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석사학위논문

TRIPS And Human Rights

**- Patents and Access to Medicines in the
Malaysian Context-**

TRIPS 와 인권

— 특허와 말레이시아에서의 의약품접근의
맥락에서 —

2016 년 8 월

서울대학교 대학원

법학과 지적재산법

Daphine Chong Yee Leng

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Malaysian Context -

지도교수 정 상 조

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서울대학교 대학원

법학과 지적재산권법

Daphine Chong Yee Leng

Daphine Chong Yee Leng 의 석사 학위논문을

인준함

2016 년 6 월

위 원 장 _____ (인)

부위원장 _____ (인)

위 원 _____ (인)

Abstract

TRIPS and Human Rights

Patents and Access to Medicines in the Malaysian Context

Daphine Chong Yee Leng

College of Law, Intellectual Property Law

The Graduate School

Seoul National University

The Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPS”) is an international agreement administered by the World Trade Organisation (“WTO”). The phenomenon was peculiar given that the administration of multilateral agreements on intellectual property rights such as the Berne and Paris Conventions are under the purview of the World Intellectual Property Organisation (“WIPO”) and not the WTO. TRIPS is not the standard trade negotiations. Its very existence demonstrates a close relationship between trade and intellectual property. The introduction of TRIPS was shocking as it imposes a minimum standard for intellectual property protection on all members of the WTO. More explicitly, it is an attempt to harmonize intellectual property laws between the developed, developing and least developed countries based on the protection standard of intellectual property rights in the developed region – evidently, a standard relatively high for the developing and least developed country members. The Members would now have to introduce legislation to provide for intellectual property protection in accordance with the agreement when it was something left to the members’ internal governance and mechanism in the past. Yet another seemingly unrelated aspect of the law comes into play with

intellectual property: human rights. Too strong a patent protection will potentially undermine human rights, which of particular interest here, is the access to medicines. As TRIPS requires developing countries to provide patents on pharmaceuticals, implications of limiting access to medicines grew apparent. Certain flexibilities are provided for by TRIPS to balance the protection of intellectual property rights and public health. However, developing countries are applying these flexibilities with apprehension when addressing internal public health concerns as there is a lack of clarity in the application of these flexibilities. Furthermore, despite the flexibilities offered by TRIPS, the mandatory implementation of a single standard pharmaceutical patent protection based on private interest to the compromise of public interest's right to health may not necessarily manifest justification in the developing region as will be seen in the case of Malaysia.

Keywords: TRIPS, Patents, Access to Medicines, Malaysia, Pharmaceutical Industry, TRIPS Flexibilities

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I. Introduction

The Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPS”) administered by the World Trade Organization (“WTO”) is perhaps one of the most comprehensive and controversial multilateral agreement on the protection of intellectual property rights¹ (“IPRs”). In recognising that inadequate protection of IPRs leads to the distortion of trade, TRIPS is perhaps the first multilateral agreement that formalises the link between intellectual property (“IP”) and international trade.

Unlike its predecessors such as the Berne Convention for the Protection of Literary and Artistic Works (the Paris Act of 24 July 1971) (“Berne Convention”), which generally covers copyright protection and the Paris Convention for the Protection of the Industrial Property (the Stockholm Act of 14 July 1967) (“Paris Convention”), which covers the protection of industrial property², TRIPS’ broad and wide-ranging scope incorporated substantive provisions of both the Conventions and even adds substantial number of obligations on matters where pre-existing conventions are silent or considered inadequate. For instance, while it is uncertain if computer programmes and original databases qualify as literary or artistic works under the Berne Convention, TRIPS provides that these programmes and databases are afforded copyright protection regardless of the form they are in.³ It also

¹ The World Intellectual Property Organization web defines intellectual property as the creations of the mind, such as inventions; literary and artistic works; designs; and symbols, names and images used in commerce. <http://www.wipo.int/about-ip/en/> (accessed 20th January 2016) The World Trade Organization web defines intellectual property rights as the rights given to persons over the creations of their minds. https://www.wto.org/english/tratop_e/trips_e/intel1_e.htm (accessed 20th January 2016)

² The scope of which includes object patents, utility models, industrial designs, trademarks, service marks, trade names, indications of source or appellations of origin, and the repression of unfair competition. See Article 1(2) Paris Convention for the Protection of Industrial Property (the Stockholm Act of 14 July 1967, as amended on 28 September 1979) http://www.wipo.int/wipolex/en/treaties/text.jsp?file_id=288514 (accessed 16th January 2016).

made references to the International Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organisations (“Rome Convention”), adopted at Rome on 26 October 1961 on related rights⁴ and the Treaty on Intellectual Property in Respect of Integrated Circuits (“IPIC Treaty”), adopted at Washington on 26 May 1989 on the protection of the layout-designs (topographies) of integrated circuits.⁵ Thus, TRIPS is at times also referred to as the Berne-plus and Paris-plus agreement.

In addition, part II of TRIPS establishes the global minimum standards of protection for these IPRs, by defining the subject-matter to be protected, the rights to be conferred as well as permissible exceptions to those rights, and the minimum duration of protection. It also contained detailed provisions on enforcement of IPRs in Part III. Under Article 2(1) of the Paris Convention, a foreign national shall receive the same treatment accorded to its national. However, unlike TRIPS, the Paris Convention does not establish a minimum standard of treatment the national shall receive. Consequently, in order to comply with TRIPS, a member state should accord the minimum standard of protection to a foreign national although it fails to protect the rights of its own national. The Berne Convention on the other hand, though imposes certain minimum standards of protection, lacks a credible enforcement mechanism and to a large extent depends on national law enforcement.⁶

³ See Article 10 TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr.15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, THE LEGAL TEXTS: THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 320 (1999), 1869 U.N.T.S. 299, 33 I.C.M. 1197 (1994) https://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm (accessed 16th January 2016)

⁴ See Article 14(6) TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, THE LEGAL TEXTS: THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 320 (1999), 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) https://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm (accessed 16th January 2016).

⁵ See Article 35 *ibid*.

⁶ Nuno Pires de Carvalho, *The TRIPS Regime of Patent Rights*, Second Edition (Netherlands: Kluwer Law International, 2005), 29.

TRIPS negotiations were highly contentious, marked by the differences in perspective between the more developed north and the less developed south on the protection of IPRs. While the developed countries see a stronger protection on patents as serving its trading interests, the developing nations view it as limitations to innovations and technological advancement. Despite this, TRIPS was adopted to the astonishment of many as the south had to regulate their IP regime according to the north's standard.

TRIPS extended IPR protection to areas previously unprotected or protected only by a minority of states. It included a 20-year patent protection for all products and processes. Article 27 which provides for patents to be available for any inventions, in all fields of technology proved to be of greatest impact to the pharmaceutical sector for the production and access to medicines. For pharmaceuticals, the key form of IP protection is a patent cover in each country. Most of the 123 participating nation in the Uruguay Round negotiation signed the Marrakesh Agreement Establishing the World Trade Organization⁷, adopting TRIPS. Of those nations, over 40 did not grant patent protection for pharmaceutical products prior to the negotiation of TRIPS.⁸ The protection and enforcement of IPRs in TRIPS were to an extent previously unseen globally and what this meant, in medicines, for some countries are the introduction of patents and limited forms of regulatory data protection, for others it meant extending patent protection from processes to pharmaceutical products for the first time, and yet for some others already granting patents, it meant extending the life of newly-granted patents.⁹ It

⁷ See Understanding the WTO: Basics; The Uruguay Round, World Trade Organization web https://www.wto.org/english/thewto_e/whatis_e/tif_e/fact5_e.htm (accessed 17th January 2016)

⁸ *WTO Agreements and Public Health: A Joint Study by the WHO and the WTO Secretariat* (World Trade Organization/World Health Organization, 2002), para 52.

⁹ Joint United Nations Programme on HIV/AIDS (UNAIDS) and United Nations Development Programme (UNDP), *TRIPS Transition Period Extensions for Least-Developed Countries, 2013*, Issue Brief

became apparent that pharmaceutical patents would potentially limit access to medicines and it is the main reason that generates criticisms and fierce oppositions to TRIPS. Hence, the central research question to be addressed in this study is the extent of the implications of pharmaceutical patents and whether or not the interests of some should take precedence over the interests of others.

As could be seen in Article 7 and 8, TRIPS recognise the inherent limitations of pharmaceutical patent protection and seek to achieve a balance between providing incentives for future innovations and ensuring affordable access to drugs through its “flexibilities” that enable WTO members to implement policies in a manner which takes into account public health consideration. Whether or not such a balance is attainable remains the objective and purpose of this study.

This paper aims to study and examine the intersection of patent and access to medicines, its evolution; implications of the TRIPS agreement in this respect globally with a focus on the Malaysian scene and its potentials to balance the concerns of the pharmaceutical industry as well as the general public. It also aims to ascertain whether or not the implementation of pharmaceutical patent protection in developing countries especially in the case of Malaysia is justified against access to affordable medicines. These are attempted through case studies, comparative analysis and literature review to support as well as to account for the different outcome derived from certain literatures. As similar researches in the area based on the Malaysian background are lacking, this study seeks to contribute to the analysis of the subject in Malaysia and to be useful reference for future researches. By identifying the characteristics of TRIPS and the shortcomings of the Malaysian patent law, this paper asks for fruitful reforms in the national

http://www.unaids.org/sites/default/files/media_asset/JC2474_TRIPS-transition-period-extensions_en_0.pdf.

intellectual property regime. Before exploring the issue in detail, the following provide a glimpse of the manner in which the paper proceeds.

In Chapter II, a background on the debate for and against stronger IPR protection via TRIPS adoption is reviewed. Statistics and data on global access to essential medicines and costs of research and development of drugs are utilised to reflect the situation leading to the debate. Next, the rationales of patent law and the role of the TRIPS agreement are demonstrated. The issue then is whether or not recognition is accorded to access to medicines as a human right in the legal perspective. Most importantly, the question of whether there exists an overwhelming interest that warrants impediment on access to medicines is addressed. The next chapter examines how effectively the safeguards in the TRIPS agreement itself tip the scale in balance given the different conflicting interests. Lastly, the conclusion elaborates on the possible solutions and challenges faced by Malaysia ahead apart from the TRIPS agreement.

II. Trade, Intellectual Property and Public Health: A Tripartite Interplay

It all started with trade, international trade. The General Agreement on Tariffs and Trade (“GATT”), which took effect in 1948 is one of the earliest multilateral agreements regulating international trade. According to its preamble, GATT endeavours to raise standards of living, develop full use of the resources of the world, and expand the production and exchange of goods by the substantial reduction of tariffs and other barriers to trade. Subject to certain modifications, it was incorporated into the WTO framework. Many countries who were then embracing the protectionist view began to see the benefits of international trade as outward oriented economies grew rapidly and out-performed the protectionists. The case for trade liberalization is well

made out in David Ricardo's what has come to be known as the theory of comparative advantage, which is essentially an improved allocation of resources leading to an increased in welfare. Exports increased, there were foreign direct investments and developing countries were making progress. Progress also came from developing countries' capability in imitating new technologies. The more advanced developed states, such as the United States ("US") and some parts of Europe were facing increasing competition in manufactured exports from these newly industrialising nations, particularly East Asia. Commercial values of IPRs were essential assets to the developed states and they were plagued by problems of product piracy and counterfeit goods, causing considerable losses and blow to these nations' economic interest. There were cases of both patented and non-patented drugs being counterfeited, which were harmful to health and its presence were significant in the developing countries.¹⁰ These were mainly due to the shorter period of patent protection afforded in developing countries to products such as pharmaceuticals resulting in the domestic market's capability to imitate and thus, gain presence in the market share.¹¹ In addition, patent-granting process and enforcement of patent protection lacked transparency; governments were tolerant with respect to product piracy and counterfeit goods.¹²

The piracy and counterfeit issues were first dealt in the Tokyo Round of GATT (1967-1969), where IP issues emerged for the first time in the context of the world trading regime.¹³ In the years to come, the matter became more pressing and was discussed once again in the Uruguay Round of GATT

¹⁰ *WTO Agreements and Public Health: A Joint Study by the WHO and the WTO Secretariat*, 40.(note 8 above)

¹¹ See Micheal Trebilcock, Robert Howse, and Antonia Eliason, *The Regulation of International Trade*, Fourth ed. (USA and Canada: Routledge, 2013), 514.

¹²Ibid.

¹³Peter-Tobias Stoll, Jan Busche, and Katrin Arend, *Max Planck Commentaries on World Trade Law, Volume 7: WTO - Trade-Related Aspects of Intellectual Property Rights* (Netherlands: Martinus Nijhoff, December 2008).

(1986-1994). Developing countries caved in under the tremendous pressure to enhance the protection of IPRs in the quest to maintain the advantages of trade liberalisation from GATT. TRIPS was introduced and reasons for its introduction is well reflected in its preamble – to reduce distortions and impediments to international trade, to promote effective and adequate protection of IPRs and that such measures in itself do not become barriers to legitimate trade.

For the developing countries, another round of predicament ensues as they struggle to reform their existing IP laws according to the relatively high minimum standards of TRIPS in the protection of IPRs: TRIPS is structured after the interests of the developed countries and hence, it reflects the legal paradigm of those nations. As mentioned in Chapter I, Article 27 mandates the patentability of any invention in all fields of technology, essentially prohibiting discrimination of any sort against products that qualify for patentability. Pharmaceutical products are of no exception too. TRIPS marks a departure from the Paris Convention, where states were permitted to exclude certain sectors such as pharmaceuticals from patentability and to determine the length of patent protection in accordance to their socio-economic needs.¹⁴

1. Defining Patent and Access to Medicine

Patent is a concept difficult to define. Most legislation do not contain a definition of patent, rather they specify the subject matter to be afforded protection, the criteria for patentability, and how the right could be infringed upon. Patent confers legal exclusive rights to the owner, or rather negative rights over process or product inventions for a fixed period of time.¹⁵ In

¹⁴ Human Rights Council, *Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover* (UN doc. A/HRC/11/12, 31 March 2009), para 24.

¹⁵ *Ibid.*, para 18.

return, the patentee is required to disclose the invention in a manner that people having ordinary skill in the art are able to practise it. This ensures that sufficient disclosure is made and knowledge of the patentee is disseminated to the society. A third party is prevented from making, using, offering for sale, selling or importing for these purposes the patented products; or from using a patented process, and from the acts of using, offering for sale, selling or importing for these purposes the product obtained directly by the patented process without the consent of the owner.¹⁶ If anyone exploits the patented product or process without such authorisation, that person is said to have infringe the patent and is liable in law to pay damages. In certain situations, an injunction may be obtained against the infringer at the discretion of the court especially when damages are deemed to be an insufficient remedy.

As a corollary to the exclusive right, the patent system creates monopolies and patentees could sell their products at a relatively high price due to limited competitions. In the pharmaceutical sector, a product patent, a patent on the actual drug itself may create absolute monopolies regardless of the process it was made and the purpose it serves.¹⁷ The use of the product is restricted though the drug may be derived from different processes. Process patents restrict only the use of the method used to manufacture the drug; generic drugs may be made if alternative processes are available.¹⁸ Hence, process patents would offer strong protection if it's the only way of making the particular drug in question but this is rarely the case in the pharmaceutical

¹⁶ Article 28 TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, THE LEGAL TEXTS: THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 320 (1999), 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994).

¹⁷ See Sigrid Sterckx, "Patents and Access to Drugs in Developing Countries: An Ethical Analysis," *Developing World Bioethics*, Blackwell Publishing Ltd. 4 no. 1 (2004): 58-75.

¹⁸ Human Rights Council, *Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health*, Anand Grover, 8.(note 14 above)

sector.¹⁹ The operation of a patent system is therefore, an important factor in determining access to medicines and consequently, the health of individuals as there is a vital link between patents, prices of drugs and access.

There are a few factors that may play a part in denying individuals in low-income countries access to medicines. While TRIPS may dictate the works of a patent system and impact access to medicines, existing national policies may also give rise to deprivations of medicines. That would be a determinant in a different dimension of access to medicines. Accessibility of medicines is said to have four dimensions: i) medicines must be accessible in all parts of the country; ii) medicines must be economically accessible to all, including those living in poverty; iii) medicines must be accessible without discrimination on any of the prohibited grounds, such as sex, race, ethnicity and socio-economic status; and iv) reliable information about medicines must be accessible to patients and health professionals for them to take well-informed decisions and use medicines safely.²⁰

This paper is concerned with the second dimension of accessibility, namely, financial affordability. Nevertheless, TRIPS should not only be viewed as impeding access to medicines. There are convictions that TRIPS is an essential attempt in striking a balance between the longer term objective of providing incentives as well as stimulating innovations for future creations, and the shorter term objective of allowing people to use existing inventions and creations.²¹ Proponents of TRIPS believe a stronger patent protection for pharmaceuticals will lead to more investments, and research and development (“R&D”) of drugs. Whether or not these are true will be assessed in Chapter

¹⁹ Sigrid Sterckx, "Patents and Access to Drugs in Developing Countries: An Ethical Analysis," 58-75.(note 17 above)

²⁰ General Assembly, *The right of everyone to the enjoyment of the highest attainable standard of physical and mental health* (UN doc. A/61/338, 13 September 2006), para 49.

²¹ *WTO Agreements and Public Health: A Joint Study by the WHO and the WTO Secretariat*, para 46.(note 8 above)

IV of the paper. The next section of the chapter provides some background on the availability of affordable medicines.

2. Access to Medicine: The Landscape Today

a) Pharmaceutical Production

The global pharmaceutical production²² is growing at a rapid rate every year. Below are figures from three different sources that detail the increase in growth. Before delving into the matter, limitations of the statistics should be considered. Data on the volume of production is not available and production is measured in the monetary terms. Since monetary values are the most easily available and convenient measures of production, trade and sales of medicines, they are widely used in most sources. This may present a distorted picture on production and consumption as it fails to reflect the actual scale of global consumption. Furthermore, the definition of pharmaceutical products compiled and used in each source may differ. Data from the World Health Organization (“WHO”) recognises this, stating that pharmaceutical products may range from first aid and cough remedies to highly specialized medicine used by hospital specialists, and to veterinary medicines. However, its data as shown in figure 1.1 focuses on medicines for human consumption.

This paper too acknowledges the incomplete and incomprehensive compilation of data to reflect the highly contentious issue related to the protection of IPRs and access to medicines. The data below serve only as a reference point to indicate the increase in the production of global pharmaceuticals.

Figure 1.1 below shows rapid growth in pharmaceutical production from

²² Production is said to refer to the value added at each stage of the manufacturing process, such as the manufacturing of active ingredients in bulk from basic chemicals, the preparation of finished new medical entities, or the repackaging of imported generic ingredients. WHO, *The World Medicines Situation* (WHO/EDM/PAR2004.5, 2004), 3.

1985-1990. The value of global pharmaceutical production in 1999 was over US\$ 320 billion which corroborated European Federation of Pharmaceutical Industries and Association's finding of US\$350 billion in 2000.²³

Figure 1.1 Estimated global value of pharmaceutical production 1985-1999, in current and constant US\$ billion

Year	1985	1990	1999
Pharmaceutical production current prices	82,1	175,9	327,2
Global GNP current prices	10,766	22,299	29,232
Pharmaceutical production constant (1995) prices	46,2	140,5	370,1
Global GNP constant (1995) prices	20,302	24,555	33,672

Source: WHO, *The World Medicines Situation* (WHO/EDM/PAR2004.5, 2004) WHO estimates from database of UNIDO, OECD Health Data, World Development Indicators 1987, 1992, 2001, International Financial Statistics Yearbook, 2002

Figure 1.2 Estimated global value of pharmaceutical production 2005-2010



Source: Organisation of Islamic Cooperation, Statistical Economic and Social Research and Training Centre for Islamic Countries (SESRIC), *Pharmaceutical Industry in OIC Member Countries: Production, Consumption and Trade*. IMS Health Market Prognosis, March 2011

Indeed, the average annual growth rate of pharmaceuticals which was

²³ Ibid.

under 10.5% at current prices outgrew the total value of goods and services, where its average annual growth rate of global gross national product (“GNP”) was valued to be under 7.5%.²⁴

Figure 1.3 Estimated value of European pharmaceutical industry in € million

INDUSTRY (EFPIA total)	1990	2000	2012	2013
Production	63,010	125,301	213,003	217,500 (e)
Exports (1) (2)	23,180	90,935	312,377	316,500 (e)
Imports	16,113	68,841	224,811	226,500 (e)
Trade balance	7,067	22,094	87,566	90,000 (e)
R&D expenditure	7,766	17,849	30,035	30,630 (e)
Employment (units)	500,879	534,882	693,195	690,000 (e)
R&D employment (units)	76,126	88,397	115,196	115,000 (e)
Pharmaceutical market value at ex-factory prices	41,147	86,704	160,574	163,000 (e)
Pharmaceutical market value at retail prices	64,509	140,345	237,240	240,800 (e)
Payment for pharmaceuticals by statutory health insurance systems (3)	40,807	76,909	119,345	119,950 (e)

(1) Data relate to Eu-27, Norway and Switzerland since 2005 (Eu-15 before 2005); Croatia and Serbia included since 2010; Turkey included since 2011

(2) Data relating to total exports and total imports include Eu-28 intra-trade (double counting in some cases)

(3) Since 1998 data relate to ambulatory care only

Source: EFPIA, *The Pharmaceutical Industry in Figures* (2014) EFPIA member associations (official figures) - (e): EFPIA estimate; Eurostat (Eu-28 trade data 1995-2013)

²⁴ Ibid.

Figure 1.2 above again witnessed the growth in pharmaceutical production from 2005-2010. According to the Organisation of Islamic Cooperation (“OIC”), the world pharmaceutical production is valued at \$ 875 billion in 2010, with a growth rate of 4.1% over the previous year at the constant exchange rate and the volume of pharmaceutical industry has surged from US\$ 647 billion in 2005 to US\$ 875 billion in 2010, corresponding to an increase of 35.2%.²⁵ The decline in growth rate in 2008 was said to be due to the slowdown in economic activity²⁶, which subsequently recovered in 2009 but took a dip once again in 2010.

Figure 1.3 above exhibits the estimated value of the European pharmaceutical industry. There has been a steady increment of pharmaceutical production in the European market from 1990 to 2013 and this corroborates the sources above on the growth of the total value of global pharmaceutical production. All in all, the pharmaceutical industry grew rapidly from a value of US\$ 320 billion in 1999 to US\$ 647 billion in 2005 to US\$ 875 billion in 2010.

Historically, the global production is geographically highly concentrated in a few high-income countries; accounting for over 90% of the world production.²⁷ Firms in the US, Japan, Germany, France and the United Kingdom (“UK”) produce two-thirds of the value of global pharmaceutical production.²⁸

As seen in figure 2.1 below, pharmaceutical production by value is dominated by the high-income countries, with an inclination from 89.1% in

²⁵ Statistical Economic and Social Research and Training Centre for Islamic Countries (SESRTC) Organisation of Islamic Cooperation, Pharmaceutical Industry in OIC Member Countries: Production, Consumption and Trade, 29 September 2011 <http://www.sesrtcic.org/files/article/433.pdf> (accessed 25th January 2016).

