes in Intellectual Property
MITI	Malaysian Ministry of International Trade and Industry
MJEPA	Malaysia-Japan Economic Partnership Agreement
MNZFTA	Malaysia-New Zealand Free Trade Agreement
MPCEPA	Malaysia-Pakistan Closer Economic Partnership Agreement
PAHO	Pan American Health Organization
PL	Patent Linkages
PTR	Patent Term Restoration
RCA	Revealed Comparative Advantage
SITC	Standard International Trade Classification
TPPA	Trans-Pacific Partnership Agreement
TRIPS	Trade Related Aspect of Intellectual Property Rights
UN	United Nations
UNDP	United Nations Development Program
UNCTAD	United Nations Conference on Trade and Development
US	United States
WHO	World Health Organization
WTO	World Trade Organization

CHAPTER ONE

INTRODUCTION

1.0 INTRODUCTION

The Trans Pacific Partnership (TPP) is a free trade agreement (FTA) initiative that involves the United States (U.S), Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore and Vietnam (USTR, 2014a). Initially in 2002, when the first negotiation took place, the TPPA was known as the Pacific Three Closer Economic Partnership (P3-CEP) where it involved only Chile, New Zealand and Singapore. The P3-CEP became the Pacific Four (P-4) after Brunei joined the group and became a full negotiating member in 2005. The P-4 became a potential twelve-member FTA known as the TPPA, after it further expanded to include Australia, Peru, the U.S, Vietnam, Malaysia, Canada, Mexico and Japan.

In November 2011, the leaders of all negotiating members expressed their commitment to forge a so called 21st century FTA to address future trade issues (USTR, 2014a). The areas included are much more comprehensive in terms of coverage. It covers not only trade in goods and services and investment, but also includes areas such as competition policy, cooperation and capacity building, cross-border services, customs, e-commerce, environment, government procurement, intellectual property, labor, rules of origin, technical barriers to trade, temporary entry, trade remedies among others (USTR, 2014b). The TPPA was just concluded in October 2015 but has not been signed.

Although Malaysia has FTA agreements with most of the TPPA members, the TPPA is seen as a positive step towards deeper economic integration within the Asia Pacific region (Barfied, 2011 and Fazzone, 2012) as well as a platform for Malaysia to

foster better trade ties with the US (MITI, 2011a). The Malaysian government perceives that a closer engagement with and better market-access to the US are strategically beneficial to Malaysia since the US is already amongst Malaysia's top trading partners (MITI, 2013). In addition, the TPPA is viewed as a stepping stone towards providing a stable and sustainable trade relationship between Malaysia and other TPPA members. The TPPA is also expected to add impetus to the economic integration and access of member countries, through the establishment of a large duty free market that comprises of approximately 800 million people, including the means to penetrate the Latin American market (MITI, 2014). In addition to the international trade benefits, the Malaysian government expects its TPPA membership to elevate Malaysia's status as a high value-added manufacturing center and important investment destination (MITI, 2014). A recent study by the UNDP reported that TPPA would improve Malaysia's trade, GDP and welfare (UNDP, 2014). The study found that TPPA would generate a 1.46 per cent welfare gain and increase GDP by 1.02 per cent by 2020 (MITI, 2014). In addition, the study found that both Malaysia's total export and import will increase by 0.82 per cent and 1.06 per cent respectively by 2020 as a result of TPPA. Another study by Peterson Institute for International Economics (2012) estimated that Malaysia's GDP and exports would increase by RM26.3 billion and RM 41.7 billion respectively, by 2025, as a result of TPPA influences.

However, some analysts concern about the US influence that could bring detrimental effects on TPPA members. The US' technical expertise and experience are likely to grant the US a dominant role in drafting the TPPA proposal. Thus it is quite possible that the chapters drafted for the FTA proposal may cater to American interests more than it aids Malaysia's economic opportunities. Civil society

organizations (CSOs) criticize governments of all the TPPA negotiating countries for keeping the TPPA proposal details a secret which has invited much suspicion and speculation regarding the content of the agreement. Apart from concerns of the US's active involvement in the TPPA agreement, other contentious issues are also highlighted by CSOs. Some of the concerns raised are comprehensiveness of the agreement, stringent provisions in the intellectual property chapter involving patent and copyright, competition policy, government procurement, establishment of Investor-State Dispute Settlement (ISDS) and politically sensitive issues such as *Bumiputera* interest and access to medicine.

Official government statement has indicated that the TPPA is expected to boost trade (MITI, 2014). However, as mentioned earlier, past studies on FTA and their effects on a country's trade have yielded mixed results. This implies that significant trade expansion cannot be guaranteed in any FTA. The same thing goes to the TPPA as it may cause significant trade expansion or vice versa. For the case of Malaysia, the TPPA may not affect Malaysia's trade significantly for the reason it does not have on-going FTA with Canada, Mexico, Peru and the United States only. For the US, the TPPA may have less significant effect and the agreement itself is not a significant enlargement since there are on-going FTAs with all negotiating members with the exception of Brunei, Malaysia, New Zealand and Vietnam. In terms of trade with the US, the US is Malaysia's fourth most important trading partner where the total trade worth approximately RM109.8 million in 2012 and for that significant expansion is expected to happen. However, few analysts have expressed doubts on the TPPA's potential in boosting trade (Fergusson et al., 2012, Dawson, 2012 and Stadius and Briggs 2012). According to them, the TPPA may not affect member countries' trade significantly. In another study, Deardorff, (2013) argues that Malaysia will gain

but mainly in trade with the US. Banga (2015) projects that Malaysia's domestic value added of exports will have an annual reduction of approximately US\$17 billion due to TPPA.