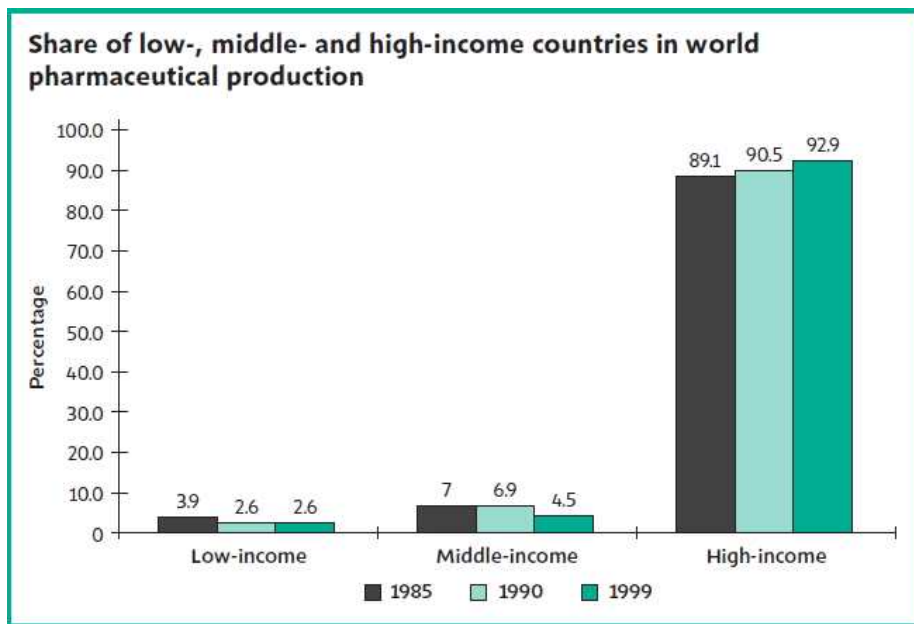
²⁶ Ibid.

²⁷ Ibid., 3.(note 22 above)

²⁸ Ibid.

1985 to 92.9% in 1999. On the contrary, production in low and middle-income countries declined between 1985 and 1999.

Figure 2.1 Share of low-, middle- and high-income countries in world pharmaceutical production²⁹

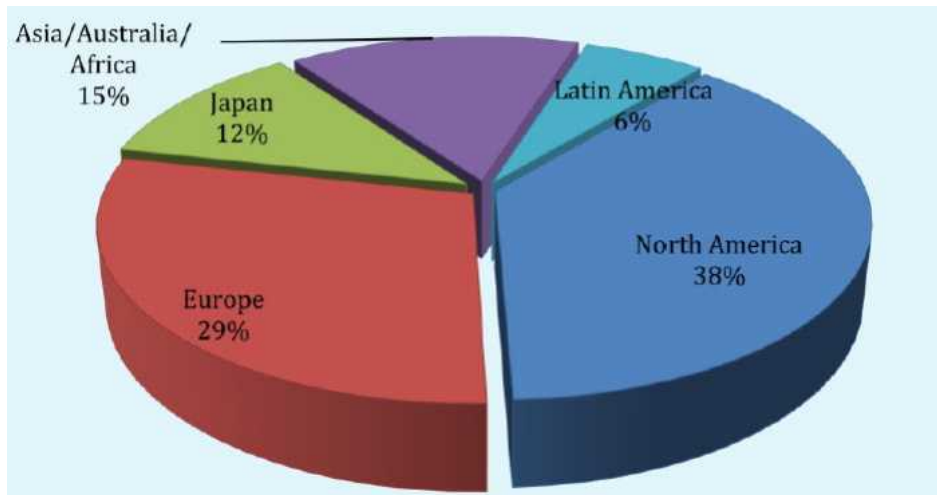


Source: WHO, *The World Medicines Situation* (WHO/EDM/PAR2004.5, 2004) WHO estimates based on data reported by UNIDO, OECD

Even in recent years, the pharmaceutical production dominations by the developed countries remained unchanged to a large extent. As reflected in figure 2.2 below, North America and Europe continue to dominate the market share of pharmaceutical production in 2010. These markets, together with Japan combined, constituted nearly 79% of the global pharmaceutical production and consumption. Developing regions which consist 85% of the world’s population only accounted for 21% of the pharmaceutical market. ³⁰

²⁹ The World Bank classification of countries groups high-income countries as having GNP per capita of US\$ 9361 or more in 1999, middle-income countries as having GNP per capita of US\$ 761-9360 in 1999, and low-income countries as having GNP per capita of US\$ 760 or less in 1999. WHO, *The World Medicines Situation*.(note 22 above)

Figure 2.2 Regional Distribution of Global Pharmaceutical Market



Source: OIC, Statistical Economic and Social Research and Training Centre for Islamic Countries (SESRIC), *Pharmaceutical Industry in OIC Member Countries: Production, Consumption and Trade*. IMS Health Market Prognosis, March 2011

Countries in North America and Europe including Japan are classified as having a “sophisticated industry with significant research” (see Figure 2.3 below) and manufacturing are mainly done by large transnational corporations headquartered there.³¹ These corporations are also the principle sources of new medicines discovery³², these originator chemically-synthesised drugs are then patented and marketed under the corporations’ brand name – thus, these medicines are known as brand name medicines.

Nevertheless, there already exist large volumes of lower priced medicines in the domestic market of countries with “innovative capability” such as China and India.³³ These lower priced medicines are generics, which are

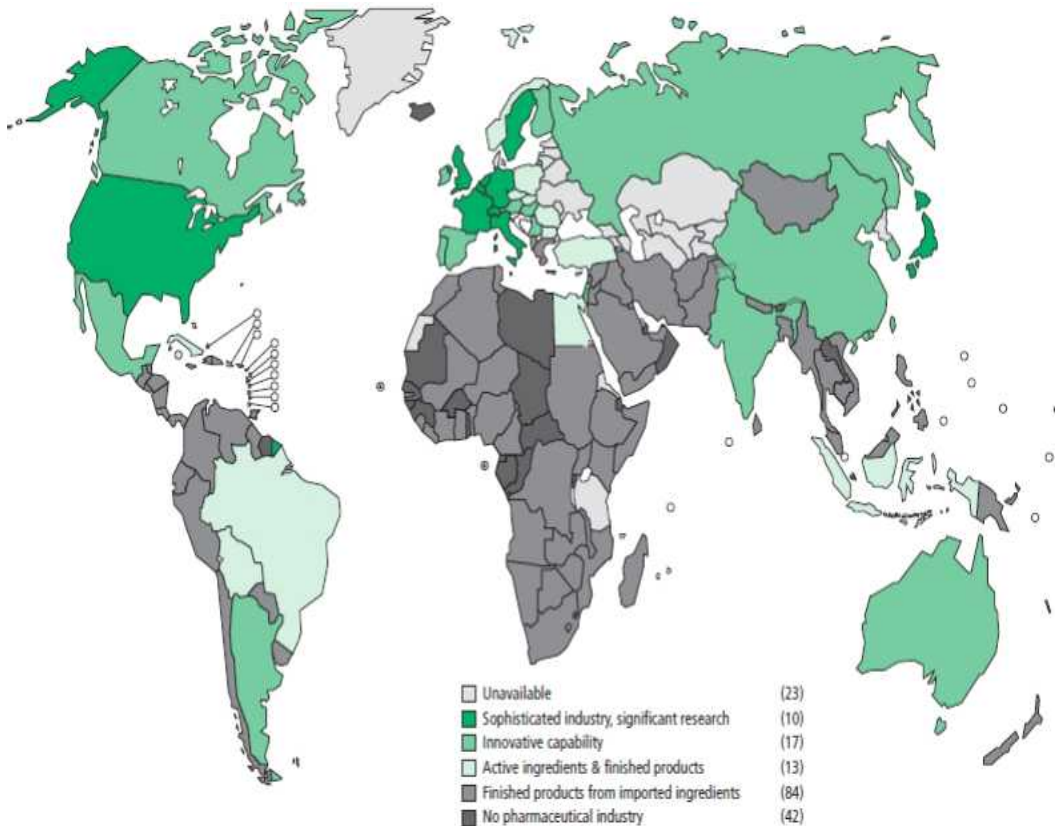
³⁰ Statistical Economic and Social Research and Training Centre for Islamic Countries (SESRIC) Organisation of Islamic Cooperation, *Pharmaceutical Industry in OIC Member Countries: Production, Consumption and Trade*.(note 25 above)

³¹ WHO, *The World Medicines Situation*, 3.(note 22 above)

³² Ibid.

duplicative copies of the originator that contain the same active ingredient and are identical in dosage form, strength, route of administration and intended use.

Figure 2.3 Global Pharmaceutical Production Capacities in 1992



Source: WHO, *The World Medicines Situation* (WHO/EDM/PAR2004.5, 2004)

Pharmaceutical production has been growing significantly in middle-income countries, especially China and India. For instance, China has a record of 4,000 pharmaceutical manufacturers in 2009³⁴ and India is said to

³³ Ibid.

³⁴ Pacific Bridge Medical, *China Regulatory and Market Access Pharmaceutical Report, 2014* <http://www.pacificbridgemedical.com/wp-content/uploads/2015/04/China-Regulatory-and-Market-Access-Pharmaceutical-Report-2014.pdf> (accessed 29th January 2016). 69.

supply 22% of the world's generic drugs and large proportion of the vaccines to the developing world.³⁵

In Malaysia, pharmacy service came into existence since 1951 with the enforcement of three pieces of legislations. Malaysia then was still under the governance of the British, and service was confined to the procurement, storage and distribution of drugs from the UK's Crown Agents.³⁶ Now, the industry can be divided into manufacturing, importation and distribution. According to Zaman (2001), manufacturing commenced in 1958 with the establishment of a production plant by Glaxo Wellcome (now GlaxoSmithKline, GSK).³⁷ At present, the pharmaceutical industry in Malaysia comprise of small and medium-sized companies; the local companies engaged primarily in the production of generic drugs, traditional medicines and herbal supplements and the multinational corporations ("MNCs") are mainly licensed importers who distribute their brand name drugs through locally incorporated companies.³⁸ This is due to the fact that only 13% have set up local manufacturing operations, while another further 7% have contract manufacturing arrangements with local companies.³⁹ This means that 80% of multinationals are constrained to importation and

³⁵ Cheri Grace, A Briefing Paper for DFID: Update on China and India and Access to Medicines, November 2005, DFID Health Resource Centre <http://hdrc.dfid.gov.uk/wp-content/uploads/2012/09/Update-on-China-an-India-and-Access-to-Medicines.pdf> (accessed 28th January 2016). 8.

³⁶ Ministry of Health Malaysia, Pharmaceutical Services Division, 3 May 2013 <http://www.pharmacy.gov.my/v2/en/content/our-history.html> (accessed 28th January 2016).

³⁷ Mohamed Azmi Hassali et al., "TRIPS, Free Trade Agreements and the Pharmaceutical Industry in Malaysia," in *The New Political Economy of Pharmaceuticals: Production, Innovation and TRIPS in the Global South*, ed. Hans Löfgren and Owain David Williams (Palgrave Macmillan, 2013).

³⁸ Istituto nazionale per il Commercio Estero, The Pharmaceutical Industry in Malaysia, December 2012 <http://www.ice.gov.it/paes/asia/malaysia/upload/173/The%20Pharmaceutical%20Industry%20in%20Malaysia%202012.pdf> (accessed 5 April 2016).

³⁹ Pharmaceutical Association of Malaysia (PhAMA), PhAMA Industry Fact Book 2012, 2012 <http://www.phama.org.my/index.cfm?&menuid=65&parentid=6> (accessed 5 April 2016).

distribution of brand name drugs.⁴⁰ Domestically owned companies are therefore, important market players as producers of generic drugs.

b) Pharmaceutical Sales and Consumption

A surge in the production of pharmaceuticals indicates an increase in the supply of medicines which perhaps, corresponds to the demand of such products. Perhaps more individuals are able to get their hands on to the medicines they have had needed. However, the rise in supply and demand does not ensure access or rather, that medicines are affordable.

According to a paper published by the WHO in 2008, it is said that one third of the world's global population still lacks access to essential medicines and in certain parts of Africa and Asia, situations are worse, with up to half of its populations having difficulty gaining access to needed drugs.⁴¹ It is also said that approximately 10 million lives a year could be saved solely by improving access to essential medicines and vaccines; Africa and South-East Asia alone have a made-up of 4 million lives and the major impediment to ensuring access is identified to be the price factor.⁴²

The question then is to where does consumption goes when pharmaceutical production has been on the rise. Global production and consumption totals should be similar, with only inventories accounting for differences. Global consumption pattern could be plotted from the volume in pharmaceutical trade and sales. International trade of pharmaceuticals is dominated by high-income industrialised countries, who are also the world's major producers: in 1999, they accounted for 93% global exports and 80% of

⁴⁰ Ibid.

⁴¹ See World Health Organization and Health Action International, Measuring Medicine Prices, Availability, Affordability and Price Components, 2008 http://www.who.int/medicines/areas/access/OMS_Medicine_prices.pdf?ua=1 (accessed 23rd January 2016).

⁴² Ibid.

global imports, whereas middle-income countries' share of world exports and imports dropped.⁴³ Dominance in global exports by the developed countries is due to the required technology sophistication they possess in manufacturing majority of the pharmaceuticals. Dominance in global imports by these countries on the other hand, could be the reflection of the substantial gap in the per capita spending for health care between the developed and the developing countries. High-income countries are financially more capable and spend significantly more on healthcare expenditure whether public or private. Middle and low-income manufacturing countries produced predominantly for the local market and exports most of their produce to the developing countries.⁴⁴

While imports have been relatively constant (the developed countries account for 70% and the developing countries account for 25% of the market share between 1995 and 2009), export market share of the developing countries has been constantly increasing from 15% to over 20% in 2008 and 2009.⁴⁵ In 2013, 60% of the world exports of pharmaceuticals originated from the European Union ("EU"), this however, represents a decrease of more than 18% compared to 2002.⁴⁶ Meanwhile, Chinese and Indian export market shares increased tremendously. In 2012, India accounted for 2.9% of global pharmaceutical exports which is 5 times the figure represented in 2002.⁴⁷

However, the exports destinations for India have also changed. In 1994, the Soviet Union was the single largest export destination; by 2012, the US became the single largest export destination, accounting for more than a

⁴³ WHO, *The World Medicines Situation*, 22.(note 22 above)

⁴⁴ Ibid.

⁴⁵ Matthias Helble, "More Trade for Better Health? International Trade and Tariffs on Health Products, October 2012."

⁴⁶ Ludivine Blanc, "The European Pharmaceutical Industry in a Global Economy: What Drives EU exports of Pharmaceuticals Overseas?" (2014).

⁴⁷ Ibid.

fourth of total pharmaceutical exports.⁴⁸

Figure 3.1 World Trade in Pharmaceuticals

Country	2014 Export £thousands	2014 Import £thousands	2014 Balance £thousands
Switzerland	40,398,291	15,322,989	25,075,302
Germany	47,980,694	30,347,223	17,633,470
Ireland	17,821,305	3,590,927	14,230,379
Sweden	5,201,275	2,669,356	2,531,919
Netherlands	11,188,025	9,106,007	2,082,017
France	21,710,349	19,638,783	2,071,566
UK	20,590,844	19,603,878	986,965
Spain	8,020,028	9,495,779	-1,475,751
Italy	13,383,160	15,025,424	-1,642,264
Japan	1,964,939	12,549,321	-10,584,382
USA	28,834,095	46,250,564	-17,416,470

Source: The Association of the British Pharmaceutical Industry (ABPI), OECD, STAN Bilateral Trade in Goods by Industry and End-use (BTDixE), ISIC Rev.4 available at <http://www.abpi.org.uk/industry-info/knowledge-hub/global-industry/Pages/global-trade.aspx> (accessed 1st February 2016)

Although developing countries account for only 25% of the import market share in 2009, they are net importers of pharmaceutical products as many do not have pharmaceutical manufacturing capability. Most developed countries on the other hand, are net exporters and have a positive trade balance⁴⁹ (see figure 3.1 above). International trade shows that many

⁴⁸ Reji K. Joseph, "Pharmaceutical Industry and Public Policy in Post-reform India," (India: Routledge, 2016).

⁴⁹ A trade balance is the difference between the values of a country's exports to other countries compared with imports from them. A net exporter is a country whose value of exported goods is higher than its value of imported goods, hence generating a positive

medicines are not consumed in the country where they were produced as volume of exports are high. Notwithstanding this, exports and imports of pharmaceuticals take place predominantly among the developed countries themselves and developed countries are also export destinations of developing countries' produce. For instance, the EU's largest trading partners for pharmaceuticals are Switzerland and the US. Even without statistical information, one could clearly gather from the trade exchange that consumption occurs mainly in the developed countries.

The WHO estimates and measures a country's consumption by adding the value of its production to the value of its imports and minus the value of its exports.⁵⁰ In 1985, the 18% of the world population living in the high-income countries consumed 89% of the world's pharmaceuticals: by 1999, the population share of these countries had fallen to 15% but their pharmaceutical consumption had grown to 91% of the total.⁵¹ Data on pharmaceutical sales could also provide measurement on the consumption of pharmaceuticals.

Figure 3.2 below shows that in 2012, North America, Europe and Japan account for almost 80% of the global pharmaceutical sales. Africa, Asia (excluding Japan) and Australia account for only 14.7% of the world pharmaceutical sales. Like production, consumption revolved around the region of pharmaceutical production as well.

In 2014, North America and Europe accounted for 44.5% and 25.3% of the world's pharmaceutical sales respectively.⁵² In spite of the persistent domination of the pharmaceutical market by these countries, according to

balance and is referred to as a trade surplus. A net importer is a country whose value of imported goods is higher than its value of exported goods, hence generating a negative balance and is referred to as a trade deficit or trade gap.

⁵⁰ WHO, *The World Medicines Situation*, 31.(note 22 above)

⁵¹ Ibid.

⁵² European Federation of Pharmaceutical Industries and Association (EFPIA), *The Pharmaceutical Industries in Figures* (2015).

IMS Health, certain middle-income countries such as China and Brazil saw market growth of 11.6% and 12.6% respectively, compared to an average market growth of 2.4% for the total European market and 12.5% for the USA market.⁵³

Figure 3.2 World Pharmaceutical Market Sales by Region, 2012



Source: European Federation of Pharmaceutical Industries and Associations, *Facts & Figures* available at <http://www.efpia.eu/facts-figures>

In Malaysia, approximately 70% of the pharmaceutical market is dominated by prescription drugs and this predominance is likely to prevail into the future.⁵⁴ Prescription drugs could be further categorized as imported proprietary drugs, generics manufactured locally by Malaysian companies, and imported generics.

Despite efforts by the government to contain the escalating cost of

⁵³ Ibid.

⁵⁴ Mohamed Azmi Hassali et al., "Malaysian Pharmaceutical Industry: Opportunities and Challenges," *Journal of Generic Medicines* 6, no. 3 (23 March 2009): 246-252; doi: 10.1057/jgm.2009.12.

medicines by increasing the generic utilization rate, the prescription market is still dominated by patented drugs, which account for about 60% of prescription sales by value.⁵⁵ In other words, about two-thirds of prescription medicines are imported and only one-third of these medicines are produced locally. Imports for non-prescription drugs on the other hand, account for half of the market share.⁵⁶ The local industry is producing about 30% of the total domestic demand and exports to the Asia-Pacific Rim countries, the Middle East, Africa, Latin America and Europe.⁵⁷ Export of pharmaceuticals is growing. In 2012, pharmaceutical exports are valued at RM954 million and in 2013, it was valued at RM981.2 million.⁵⁸

In spite of generic production, high reliance is still placed on imports of brand name drugs. According to *Business Monitor's* unpublished Strategic Report in 2007, Malaysia Pharmaceuticals and Healthcare, brand name drugs which command a much larger share of value at approximately 70% of the total pharmaceutical consumption and sales are a major source of high drug expenditure in the country.⁵⁹

C) Price as a Limitation to Access to Medicine

Given that most of the world's pharmaceutical giants are mostly headquartered in a handful of countries such as the US, the UK, Germany,

⁵⁵ Zhi Yen Wong et al., "Malaysian Generic Pharmaceutical Industries: Perspective from Healthcare Stakeholders," *Journal of Pharmaceutical Health Services Research* 5, no. 4: 193-203; doi: 10.1111/jphs.120722014.

⁵⁶ Zaheer-Ud-Din Babar, Mohamed Izham Mohamed Ibrahim, and Mohamed Azmi Ahmad Hassali, "Pharmaceutical Industry, Innovation and Challenges for Public Health: Case Studies from Malaysia and Pakistan," *Journal of Pharmaceutical Health Services Research* 2, no. 4 (2011): 193-204; doi: 10.1111/j.1759-8893.2011.00058.x.

⁵⁷ Malaysia Investment Development Authority (MIDA), Pharmaceuticals <http://www.mida.gov.my/home/pharmaceuticals/posts/> (accessed 2nd February 2016).

⁵⁸ Ministry of International Trade and Industry (MITI) Malaysia, *Ministry of International Trade and Industry Report* (2013).

⁵⁹ Zaheer-Ud-Din Babar et al., "Pharmaceutical Industry, Innovation and Challenges for Public Health: Case Studies from Malaysia and Pakistan," 193-204.(note 56 above)

Switzerland and Japan, it is not surprising that pharmaceutical activities are highly concentrated in those areas. These multinational companies are dubbed big Pharma, a term so widely-used that it is defined by the Cambridge Business Dictionary as “large and successful pharmaceutical companies considered as a business group with important economic, political, or social influence”. Big Pharma has so much influence that the protection of IPRs (i.e. TRIPS) was brought into the international trade arena.

Figure 4.1 Big Pharma and their Market Share

Companies	Headquarters	Worldwide Market share		Rank change
		2012	2018	
1. Novartis	Switzerland	6.4%	5.8%	+1
2. Sanofi	France	5.4%	5.5%	+2
3. Pfizer	USA	6.6%	5.2%	-2
4. Roche	Switzerland	5.3%	5.2%	+1
5. GlaxoSmithKline	UK	4.6%	4.5%	+1
6. Merck&Co	USA	5.8%	4.5%	-3
7. Johnson&Johnson	USA	3.3%	2.9%	+1
8. Novo Nordisk	Denmark	1.9%	2.4%	+9
9. Bristol-Myers Squibb	USA	1.9%	2.4%	+9
10. AbbVie	USA	3.2%	2.4%	-1
11. Gilead Sciences	USA	1.3%	2.4%	+10
12. AstraZeneca	UK	3.8%	2.3%	-5
13. Bayer	Germany	2.1%	2.2%	+2
14. Takeda	Japan	2.3%	2.0%	-
15. Amgen	USA	2.5%	1.8%	-2
16. Teva Pharmaceutical	Israel	2.5%	1.8%	-4
17. Eli Lilly	USA	2.8%	1.7%	-6
18. Boehringer Ingelheim	Germany	2.1%	1.4%	-2
19. Baxter International	USA	1.2%	1.4%	+3
20. Astellas Pharma	Japan	1.5%	1.3%	-1
Total Top 20	-	66.0%	59.1%	

Source: Ludivine Blanc, "The European Pharmaceutical Industry in a Global Economy: What Drives EU exports of Pharmaceuticals Overseas?", Evaluate Pharma, 2013

Figure 4.1 above shows that in 2012, big Pharma occupied 66% of the global pharmaceutical market. As mentioned earlier, big Pharma is big on medical innovation and a study by Munos in 2009 reveals that 50% of the new molecular entities⁶⁰ (“NMEs”) introduced in the market since 1950 were

⁶⁰ The FDA defines new molecular entities as products containing active moieties that have not been approved by FDA previously, either as a single ingredient drug or as part of a

discovered by the top 15 pharmaceutical companies in 2008.⁶¹ This explains the reason big Pharma lobbied for the inclusion of TRIPS as part of the Agreement establishing the WTO. Since big Pharma are mainly innovators and rarely produce cheap generics, they could earn substantially from the exploitation of pharmaceutical patents. Of all the innovative drugs developed, the gains are exceptionally high when a blockbuster drug is created. Blockbuster, a bomb capable of demolishing extensive areas as large as a city, mainly refers to an unusually successful product with widespread popularity and huge sales. While an average drug is expected to deliver only 5% return on investment, a successful blockbuster yields a larger 10-20 times returns.⁶² The reward in the industry therefore, is the blockbuster drug with US\$ 1 billion or more in annual global sales.⁶³ Thus, big Pharma has been operating the blockbuster business model – spending large sums for R&D, in search for successful blockbuster(s) amongst the many unsuccessful results to generate high returns. For decades, big Pharma has been built around the success of these single products. In 2000, 17 drugs brought in more than \$1 billion each in global sales and in 2005, 94 drugs met this threshold.⁶⁴

Large companies like big Pharma rely on blockbusters to sustain their growth as blockbusters produce a major share of the revenue and dictate the companies' strategic direction (see figure 4.2 below). In 2005, blockbuster drugs accounted for 60% of the US\$ 245 billion of the ten leading pharmaceutical companies.⁶⁵ The importance of blockbusters is demonstrated

combination product; these products frequently provide important new therapies for patients.

⁶¹ Ludivine Blanc, "The European Pharmaceutical Industry in a Global Economy: What Drives EU exports of Pharmaceuticals Overseas?", 10.(note 46 above)

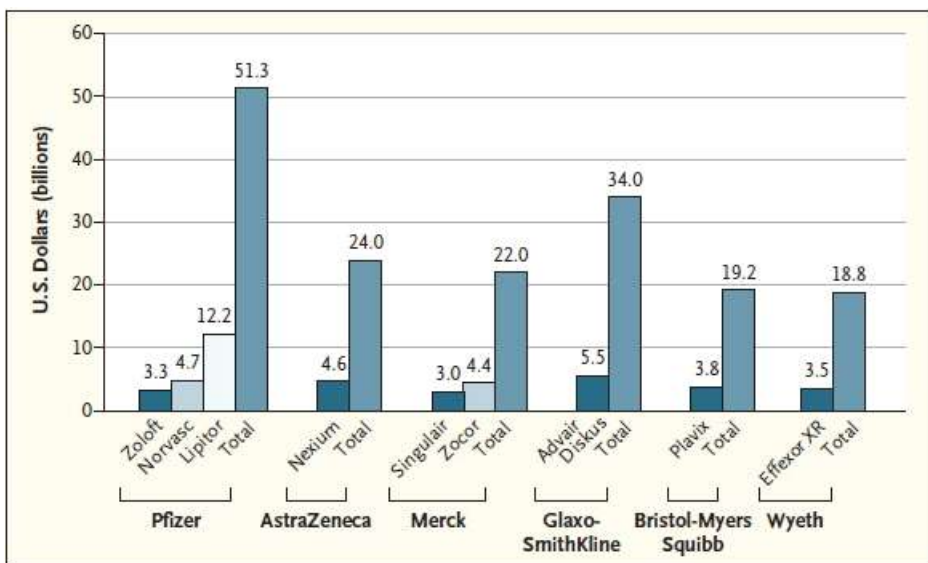
⁶² Jim Gilbert, Preston Henske, and Ashish Singh, "Rebuilding Big Pharma's Business Model," *In Vivo, The Business & Medicine Report* November 2003.

⁶³ David M. Cutler, "The Demise of the Blockbuster?," *The New England Journal of Medicine* 356, (2007): 1292-1293.

⁶⁴ *Ibid.*

in the following cases: Pfizer’s announcement to halt clinical testing for torcetrapib, its new cholesterol drug. The company’s market value fell by US\$ 21 billion overnight, followed by ten thousand job cuts.⁶⁶ When Merck pulled Vioxx (rofecoxib) from the shelves, the company’s market value fell by US\$ 25 billion.⁶⁷

Figure 4.2 Sales of Blockbuster Drugs in 2005 as a Portion of the Total Revenues of Pharmaceutical Companies



Source: David M. Cutler, *The Demise of the Blockbuster?* The New England Journal of Medicine 356 (2007) :1292-1293.

The success of blockbusters lies in the common features shared by them. These are characterised by the great therapeutic value, big and growing demand for the medicine, and the lack of competition with other drugs as they are protected by patents, thus leading to high pricing power. Lipitor for instance was 95% more expensive before its generic version was produced.⁶⁸

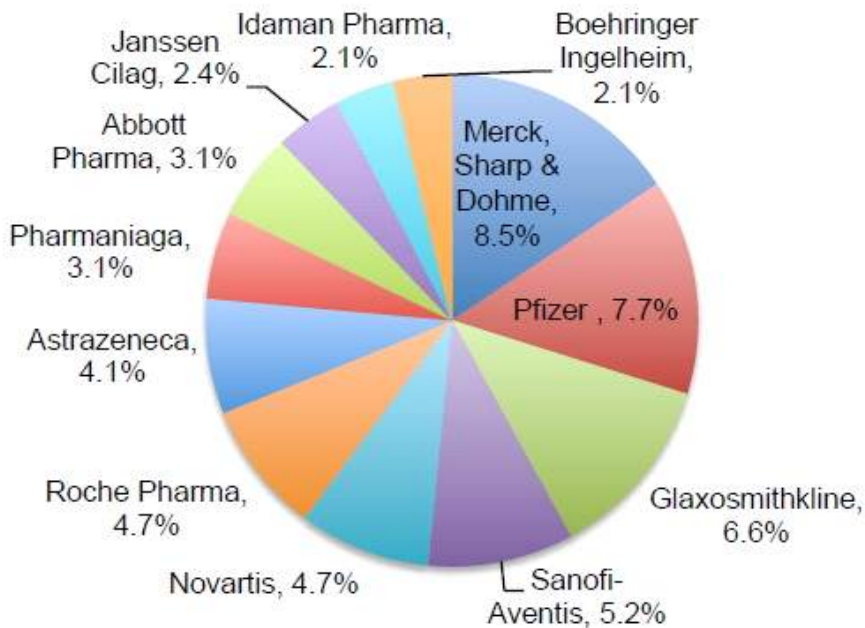
⁶⁵ Nafees Malik, *Has the Era of Blockbuster Drugs Come to an End?*, 1 December 2007, BioPharm International Vol. 20, Issue 12 <http://www.biopharminternational.com/has-era-blockbuster-drugs-come-end> (accessed 3 February 2016).

⁶⁶ David M. Cutler, "The Demise of the Blockbuster?," 1292-1293.(note 63 above)

⁶⁷ Ibid.

Lipitor is used to treat the common illness of raised cholesterol, which has a global prevalence of 39% among adults in 2008.⁶⁹

Figure 4.3 Top Pharmaceutical Companies in Malaysia by Market Share, 2011-2012



Source: Selangor State Investment Center (SSIC), *Life Sciences Cluster in Selangor (Part III: Pharmaceuticals)* (2015), IMS Health 2011.

The Malaysian pharmaceutical market is infiltrated by multinational companies. Figure 4.3 above shows the market share of the top pharmaceutical companies in Malaysia for the year 2011-2012 by IMS Health. Of the top 12 pharmaceutical companies, only two are local pharmaceutical companies.

⁶⁸ Micheal Rosenblatt, The Real Cost of "High-Priced" Drugs, 17 November 2014, Harvard Business Review <https://hbr.org/2014/11/the-real-cost-of-high-priced-drugs> (accessed 3 February 2016).

⁶⁹ World Heart Foundation, Quick Facts on Cholesterol/Lipids <http://www.world-heart-federation.org/heart-facts/fact-sheets/cardiovascular-disease-risk-factors/quick-facts-on-cholesterolipids/> (accessed 3 February 2016).

In conclusion, the global pharmaceutical industry is characterized by the concentration of consumption, production and innovation in a relatively small number of high-income countries.

3. Conceiving and Developing a Drug

High-income countries dominate in both public and private sectors for pharmaceutical R&D. According to Burke and Matlin (2008, 27-28) in 2005, 97% of health R&D occurred in high-income countries with pharmaceutical companies spending US\$ 80 billion on R&D in high-income countries and only US\$ 1.6 billion in low- and middle-income countries.⁷⁰ The US, UK, Japan, Germany and France accounted for 70% of pharmaceutical patents filed in 2004-06 under the Patent Co-operation Treaty (OECD 2009).⁷¹ Amongst these countries, the US pharmaceutical industry is considered the leader in drug innovation.

The US produces more new molecular entities (“NMEs”), both chemical and biological, than Europe and Japan.⁷² According to the Economist (2004) from 1998-2002, Europe launched 44 NMEs compared to 85 NMEs launched in the US.⁷³ 60% of the world’s clinical trials are run under the US Food and Drug Administration (“FDA”), followed by 30% under the European Medicines Agency (“EMA”) and the remaining 10% under other agencies, mainly the Japanese Pharmaceuticals and Medical Devices Agency (“PDMA”).⁷⁴ The US also leads Europe and Japan in the number of new

⁷⁰ Marc J. Roberts and Micheal R. Reich, *Pharmaceutical Reform* (World Bank Publications, August 2011).

⁷¹ Ibid.

⁷² Stuart O. Schweitzer, *Pharmaceutical Economics and Policy*, Second ed. (Oxford University Press, October 2006).

⁷³ Ibid.

⁷⁴ Daniele De Martini, *Success Probability Estimation with Applications to Clinical Trials* (John Wiley & Sons, August 2013), xxii.

patents filed for pharmaceuticals at the European Patent Office.⁷⁵ Most data regarding drug development and costs available are modelled after the US pharmaceutical industry. Therefore, the drug development process and costs below are reviewed on the basis of those data.

a) Drug Development Process

Developing a new drug is complex and it is a process of high risk as it consumes considerable human and financial resources – 1) it requires the intensive interaction among different scientific disciplines, hence requiring talented group of scientists, engineers and clinicians and; 2) it is characterised by failures, reiterations and reassessments of scientific data, so there is continuous uncertainty for a period of 6-10 years during the process of whether the drug will emerge effective and safe for patients.⁷⁶ If successful, it would then have to go through the scrutiny and approval of the authorities before being released to the public. Therefore, only large multinationals with substantial resources typically bring to the market new drugs as they are able to engage in the expensive and extensive process of R&D.

In the R&D process, what these companies are focusing on is the development of a drug containing a novel chemical compound as its active ingredient, which is the NME or the new chemical entity (“NCE”). The first step in developing an NCE is a drug discovery. This starts at the laboratory and the goal is to identify a chemical compound for treating a disease or condition. In order to do so, basic research on therapeutic methods to target underlying causes are explored and are applied to the target such as a protein, RNA or DNA in cells, tissues and animal models that is involved in the disease.⁷⁷ Researches will look for a lead compound that could influence the

⁷⁵ European Patent Office, *Annual Report* (2014).

⁷⁶ Jan A. Rosier, Mark A. Martens, and Josse R. Thomas, *Global New Drug Development: An Introduction*, First ed. (John Wiley & Sons, Ltd., July 2014), 1-2.

target and potentially becomes a medicine. Compounds or molecules could be found from nature or created using biotechnology, in which living systems are genetically engineered to produce disease-fighting molecules and only a few hundred promising possibilities from among thousands of potential candidates are selected for preclinical testing.⁷⁸ Laboratory and animal studies are conducted to determine whether a compound is suitable for human testing. These studies usually provide detailed information on dosing and levels of toxicity. The entire drug discovery and preclinical research process may take up to 3½ years.⁷⁹

An application is then filed with the FDA and it has to be approved before the three phase clinical trials on humans are conducted. In phase 1, the drug is tested on a group of 20 to 100 healthy volunteers to determine the safety of the compound. In phase 2, the drug is given to a larger group of 100 to 500 volunteers with the studied disease or condition to determine the drug effectiveness, toxicity and the proper dosage to be administered. In phase 3, the test is conducted on 1,000 to 5,000 participants with the specific disease to confirm the drug safety and efficacy. The entire clinical trial process may consume an average 6 to 7 years to complete. ⁸⁰

b) Drug Regulatory Approval

If the results of all three clinical trial phases indicate that the compound is safe and effective, the company submits an application together with all test data for FDA approval to market the new medicine. The FDA has 6 to 10

⁷⁷ See Pharmaceutical Research and Manufacturers of America (PhRMA), "Biopharmaceutical Research Industry Profile," (2013).

⁷⁸ Ibid.

⁷⁹ California Biomedical Research Association, Fact Sheet New Drug Development Process <http://www.ca-biomed.org/pdf/media-kit/fact-sheets/CBRADrugDevelop.pdf> (accessed 4 February 2016).

⁸⁰ Pharmaceutical Research and Manufacturers of America (PhRMA), "Biopharmaceutical Research Industry Profile."(note 77 above)

months to review clinical data and studies, conduct routine inspection on clinical study sites before deciding whether to approve the drug.⁸¹ Certain “new” drugs may have a shorter development trajectory such as new dosages or delivery systems of previously approved compounds, combinations of previously approved compounds, new indications for a previously approved compound or a slight variation of a previously approved compound.⁸² Thus, approvals may be speedier and granted based on less clinical data in conjunction with reliance on published literature and prior approvals.⁸³ A company that wishes to commercialize the new drug must gain marketing approval in every country it desires to sell the product.

In Malaysia, the regulatory of pharmaceutical products is carried out by the National Pharmaceutical Control Bureau (“NPCB”) under the Ministry of Health. The NPCB is tasked with ensuring the quality, efficacy and safety of pharmaceuticals through the registration and licensing scheme. The NPCB also has to monitor the quality of registered products for any drug adverse reaction. Under the law, all pharmaceutical products with medicinal purposes intended for human consumption are required to be registered with the Drug Control Authority (“DCA”) under the NPCB.⁸⁴ In addition, it is mandatory to obtain licences when manufacturing, importing and selling the registered products.⁸⁵

In order to qualify for registration and licensing, it is pertinent that clinical research undertaken as well as medicinal products developed must comply with the accepted global standards. The current guidelines include

⁸¹ US Food and Drug Administration (FDA), The Drug Development Process <http://www.fda.gov/ForPatients/Approvals/Drugs/ucm405570.htm> (accessed 5 February 2016).

⁸² See Cynthia M. Ho, *Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights* (New York: Oxford University Press, 2011), 10.

⁸³ *Ibid.*, 14.

⁸⁴ See Regulation 7(1) Control of Drugs and Cosmetics Regulations 1984.

⁸⁵ See Regulation 7(1) & 12 Control of Drugs and Cosmetics Regulations 1984.

Good Laboratory Practice (“GLP”), Good Clinical Laboratory Practice (“GCLP”), Good Clinical Practice (“GCP”) and Good Manufacturing Practice (“GMP”).⁸⁶ In 1996, the NPCB was given international recognition by the WHO as a WHO Collaborating Centre for Regulatory Control of Pharmaceuticals and has since been providing training in all aspects of pharmaceutical quality assurance programme and regulatory matters in the region. The manufacturer’s license will only be issued to manufacturers who are in compliance with the GMP which is based on the international harmonized standards and quality inspectorates of the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (jointly referred to as “PIC/S”). Malaysia’s GLP is based on OECD’s Principles on GLP and since March 2013, Malaysia is officially a non-member with full adherence to the OECD Council Acts related to Mutual Acceptance of Data (“MAD”) in the assessment of chemicals on GLP. The MAD states that the test data generated in any member country or full adherents in accordance with the OECD’s principle of GLP shall be accepted by other member countries saving governments and chemical producers costs of duplicative test. Hence, multinationals license importers from the US save relatively much time and costs when registering pharmaceuticals in Malaysia as the US is a member of both the OECD and the PIC/S.

C) Drug Development Costs and Attrition Rate

The failure rate of drug candidates to make it through the development process is known as attrition. An attrition rate of x% refers to the x% of the

⁸⁶ The Drug Control Authority Malaysia, *Ubat-ubatan Berita* (June 2007). These guidelines are used to achieve accepted international standards of safe and efficacious quality in developing test data and drugs. The principles of GLP are applied to non-clinical safety testing of test items contained in pharmaceutical products; the principles of GCLP and GCP are applied to clinical trials and; the principles of GMP are applied to manufacturing of pharmaceuticals.

projects has been terminated during a given phase in the drug development process and high attrition means that the substantially high number of drug candidates introduced into the drug pipeline drops during the development phases.⁸⁷

It is said in the drug discovery stage that whilst 5,000 to 10,000 compounds are used to test their reaction with the researched disease, only approximately 250 compounds are selected for preclinical testing and ultimately, only one is approved by the FDA.⁸⁸ Even medicines that reach clinical trials have only a 16% chance of being approved.⁸⁹ Despite this, thousands of clinical trials are run. According to clinicaltrials.gov on average, approximately 2,600 phase I, 3,700 phase II and 2,300 phase III trials are presented annually for approval under the FDA.⁹⁰

The failure of clinical trials is influenced by numerous factors. Various sources indicate that in phase II and phase III trials, up to 50% of failures are due to safety and clinical or organisational reasons and the remaining 50% of failures is due to a lack of proved efficacy.⁹¹ Success rates differ according to therapeutic areas and molecule type as well. Success rates ranges from 5% for oncology drugs to 20% for cardiovascular drugs and a NME has a lower success rate than non-NMEs and biologics.⁹²

Attrition rates are important in indicating the productivity and efficiency or otherwise a determinant in the drug developing costs of a pharmaceutical

⁸⁷ Jan A. Rosier et al., *Global New Drug Development: An Introduction*, 7.(note 76 above)

⁸⁸ Pharmaceutical Research and Manufacturers of America (PhRMA), "Biopharmaceutical Research Industry Profile."(note 77 above)

⁸⁹ Ibid.

⁹⁰ Daniele De Martini, *Success Probability Estimation with Applications to Clinical Trials*, xxii.(note 74 above)

⁹¹ Ibid.

⁹² See Jan A. Rosier et al., *Global New Drug Development: An Introduction*, 8.(note 76 above); Daniele De Martini, *Success Probability Estimation with Applications to Clinical Trials*, xxv.(note 74 above)

company in R&D. This has huge impacts on pharmaceutical companies. A single failure is capable of wiping a small company out of the market and even large companies may face dramatic consequences if met with consecutive failures. Hence, this is another reason why big Pharma typically focus on discovering and developing NMEs as blockbuster drugs apart from the high return on investments - to compensate the R&D costs of failures.

The cost of developing a drug is distinguished from producing a drug. The cost of bringing a new drug to market is estimated to be about US\$ 800 million.⁹³ Once a drug is developed, production costs are typically low – in many cases, it is said to cost only nickels per tablet.⁹⁴ More recently, the same authors who estimated cost of drug development at US\$ 800 million peg the cost and winning market approval at US\$2.6 billion.⁹⁵ Nevertheless, it is said that the generally accepted estimates vary from US\$ 800 million to US\$ 1 billion.⁹⁶ Many criticised these figures as development costs are highly variable or unknown.⁹⁷ For instance, clinical trial costs may be inflated, prices vary on where treatment is targeted and putting numerals on indirect costs such as time may be difficult to determine. Some have projected costs to range between US\$ 180 and US\$ 230 million or between US\$ 500 million and more than US\$ 2 billion.⁹⁸ The Pharmaceutical Research and Manufacturers of America (PhRMA) estimated its members to spend US\$

⁹³ Joseph A DiMasi, Ronald W Hansen, and Henry G Grabowski, "The Price of Innovation: New Estimates of Drug Development Costs," *Journal of Health Economics* 22, no. 2 (March 2003): 151-185.

⁹⁴ David M. Cutler, "The Demise of the Blockbuster?," 1292-1293.(note 63 above)

⁹⁵ Cost to Develop and Win Marketing Approval for a New Drug Is \$2.6 Billion, 18 November 2014, Tufts Center for the Study of Drug Development http://csdd.tufts.edu/news/complete_story/pr_tufts_csdd_2014_cost_study (accessed 11 February 2016).

⁹⁶ See Jan A. Rosier et al., *Global New Drug Development: An Introduction*, 7.(note 76 above)

⁹⁷ Ibid.

⁹⁸ Ibid.See ; Daniele De Martini, *Success Probability Estimation with Applications to Clinical Trials*.(note 74 above)

51.2 billion investment on R&D in 2014 alone.⁹⁹

The considerable cost of R&D is primarily driven by clinical trials, which accounts for approximately 60% of total costs whereas chemical and pharmaceutical R&D accounts for approximately 30% of total costs.¹⁰⁰ In the last decade, cost for clinical trials increased at a rate of about 4-5% per year and sources reported an average cost per patient in phase I during 2011 was about US\$ 20,000 and of about US \$30,000 and US\$ 40,000 in phases II-III.¹⁰¹

There are also the remaining costs of drug marketing, manufacturing and distribution. These costs while small are far from insignificant. In 2001, US pharmaceutical companies were reported to have spent US\$ 2.7 billion, roughly 2% of domestic sales on advertising and US\$ 11 billion for the distribution of free samples.¹⁰² Overall, the investment in pharmaceutical R&D is substantial and involves considerable risk as safety and efficacy of the research drug may only be known at a very late stage of the development process.

D) Generics

The creation of a generic drug is much simpler and inexpensive as opposed to discovering and developing a NME. As described earlier, a generic drug manufacturer duplicates an existing off-patent drug, in which its characteristics are disclosed from the publicly available patent. Hence, the manufacturer does not have to search for a compound or molecule that

⁹⁹ Pharmaceutical Research and Manufacturers of America (PhRMA), *2015 Profile Biopharmaceutical Research Industry* (2015).

¹⁰⁰ Jan A. Rosier et al., *Global New Drug Development: An Introduction*, 6.(note 76 above)

¹⁰¹ Daniele De Martini, *Success Probability Estimation with Applications to Clinical Trials*, xxiv.(note 74 above)

¹⁰² F.M. Scherer, "The Pharmaceutical Industry - Prices and Progress," *The New England Journal of Medicine* 351, no. 9 (26 August 2004): 927-932.

displays the therapeutic effect of the drug as this had previously been done by the original innovator. The manufacturer needs only to develop an efficient commercial manufacturing process as this information may not necessarily be made available by the patent and conducts a limited type of clinical tests.¹⁰³

Like new drugs, all drugs including generics must be approved by the relevant regulatory agencies before being placed on the market for sale and consumption. Since the originator drug has obtained prior approval for safety and efficacy, the generic drug needs to be pharmaceutically equivalent to the reference listed drug and exhibit characteristics of bioequivalence. This in essence means that the product should have the same active ingredient, dosage form, strength, and route of administration under the same conditions of use.¹⁰⁴ In order to be bioequivalent to the reference listed drug, there should be no significant difference in the rate and extent of absorption of the active pharmaceutical ingredient.¹⁰⁵ These requirements can be met fairly quickly and inexpensively compared to the numerous stages of tests and clinical trials run with the originator drug. Once the product is found to be pharmaceutically equivalent and bioequivalent to the reference listed drug, it infers that the generic is therapeutically equivalent, as efficacious and as safe as the reference listed drug.

Certain countries with extensive regulatory approval procedures such as the US and the EU rely only on the data of its previously approved innovator drugs.¹⁰⁶ For instance, when proving bioequivalence of a generic to an innovator drug in the US, the innovator drug should be an approved drug by the FDA in the reference listed drug. Developing countries who have limited

¹⁰³ Cynthia M. Ho, *Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights*, 12.(note 82 above)

¹⁰⁴ See 21 Code of Federal Regulations (C.F.R) §314.94(4),(5),(6).

¹⁰⁵ See 21 C.F.R §314.94(7).

¹⁰⁶ Cynthia M. Ho, *Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights*, 15.(note 82 above)

resources in evaluating extensive clinical data tend to refer to a previously approved drug from those countries with extensive regulatory approval processes.¹⁰⁷

In Malaysia, generics are subject to registration with the NPCB before it can be sold. Like the US and the EU, Malaysia requires a generic product to be similar to a currently registered product in the country.¹⁰⁸ Generics, like innovator drugs are subject to a full evaluation by the NPCB while only certain generics classified as non-scheduled poison are subject to an abridged evaluation.¹⁰⁹ Although pre-clinical and clinical studies need not be submitted, a bioequivalence study is required for all generics classified as scheduled poison (also known as controlled medicine).¹¹⁰ Local manufacturers will also have to comply with the GMP when producing generics.