The potential TPPA's intellectual property (IP) chapter is reported to contain the TRIPS¹-Plus² provisions. This means member countries would be required to sign nine international treaties related to intellectual property, to have provision on data exclusivity, extension of copyright term of protection, patent term restoration, patenting of diagnostic, therapeutic and surgical methods, patent linkage, compulsory licensing and certain copyright provisions under the intellectual property chapter (IP) (Palmedo, 2012). Such IP chapter in FTAs has been of great concern for Malaysia and has met constant criticisms from CSOs. The resentment intensified particularly after the TPPA proposal on IP chapter was leaked in 2011 (TWN, 2012). Van Grastek (2010) explains that the US has used FTAs to advance its positions on IP through the TRIPs-Plus mechanism. In addition, Stadius (2012) states that if the TRIPS-Plus IP chapter in the TPPA were to be implemented, it would represent the strongest IP protection and enforcement mechanism in any FTA to date.

Among all the provisions on IP discussed above, the issue of accessing affordable medicines has become the subject of much heated debate. Three provisions in the IP chapter which include patent term extension, data exclusivity and patent linkages are the provisions that may affect medicine access negatively. Patent term restoration is a provision which give extension of patent due to delay in drug

¹ The Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement is an agreement under WTO which allows the minimum standards for protection and enforcement of intellectual property rights (IPR) among member countries. TRIPS permit member countries to design their own IPR regulations to protect their national interests. Among the elements included in the TRIPS Agreement are copyright, geographical indications, trademarks, industrial designs and patents.

² TRIPS-Plus Agreement is a higher protectionist standard (than the TRIPS) that has been adopted in recent FTA negotiations. Stringent provisions like patent term restoration, patent linkages and data exclusivity are included in the agreement, and not found in the existing TRIPS agreements.

registration or patent registration. In TRIPS, patent term is 20 years from the date of registration. Therefore, in some countries patent terms have additional years of compensation due to delay in patent or medicine registration. In Australia, 10 years of extension is allowed (Mondaq, 2014), while in the US and Japan both allow a maximum of 5 years extension (US FDA, 2014; Japan Patent Office, 2014). Patent linkages is a provision which requires the national drug control authority to inform patent holders if there is any new applications made by generic manufacturers using similar drugs for marketing purposes (Kessomboon et al., 2010). This implies that marketing authorization applications cannot be made by another party, until the normal patent term expires. This will add an extra burden to the drug control authority in the form of additional tasks and delays the entry of generic medicines into the market (Kessomboon et al., 2010). Data exclusivity prohibits the use of data/information developed by originators' product manufacturer until the patent term expires. This prevents generic manufacturers from using clinical trial data which submitted by the originators' manufacturer to the authority. All these provisions may narrow the policy space, give additional monopoly power to patent owner, and put upward pressure on the price of medicines and therefore making healthcare less affordable to the public.

The experience of Jordan having the TRIPS-Plus element in its FTA agreement has indicated that there is a 20 per cent increase in medicine prices over five years after Jordan-US FTA was implemented (Medecins Sans Frontieres, 2011). A similar impact was found in Colombia where higher medication costs were also reported as a result of applying more stringent data protection or patent laws (UNCTAD, 2011).

1.1 PROBLEM STATEMENT

Being a member in TPPA opens door of opportunities as well as challenges to Malaysia. The key concern is the involvement of the US which is feared to bring in many WTO-Plus commitments in the agreement, even though the TPPA may help to provide significant market in terms of penetrating to the US huge market as well as other TPPA members market. The US is potentially a big market for penetration due to the fact that the US is already among Malaysia's most important trading partner and both countries have not been integrated through any FTA.

This study focuses on two contentious issues in relation to Malaysia's participation in TPPA. Firstly, the issue of possible insignificant FTA effect on trade. In this regard, many have expressed doubts on the potential effects of the TPPA on trade. Few analysts argued that the impact on trade may not be significant (Fergusson et al., 2012, Dawson, 2012 and Stadius and Briggs 2012). Hence, this study attempts to assess the potential impact of TPPA on trade. It investigates whether or not the TPPA open doors of opportunities for Malaysia to obtain market access into member countries market in general and the US market in particular. If so, the study shall also identify the products that have got potentials in gaining the benefits.

The second issue is concerning the impact of TRIPS-Plus provision on access to medicine in Malaysia. As mentioned earlier, TRIPS-Plus provisions would have negative impact on access to medicines as well as on the domestic pharmaceutical industry. The possible introductions and implementations of these three TRIPS-Plus provisions which are namely data exclusivity, patent linkages and patent term restoration have become subject of heated debate in the media. Civil society organizations (CSOs) around the world have made constant opposition on this matter for the reason that those provisions will cause the increase in medicine price and

expenditure. So far there are limited studies which assess the impact of TPPA on Malaysia's trade and there are no studies that have systematically evaluated the impact of TRIPS-Plus agreement on these issues in Malaysia. The findings of this study is hoped to provide information that may be useful for the Malaysian government and other stakeholders.

1.2 RESEARCH QUESTIONS

In general, this study seeks to address the following question:

What are the potential impacts of Trans Pacific Partnership Agreement as another FTA on Malaysia's trade and access to medicine?

In addition, there are three specific research questions which are:

1. What is the effect of FTA on Malaysia's exports and imports?
2. Will the FTA result in higher US imports from its trading partners, particularly Malaysia?
3. What are the effects of TRIPS-Plus provisions on Malaysia's access to medicines?

1.3 OBJECTIVES OF THE STUDY

This study investigates the potential effect of the TPPA on Malaysia's trade and market access to the US, as well as its impact on Malaysia's access to medicine. The specific objectives of this study are as follows:

- i) to examine the potential effect of the TPPA on Malaysia's exports and imports at aggregated and disaggregated levels. This is achieved by examining the effects of existing FTAs and its impact on trade between member nations.