To conclude, generic manufacturers save substantial costs on developing drugs and production costs are typically low as mentioned above.

4. The Conflict between Patents and Access to Medicine

Pharmaceutical industry's main argument for a stringent protection of IPR regime is the determinant role it acts as an incentive to R&D, and thus leading to innovation and advancement of pharmaceuticals for the better good. This proposition is further backed by Mansfield's study that around 65% of pharmaceutical and 30% of chemical inventions would not have had taken place but for patent protection.¹¹¹ Needless to say, there is the contradicting

¹⁰⁷ Ibid.

¹⁰⁸ National Pharmaceutical Control Bureau and Ministry of Health Malaysia, *Drug Registration Guidance Document (DRGD)* March 2015.

¹⁰⁹ Ibid.

¹¹⁰ Ibid.

¹¹¹ Edwin Mansfield, *Patents and Innovation: An Empirical Study*, 1986, *Management Science* 32(2): 173-181. <http://dx.doi.org/10.1287/mnsc.32.2.173>.

effect of a premium fixed on medicine prices as well as creating barriers for generic entry at the same time. This works in the favour of research-based pharmaceutical companies to recoup costs of R&D from sales revenue. Thus, it is essentially in the interest of these firms for a strong patent protection regime in existence. For the low- and middle-income countries (“LMICs”), the opposite would be in their interest as barriers are lower for the cheaper generics to enter the market.

The matter is further exacerbated by the changing landscape of the global burden of disease. Chronic, non communicable diseases (“NCDs”) – primarily cardiovascular disease, chronic respiratory disease, diabetes and cancer, which slowly progress and involve long duration of treatment, were once thought to be associated with economic development and diseases of the rich.¹¹² By the dawn of the third millennium, NCDs are increasing in developing countries with its recent changing lifestyle choices.¹¹³ This means that developing countries are very reliant on developed nations’ expensive medicines. Much of the burden is falling on developing countries: in 2012, almost three quarters – 28 million out of 38 million NCDs deaths occurred in LMICs as inexpensive, energy-dense foods become more available and unhealthy lifestyle choices of tobacco use, and insufficient physical activity are adopted.¹¹⁴ In 2013, 80% of deaths from NCDs occurred in LMICs.¹¹⁵ In 2008, NCDs are estimated to account for 67% of all deaths in Malaysia.¹¹⁶

¹¹² Abdesslam Boutayeb and Saber Boutayeb, "The Burden of Non Communicable Diseases in Developing Countries," *International Journal for Equity in Health* 4, no. 2 (14 January 2005).

¹¹³See *ibid.*

¹¹⁴ World Health Organization (WHO), Global Status Report on Non Communicable Diseases, 2014 http://apps.who.int/iris/bitstream/10665/148114/1/9789241564854_eng.pdf?ua=1.

¹¹⁵ Millennium Development Goal (MDG) Task Force, Millennium Development Goal 8, Taking Stock of the Global Partnership for Development, 2015 <http://www.un.org/millenniumgoals/>.

¹¹⁶ WHO, Noncommunicable diseases country profile, 2011 http://www.who.int/nmh/countries/mys_en.pdf?ua=1 (accessed 17 February 2016).

Figure 5 Brand name drugs facing patent expirations

Brand	Generic Name	Manufacturer	Expected Availability ^a
Aciphex	Rabeprazole	Eisai	2013
Actos	Pioglitazone	Takeda	2012
Actoplus Met	Pioglitazone/metformin	Takeda	2012
AndroGel 1%	Testosterone	Solvay	2016
Atripla	Efavirenz/emtricitabine/tenofovir disoproxil	Gilead	Uncertain
Avapro	Irbesartan	Bristol-Myers Squibb	Generic available
Avodart	Dutasteride	GlaxoSmithKline	2015
Benicar	Olmesartan	Daiichi Sankyo	2016
Benicar HCT	Olmesartan/hydrochlorothiazide	Daiichi Sankyo	2016
Boniva	Ibandronate	Roche	Generic available
Caduet	Amlodipine/atorvastatin	Pfizer	Generic available
Celebrex	Celecoxib	Pfizer	2014
Combivir	Lamivudine/zidovudine	GlaxoSmithKline	Generic available
Crestor	Rosuvastatin	AstraZeneca	2016
Cymbalta	Duloxetine	Lilly	2013
Detrol	Tolterodine	Pfizer	2012
Diovan	Valsartan	Novartis	2012
Diovan HCT	Valsartan/hydrochlorothiazide	Novartis	2012
Evista	Raloxifene	Lilly	2014
Focalin XR	Dexmethylphenidate ER	Novartis	2012
Geodon	Ziprasidone	Pfizer	Generic available
Gleevec	Imatinib	Novartis	2015
Levaquin	Levofloxacin	Ortho-McNeil-Janssen	Generic available
Lexapro	Escitalopram	Forest	Generic available
Lipitor	Atorvastatin	Pfizer	Generic available
Loestrin 24 Fe	Ethinyl estradiol/norethindrone acetate/ferrous fumarate	Warner Chilcott	2014
Lovaza	Omega-3-acid esters	GlaxoSmithKline	2015
Lunesta	Eszopiclone	Sepracor	2012
Lyrica	Pregabalin	Pfizer	2013
Namenda	Memantine	Forest	2015
Nexium	Esomeprazole	AstraZeneca	2014
Niaspan	Niacin ER	Abbott	2013
Opana ER	Oxymorphone ER	Endo	2013
OxyContin	Oxycodone ER	Purdue Pharma	2013
Plavix	Clopidogrel	Sanofi-Aventis	2012
Protonix	Pantoprazole	Pfizer	Generic available
Reyataz	Atazanavir	Bristol-Myers Squibb	2017
Sensipar	Cinacalcet	Amgen	2016
Seroquel	Quetiapine	AstraZeneca	Generic available
Seroquel XR	Quetiapine ER	AstraZeneca	2017
Singulair	Montelukast	Merck	2012
Strattera	Atomoxetine	Lilly	2017
Tricor	Fenofibrate	Abbott	2012

Source: PL Detail-Documents. Anticipated Availability of First-Time Generics. *Pharmacist's Letter/Prescriber's Letter*. April 2012; Jack DeRuiter and Pamela L. Holston, *Drug Patent Expirations and the "Patent Cliff"* *U.S. Pharm.* 2012;37(6)(Generic suppl):12-20 available at <http://www.uspharmacist.com/content/s/216/c/35249> (accessed 17 February 2016)

Spurred by the global burden of disease, efforts to improve access to medicines such as the United Nations' Millennium Development Goals Target 8E was launched. It aims to collaborate with pharmaceutical companies in

providing access to affordable essential drugs in the developing world. Apart from this, Article 65 and 66 of TRIPS give developing and least developed countries (“LDCs”) longer transition periods to meet its obligations under TRIPS. While developed countries were only afforded a one-year transition period, developing countries were afforded five years, and LDCs were given a ten-year transition period, which was subsequently extended twice in 2002 for pharmaceutical products until 1 January 2016, and in 2005 for all products (other than Articles 3, 4 and 5) until 1 July 2013.¹¹⁷

Furthermore, beginning in 2010 up to the next six or seven years, the pharmaceutical industry is facing one of the biggest waves of patent expirations in history, a phenomenon known as “patent cliff” (see figure 5 above). Brand named blockbuster drugs that lose patent protection open doors for generic drugs entrance to the market.

In fact, only a handful of drugs on WHO’s Model List of Essential Medicines¹¹⁸ (“EML”) are protected by patent, some suggested less than 5%.¹¹⁹ This list addresses the “priority health care needs of the population” and are selected “with due regard to disease prevalence and public health relevance, evidence of clinical efficacy and safety, and comparative costs and cost-effectiveness”.¹²⁰ Although the EML is not legally binding, it has gained widespread acceptance with 4 out of 5 countries having adopted a national list based on the EML.¹²¹

¹¹⁷ Joint United Nations Programme on HIV/AIDS (UNAIDS) and United Nations Development Programme (UNDP), TRIPS Transition Period Extensions for Least-Developed Countries.(note 9 above)

¹¹⁸ The Essential Medicines List is first pioneered by the WHO in 1977 and is revised every two years by the Expert Committee on Selection and Use of Medicines.

¹¹⁹ Sumner La Croix and Ming Liu, "Patents and Access to Essential Medicines," *Frontiers of Economics and Globalization* 2; DOI: 10.1016/S1574-8715 (07) 00013-9 (2008): 423-464.

¹²⁰ WHO, Essential Medicines and Health Products http://www.who.int/medicines/services/essmedicines_def/en/ (accessed 17 February 2016).

¹²¹ Jonathan D. Quick et al., "Twenty-Five Years of Essential Medicines," *Bulletin of the World Health Organization* 80, no. 11 (2002): 913-914.

According to a study, only 17 of the 319 listed essential medicines in 2003 were patented in developing countries, suggesting that poverty rather than patents limit access.¹²² Another study found that of the 79 medicines targeted to address NCDs in the EML, only eight required in-depth patent or exclusivity assessment and upon further review, none of these 79 medicines were found to have patent or exclusivity protection to hinder possible generic production of the active pharmaceutical ingredient¹²³ (“API”) or EML indicated formulation or dosage.¹²⁴ The authors proposed that the study inferred that the availability and affordability of NCD medicines in LMICs may be affected by other and/or additional considerations. Many pharmaceutical companies are on the same stand, insisting that patents have little to do with access as most “essential medicines” are already off patent.¹²⁵

It is undeniable that factors affecting access to medicines are multiple, ranging from low per-capita income, mark-ups, to the absence of well-functioning distribution system and more. However, the proposition that patents do not affect affordability of medicines cannot stand. One important criterion for the inclusion of medicine in the WHO’s EML is cost effectiveness.¹²⁶ As many States are not able to afford patented medicines, those medicines are excluded from the list. The exclusion of vast majority of patented drugs in WHO’s EML generates criticisms. An article commented that the list is “replete with antiquated and increasingly ineffective drugs” and

¹²² Amir Attaran, "How Do Patents and Economic Policies Affect Access to Essential Medicines In Developing Countries?," *Health Affairs* 23, no. 3 (2004): 155-166; doi:10.1377/hlthaff.23.3.155.

¹²³ The chemically active substance which is the main ingredient in a medicine that causes the direct effect on the diagnosed disease, treatment or cure.

¹²⁴ Tim K. Mackey and Bryan A. Liang, "Patent and Exclusivity Status of Essential Medicines for Non-Communicable Disease," *PLoS ONE* 7, no. 11: : e51022. doi:10.1371/journal.pone.0051022 (2012).

¹²⁵ See Anonymous, Industry Use of WHO Model List of Essential Medicines as Defense Against Patent Abuses, 2014 <http://keionline.org/node/1915> (accessed 18 February 2016).

¹²⁶ WHO, *The World Medicines Situation*, 65.(note 22 above)

includes “less than 2 percent (21) of the 1,377 drugs indicated for global diseases” for the last quarter of the twentieth century.¹²⁷As identified, the problem lies on the fact that many newer and more effective “essential medicines” are patented and are either unavailable in certain LMICs or are simply unaffordable by people in these regions.¹²⁸

As has been mentioned above previously, the WHO identified that price is the major impediment to access to medicines. The definition of essential medicines should not dictate the accessibility of medicines. Neither should the fact that other factors impede access negate the question of whether patents hinder access to medicines. There are economic theories of price models and empirical studies that support the advancement that patents increase drug prices. Therefore, the next section of the paper focuses on how a product patent on a drug affects access to medicine due to price effects by reviewing these theories and studies. The claim that higher prices are justified as an incentive for further research and innovation without which, many wonder drugs would not have materialised will be examine later in chapter IV of the paper.

a) Economic Theories

In a market economy, the interaction of producers (supply) and consumers (demand) determined the price of goods. In a perfectly competitive market, neither the producers nor the consumers determine the product price and price equilibrium is determined by the market force of interaction between supply and demand. The perfect competition model is usually characterised by large number of buyers and sellers in the market; rational

¹²⁷ Maxwell R. Morgan, "Medicines for the Developing World: Promoting Access and Innovation in the Post-TRIPS Environment," *64 U.T. Fac. L. Rev.* 45, (2006): 71-72.

¹²⁸ Sumner La Croix and Ming Liu, "Patents and Access to Essential Medicines," 423-464.(note 119 above)

buyers with excellent information to compare prices of suppliers; suppliers have free entry and exit to the market; and quality homogenous products offered by different suppliers.

The generic drug market is a relatively close model reflecting perfect competition. Competition is steep between different manufacturers for the same product, the patent expires and there is no legal barrier of entry to the market and costs of manufacturing the medicine is comparatively low. For instance, aspirin is manufactured by many different companies. A rise in the price of aspirin by a company will result in the loss of market share as consumers will purchase the cheaper and equivalent product from other companies. This exemplifies price elasticity, where demand is highly responsive to the price of goods in a market where close substitutes exist.

The market price mechanism can be distorted when buyers or sellers have market power. Research-based pharmaceutical companies, contrary to generic drug manufacturers have the market power to interfere with prices due to the lack of price competition and the inability of consumers to select products. To illustrate lack of price competition, patents create barriers to market entry by arming brand name drugs innovators with the ability to exclude competitors who might have marketed similar medicines with the same API. The inability of consumers to select products is demonstrated by buyers who commonly rely on health care providers to give them information about treatment.

Furthermore, patented medicines are usually heterogeneous and each can be used only for treatment of a specific disease – many new and essential APIs are normally single-source products with no substitute product available elsewhere.¹²⁹ Also, the more essential the medicine is with no or fewer direct substitutes, especially in the case of life-saving drugs, the more demand is price inelastic as patients are willing to pay almost any price for the medicine.

¹²⁹ Jakkrit Kuanpoth, *Patent Rights in Pharmaceuticals in Developing Countries: Major Challenges for the Future* (Edward Elgar Publishing, 2010), 117.

The main element that influences a patient's demand is his or her income rather than price. The result is often a non-competitive market such as monopoly, which features only one seller of a product that has no close substitutes. This allows pharmaceutical companies to charge a higher price for its medicine than otherwise.

Where there are similar therapeutic substitutes by a few pharmaceutical companies, the market structure is defined as an oligopoly in which companies are interdependent and some degree of competition remains. Hence, the presence or absence of pharmaceutical patents conditions the existence of price competition to a large extent.

b) Empirical Studies and Extrapolation

The UN Sub-Commission on the Promotion of and Protection of Human Rights in its Resolution 2000/7 explicitly recognises that “TRIPS could affect the enjoyment of the right to health – in particular through its effect on access to pharmaceuticals”.

i) Health and Pharmaceutical Financing

Health and pharmaceutical funding as well as financing stem from public sources such as government budgets and national social health insurance, and private sources such as patients' direct out-of-pocket expenses which are not reimbursed. An insurance coverage or public spending may reduce consumers' sensitivity to price differences. The intensity of funding by these sources however, varies distinctively among regions and countries. This irony of access to healthcare is well conceived by Tudor Hart's Inverse Care Law – public healthcare services tend to benefit people with the most means and need it less rather than people with the least means and are in great need of healthcare.¹³⁰

Health spending is directly related to a nation's economic output, which is measured by the gross domestic product ("GDP). Health expenditures of developing countries are comparatively lower than developed countries' global average of 8.7% of GDP.¹³¹ For instance, Congo and Indonesia's health spending was 2.1% and 2.5% of its GDP respectively; Uganda and Bolivia spent more with 7% and 6.4% respectively.¹³² Public health expenditure accounts for 57%, while private health expenditure accounts for 42% of the global health expenses.¹³³ Excluding the US, approximately 70% of healthcare expenses are supported publicly in developed countries, while out-of-pocket expenses are proportionately higher in developing countries like Guinea, with up to 86% of healthcare spending being private.¹³⁴ Moreover, in developing countries region, the government devote less public spending on healthcare: close to 9% in Africa and less than 5% in South East Asia compared to Europe's 15%.¹³⁵

In 2013, Malaysia spent 4% of its GDP on healthcare.¹³⁶ Government and out-of-pocket expenses account for 53% and 47% respectively in 2012.¹³⁷ The figures though comparatively better than certain developing countries are still minimal compared to developed nations. A local medical expert commented that the public healthcare spending is below the level

¹³⁰ See Julian Tudor Hart, "The Inverse Care Law," *The Lancet*, (27 February 1971): 405-412; doi: 10.1016/S0140-6736(71)92410-X.

¹³¹ Management Sciences for Health, *MDS-3: Managing Access to Medicines and Health Technologies* (Arlington, VA: Management Sciences for Health, 2012), 11.4.

¹³² Ibid.

¹³³ Ibid., 11.5.

¹³⁴ Ibid.

¹³⁵ Ibid.

¹³⁶ The World Bank, Health Expenditure, total (% of GDP) <http://data.worldbank.org/indicator/SH.XPD.TOTL.ZS> (accessed 23 February 2016).

¹³⁷ Malaysia National Health Accounts: Health Expenditure Report 1997-2012, ed. Malaysia Ministry of Health, <http://www.mma.org.my/Portals/0/PDF%202015/Health%20Expenditure%20Report%201997%20-%202012.pdf>.

recommended by the WHO.¹³⁸ The country does not regulate the prices of medicines and it is reported that prices are rising faster than the developed countries.¹³⁹ WHO-Health Action International survey showed prices of essential medicines are generally about 2 to 4 fold and some to 16 times higher than international reference price, indicating high medical costs.¹⁴⁰ The government is finding it challenging to sustain the escalating cost of drug prices and patients are increasingly asked to buy their own medicines.¹⁴¹ Many purchase medicines on their own expense due to the low availability of medicines and generics on the National Essential Drugs List.¹⁴² A study by Lopez *et al.* revealed that developing countries carry 90% of the global disease burden with over 80% of the world's population, but account only for 12% of the global healthcare expenditure.¹⁴³

ii) Role of Generics

Empirical studies have shown that prices of drugs declined tremendously after generic entry, with one indicating a decline of approximately 38-46.4% for physician administered drugs.¹⁴⁴ In addition, generics are priced 75%

¹³⁸ FMT Reporters, Prof: Govt's Public Healthcare Budget Still Too Small, 15 October 2015, FMT News <http://www.freemalaysiatoday.com/category/nation/2015/10/15/prof-govts-public-healthcar-e-budget-still-too-small/> (accessed 23 February 2016).

¹³⁹ Zaheer Ud Din Babar et al., "Evaluating Drug Prices, Availability, Affordability, and Price Components: Implications for Access to Drugs in Malaysia," *PLOS Med* 4, no. 3: e82 (2007); doi: 10.1371/journal.pmed.0040082.

¹⁴⁰ Ibid.

¹⁴¹ Ibid.

¹⁴² Zaheer-Ud-Din Babar et al., "Pharmaceutical Industry, Innovation and Challenges for Public Health: Case Studies from Malaysia and Pakistan," 193-204.(note 56 above)

¹⁴³ Management Sciences for Health, *MDS-3: Managing Access to Medicines and Health Technologies*, 11.5.(note 131 above)

¹⁴⁴ See Rena M. Conti and Ernst R. Berndt, "Specialty Drug Prices and Utilization after loss of U.S. Patent Exclusivity, 2001-2007," *National Bureau of Economics Research (NBER) Working Paper No. 20016*, (March 2014); Dong-Churl Suh et al., "Effect of Multiple-Source Entry on Price Competition After Patent Expiration in the Pharmaceutical Industry " *Health Services*

lower than the retail price of innovator drugs.¹⁴⁵ The result is that in 2014, generic drugs brought a savings of US\$ 254 billion to the US health system.¹⁴⁶ The consequence of patent protection on drug pricing is clearly visible from the price differences between a patented drug and a generic. In Malaysia, the antibiotic Amoxicillin Oral Suspension 125mg/5ml was 1044% more expensive than its generic version; the antirheumatic drug Voltaren® 25mg priced at RM0.27 per tablet was 900% higher than the generic equivalent priced at RM0.03 per tablet; and similarly, the branded equivalent of Terfenadine 60mg at RM0.42 per tablet in comparison to the generic at RM0.19 per tablet was 221% more expensive.¹⁴⁷

Other instances that strongly support patents lead to higher prices in developing countries are the HIV/AIDS pandemic crisis and the issuance of compulsory licensing on Bayer's Sorafenib by India. When a patent protected antiretroviral treatment was first introduced, cost of treatment per patient per year was priced at US\$ 10,000.¹⁴⁸ Its generic equivalent of the therapy brought down the cost to US\$ 350 per patient per year.¹⁴⁹

The pharmaceutical companies themselves know the importance of patents and its impacts once a patent expires. Hence, many have employed tactics such as evergreening. Here, slight modifications of old drugs with no significant therapeutic changes are done to patent the "new invention". In a

Research 35, no. 2 (2000): 529-547.

¹⁴⁵ Congressional Budget Office Congress of the United States, *Effects of Using Generic Drugs on Medicare's Prescription Drug Spending* (Publication 4043, September 2010).

¹⁴⁶ Generic Pharmaceutical Association, *Generic Drug Savings in the U.S., Seventh Annual Edition*: 2015
http://www.gphaonline.org/media/wysiwyg/PDF/GPhA_Savings_Report_2015.pdf (accessed 23 February 2016).

¹⁴⁷ Mohamed Izham Mohamed Ibrahim and Salmah Bahri, "Drug Policies and Pricing Mechanism: The Malaysian Perspective," in *International Drug Regulatory Mechanisms*, ed. Albert I. Wertheimer and Mickey C. Smith (Pharmaceutical Products Press, imprint of the Haworth Press, 2003).

¹⁴⁸ WHO, "Access to Medicines," *WHO Drug Information* 19, no. 3 (2005): 236-241.

¹⁴⁹ *Ibid.*

study conducted in 2010, one of the main barriers to local production of generic medicines in Malaysia is identified to branded innovator companies' uses of patent clustering – acquisition of multiple patents surrounding the basic patents of the drug products.¹⁵⁰

Even with escalating development costs, depleted NME pipelines and patent cliffs, pharmaceutical companies are moving towards new directions and strategies with ample of evidence to suggest that drugs are going to be more expensive. Pharmaceutical companies have sought salvation in biotechnology, creating biologics – large protein molecules derived from living organisms. Unlike the typical conventional drugs, biologics are said to fetch a price 20 times more.¹⁵¹ Given its larger and complex structure, biologics are frequently administered into the patient's body directly via injection or infusion. They are therefore, more difficult to characterise and a minute difference in the production process may generate variations in the resulting protein molecule. As a consequence, quality control is all the more important. This translates into an even higher barrier of entry for biosimilars, the generic bioequivalent of biologics and thus, fewer entrants. Against this backdrop, large pharmaceutical companies' modus operandi seems to be partnerships, mergers and acquisitions of biotechnology firms to bolster their pipelines and improve efficiencies. The slow growth in developed markets has also steered big Pharma's attention to emerging economies such as Brazil, Russia, India and China. From 2012 to 2017, IMS Health has forecasted the growth rate for “pharmerging” markets to be 13% in comparison to the mature markets' 2%. The theories and events above evince that pharmaceutical patents lead to higher prices and consequently, impedes access to medicine and that it is here to stay as new products emerge.

¹⁵⁰ Zhi Yen Wong et al., "Malaysian Generic Pharmaceutical Industries: Perspective from Healthcare Stakeholders," 193-203.(note 55 above)

¹⁵¹ Ian Evans, "Follow-on Biologics: A New Play For Big Pharma," *Yale Journal of Biology and Medicine* 83, no. 2 (2010): 97-100.

III. Patent Law

The common features shared by patents anywhere are that they are usually obtained by the inventor or by the person first to file a product or a process which are novel, of certain inventiveness and are of industrial application at the patent office. TRIPS require all those things for a subject matter to be patentable and most countries' law may have similar but not necessarily identical requirements. The right to exclude others from making or using the invention in any way whatsoever is then granted for a limited period of time to the benefit of the inventor in return for the disclosure of the invention to the public.

1. International Patent Law

To date, there is neither a single world patent court to adjudicate patent infringement matters nor a global patent to protect novel, non-obvious inventions of industrial application. The protection regime of IPRs is essentially domestic and territorial in nature. A patent granted in one country cannot be enforced in another country. Such a right is only enforceable if the product in question is afforded patent protection in the disputed state.

By the 19th century, international trade had become a common occurrence. Naturally, it became apparent that purely national protection was not sufficiently effective and many were seeking to patent their inventions abroad. National laws differ from one another and many were not foreigner-friendly. International attempts to remedy the confused state of patent law and facilitate patent protection in foreign states brought about the conclusion of several international conventions. The convention which mainly concerns patent protection is the Paris Convention.

The Paris Convention set up a Union for the protection of industrial property constituted by all members to the convention.¹⁵² The Paris

Convention is today administered by the World Intellectual Property Organization (“WIPO”), which administers another 25 IP conventions with 188 member states.¹⁵³ Substantively, the Paris Convention imposes the national treatment obligation on member states so that nationals of all member states enjoy the same protection and legal remedy granted to its own nationals.¹⁵⁴ Inventors are also given a priority period of 12-months to file for patents in other countries of the Union once a duly application for patent is filed in one of the member states.¹⁵⁵ Consequently, the application will not be invalidated by filings of third parties during the interval period.¹⁵⁶

Member states are also given the right to impose non-exclusive compulsory licenses to prevent abuses that may arise from the exercise of the exclusive rights conferred by the patent; but the imposition of compulsory licenses may only be applied after a certain fixed period.¹⁵⁷ A forfeiture of the patent will be provided only in cases where the grant of compulsory licenses is proven to be insufficient in preventing the said abuses and such proceeding may only be instituted before the expiration of two years from the grant of the first compulsory license.¹⁵⁸ The Paris Convention, however, did not attempt to harmonize national patent laws. Patents obtained for the same invention in other countries remained independent concerning their grant and validity.¹⁵⁹

The Patent Cooperation Treaty (“PCT”) is another major international law

¹⁵² Article 1(1) of the Paris Convention

¹⁵³ World Intellectual Property Organization (WIPO), WIPO-Administered Treaties <http://www.wipo.int/treaties/en/> (accessed 4 March 2016); World Intellectual Property Organization (WIPO), Member States <http://www.wipo.int/about-wipo/en/> (accessed 4 March 2016).

¹⁵⁴ Article 2(1) of the Paris Convention

¹⁵⁵ Article 4A(1) and C(1) of the Paris Convention

¹⁵⁶ Article 4B of the Paris Convention

¹⁵⁷ Article 5A(2) and (4) of the Paris Convention

¹⁵⁸ Article 5A(3) of the Paris Convention

¹⁵⁹ Article 4*bis* of the Paris Convention

treaty signed in 1970. It provides a unified filing procedure of a single “international” patent application in the designated states of the desired protection.¹⁶⁰ The single “international” patent application may be misleading in the sense that it is not a filing of an international patent application and it does not attempt to harmonize patent laws. The PCT only facilitates the filing of an application at national and regional offices under a single procedure. The decision on granting the patent remains the responsibility of each of the national and regional offices.¹⁶¹

The harmonization of patent protection is expanded at a regional level, when the European Patent Convention (“EPC”) established the European Patent Office (“EPO”) that grants European patents. Article 64 of the EPC provides that a European patent once granted, confers the same right as would be conferred by a national patent.

Despite the multiple international treaties and conventions in place, patent law on a universal level was fragmented and lacked uniformity. Procedures for the revision and amendment of the conventions were barely regulated and vast majority of the amendments only took place with unanimous agreement.¹⁶² Furthermore, signatories were free to decide whether to accept or ratify the conventions.¹⁶³ Membership of the Paris Convention then was far from universal and many developing countries view it as deterrence to the development of their own technology.¹⁶⁴

Even if a patent right is obtained, enforcing the right is another matter of predicament. Under the PCT, though patents could be obtained on a single

¹⁶⁰ Article 3(1) of the Patent Cooperation Treaty

¹⁶¹ See Article 11(4) of the Patent Cooperation Treaty

¹⁶² Peter-Tobias Stoll et al., *Max Planck Commentaries on World Trade Law, Volume 7: WTO - Trade-Related Aspects of Intellectual Property Rights*, 3.(note 13 above)

¹⁶³ Ibid.

¹⁶⁴ Susan K. Sell, *Power and Ideas: North-South Politics of Intellectual Property and Antitrust* (State University of New York Press, 1998), 110.

international application, patent right holders still have to enforce the national patents country by country. Such enforcement rights by patentees in national courts were from the beginning outside the regulatory scope of the conventions and many were originally silent on the implementation and enforcement of patent rights by national judicial authorities.¹⁶⁵ Later, the issue was addressed and taken up by some conventions. For instance, Article 28 of the Paris Convention provides that disputes between member states concerning the interpretation or application of the Convention may be brought before the International Court of Justice (“ICJ”). This however, was criticised to barely have had any practical effect as the ICJ lacks teeth.¹⁶⁶ A very important principle of international law is that the ICJ will only have jurisdiction to adjudicate proceedings if both states mutually consent to the proceedings.¹⁶⁷ Likewise under the Paris Convention, member states are inferred to have contractually submitted to the jurisdiction of the ICJ unless they have declared that they do not consider themselves bound.¹⁶⁸ It was also said that Article 28 was only adopted during the Stockholm revision of the Paris Convention and not all member states ratified the provision.¹⁶⁹

The effectiveness of patent enforcement by individual patentees of the developed states is questionable given that the only remedy available is that recourse can only be taken to the judicial system of the developing countries -the very place they want to seek redress in which patent infringement took place. As mentioned above, the enforcement of patent protection in these countries lacked transparency. The question then is why patents are viewed

¹⁶⁵ Peter-Tobias Stoll et al., *Max Planck Commentaries on World Trade Law, Volume 7: WTO - Trade-Related Aspects of Intellectual Property Rights*.(note 13 above)

¹⁶⁶ See *ibid.*, 4; Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (United States: Oxford University Press, 2008), 37.

¹⁶⁷ Article 36 of the Statute of the International Court of Justice

¹⁶⁸ Article 28(2) of the Paris Convention

¹⁶⁹ Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines*, 37.(note 166 above)

with such importance and what justifies the existence of a patent regime.

2. Rationales of Patent System

Ever since the inception of patent rights, many theories and justifications were given in support of the patent system. Philosopher John Locke propelled that an individual should have a natural or moral right to their ideas and naturally, these ideas and works of the individual should be protected just like other property. The notion however seems to run afoul of many aspects of patent law - for instance, the period fixed to the protection of one's patent right, a modification may be made to a product based on the idea of a predecessor, certain categories are excluded from patentability, and so on.¹⁷⁰ This theory also focuses on the individual inventor and fails to acknowledge the collectively-engineered effort of individuals or provide an explanation for the granting of pharmaceutical patents to companies.¹⁷¹

The reward theory posits that an inventor deserves to be rewarded for introducing a new knowledge to the contribution of the society. In turn, this creates incentives to invent, without which, inventions and innovations might not have had taken place. This theory is subject to criticisms as the reward may fail to reflect or be disproportionate to the actual social value of the creation.¹⁷² Oddi (1987) argues that significant amount of inventions are still made regardless of patent as rewards.¹⁷³ In fact the initial intended purpose

¹⁷⁰ See *ibid.*, 30; Sirgid Sterckx, "The Moral Justifiability of Patents," *Journal of the European Ethics Network* 13, no. 2 (2006): 249-265; William Fisher, "Theories of Intellectual Property," in *New Essays in the Legal and Political Theory of Property* (Cambridge University Press, 2001).

¹⁷¹ Poku Adusei, *Patenting of Pharmaceuticals and Development in Sub-Saharan Africa Laws, Institutions, Practices and Politics* (Springer, 2013), 117.

¹⁷² Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines*, 31.(note 166 above); Birgitte Andersen, The Rationales for Intellectual Property Rights: The Twenty-First Century Controversies, 2003, Druid Summer Conference, Copenhagen http://www.druid.dk/conferences/summer2003/Papers/B_ANDERSEN.pdf (accessed 9 March 2016).

¹⁷³ Poku Adusei, *Patenting of Pharmaceuticals and Development in Sub-Saharan Africa*

of the reward rationale could work to the undesired effect of the current patent system. For instance, the US Government Accountability Office (2006) commented that patent law discouraged pharmaceutical companies from developing new drugs as focus shifts to making excessive profits through slight modification of existing pharmaceuticals.¹⁷⁴

Yet another theory that seeks to rationalise the existence of patent is the contract theory. The patentee reveals information of his invention in manner ordinary persons skilled in the art is able to utilise and practise the invention. The public, in providing consideration for the disclosure, grants the patentee an exclusive right for a certain period. This theory too has its limitations. While some have criticised that the patentee may present the patent as arcane and ambiguous as possible to reveal little information, the law has focused on requiring the disclosure to be enabling, failing which, a patent may not be granted. A more coherent reasoning Hestermeyer advanced is that many inventions could be reproduced via reverse engineering without the need for the disclosure of the makings. In cases where reverse engineering proves challenging, the inventor may not have the incentive to opt for patent protection as they can keep the invention a secret perpetually.¹⁷⁵

Perhaps the most common and influential rationale in modern patent law system is the incentive theory, its rationales of which traces back to the history of the establishment of a patent system. Back in the past, patents were granted at the discretion of the ruler to incentivise innovations and reward the inventor instead of granting monopoly privileges to exclude competitors.¹⁷⁶ This remains the main purpose of the establishment of a patent system even in

Laws, Institutions, Practices and Politics, 118.(note 171 above)

¹⁷⁴ Ibid.

¹⁷⁵ Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines*, 30.(note 166 above)

¹⁷⁶ Ronald A. Cass and Keith N. Hylton, *Laws of Creation: Property Rights in the World of Ideas* (Cambridge, Mass: Harvard University Press, 2013), 49.

modern days. For instance, Article 1 Section 8 of the US Constitution provides that “Congress shall have the power...to promote the progress of Science and useful Arts by securing for limited times to... inventors the exclusive right to their respective...discoveries”.

Of all the IPRs, patents remain the most controversial as not only do they confer significantly stronger exclusive rights, the subject matter of patents – technology is said to directly impinge on economic prosperity.¹⁷⁷ The protection of patents is considered necessary to maintain economic efficiency, in which resources are allocated and used in the most productive manner possible. Absent the protection of patents, market failure occurs, where goods are allocated in an inefficient manner. One of the common causes of market failure is public goods. The abstract, intangible notions and creation of the mind that IPRs seek to protect are typical illustrations that display the properties and characteristics of a public good. They display attributes that are non-rival and non-excludable in consumption. These mean that one person’s use of the public good does not diminish the quantity that is available for others and it is also not possible to deter one from enjoying the public good once it is made available. Typically associated as a public good are things like roads and national defence while knowledge is an abstract example. One’s use of the knowledge does not affect the originator’s knowledge and neither could the originator stop others from using it once disclosed. The problem then is there is an incentive to free-ride on the innovative effort of the originator. Others will start imitating the same technology and compete with the inventor. The incentive to innovate is eroded since the costs of developing the innovation is borne by the inventor without possibility of recoupment, let alone

¹⁷⁷ Sean A. Pager, "Patents on a Shoestring: Making Patent Protection Work for Developing Countries," *Georgia State University Law Review* 23, no. 4 (2006-2007): 755-808. In the context that patents confer stronger exclusive rights: Sean mentioned that unlike copyrights, an individual who independently discovered the same patented invention will not be granted a patent and unlike trademarks, any use of the invention is governed rather than uses within specific context.

make a profit.

On the other hand, the society has an interest in promoting widespread access to new information and technology. The patent system therefore, encourages inventors to disclose their inventions instead of keeping them a secret. Technological progress is possible with the spread of such information and consequently, such activity induces the economic growth of a country. Given that the interests of the inventor and the public are at differing ends, there is an obvious tension between invention and dissemination. To achieve a balance between the two, the patent regime, throughout history, operates to reconcile the tension between public interest in gaining access to the benefits of inventions and private interest of patentees in fully exploiting the economic benefits flowing from the exclusive rights afforded them. Hence, this serves as the main reason of the debate between the invention-prone developed countries and the dissemination-oriented developing countries.

a) The Debate For and Against Stronger Protection of Patents

The trend has always had the developed countries leaning towards a stronger protection for patent rights while the developing countries had imposed restrictions with weak protections enforced. These frameworks and practises were mainly determined by the economic, social and political interests in these countries. The bulk of new and advanced technologies are inadvertently found in developed countries. Consequently, possession of patent rights is also heavily concentrated in these parts of the world. The underlying assumption is that new technologies and products are often costly to develop. The argument then is that these R&D costs are recovered through the temporary monopoly availed by patent rights. Clearly, it is only desirable for countries with a high devotion ratio of R&D in GDP to protect returns to inventive activity via strong patent protection. Consequently, developed

countries are losing out on market share in sectors they used to dominate given that developing countries with weak patent protection could free ride on the technology. Therefore, patents work to correct the situation and promote investments in R&D as well as technological innovations. However, it should be noted that patents are not effective in all sectors and fields. Patents are effective in R&D intensive industries and studies have proven that it is the most effective in pharmaceuticals.¹⁷⁸

Another line of argument for the protection of patents in developing countries is said to be in the self-interest of those very states.¹⁷⁹ Local innovations are spurred as more active participation in R&Ds take place under enhanced protection of patents.¹⁸⁰ Technology transfer and foreign direct investments (“FDIs”) increases as companies are more willing to transfer technology and invest in places where patent rights are well-protected.¹⁸¹ One is deterred from exporting its patented goods into a market where piracy and counterfeiting are likely to occur.

At the other extreme, studies suggest that developing countries derives significant advantages from lax regulation of the IP regime.¹⁸² This applies to developing countries characterised by little inventions and are reliant on the imitation and adaptation of technologies available in the public domain. In

¹⁷⁸ See Edwin Mansfield, *Patents and Innovation: An Empirical Study*.(note 111 above); Roberto Mazzoleni and Richard R. Nelson, "The Benefits and Costs of Strong Patent Protection: A Contribution to the Current Debate," *Elsevier Science B.V. Research Policy* 27, (1998): 273-284.

¹⁷⁹ Carlos Alberto Primo Braga, "The Economics of Intellectual Property Rights and the GATT: A View From the South," *Vand. J. Transnat'L*. 22, (1989): 243-264.

¹⁸⁰ *Ibid.*

¹⁸¹ *Ibid.*

¹⁸² See Roberto Mazzoleni and Richard R. Nelson, "The Benefits and Costs of Strong Patent Protection: A Contribution to the Current Debate," 273-284.(note 178 above); Carlos Alberto Primo Braga, "The Economics of Intellectual Property Rights and the GATT: A View From the South," 243-264.(note 179 above); J.H. Reichman, "Intellectual Property in International Trade: Opportunities and Risks of a GATT Connection," *Vanderbilt Journal of Transnational Law* 22, (1989): 747-891.

terms of consumer welfare, these countries gain from explicitly permitting cheap domestic imitations of innovations elsewhere and little to lose if domestic R&D is not of core importance to the development of the country.¹⁸³

The US is traditionally a country where its comparative advantage lies more in innovation. It would therefore be in the country's interest for a strong patent system to be constituted in countries whose comparative advantage lies in the imitation of other's technologies. The US was plagued with problems of counterfeit goods and product piracy in developing countries, which also made their way into the US market. According to Abbott (1989), the US International Trade Commission estimated losses of US companies at US\$ 43 billion to US\$ 61 billion in 1986 solely from the misappropriation of intellectual property.¹⁸⁴ Hence, it is not surprising that the US spearheaded the action in placing a strong IP regime in developing countries. However, the principle of territoriality denotes that imitation is not illegal per se in a country where patent is weakly enforced though the product is patented elsewhere. Hestermeyer postulates that to speak of losses suffered due to piracy in such countries is misplaced and the argument is one based on moral rather than legal grounds.¹⁸⁵ This is also easily the main reason why developed countries have been insisting on the existence of a strong patent regime in developing countries. Whether or not the debate for stronger patent protection in pharmaceutical products is justified is examined in Chapter IV.

3. WTO/GATT System

After the Second World War ended, three institutions were envisaged to

¹⁸³ Micheal Trebilcock et al., *The Regulation of International Trade*, 517.(note 11 above)

¹⁸⁴ Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines*, 38.(note 166 above)

¹⁸⁵ Ibid.

rebuild and strengthen the global economy. Of relevance here is the International Trade Organization (“ITO”), which was intended to regulate international trade and promote free trade.¹⁸⁶ The ITO however, was never formed as it was met with resistance from the US Congress and only its agreement on the trade of goods, GATT came into force.¹⁸⁷

GATT contains the member states’ tariff concessions as well as general obligations. Article XI for instance, prohibits the use of quantitative restrictions on imports and exports. Failure of compliance with GATT renders the victimised member a right to complain under its comprehensive dispute settlement system, in which, the WTO largely drew experiences from and established a more structured as well as refined system. The Understanding on Rules and Procedures Governing the Settlement of Disputes (“DSU”) integrated all disputes in the WTO under one dispute settlement procedure. This means that claims may be based on any of the multilateral trade agreements included in the Annexes to the Agreement establishing the WTO¹⁸⁸ - article 64 TRIPS provides for the application of the DSU when dispute arises.

The rules and procedures of the DSU is administered by the Dispute Settlement Body¹⁸⁹ (“DSB), which is constituted by the General Council that meets under special chair and rules of procedure when acting as the DSB.¹⁹⁰ Where a dispute arises, members should have a series of consultation before requesting for an establishment of a panel.¹⁹¹ Only when members failed to arrive at an agreement will the DSB established a panel to address the

¹⁸⁶ Sarah Joseph, *Blame It on the WTO?* (Oxford University Press, 2011), 8.

¹⁸⁷ Ibid.

¹⁸⁸ Article 1 of the DSU

¹⁸⁹ Article 2 of the DSU

¹⁹⁰ Peter-Tobias Stoll et al., *Max Planck Commentaries on World Trade Law, Volume 7: WTO - Trade-Related Aspects of Intellectual Property Rights*, 6.(note 13 above)

¹⁹¹ Article 4 of the DSU

issue.¹⁹² The disputants may also seek further redress before a standing Appellate Body, which comprises seven judges.¹⁹³ The final decisions and recommendations of the panel or Appellate Body should be adopted by the DSB and members should comply with such rulings.¹⁹⁴ If the wrongdoing member failed to implement the recommendations and rulings within the reasonable period of time determined, the wronged member may request for a mutually acceptable compensation and in severe cases, request authorization from the DSB to suspend the application to the member concerned of concessions or other obligations under the covered agreements.¹⁹⁵

The result of the DSU formulation is said to be of “ambivalent significance” – on one hand, members may “counter TRIPS violations with the institution of trade sanction. On the other hand, members may suspend rights under the TRIPS Agreement as a “trade sanction” to induce compliance with another WTO agreement.”¹⁹⁶

Intellectual property was largely excluded in GATT. The main article providing for the matter is the Article XX(d) exception. It provides leeway to members’ basic obligation in GATT with respect to trade. Members are allowed to adopt “measures...necessary to secure compliance with laws or regulations which are not inconsistent with the provisions of this Agreement, including those related to...the protection of patents”. This exception however, is subject to the chapeau of Article XX which provides that the measures should not be “applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade”. The

¹⁹² Article 6 of the DSU

¹⁹³ Article 17 of the DSU

¹⁹⁴ Article 16(4), 17(14), and 21(1) of the DSU

¹⁹⁵ Article 22(2) of the DSU

¹⁹⁶ Peter-Tobias Stoll et al., *Max Planck Commentaries on World Trade Law, Volume 7: WTO - Trade-Related Aspects of Intellectual Property Rights*, 8.(note 13 above)

threshold is ultimately high in order to succeed in proving the justified use of a measure in protecting patents. First, the measure in question should aim to fulfil the objective in protecting patents; second, the measure should be necessary to achieve the desired result; and lastly, in order to fulfil the requirements of the chapeau, the measure should not be applied in a manner that would constitute arbitrary or unjustifiable discrimination. Furthermore, very little cases involved IP in GATT. It was said that in the hundreds of cases before the GATT panel, only three involved IP, with the US as a defendant each time.¹⁹⁷ Regulations in respect of IP were mainly left to domestic law, which however, should be done in observance of the four corners of GATT. A member should not unilaterally withdraw trade concessions or reduce access to its market on grounds that it considers appropriate in relation to regimes outside the scope of GATT such as IP.¹⁹⁸ That was precisely what the US seeks to do under its unfair trade practice statutes such as the section 337 of the Tariff Act and section 301 of the US Trade Act 1974.

Under section 301, the US could unilaterally imposed trade sanctions against foreign countries with trade practises that are perceived to be unjustifiable, unreasonable or inconsistent with trade agreements. Countries that did not effectively provide for the protection of IPRs too could trigger an investigation under the Act. The law proved effective. Back then, South Korea did not provide patents on foods, chemicals and drugs while Brazil excluded pharmaceutical products and processes from patentability.¹⁹⁹ The

¹⁹⁷ Peter Drahos and John Braithwaite, *Information Feudalism: Who Owns the Knowledge Economy?* (Earthscan Publications Ltd, London, 2002), 109; See also PublicCitizen, Only One of 44 Attempts to Use the GATT Article XX/GATS Article XIV "General Exception" Has Ever Succeeded: Replicating the WTO Exception Construct Will Not Provide for an Effective TPP General Exception, August 2015 <https://www.citizen.org/documents/general-exception.pdf> (accessed 14 March 2016).

¹⁹⁸ "Intellectual Property Rights: The Geneva Surrender," *Economic and Political Weekly* 24, no. 22 (1989): 1201-1204.

US' action under section 301 brought about changes to the patent laws of both countries.²⁰⁰ Section 301's consistency with the GATT was challenged in *United States – Sections 301-310 of the Trade Act of 1974*, WT/DS/152/R (1999) as it enables the US to implement retaliatory actions prior to the DSB's authorisation. Until the 1974 Trade Act was put into force, section 337 was used primarily to protect IPRs. The provision was held to be GATT incompliant in *United States – Section 337 of the Tariff Act of 1930*, L/6439-36S/345 (1989) and the amended version too was challenged in *United States - Section 337 of the Tariff Act of 1930 and Amendments Thereto, Request for Consultations by the European Communities and their Member States*, WT/DS186/1 (2000).

4. Introduction of TRIPS

The attempt to obligate developing countries to impose the protection of patents time and again failed. At the international level, patent-related conventions remain disharmonized and fragmented. Most part of implementations was largely left to domestic law and enforcement mechanisms were weak. Negotiations on the revision of the Paris convention ended in a deadlock due to conflicting interests between the developing and developed countries. In a forum like WIPO where each country has a vote, the negotiation reached a stalemate.²⁰¹ As for GATT, IP was hardly the main concern in a tariff concession agreement. And efforts by the US to impose patent protection conformity extraterritorially were met with fierce opposition.

The US was disillusioned that WIPO could settle the on-going conflict.

¹⁹⁹ Joo-Young Lee, *A Human Rights Framework for Intellectual Property, Innovation and Access to Medicines* (Routledge, 2016), 19.

²⁰⁰ Ibid.

²⁰¹ Preslava Stoeva, *New Norms and Knowledge in World Politics: Protecting People, Intellectual Property and the Environment* (Routledge, 2010), 81.

Unlike the WTO, WIPO does not have a formal court-like mechanism to solve and enforce regulations. Even if a treaty regarding IP standards were negotiated through, it meant nothing much if its standards were unenforceable. WIPO is a United Nations (“UN”) specialised agency and it was traditionally perceived that developing countries had more influence in the UN system as opposed to in GATT.²⁰² The US trade deficit was surging as it faced increasing competitions from newly industrialized nations and US companies were lobbying for more enhanced protection of IPRs abroad. The strategy was said to have been initiated by pharmaceutical company, Pfizer.²⁰³ A sustainable and long term strategy was needed to achieve such an objective. The forum of discussion moved from WIPO to a GATT setting, in which the US tried to bring GATT into conformity with its national law. Under GATT, developed countries could exert more influence and the issue of IP protection was redefined as one closely related to international trade.

GATT rules were developed over various trade rounds of negotiations. The US attempted to garner support to create an anti-counterfeiting code at the Tokyo Round of the GATT negotiations (1973-1979). The code though gained the support of the European Communities, Japan and Canada failed to receive the amount of consensus needed for incorporation.²⁰⁴ These developments however, paved way for the discussion of IP protection at the subsequent GATT negotiation: the Uruguay Round. It took four years before consensus to launch the Uruguay Round of negotiation was formed. The Uruguay Round ministerial meetings of GATT began in Geneva, 1986 and it took almost eight years to close. Its agenda covered virtually all outstanding trade issues and extended into areas such as IP. Developing countries strongly

²⁰² Micheal Trebilcock et al., *The Regulation of International Trade*, 523.(note 11 above)

²⁰³ Joo-Young Lee, *A Human Rights Framework for Intellectual Property, Innovation and Access to Medicines*, 18.(note 199 above)

²⁰⁴ Carlos Alberto Primo Braga, "The Economics of Intellectual Property Rights and the GATT: A View From the South," 243-264.(note 179 above)

objected to the involvement of GATT on substantive standards of IP as such was beyond its legal mandate and insisted that WIPO was the appropriate institution to deal with standard settings of IP norms.²⁰⁵ In the end, the developed countries prevailed. The developing countries caved in under tremendous pressure and some believed that there would be a net gain for them in other sectors that would justify the IP concessions.²⁰⁶ Clearly, developing countries then were unable to fully comprehend the magnitude of the implications TRIPS could have had brought. In addition, democratic process was said to be lacking in the formulation of TRIPS as the US was carrying out bilateral negotiations on IP with developing countries at the same time²⁰⁷, further diminishing the bargaining power of the developing members.

When the Uruguay Round came to an end on 15 April 1994, the Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiation and the Marrakesh Agreement Establishing the World Trade Organization (“WTO Agreement”) was signed. GATT was transformed from a negotiating forum to an agreement incorporated into the newly formed international organization, WTO. The institution is based in Geneva, Switzerland and since 30 November 2015, the WTO has 162 member states.²⁰⁸

The Uruguay Round also generated a series of agreements to be adopted in a ‘single-package’ approach. This included documents such as GATT, TRIPS and the DSU. In order to join the WTO at its inception, members were

²⁰⁵ Ibid.; Peter Drahos and John Braithwaite, *Information Feudalism: Who Owns the Knowledge Economy?*, 114.(note 197 above); Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines*, 44.(note 166 above)

²⁰⁶ Joo-Young Lee, *A Human Rights Framework for Intellectual Property, Innovation and Access to Medicines*, 20.(note 199 above)

²⁰⁷ Peter Drahos and John Braithwaite, *Information Feudalism: Who Owns the Knowledge Economy?*, 134.(note 197 above)

²⁰⁸ World Trade Organization, Members and Observers https://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm (accessed 15 March 2016).

required to adopt TRIPS without reservation. As mentioned previously, these WTO agreements, including TRIPS could be enforced by the unified dispute settlement procedure contained in the DSU. Hence, the mandate and strength of the WTO stretches beyond that of the GATT predecessor. The WTO Agreement came into force on 1 January 1995 and TRIPS entered into force at the same time as Annex 1C to the WTO Agreement.

a) The TRIPS Agreement

The TRIPS agreement covered almost every IPR and is considered as the most successful attempt to harmonize IP laws. It imposes minimum obligation to provide for the protection of IPRs and members should give effect to the provisions in a manner not more extensive than is required.²⁰⁹ Members have to comply with the substantive provisions of the Paris Convention too.²¹⁰ Moreover, like GATT, TRIPS contains obligations of national treatment²¹¹ and most favoured-nation treatment²¹². The objective of the agreement could be found in its preamble, Article 7 and Article 8 – recognising the desire to reduce distortions and impediments to international trade; to promote technological innovation and dissemination of technology; as well as balancing public interests such as public health.

The key IPR pertaining to access to medicines is patent. Pursuant to Article 27, all members are obligated to grant product and process patents for any inventions in all fields of technology regardless the place of invention and whether the product is imported or produced locally, provided the

²⁰⁹ Article 1.1 of TRIPS

²¹⁰ Article 2.1 of TRIPS

²¹¹ According to Article 3, nationals of other Members shall be accorded treatment no less favourable than that it accords to its own nationals with regard to the protection of intellectual property.

²¹² Article 4 provides that any advantage, favour, privilege or immunity granted with regard to the protection of intellectual property granted to the nationals of any other country shall also be accorded to the nationals of all members. Certain exceptions are provided.

patentability criteria of novelty, inventive step and industrial applicability are met. Nevertheless, patents will only be granted on the condition that clear and complete disclosure of the invention is made in accordance to Article 29. Once a patent is granted, Article 28 confers on the patent owner exclusive rights to prevent third parties from using the patented process; to prevent third parties from making, using, offering for sale, selling or importing the patented product or product obtained directly from the patented process without the consent of the patent owner. By Article 33, these rights are afforded a minimum 20-year term of protection from the date of filing.

The words in Article 27 meant that patent protection should extend to the pharmaceutical field. Prior to TRIPS, 49 member states to the Paris Convention excluded pharmaceutical products from patentability²¹³ and many countries only provided for process patents but not product patents as patented products could still be manufactured using a different method.²¹⁴ Patent protection term was significantly shorter too, ranging from 15 to 17 years.²¹⁵ Article 28 does not confer rights to the patent owner to market its products. In Malaysia, the patent owner has to register and obtain regulatory approval from the authorities before marketing the pharmaceutical products.

Apart from patent protection, Article 39.3 TRIPS also provided limited protection for pharmaceutical regulatory data that is submitted for the purpose of obtaining marketing approval. There are conflicting interpretations of whether this provision serves the role of data protection or data exclusivity. Most scholars view Article 39.3 as generally akin to trade secrets and the obligation of protecting data submitted to regulatory agencies against unfair commercial usage.²¹⁶ Others such as the US and the EC assert that Article

²¹³ J Straus, *Implications of the TRIPS Agreement in the Field of Patent Law* in Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines*, 55.(note 165 above)

²¹⁴ WHO, "Access to Medicines," 236-241.(note 148 above)

²¹⁵ *Ibid.*

39.3 requires data exclusivity.²¹⁷ Data exclusivity was a regime adopted by the US and the EC prior to the implementation of TRIPS. It hinders regulatory authorities from relying on original test data to assess the safety and efficacy of a bioequivalent generic medicine without the originator company's prior approval. The former is the acceptable view and it has been established that it is fully compatible with Article 39.3 for national health authorities to rely on the test data submitted by the originator company when registering generic substitutes based on bioequivalence as TRIPS does not require the grant of data exclusivity.²¹⁸ The US has been including data exclusivity when negotiating bilateral agreements with other countries. The recent Trans-Pacific Partnership ("TPP") agreement includes data exclusivity as a form of IPRs protection and this is discussed in the last chapter of the paper.

5. The Malaysian Patent Law

The patent law of Malaysia is presently governed by the Patents Act 1983, which came into effect on 1 October 1986. The Patents Act 1983 was further amended in 1993, 2000, 2003 and 2006. As Malaysia was a British colony, the Malaysian Legal System as a whole replicates the British Legal System. Thus, the current Patents Act has traces of similarity with the UK Patent Act 1977 and the European Patent Convention. Prior to the

²¹⁶ See generally Carlos Maria Correa, Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement, 2002, The South Centre http://www.who.int/medicines/areas/policy/protection_of_data.pdf (accessed 15 March 2016); Brook K. Baker and Tenu Avafia, "The Evolution of IPRs from Humble Beginnings to the Modern Day TRIPS-plus Era: Implications for Treatment Access," *Working Paper prepared for the Third Meeting of the Technical Advisory Group of the Global Commission on HIV and the Law*, 7-9 July 2011, (2011).

²¹⁷ Brook K. Baker and Tenu Avafia, "The Evolution of IPRs from Humble Beginnings to the Modern Day TRIPS-plus Era: Implications for Treatment Access." (note 216 above)

²¹⁸ Sisule F. Musungu and Cecilia Oh, The Use of Flexibilities in TRIPS by Developing Countries: Can They Promote Access to Medicines?, August 2005, Commission on Intellectual Property Rights, Innovation and Public Health (CIPRH) <http://www.who.int/intellectualproperty/studies/TRIPSFLEXI.pdf> (accessed 21 March 2016).

implementation of the 1983 Act, different component states of Malaysia were governed by different pieces of patent legislation. Those repealed by the 1983 Act were the Registration of United Kingdom Patents Act 1951, the Patent Ordinances of Sarawak, the Registration of United Kingdom Patent Ordinance of Sabah and the Patents (Rights of Government) Act 1967. The enactment of the 1983 Act enables applications for patents to be made domestically. Previously, applications had to be submitted to the Patent Office of the United Kingdom and subsequently register the same in Malaysia.²¹⁹ The Patents Act is administered by the Intellectual Property Corporation of Malaysia (“MyIPO”)

Mainly due to the influence of the UK patent law, the Malaysian Patents Act 1983 has never expressly forbid pharmaceutical products as a patentable subject matter although Section 13(1)(d) provides that medical treatment methods are not patentable. With a view to encourage research in the medical field, amendments were made in 1995 under the Patents (Amendment) Act 1993 Section 14(4) to allow patentability for products in the prior art used for a method of medical treatment, provided such method is not comprised in the prior art. Such amendment took place even before TRIPS was implemented. Such a provision does not give the patent owner claims to the product itself, but only when the product is used for such medical purpose.²²⁰

Malaysia acceded to the Paris Convention in 1989 and the Berne Convention in 1990. Given the high standards of IP protection Malaysia tried to maintain, there were not much obstacles in implementing TRIPS. The

²¹⁹ Lim Heng Gee, Ida Madieha bt Abdul Ghani Azmi, and Rokiah Alavi, Impact of the Intellectual Property System on Economic Growth: Malaysia, 2007, WIPO-UNU Joint Research Project http://www.wipo.int/export/sites/www/about-ip/en/studies/pdf/wipo_unu_07_malaysia.pdf (accessed 15 March 2016).

²²⁰ Lim Heng Gee, Ida Madieha Azmi, and Rokiah Alavi, "Reforms Towards Intellectual Property-Based Economic Development in Malaysia," *The Journal of World Intellectual Property* 12, no. 4 (2009): 317-337; doi: 10.1111/j.1747-1796.2009.00368.x.

Patents (Amendment) Act 2000 brought about various changes in compliance with the TRIPS Agreement. In accordance with Article 27(2) of TRIPS, Section 31(1) of the Patents Act added morality as a ground for the refusal of patent. Previously, the section provides for refusal only if the invention claimed was contrary to public order.

The most impactful amendment is perhaps the extension of the duration of patent protection from 15 years after the date of granting patent to 20 years from the date of filing the application.²²¹ Requirements for granting compulsory licensing²²² were also tightened to ensure compliance with Article 31 of TRIPS. The new Section 49 of the Patents Act 1983 provides additionally that application for compulsory licences can also be made four years from the filing date of the patent application. Before the amendment, application could be made at any time after the expiration of three years from the grant of a patent.²²³ Now, the application could be made whichever occurs later. Circumstances that warrant the application of compulsory licensing are also laid out in Section 49(1)(a) and (b) – there is no production of the patented product or application of the patented process in Malaysia without any legitimate reason; and there is no product produced in Malaysia under the patent for sale in any domestic market, or there are some but they are sold at unreasonably high prices or do not meet the public demand without any legitimate reason. Application may be made if either one of the grounds are fulfilled. While beneficiary of a compulsory licence are prohibited from concluding licence contracts with third parties, Section 9 of the Patents (Amendment) Act 2000 adds that the licence should not be assigned unless

²²¹ Section 35(1) of the Patents Act 1983

²²² Compulsory licence means that a third party is authorised to make, use, offer for sale, sell or import a patented invention without the need to obtain approval from the patent owner.

²²³ M. Supperamian, Rokiah Alavi, and Lim Heng Gee, "The Implications of TRIPS to the Pharmaceutical Sector and Access to Medicine: Malaysian Experience," *Asian Journal of WTO and International Health Law and Policy* 4, no. 225 (2009): 225-248.

connected with the goodwill or business in which the patented invention is used and that the licence is limited to the supply of the patented invention predominantly in Malaysia. Section 8 of the Amendment Act 2000 also imposes additional condition of “considerable economic significance” for an applicant to prove the existence of such element in his patented invention in order to obtain a compulsory licence based on interdependency. The applicant would have to show that his patented invention constitutes an “important technical advance” over the earlier patent and is of “considerable economic significance”.

Previously, the government or anyone authorised by the government is allowed to exploit a patented invention without the consent of the patentee so long as a reasonable amount is compensated.²²⁴ Such exploitation however is now limited under Section 84 of the Patents Act to circumstances of national emergency or where public interest so requires or where the authorities has determined that the patentee’s usage of his right is anti-competitive. These amendments are made to comply with Article 31(b) of TRIPS. The amendments above were the principal amendments made by Malaysia in order to be TRIPS compliant.

The substantive provisions of the Patents Act are very much typical to a patent regime elsewhere and in compliance with TRIPS. The Act provides the protection of patents and utility innovation. Likewise, an invention is only patentable if it is new, involves an inventive step and is industrially applicable.²²⁵ Section 14 (1) provides that an invention is deemed to be new if it is not part of the prior art. Subsection (2) provides that prior art shall consist of: (a) everything disclosed to the public anywhere in the world, by written publication, by oral disclosure, by use or in any other way, prior to the priority date of the patent application claiming the invention. Section 15

²²⁴ Ibid.

²²⁵ Section 11 of the Patents Act 1983

provides that an invention would only be considered as involving an inventive step if such step is not obvious to a person having ordinary skill in the art. Section 13 provides that discoveries, scientific theories, plants, animal varieties, methods of doing business, and surgical methods are not patentable subject matters. Section 36 provides that the patentee shall have the exclusive rights to exclude others from making, using, offering for sale, selling or importing the patented product without consent. The patentee also has the right to assign the patent and conclude licence contracts.

IV. Justification of Patents on the Interference of Access to Medicines

Although it has been established that patent protection has an adverse impact on the prices and availability of generic medicines, whether or not patent protection warrant such interference should also be examined.

1. Human Rights Justification of Material Interests

One possible justification of the interference in developing countries is that patent protection is essentially a human right afforded to patent owners. Article 15(1)(c) of the ICESCR recognises the right of *everyone* ‘to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author’. The right to health is protected under Article 12 of the ICESCR (the right to health as a human right is discussed in the next chapter). In cases where the provisions of the ICESCR contradict, which of the two provisions should take precedence? First and foremost, the scope to which Article 15(1)(c) extends its rights to IP creators have to be determined.

Article 15(1)(c) speaks of ‘everyone’, ‘he’ and ‘author’. Clearly, it refers to the moral and material rights of natural persons. It is dubious whether legal

entities such as pharmaceutical companies are able to rely on such a right. Second, wordings of the provision focused on the scientific, literary or artistic production of the author rather than invention or inventors. Lastly, the Article sought to protect the moral and material interests of authors. Moral rights relate for instance, to the right of authors to preserve his original literary and copyrighted works and to be named as the author. Here, in the context of impediment to access to medicines, material interest of the patent owner is of relevance. Again, most patents are owned by pharmaceutical companies, it is unlikely that a human right instrument seeks to protect the material interests of such companies.

These issues were addressed and clarified in the CESCR's General Comment 17. The Committee clearly drew a distinguishing line between 'fundamental, inalienable and universal entitlement' of each individual to human rights and the 'temporary nature' of IP rights which can be 'revoked, licensed and assigned to someone else'.²²⁶ Article 15(1)(c) 'safeguards the personal link between authors and their creations...as well as their basic material interests which are necessary to enable authors to enjoy an adequate standard of living' and it should not be equated to IP rights that 'primarily protect business and corporate interests and investment'.²²⁷ The Committee affirms that only natural persons and not corporations can be the beneficiaries of Article 15(1)(c).²²⁸ Hence it is unlikely that Article 15(1)(c) could stand as a ground for justification of pharmaceutical patent protection to the impediment of access to medicines in developing countries.

²²⁶ Social and Cultural Rights (CESCR) UN Committee on Economic, General Comment No. 17: The Right of Everyone to Benefit from the Protection of the Moral and Material Interests Resulting from any Scientific, Literary or Artistic Production of Which He or She is the Author (Art 15 Para 1(c) of the Covenant), E/C.12/GC/12, 12 January 2006 <http://www.refworld.org/docid/441543594.html> (accessed 29 March 2016).para 1-2

²²⁷ Ibid.

²²⁸ Ibid.para 7

2. Incentive for Future Research

One of the objectives of TRIPS in protecting and enforcing IPRs is to contribute to the promotion of technological innovation. A joint study by the WHO and the WTO Secretariat stated that TRIPS is an attempt to ‘strike a balance between the longer term objective of providing incentives for future inventions and creations, and the shorter term objective of allowing people to use existing inventions and creations’.²²⁹ This is also the claim of the pharmaceutical companies – essentially patent protection ensures access to future new medicines at the price of current medications.

As mentioned previously, the claim that patent protection acts as an incentive for future research does not prove to be true in all fields of technology. It is only in areas where reliance is placed on extensive research is the claim proven true. Therefore, justification for pharmaceutical patents must proceed on the proven fact that pharmaceutical patents do spur innovations. Mansfield confirmed such finding. The pharmaceutical industry is one of the most research-intensive sector and around 65% of pharmaceutical and 30% of chemical inventions would not have had taken place but for patent protection.²³⁰ In chapter I, the R&D costs for pharmaceuticals are priced on an average of US\$ 800 million to US\$ 1 billion, with the amount now even higher as biotechnology develops. The attrition rate is high and the formulation of a medicine may take more than a decade. Furthermore, patent applications are usually made shortly before clinical tests in human commence.²³¹ Thus, by the time a product is commercially marketed, the pharmaceutical company is estimated to have left 12 to 13 years of its patent protection lifespan to recoup investments and

²²⁹ *WTO Agreements and Public Health: A Joint Study by the WHO and the WTO Secretariat*.para 46. (note 8 above)

²³⁰ Edwin Mansfield, *Patents and Innovation: An Empirical Study*.(note 111 above)

²³¹ F.M. Scherer, "The Pharmaceutical Industry - Prices and Progress," 927-932.(note 102 above)

exploit the product commercially.²³² Justice requires the presence of patent protection to compensate firms and correct market failures associated with a public good. Absent patent protection, generic pharmaceutical firms could enter the market immediately so that drug prices could quickly equal its marginal cost. The originator producer would be unable to recoup R&D costs and would rationally choose not to invest for future innovations.

The question then is does not access to medicine requires the equal amount of justice which is impeded by the patent regime. In Malaysia, drug prices increased 28% per year between 1996 and 2005 following the implementation of TRIPS.²³³ Fundamentally, most developing countries are net importers of technology and an increase in patents would mean an increase in royalty payments to foreigners.²³⁴ In Malaysia, growth of royalty payments for technology acquisition abroad increased at a rate of 11.7% per annum from 1996 to 2007.²³⁵ Growth of pharmaceutical patents has been tremendous, from 10 in 1989 to 321 in 2006.²³⁶ However, all of those patents are foreign owned.²³⁷ Moreover, Malaysia imports about 70% of its pharmaceutical needs as mentioned above in Chapter I. In 2000, the top 10 developed countries in terms of patents owned, hold 94% of the world's technological patents and receive 91% of global cross-border royalties and licence fees.²³⁸ The pharmaceutical industry has always been ranked as one

²³² Ibid.

²³³ Human Rights Council, Report of the 2015 Social Forum, 2015, United Nations General Assembly A/HRC/29/44 <http://www.ohchr.org/EN/Issues/Poverty/SForum/Pages/SForum2015.aspx> (accessed 30 March 2016).para 26

²³⁴ Carlos Alberto Primo Braga, "The Economics of Intellectual Property Rights and the GATT: A View From the South," 243-264.(note 179 above)

²³⁵ Lim Heng Gee et al., "Reforms Towards Intellectual Property-Based Economic Development in Malaysia," 317-337.(note 220 above)

²³⁶ Ibid.

²³⁷ M. Supperamaniam et al., "The Implications of TRIPS to the Pharmaceutical Sector and Access to Medicine: Malaysian Experience," 225-248.(note 223 above)

²³⁸ Nagesh Kumar, "Intellectual Property Rights, Technology and Economic Development:

of the most profitable industry in America year after year, yet only 18% of the sales revenue is devoted to R&D.²³⁹ However, it is also mentioned that due to the fallacy of accounting practises, the percentage returns on capital base may be overstated and excluded in the 18% figure is approximately another US\$ 10 billion spent by start-up biotechnology companies on R&D that has not yielded any profits.²⁴⁰ Nevertheless, a significant proportion of R&D is funded publicly. The United Nations Development Programme ("UNDP") estimated 70% of therapeutic drugs to be government funded.²⁴¹ According to the US National Institute of Health, 55% of R&D projects leading to the discovery of the five best selling drugs in 1995 operated on taxpayers-financed researchers.²⁴² A significant part of pharmaceutical R&D is not dependent on the availability of patent protection given that these R&Ds would have still be carried out by public laboratories. It seems hardly fair that the minority private IPRs should take precedence over the majority public's right to health. It is questionable whether or not patent as a determinant of innovative activity sufficiently compensates for the welfare losses incurred.

Quality of the patents approved in recent years is another issue. It has been pointed out that even a patent office in developed countries such as the US grants many patents that should not be granted.²⁴³ According to the European Generic Medicines Association, while the USPTO granted 6,730

Experiences of Asian Countries," *Economic and Political Weekly* 38, no. 3 (2003): 209-215,217-226.

²³⁹ See F.M. Scherer, "The Pharmaceutical Industry - Prices and Progress," 927-932.(note 102 above)

²⁴⁰ Ibid.

²⁴¹ Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines*, 160-161.(note 166 above)

²⁴² Sigrid Sterckx, "Patents and Access to Drugs in Developing Countries: An Ethical Analysis," 58-75.(note 17 above)

²⁴³ Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines*, 159.(note 166 above)

pharmaceutical patents in 2000, only 27 NCEs were registered.²⁴⁴ Since 1993, R&D expenses increased by 147% but new drug applications submitted to the FDA increased by only 38%.²⁴⁵ A major part of R&D budgets is spent on the slightly altered successful versions of blockbuster modelled 'me-too' drugs.²⁴⁶ Furthermore, most drugs approved by the FDA are classified as 'standard drugs' rather than 'priority drugs' and the trend has seen more drugs approval leaning towards standard rated drugs.²⁴⁷

The patent regime is also limited in its effect. Competitors may legally invent around patents.²⁴⁸ However, unlike a technological invention, a high degree of difficulty is associated inventing around the patented therapeutic product. Regardless, the patent system confers exclusive rights to the patent owner for 20 years without addressing how much of a profit is sufficient incentive for innovative activity. It has been suggested that the term 20 years is pure coincidence that traces back to patent legislation history.²⁴⁹ Kumar and Siddhartan (1997) warn of the potential unintended effect of long patent protection duration that could prevent competition and lead to the erosion of improvement as inventors become complacent.²⁵⁰ There are instances that

²⁴⁴ Ibid., 161.

²⁴⁵ Ellen FM 't Hoen, *The Global Politics of Pharmaceutical Monopoly Power: Drug Patents, Access, Innovation and the Application of the WTO Doha Declaration on TRIPS and Public Health*, 2009, AMB Publisher, the Netherlands https://www.msfaaccess.org/sites/default/files/MSF_assets/Access/Docs/ACCESS_book_GlobalPolitics_tHoen_ENG_2009.pdf (accessed 28 March 2016).pg 81.

²⁴⁶ Sigrid Sterckx, "Patents and Access to Drugs in Developing Countries: An Ethical Analysis," 58-75.(note 17 above); Ellen FM 't Hoen, *The Global Politics of Pharmaceutical Monopoly Power: Drug Patents, Access, Innovation and the Application of the WTO Doha Declaration on TRIPS and Public Health*.pg 81.(note 245 above)

²⁴⁷ Sigrid Sterckx, "Patents and Access to Drugs in Developing Countries: An Ethical Analysis," 58-75.(note 17 above)

²⁴⁸ Nagesh Kumar, "Intellectual Property Rights, Technology and Economic Development: Experiences of Asian Countries," 209-215,217-226.(note 238 above)

²⁴⁹ Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines*, 159.(note 166 above)

²⁵⁰ Nagesh Kumar, "Intellectual Property Rights, Technology and Economic Development: Experiences of Asian Countries," 209-215,217-226.(note 238 above)

countries who did not implement pharmaceutical patents were not hindered from developing a strong pharmaceutical industry. Such countries include Switzerland and Italy, which only introduced pharmaceutical patents in 1977 and 1978 respectively. Back then Switzerland was reckoned as a strong competitor for the German and Italy was the fifth world producer and seventh exporter of pharmaceuticals in the 1970s.²⁵¹ Scherer and Weisburst (1995) also concluded that the strengthening of pharmaceutical patent in Italy had little or no impact on R&D expenditures or the introduction of NCEs and thus, were sceptical about TRIPS' 20 years patent protection term in significantly raising innovative activity.²⁵²

While some countries did not provide for pharmaceutical patents, the need to lengthen patent protection to 20 years for developing countries is questionable, as will be seen below. After all, most patent regimes of developing countries are modelled after the developed countries. Malaysia is one of them.

Although TRIPS provided transitional periods, countries were obliged under Article 70(8) to have provisions for receiving patent application since the day TRIPS was of general application. Commonly referred to as the mailbox system, it has the effect of granting exclusive market rights to the applicant. Furthermore, LDCs lacked manufacturing capacity and thus, obtaining patents in these countries does not seem to serve the purpose of excluding generic manufacturing competition.

The pharmaceutical industry has long reaped substantial amount of profits before the implementation of TRIPS. Moreover, as seen in chapter I, the production, consumption and trade of pharmaceuticals are heavily

²⁵¹ Michele Boldrin and David K. Levine, *Against Intellectual Monopoly*, 2008, Cambridge University Press <http://levine.sscnet.ucla.edu/papers/imbookfinalall.pdf> (accessed 30 March 2016).pg 245

²⁵² Nagesh Kumar, "Intellectual Property Rights, Technology and Economic Development: Experiences of Asian Countries," 209-215,217-226.(note 238 above)

concentrated in the developed region. Hence, it is unlikely that the profits obtained from developing countries are necessary to maintain R&D expenditure and their marginal contribution is said to be negligible.²⁵³ As a consequence, the diseases in these countries are also neglected. There was practically no progress in the innovation of 'neglected diseases'- between 1975 and 2004, only a mere 1.3% of the 1,556 NCEs marketed globally were devoted to the treatment of tropical diseases and tuberculosis.²⁵⁴ The introduction of patent protection in developing countries does little to change the status quo. Studies indicate that the availability of patent protection in these countries does not stimulate much additional R&D by foreign pharmaceutical companies.²⁵⁵ The pharmaceutical companies' priority of R&D follows economic rationales. The industry may not be expected to allocate resources in areas where the gains are low no matter how strong a patent protection is enforced. There were no increases in R&D for tropical diseases despite the implementation of TRIPS and the mailbox system.²⁵⁶ In addition, pharmaceutical companies saved financially when obtaining regulatory approval in countries like Malaysia where the same test data are accepted as long as the GLP guidelines are observed (see chapter I, page 28).

This raises the question as to why pharmaceutical companies lobbied for the implementation of patent protection in developing countries. One possible explanation is the concern of lower priced pharmaceuticals flowing into the

²⁵³ Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines*, 162.(note 166 above)

²⁵⁴ Ellen FM 't Hoen, *The Global Politics of Pharmaceutical Monopoly Power: Drug Patents, Access, Innovation and the Application of the WTO Doha Declaration on TRIPS and Public Health*.pg 83.(note 245 above)

²⁵⁵ Carlos M. Correa, *Some Assumptions on Patent Law and Pharmaceutical R&D*, 2001, Quaker United Nations Office - Geneva <http://www.geneva.uno.info/pdf/OP6Correa.pdf> (accessed 30 March 2016).pg 6 Nagesh Kumar, "Intellectual Property Rights, Technology and Economic Development: Experiences of Asian Countries," 209-215,217-226.(note 238 above)

²⁵⁶ Carlos M. Correa, *Some Assumptions on Patent Law and Pharmaceutical R&D*.pg 5.(note255 above)

developed world through parallel importation but is rebutted by the adoption of national exhaustion policy in developed countries.²⁵⁷ Another possible explanation is the emergence of ‘pharmerging’ markets in developing countries. The changing landscape of global diseases meant that these markets are also significantly affected by NCDs. The Malaysian pharmaceutical market is valued at US\$ 300 million²⁵⁸ and according to the Malaysian Ministry of International Trade and Industry some 65-80% of pharmaceutical needs, especially new generation antibiotics, cholesterol-lowering, anti-diabetic, cardiovascular and cancer treatment medications are mainly imported from Germany, France and the UK.²⁵⁹ The strengthening of patent protection will only lead to substantial increase of royalties and licence fees from developing countries to developed countries.

In sum, stringent patent protection in developing countries hardly acts as a determinant for the innovative activity of pharmaceutical companies in the developed countries. The incentive to conduct R&D is rather influenced by the economic profitability from the sales of pharmaceutical products.

3. Local innovations, FDIs, and Technology Transfer

In his study, Mansfield concluded that the strength of a country’s IP protection regime has positive substantial effects on industries such as chemicals and pharmaceuticals – it determines the amount of technology transfer and direct investments.²⁶⁰ However, the study was conducted in the

²⁵⁷ Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines*, 165.(note 166 above)

²⁵⁸ Navin Swaroop and Anand Srinivasan, *The Pharmacy Channel Emerges in Malaysia's Evolving Pharma Climate*, 2011, IMS Health <https://www.imshealth.com/files/web/Asia%20Pac/Asia%20Pacific%20Insights/Asia%20Pacific%20Insights%20Archive/2011-06%20Malaysia%20Pharmacy%20Channel.pdf> (accessed 30 March 2016).

²⁵⁹ Richard D Smith, Carlos Correa, and Cecilia Oh, "Trade, TRIPS, and Pharmaceuticals," *Lancet* 373, (2009): 684-691; doi: 10.1016/S0140-6736(08)61779-1.

US, a developed country with high-technology capacity. The justification that a stringent patent protection spurs local innovations is inflated in developing countries as many local pharmaceutical industries lack the capacity to do R&D due to constraints of technological skills, infrastructural capacities, and insufficient financial resources.²⁶¹ On the contrary, weaker patent protection has been found to stimulate domestic innovative activity.²⁶² TRIPS may encourage technology transfer but this fades in comparison to unreserved and unlimited strategies of reverse-engineering and imitation that industrialised countries such as the US, Japan, Taiwan and South Korea resorted to in development.²⁶³ Another example can be seen in the case of India before the implementation of TRIPS. India reverse-engineered most medications and its domestic pharmaceutical industry grew specialising in the generic versions of patented medicines.²⁶⁴ This transformed India from a country importing medicines at extremely high prices to one of the most important exporters of affordable life-saving medicines to the developing world.²⁶⁵ Nevertheless, after the adoption of TRIPS, Gervais found that certain developing countries such as India and China have been performing significant R&D.²⁶⁶ Many still lack the capacities India and China possess. TRIPS fail to take into account that in reality, the different regional capabilities and endowments of

²⁶⁰ Edwin Mansfield, *Patents and Innovation: An Empirical Study*.(note 111 above)

²⁶¹ Sigrid Sterckx, "Patents and Access to Drugs in Developing Countries: An Ethical Analysis," 58-75.(note 17 above); Sisule F. Musungu and Cecilia Oh, *The Use of Flexibilities in TRIPS by Developing Countries: Can They Promote Access to Medicines?*pg 25-29.(note 218 above)

²⁶² Nagesh Kumar, "Intellectual Property Rights, Technology and Economic Development: Experiences of Asian Countries," 209-215,217-226.(note 238 above)

²⁶³ Robert Hunter Wade, *What Strategies are Viable for Developing Countries Today? The World Trade Organization and the Shrinking of 'Development Space'*, June 2003 <http://eprints.lse.ac.uk/28239/1/WP31RW.pdf> (accessed 31 March 2016).pg 5

²⁶⁴ Human Rights Council, *Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover*.para 29.(note 14 above)

²⁶⁵ Ibid.

²⁶⁶ Sarah Joseph, *Blame It on the WTO?*, 233.(note 186 above)

the WTO Members limit their absorptive capacities in the technological development process. It is only after achieving a certain standard of technological achievement could such countries attain what is intended under TRIPS.

Furthermore, where such capacities exist, as mentioned previously, the economic rationale dictates the target disease of a R&D. Developing countries will still invest in where returns are the highest. A study reveals that pharmaceutical companies in India devoted only 16% of R&D expenditure on diseases of the LDCs market and interestingly, 46.2% of the expenditure is used on products targeted for diseases found globally.²⁶⁷

In Malaysia, the level of R&D on the whole is increasing but is still relatively low compared to other countries.²⁶⁸ According to the Malaysian Ministry of International Trade and Industry, total government expenditures on R&D were only 0.2% and 0.9% of the GDP in 1996 and 2005 and private R&D expenditure increased from RM400.1 million in 1996 to RM746.1 million in 1998 according to the Economic Planning Unit Malaysia, 2001.²⁶⁹ There has also been a gradual increase in patent applications from Malaysians.²⁷⁰ However, it was also acknowledged that R&D among the small and medium enterprises was marginal and improvements were largely directed towards local needs, while original design and development of new products were limited.²⁷¹ In terms of the pharmaceutical industry, local pharmaceutical companies are small and 80% of its production accounts for low-value generics, over-the-counter treatments, vitamin supplements, and

²⁶⁷ Jean O. Lanjouw and Iain M. Cockburn, "New Pills for Poor People? Empirical Evidence After GATT," *Elsevier Science Ltd, World Development* 29, no. 2 (2001): 265-289.

²⁶⁸ Lim Heng Gee et al., "Reforms Towards Intellectual Property-Based Economic Development in Malaysia," 317-337.(note 220 above)

²⁶⁹ Ibid.

²⁷⁰ Ibid.

²⁷¹ Ibid.

medical devices.²⁷² Export revenue in 2006 was also largely attributed to the manufacture of vitamins.²⁷³ Innovative domestic pharmaceutical research and development is restricted with only 87 of 246 registered pharmaceutical companies manufacturing modern medicines; most produce traditional and herbal medicines.²⁷⁴ Although some off-patent medicines within the high-selling therapeutic categories (antibiotics, and antiviral, antiulcer, and cholesterol-lowering drugs) are produced, most manufacturers are small-sized or medium-sized enterprises.²⁷⁵ This suggests that robust patent protection does not necessarily spur more local innovations.

TRIPS also advocate increased FDIs and transfer technology from developed countries to developing countries that strengthen patent protection since imitation and counterfeiting is outlawed and the value of a firm's IP is maintained. Empirical evidence however, suggests that the protection of IPRs generally does not have a significant role in influencing inward FDIs, though the increase of inward FDIs was significant in emerging markets.²⁷⁶ Even so, the share of FDI in developing countries is small and it is falling from 40% in 1994 to less than 20% in 2000.²⁷⁷ The high concentration of FDIs on a few developing countries remained the same since the 1980s and there has been no 'evolutionary' spreading out to more and more countries.²⁷⁸

The distribution of FDIs is uneven in developing countries: in the 1980s, Amihrahmadi and Wu (1994) documented that 15 countries received 80% of all FDI inflows to the developing region.²⁷⁹ China, Hong Kong, Indonesia,

²⁷² Richard D Smith et al., "Trade, TRIPS, and Pharmaceuticals," 684-691.(note 259 above)

²⁷³ Ibid.

²⁷⁴ Ibid.

²⁷⁵ Ibid.

²⁷⁶ Nagesh Kumar, "Intellectual Property Rights, Technology and Economic Development: Experiences of Asian Countries," 209-215,217-226.(note 238 above)

²⁷⁷ Robert Hunter Wade, What Strategies are Viable for Developing Countries Today? The World Trade Organization and the Shrinking of 'Development Space'.pg 10.(note 263 above)

²⁷⁸ Ibid.

South Korea, Malaysia, Singapore, Taiwan and Thailand absorbed more than 90% of FDIs in developing countries over the decade.²⁸⁰ On the other hand, Africa as a continent experienced an absolute decline in investment stock over the 1990s with its share falling from 2.6% to 0.9%, indicating a sizeable disinvestment. ²⁸¹ An explanation is provided by Kumar (1999), who found that MNCs have been locating chemical and pharmaceutical R&D centres, joint ventures and contracting research in India despite its patent regime not recognising product patents in those sectors then.²⁸² Factors influencing the inflow of FDIs in developing countries are said to be the availability of abundant trained low cost human resources and scale of ongoing R&D projects rather than the strength of an IPR regime; the hypotheses were subsequently verified in a later study of Kumar (2001).²⁸³ Another fact that corroborates such explanation can be seen in the case of US. The bulk of its investment remained in industrialised countries despite increased attractiveness of developing countries as an investment destination: Europe, Canada and Japan summed to 66.9% of the global US foreign capital stock in 1994. ²⁸⁴

In Malaysia, after its accession to the Paris Convention, Malaysia saw an increase in patent applications in the 1990s. Like most developing countries, Malaysia is a technology importer with 94% of patent applications and 97% of patents granted coming from outside the country.²⁸⁵ The top patent

²⁷⁹ Keith E. Maskus, "The Role of Intellectual Property Rights in Encouraging Foreign Direct Investment and Technology Transfer," in *Intellectual Property and Development: Lessons from Recent Economic Research*, ed. Carsten Fink and Keith E. Maskus (A copublication of the World Bank and Oxford University Press, 2005), 48.

²⁸⁰ Ibid.

²⁸¹ Ibid.

²⁸² Nagesh Kumar, "Intellectual Property Rights, Technology and Economic Development: Experiences of Asian Countries," 209-215, 217-226. (note 238 above)

²⁸³ Ibid.

²⁸⁴ Keith E. Maskus, "The Role of Intellectual Property Rights in Encouraging Foreign Direct Investment and Technology Transfer," 47-48. (note 279 above)

applicants are the US, Japan and Germany. Interestingly, these countries are also Malaysia's major foreign direct investors.²⁸⁶ The incidence may be purely coincidental or rather, due to a combination of various factors. As Maskus pointed out, strong IPRs alone are insufficient for generating strong incentives for firms to invest in a country – else FDI flows would have gone largely to Sub-Saharan Africa and Eastern Europe instead of high-growth, large-market developing countries with weak IPR protection such as Brazil and China then.²⁸⁷

In a case like Malaysia where the inflow of FDIs corresponds to the surge in patent issuance, the question then is whether or not there is actual technology transfer from these investors. When considering whether or not to invest in a country, there are complex factors that influence a firm's decision. Transfer of technology occurs via the internalised method such as FDI or joint venture and the externalised method of contractual arrangements such as licensing.²⁸⁸ In most cases, MNCs will prefer technology transfer through FDIs as effective control is maintained by the company: the company is able to oversee operational activities and make decisions.²⁸⁹ In addition, Baranson (1969) mentioned other factors such as adequate resources to invest abroad, fear that the adoption of other channel of transfer technology may divulge valuable know-hows, the product is an integral part of marketing and financial management of the company, the technology to be transferred is highly complex and the destination country lacks skills and capacity to manufacture

²⁸⁵ Richard D Smith et al., "Trade, TRIPS, and Pharmaceuticals," 684-691.(note 259 above)

²⁸⁶ Lim Heng Gee et al., "Reforms Towards Intellectual Property-Based Economic Development in Malaysia," 317-337.(note 220 above)

²⁸⁷ Keith E. Maskus, "The Role of Intellectual Property Rights in Encouraging Foreign Direct Investment and Technology Transfer," 54.(note 279 above)

²⁸⁸ Ali Shamsavari, Owen Adikibi, and Yasser Taha, Technology and Technology Transfer: Some Basic Issues <http://eprints.kingston.ac.uk/6629/1/Shamsavari-A-6629.pdf> (accessed 31 March 2016).pg 17

²⁸⁹ Ibid.

the product, and lastly, there arise the need for the company to protect product quality as well as brand name.²⁹⁰ In the case of licensing, the company may choose to divulge knowledge-based asset to an unrelated firm in the destination country and allow local production in return for royalties and fees.²⁹¹ According to scholars, a firm is more likely to undertake FDI than licensing when manufacturing of a highly differentiated product or it involves complex technology and the cost of transferring the technology through licensing is high.²⁹² Clearly, exports are likely to be the primary mode of supply when transport costs and tariffs are low in comparison to the costs of FDI and licensing.²⁹³

FDIs, licensing and exports has a common factor that will influence the decision of a firm when selecting which method to manufacture a product. Apart from economic savings and value, the firm will take into account the relative strength of IPRs in the destination country. When the product or technology involved can be easily copied such as pharmaceuticals, the firm is concerned with the ability of local IPR regime to limit imitation.²⁹⁴ A strong patent protection blocks copying and competition and thus, induces exporters to sell more, attracts inflow FDIs and encourages licence distributions.²⁹⁵ Nevertheless, patents may act as both a tool to disseminate knowledge through disclosures and limit the use of key technologies, and therefore, limit knowledge and technology transfer through restrictive licensing arrangements.²⁹⁶

²⁹⁰ Ibid.

²⁹¹ Keith E. Maskus, "The Role of Intellectual Property Rights in Encouraging Foreign Direct Investment and Technology Transfer," 54.(note 279 above)

²⁹² Ibid., 60.

²⁹³ Ibid., 55.

²⁹⁴ Ibid., 56.

²⁹⁵ Ibid., 55-60.

²⁹⁶ Ibid., 61.

Trends indicate that actual technology transfer from developed countries to developing countries may be limited. Kumar (1998) submits that there is a reversal of utilising licensing as a mode of technology transfer and MNCs prefer undertaking FDI to licensing.²⁹⁷ Similarly, Kim (1997) finds that a number of Korean corporations were denied licensing technology by patent owners in the west, forcing them to resort to reverse engineering of the products.²⁹⁸ Furthermore, as more MNCs enter the local market, local small and medium enterprises may come under pressure to close down if they are incapable of keeping up with the latest technology. This may lead to heavy reliance on FDIs and imports to fulfil domestic needs. Such was the crisis that Malaysia probably had faced when it experienced a fall in FDI by 81% and FDI outflows of US\$ 8.04 billion during the global economic collapse in 2008.²⁹⁹ Although a contraction in FDI is expected, the global FDI only dipped by 37%.³⁰⁰ This depicts that stringent protection of IPRs has little to do with the inflow of FDIs.

It is said that technology transfers to developing countries have grown at slower rate than FDI inflows, suggesting that a surge in FDI inflows may not have been accompanied by disembodied technology transfers in the same proportion.³⁰¹ Rather Vaitos (1972) found patent protection serves the purpose of protecting the patent owner's market and Katz (1973) found that only a small amount of patents are utilised in local production.³⁰² Such

²⁹⁷ Nagesh Kumar, "Intellectual Property Rights, Technology and Economic Development: Experiences of Asian Countries," 209-215,217-226.(note 238 above)

²⁹⁸ Ibid.

²⁹⁹ Charis Solomon, Md. Aminul Islam, and Rosni Bakar, "Attracting Foreign Direct Investment: The Case of Malaysia," *International Business Management* 9, no. 4 (2015): 349-357.

³⁰⁰ Ibid.

³⁰¹ Rokiah Alavi, "Technology Transfer and Patents: The Impact of TRIPs on Muslim Countries," *Journal of Economic Cooperation* 20, no. 3 (1999): 21-38.

³⁰² Ibid.

findings seem to characterize Malaysia's pharmaceutical industry. In Malaysia, high reliance is placed on patented medicines and MNCs are mainly licensed importers who distribute their brand name drugs through locally incorporated companies.³⁰³ Only 13% have set up local manufacturing operations, while another further 7% have contract manufacturing arrangements with local companies.³⁰⁴ Local companies who have manufacturing contracts with MNCs do perform some product modification to meet local needs but the lack of technological capacity, high investment costs and heavy reliance on imported APIs restrict R&D.³⁰⁵ Although MNCs consider Malaysia to offer robust patent protection, they have not promoted the transfer of technology in terms of location of R&D and manufacturing facilities.³⁰⁶ Neither is there transfer of technology in actual terms judging from the situation in Malaysia. As mention above, it might just simply be more cost-efficient to export a product as opposed to direct investments.

I. Access to Medicine as a Human Right

While the right to exclude others from making or selling pharmaceutical products and charge a high price on medicines is embedded as a legal right under the guise of technological advancement, the constitution of access to medicines as a legal right seems less distinct.

³⁰³ Istituto nazionale per il Commercio Estero, *The Pharmaceutical Industry in Malaysia*.(note 38 above)

³⁰⁴ Pharmaceutical Association of Malaysia (PhAMA), *PhAMA Industry Fact Book 2012*.(note 39 above)

³⁰⁵ Ida Madieha Azmi and Rokiah Alavi, "TRIPS, Patents, Technology Transfer, Foreign Direct Investment and the Pharmaceutical Industry in Malaysia," *Journal of World Intellectual Property* 4, no. 6 (2001): 947-976; doi: 10.1111/j.1747-1796.2001.tb00144.x.

³⁰⁶ Richard D Smith et al., "Trade, TRIPS, and Pharmaceuticals," 684-691.(note 259 above)

1. International Human Rights Law

Traditionally, only states could be subjected to the operations of the international legal system. International law was to regulate the behaviour of States and the relationship amongst States. Prior to the Second World War, human rights were practically inexistent in the international sphere. If one was subjected to degrading treatments by another state, only the state of that national could bring an action against the other state. Treatment of an individual was left entirely to the discretion of the state he owed allegiance to. The aftermath of the Second World War woke many to the shocking atrocities a state could commit on its own people. The UN was established to maintain international peace and security. It also aims to promote human rights and fundamental freedoms as stated in Article 1(3) of the UN Charter. The UN endorsed a list of human rights in the form of the Universal Declaration of Human Rights (“UDHR”), which was adopted by the UN General Assembly in 1948. The UDHR however, is not a legally binding instrument.

Today, according to the website of the United Nations Human Rights Office of the High Commissioner, there are ten core international human rights instruments. Of these ten core instruments, two major universal human rights Covenants of concern here are the International Covenant on Civil and Political Rights (“ICCPR”) and International Covenant on Economic, Social and Cultural Rights (“ICESCR”). The norms of the UDHR are mainly enshrined in these two Covenants. Together, the three instruments are referred to collectively as the International Bill of Human Rights.

A UN treaty based-body or committee is set up to administer and monitor the implementation of each international human rights instrument. For instance, the Human Rights Committee (“CCPR”) is the body of independent experts established under Article 28 of the ICCPR that monitors implementation of the Covenant by its State parties. State parties are usually

obliged to submit regular reports regarding the implementation of the provisions to the Committee and the Committee will issue ‘concluding observations’ on the State. Article 41 of the ICCPR mandates the Committee to consider inter-state complaints and the First Optional Protocol to the Covenant gives the Committee competence to examine individual complaints in respect of violations of the ICCPR by State parties that ratify the Protocol.

The Committee on Economic, Social and Cultural Rights (“CESCR”) is the body of 18 independent experts that monitors implementation of the ICESCR. Similarly, State parties are obliged to submit regular reports to the Committee regarding the implementation of the Covenant and the Committee will issue ‘concluding observations’ on the State. The Optional Protocol to the ICESCR gives the Committee competence to examine individual complaints claiming that rights under the Covenant have been violated. Article 10 of the Optional Protocol empowers the Committee to consider inter-state complaints.

2. The Human Rights Dichotomy

Theories have been advanced to distinguish civil and political rights on the one hand and economic, social and cultural rights on the other hand. The former includes fundamental rights such as a right to life, a right to fair hearing, freedom from slavery and so on as contained in the ICCPR. Enjoyment of just and favourable conditions of work, a right to social security, a right to education and so forth are considered to be under the purview of the latter as could be seen in the ICESCR. The UN is committed to handling both rights with equal importance but the norms in the ICCPR is said to be more developed in comparison to the ICESCR.³⁰⁷ For one, the civil and political rights generated much jurisprudence under domestic

³⁰⁷ Sarah Joseph, *Blame It on the WTO?*, 19.(note 186 above)

constitutional documents and these domestic laws were of great aid in developing civil and political rights at the international sphere.³⁰⁸ Secondly, non-governmental Organisations (“NGOs”) have always only engaged in advocating civil and political rights.³⁰⁹ Economic and social rights on the other hand, have often been neglected in the system.³¹⁰

Such tendency could also be seen in the governance of the ICCPR and the ICESCR. The oversight of the ICESCR was initially undertaken by the United Nations Economic and Social Council (“ECOSOC”), a political body. The establishment of CESCR to take over functions from the ECOSOC in supervising the implementation of the ICESCR took place eight years after the CCPR was set up to oversee the implementation of the ICCPR.³¹¹ The Optional Protocol to the ICCPR entered into force 23 March 1976. However, the Optional Protocol to the ICESCR came into force on 5 May 2013. For over 30 years, the CCPR has been receiving and considering individual petitions while the CESCR could only do so recently. Even the key obligations of the State parties are worded differently in the Covenant. While States “undertakes to respect and to ensure to all individuals...the rights recognised in the present Covenant, without distinction...” under Article 2(1) ICCPR, the parallel provision under Article 2(1) ICESCR obligates States to “take steps...through international assistance and co-operation...to the maximum of its available resources, with a view to achieving...the rights recognised in the present Covenant...”. The tone in the latter provision is definitely softer with less urgency compared to the former. Unlike the ICCPR,

³⁰⁸ Ibid.

³⁰⁹ Ibid.

³¹⁰ Daphne Barak-Erez and Aeyal M. Gross, "Introduction: Do We Need Social Rights? Questions in the Era of Globalisation, Privatisation, and the Diminished Welfare State," in *Exploring Social Rights: Between Theory and Practice*, ed. Daphne Barak-Erez and Aeyal M. Gross (Hart Publishing, 2007), 6.

³¹¹ Sarah Joseph, *Blame It on the WTO?*, 20. (note 186 above)

the ICESCR does not demand the immediate full implementation of its rights.

The rationale for the dichotomy stems from the theory that civil and political rights are essentially ‘liberty rights’ or ‘negative rights’, requiring States to only refrain themselves from violating these rights. Economic and social rights on the other hand, are essentially ‘welfare rights’ or ‘positive rights’, requiring States to allocate resources for the well-being of the people. Shue (1980) suggested that the duty not to violate liberty rights is justified by stringent rules of justice and thus corresponds to human rights while the duty to provide for the well-being of the people corresponds to special rights rather than human rights.³¹² Scholars have criticised the view, maintaining that the dichotomy in practice is unsustainable given that both type of rights entail States to act positively and negatively at times.³¹³

3. Justiciability and Enforceability of Right to Health

Access to medicine is protected under the right to health contained in Article 12 of the ICESCR. It was also elaborated by the CESCR in General Comment 14 that access to medicine is a core component of right to health.³¹⁴ As these rights are deemed to be less pressing and fundamental in comparison to civil and political rights, issues arose regarding the justiciability and qualms as to whether or not these rights may be enforced in judicial proceedings. Civil and political rights have long been recognized as

³¹² Elizabeth Ashford, "The Alleged Dichotomy Between Positive and Negative Rights and Duties," in *Global Basic Rights*, ed. Robert E. Goodin and Charles R. Beitz (Oxford University Press, 2009), 92-93.

³¹³ See Sarah Joseph, *Blame It on the WTO?*, 21.(note 186 above); Daphne Barak-Erez and Aeyal M. Gross, "Introduction: Do We Need Social Rights? Questions in the Era of Globalisation, Privatisation, and the Diminished Welfare State."(note 310 above); Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines*, 90.(note 166 above)

³¹⁴ Social and Cultural Rights Committee on Covenant on Economic, "General Comment No.14: The Right to the Highest Attainable Standard of Health (Art. 12)," *UN Doc. E/C.12/2000/4*, (11 August 2000).

justiciable and individual petitions can be made to the CCPR under the Optional Protocol to the ICCPR. In the past, references have been made to cases of national jurisdictions and advisory opinion of the ICJ to establish the justiciability of economic and social rights. These rights are now clearly recognized to be justiciable as the CESCR too may examine individual and inter-state complaints under the Optional Protocol to the ICESCR.

Both the ICCPR and the ICESCR serve to protect the rights of individuals and individual complaints can be made to the Committee. The question is against whom can complaints be brought? A look at both the Covenants indicates that State Parties are obligated to protect the rights stated in the Covenants and that both Covenants are open to ratification by States. They do not impose obligations on individuals. Clearly, only States that ratified the Covenants are bound by the rights of the Covenants under international law. Private parties and thus, corporations such as the pharmaceutical companies are not bound by the ICESCR. International law has confirmed that in some settings, international organisations are capable of having legal personality in international law with their own rights and obligations.³¹⁵ Therefore, they can sign treaties and conventions on their own. The WTO is neither a party to the ICESCR nor any human rights conventions. Within the WTO, the DSB is also unable to interpret and enforce human rights as well as the obligations that WTO Members may have under other treaties as the WTO is not mandated with such authority apart from the enforcement of the covered agreements. Within the covered agreements, a human right agreement is also not available. Furthermore, a private individual cannot bring an action against a WTO Member in its dispute settlement system. Hence, an individual who finds that his right to health is violated due to TRIPS or a state for that matter is unable to bring an action against the pharmaceutical companies or the WTO

³¹⁵ *Reparation for Injuries Suffered in the Service of the United Nations*, Advisory Opinion, [1949] ICJ Reports 174

under international law. There are views that the rules of the WTO do incorporate human right values through the flexibilities provided. The flexibilities and the interpretation of TRIPS in correspondent to human rights will be examined in the next chapter.

Under the ICESCR, complaints can only be made against State Parties. The enforcement mechanism however is lacking in comparison to the WTO's dispute settlement system. The CCPR is neither a court nor a body with a quasi-judicial mandate and has no power to hand down binding decisions.³¹⁶ Despite this, the Committee is of the position that its decision bears authoritative judicial determination and expects State parties to give effect to the views issued by the Committee.³¹⁷ Regardless, the Optional Protocol does not provide for an enforcement mechanism or sanctions in cases of non-compliance by a State party.³¹⁸ These characteristics apply to the CESCR as well: the Committee's suggestions and recommendations do not carry legally binding status.³¹⁹ The rules of general international law denote that all observations, views or comments of UN treaty-bodies are not legally binding on states but they do carry considerable legal weight.³²⁰ The weak enforcement measure as opposed to the economic sanctions ensued from the non-compliance of the WTO rules meant that the record of compliance with the UN human rights bodies pales in comparison to the record of compliance

³¹⁶ Human Rights Committee, "General Comment No. 33: The Obligations of States Parties under the Optional Protocol to the International Covenant on Civil and Political Rights," *UN Doc. CCPR/C/GC/33*, (5 November 2008).para 11

³¹⁷ *Ibid.* para 11, 13 and 20

³¹⁸ International Covenant on Civil and Political Rights: Selected Decisions of the Human Rights Committee Under the Optional Protocol, 2002, United Nations Publication CCPR/C/OP/3 <http://www.ohchr.org/Documents/Publications/SDecisionsVol3en.pdf> (accessed 16 March 2016).

³¹⁹ UN Office of the High Commissioner for Human Rights (OHCHR), Fact Sheet No. 16 (Rev.1), The Committee on Economic, Social and Cultural Rights, May 1996 <http://www.refworld.org/docid/4794773cd.html> (accessed 17 March 2016).

³²⁰ M. Magdalena Sepúlveda, *The Nature of the Obligations under the International Covenant on Economic, Social and Cultural Rights* (Intersentia, 2003), 87-88.

by the WTO Members under the DSU.³²¹

Only the UN Security Council and the ICJ are empowered to make legally binding decisions on human rights. The UN Security Council is a political body and rarely deals with the enforcement of human right in manners how treaty bodies do. It concerns itself with international peace and security. In the ICJ setting, human rights cases occupy only a small part of its docket and the ICJ can only hear contentious cases between States.³²² Furthermore, as previously mentioned above, the Court may only adjudicate the matter if both States consent to be bound by the jurisdiction of the Court.

In accordance with the general principles of international law, a treaty only binds states that ratify it. Likewise, the ICESCR only binds States that ratified the Covenant. Although the Covenant enjoys wide membership, not all WTO members are parties to the ICESCR. According to Hestermeyer's publication in 2008, only approximately 85 per cent of the WTO Members have ratified both the ICCPR and ICESCR.³²³ The United States has not ratified the ICESCR and only a handful of states had ratified the Optional Protocol to the ICESCR. Malaysia has neither signed nor ratified both the ICCPR and ICESCR.

Given that a state may only be held accountable under the treaty it ratifies, the next issue that merits discussion is whether or not access to medicine is part of customary international law. Once a general practice is accepted as an international custom, all States are bound by the law regardless of the treaties they ratify. This is particularly useful against States who had not ratified any of the core human rights covenant such as Malaysia. Customary international law is constituted through State practice and the State's belief that the norm is

³²¹ Sarah Joseph, *Blame It on the WTO?*, 16.(note 186 above)

³²² Article 34(1) of the Statute of the International Court of Justice

³²³ Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines*, 295.(note 166 above)

legally binding, which is known as *opinio juris*. Hence, a customary rule is not binding on a state that persistently objected to it. The problem is how much of a state practice is needed and how should *opinio juris* be proven for human rights to be transformed into binding international law. The topic is of great controversy and is dominated by academic debate.³²⁴ Suffice to say that it could be used as an alternative to establish a State's human rights obligation.

As Malaysia is not a party to the ICESCR, reference to its human rights obligation would have to be read from its national law. The state does have a duty to protect individuals from violation of their rights by private parties but how much of a legal obligation to protect is contingent on the type of right inscribed in its domestic law. Although there is no direct obligation to ensure medicines are accessible to the public, the recent visit by Special Rapporteur Dainius Pūras to Malaysia from 19 November to 2 December 2014 commented that:

“The Federal Constitution of Malaysia contains a number of provisions for the enjoyment of the right to health, directly or indirectly, most of which are contained in articles 5–13. If these rights are infringed, the victim(s) can seize the High Court Division. Legislation in Malaysia related to the realization of the right to health includes the Penal Code and the Criminal Procedure Code. Also worth highlighting are the Dangerous Drugs Act 1952; the Aboriginal Peoples Act 1954; the Immigration Act 1959/63; the Medical Act 1971; the Drug Dependants (Treatment and Rehabilitation) Act 1983; the Care Centres Act 1993; the Private Healthcare Facilities and Services Act 1998; the Human Rights Commission of Malaysia Act 1999; the Child Act 2001; and the Mental Health Act 2001.”³²⁵

³²⁴ See generally Anthony E. Cassimatis, *Human Rights Related Trade Measures under International Law*, *International Studies in Human Rights*, vol. 94 (Martinus Nijhoff Publishers, 2007), 72-91.

³²⁵ Human Rights Council, Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, Dainius Pūras;

Malaysia strives to provide excellent health care system and is a member of the WHO. The WHO Constitution was one of the earliest international legal documents to contain an explicit right to health, its preamble states that:

The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition.

The health of all peoples is fundamental to the attainment of peace and security and is dependent upon the fullest cooperation of individuals and States. The achievement of any State in the promotion and protection of health is a value to all.

The preamble though not legally binding set forth the object and purpose of the Treaty. The right to health was subsequently adopted in the much cited Article 12 of the ICESCR. Malaysia aimed to improve access to and affordable essential medicines to all by implementing the National Medicines Policy. In the 2012 second edition of the Malaysian National Medicines Policy documented review, the Malaysian Ministry of Health maintained that the implementation of the policy successfully established a comprehensive regulation system and extensive pharmaceutical distribution network. Studies have shown the Malaysian health care system is generally of high standards³²⁶ and was ranked 31 out of 191 countries in the 2000 World Health Report. The Special Rapporteur also commended Malaysia for its ‘achievements in improving the health status in the country through a sustained commitment to health policy’ and its health sector has achieved

Addendum Visit to Malaysia (19 November - 2 December 2014), 1 May 2015, United Nations doc. [A/HRC/29/33/Add.1](https://documents-dds-ny.un.org/doc/UNDOC/GEN/G15/087/06/PDF/G1508706.pdf?OpenElement) <https://documents-dds-ny.un.org/doc/UNDOC/GEN/G15/087/06/PDF/G1508706.pdf?OpenElement> (accessed 5 April 2016).para 16

³²⁶ See Donald S. Shepard, William Savedoff, and Phua Kai Hong, Health Care Reform Initiatives in Malaysia, 2002 http://www.who.int/health_financing/documents/malaysia-reform-initiatives.pdf (accessed 18 March 2016); World Health Organization (WHO), "Malaysia Health System Review," *Health Systems in Transition* 3, no. 1 (2013).

universal coverage for most of its population with fairly good standards of availability, accessibility, acceptability and quality.³²⁷

However, the Special Rapporteur also identified challenges related to a selective approach to human rights: in particular, the right to health of women and girls; indigenous communities; migrants, refugees and asylum seekers; lesbian, gay, bisexual and transgender persons; persons living with HIV/AIDS and drug users; children; and persons with developmental and psychosocial disabilities faced exclusion and discrimination from the full enjoyment of the right to health.³²⁸ The Special Rapporteur though commended Malaysia for a relatively good health system, considered its health-care financing as a share of GDP to be low according to international standards and ought to be increased.³²⁹ Clearly, much can be done and should be done to improve the standards of right to health in order to adhere to international standards.

II. Attempt of a Balanced Approach: TRIPS Flexibilities

1. Flexibilities

While TRIPS imposes a one-size –fits-all minimum standards of intellectual property rights protection that all WTO Members have to establish, it does provide certain flexibilities within its provisions so that Members may take national policies and priorities into consideration when implementing TRIPS. TRIPS objectives are found in Article 7, which stated that IPRs should serve the ‘promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of

³²⁷ Human Rights Council, Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, Dainius Pūras; Addendum Visit to Malaysia (19 November - 2 December 2014).para 6 and 9.(note 325 above)

³²⁸ See generally *ibid.*

³²⁹ *Ibid.*para 17-22

producers and users of technological’ and emphasizes ‘a balance of rights and obligations’. Its principles laid out in Article 8 states that:

Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

Apart from these general qualifications, a number of important exceptions are found in the patents section itself. Article 27(2) allows States to prohibit the patentability of an invention, ‘of which is necessary to protect...human, animal or plant life or health’. Sara Ford (2000) argued that this limitation provide for the exclusion of pharmaceutical patentability but a stronger and more rational argument according to Adam Mcbeth (2009) is that the provision serves to safeguard against the patentability of harmful innovations such as inhumane weapons and dangerous narcotics.³³⁰ Mcbeth’s argument is definitely more persuasive as Article 27 TRIPS has clearly stated that it excludes inventions whose commercial exploitation is detrimental to human life and health. It seems unlikely that the prohibition of commercial exploitation on medicines will result in the protection of human life and health.

Another type of flexibility could also be found under Article 27. The fact that Article 27 did not define the criteria of novelty, inventive step and industrial application is said to be an important freedom tool given to Members to set patentability criteria. Members could exclude inventions that attempt to evergreen patents and grant patents to genuine pharmaceutical products.³³¹

³³⁰ Sarah Joseph, *Blame It on the WTO?*, 221.(note 186 above)

³³¹ Human Rights Council, *Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover*.para 25; (note 14 above)

An explicit provision for flexibility can be found in Article 30. It provides that:

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

The provision does not provide an exhaustive list of exceptions and words are rather vague. In *Canada – Patent Protection of Pharmaceutical Products (Canada – Pharmaceutical Patents)*³³², the Panel found that the Bolar exemption, the testing of generic drugs during the patent protection period for regulatory approval under the Canadian Patents Act falls under such ‘limited exception’. The effect of the Bolar exemption is to enable generic drug manufacturers to put pharmaceutical products in the market for sale immediately after the patent expires. In the same case, the Panel however, held that stockpiling generic drugs before the expiration of the patent does not fall under the ambit of ‘limited exceptions’ allowed under Article 30. The Bolar exemption is adopted to a certain extent by Malaysia under Section 37(1A) of the Patents Act 1983. Section 37 of the Malaysian Patents Act states that rights under the patent should only extend to acts of industrial and commercial purposes and limits the Bolar exception to usage of patented drugs in scientific researches only.

a) Parallel Imports

A phenomenon known as the parallel imports provide for certain flexibility too. This phenomenon occurs in essence due to the consequence of the first sale doctrine, also known as the doctrine of exhaustion. The doctrine of exhaustion serves to limit the rights afforded under patent law to the

³³² WT/DS114/R (2000)

patentee. Once a patented product is sold by the patentee or his licensee, the patentee is said to have banished his rights to the subsequent circulation of the patented product. Hence, the buyer of the product is free to resell the product if he wishes without being bound by the patentee. The rationale for the doctrine is said to avoid the perpetual control of the patentee on subsequent transactions after the first sale and that the patentee has fully exploited the commercial value of the product.³³³ From the legal perspective, the justification derives from the fact that the patentee only has the right to exploit the intangible asset of his invention rather than the physical product itself.³³⁴ The patentee could only forbid a third party from producing and selling his invention without his consent rather than reselling the same product obtained through legal means.

An interesting practice in international trade arose as a consequence to the doctrine of exhaustion. Parallel imports places products bought from one country to another country for resale without the authorisation of the patentee in the second marketplace.³³⁵ While exhaustion in the national context is permitted, the issue is highly contested where the patentee's product has been placed in the foreign market by the patentee directly or with the patentee's consent and the said patented product is imported for sale in the same foreign market without the consent of the patent owner.³³⁶ The debate is one regarding the permissibility of international exhaustion: does the marketing of a patentee's good in a market by the patentee or with his consent diminishes his rights in relation to the sale of the goods elsewhere in the world?

³³³ E. Bonadio, "Parallel Imports in a Global Market: Should a Generalised International Exhaustion be the Next Step?," *European Intellectual Property Review* 33, no. 3 (2011): 153-161.

³³⁴ Ibid.

³³⁵ Stefan M. Miller, "Parallel Imports: Towards a Flexible Uniform International Rule," *Journal of Commercial Biotechnology* 15, no. 1 (2009): 21-43 doi: 10.1057/jcb.2008.40.

³³⁶ Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines*, 230.(note 166 above)

Pharmaceutical products are marked by substantial price differences in different markets. This may be due to various reasons such as local market conditions and the presence of competition from generic drug manufacturers. Thus, the parallel imports phenomenon is said to be of relevance importance for the pricing strategy of producers – a patent owner may sell products at different prices in different markets when parallel imports are inadmissible (*i.e.* product may be sold at a low price where demand is weak and a high price when demand for the product is strong and people are willing to pay); and consequently importers may take advantage of the price discrimination and buy the products where it is priced lower to resell at a higher price elsewhere.³³⁷

A study by the Commission on Intellectual Property Rights, Innovation and Public Health (“CIPIH”) recommended that the advantageous policy to adopt for developing countries generally is the incorporation of the international exhaustion regime into their national patent laws as medicines could be purchased from the manufacturer that offers the lowest price globally.³³⁸ Parallel importation is advantageous to a country like Malaysia, where prices of medicines are said to be much higher than the international reference prices.³³⁹ Opponents of parallel trade contended that this is inconsistent with preferential or the equity pricing of medicines.³⁴⁰ The tension is well-illustrated in an action by South African licensed pharmaceutical distributors to overturn South Africa's legislation that permit

³³⁷ Ibid.

³³⁸ Sisule F. Musungu and Cecilia Oh, *The Use of Flexibilities in TRIPS by Developing Countries: Can They Promote Access to Medicines?* pg 30. (note 218 above)

³³⁹ Medicines in Malaysia are generally priced higher. See Zaheer Ud Din Babar et al., "Evaluating Drug Prices, Availability, Affordability, and Price Components: Implications for Access to Drugs in Malaysia."(note 139 above); Zaheer Ud din Babar, Mohamed Izham Mohamed Ibrahim, and Nadeem Irfan Bukhari, "Medicine Utilisation and Pricing in Malaysia: The Findings of a Household Survey," *Journal of Generic Medicines* 3, no. 1 (2005): 47-61.

³⁴⁰ Sisule F. Musungu and Cecilia Oh, *The Use of Flexibilities in TRIPS by Developing Countries: Can They Promote Access to Medicines?*(note 218 above)

South Africa's health minister to resort to parallel imports in cases where a patented drug is priced at excessive levels in South Africa. Opponents argued that parallel importation would only prompt patent owners to raise the price of medicines in order to eliminate low price leakage into the high-priced markets and patent owners will also be reluctant to facilitate technology transfer in countries that adopt the international exhaustion regime.³⁴¹ As a result, measures to counter international exhaustion policy will only work to the detriment of developing countries. To facilitate a win-win situation for the developed and the developing countries, developed countries should at the same time, deter parallel imports of pharmaceutical products from developing countries. The grounds for the rejection of parallel importations are baseless given that almost all of the developed countries have rules in place to prohibit importation of preferentially-priced medicines.³⁴²

Article 6 of TRIPS explicitly covers the exhaustion of IPRs. It provides that subject to the National Treatment and Most-Favoured-Nation Treatment, nothing in the TRIPS Agreement should be used to address the issue of the exhaustion of IPRs. The provision does not seem to prohibit international exhaustion but there were conflicting views on the legality of the matter. Author J. Straus (1997) considers Article 6 to be a mere procedural rule for 'purposes of dispute settlement'.³⁴³ On the other hand, some believe the essence of Article XI of GATT in prohibiting quantitative restrictions is construed to prohibit non-tariff measures such as banning parallel imports.³⁴⁴ Many believe the choice whether or not to adopt an international exhaustion

³⁴¹ E. Bonadio, "Parallel Imports in a Global Market: Shoud a Generalised International Exhaustion be the Next Step?," 153-161.(note 333 above)

³⁴² Sisule F. Musungu and Cecilia Oh, *The Use of Flexibilities in TRIPS by Developing Countries: Can They Promote Access to Medicines?*(note 218 above)

³⁴³ Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines*, 232.(note 166 above)

³⁴⁴ See E. Bonadio, "Parallel Imports in a Global Market: Shoud a Generalised International Exhaustion be the Next Step?," 153-161.(note 333 above)

policy is a matter left to the discretion of the Members.³⁴⁵ In Malaysia, parallel importation is generally permitted as it is provided under Section 40(1)(d) of the Trade Marks Act 1976 and Section 58A of the Patents Act 1983. Prior to Section 58A, the doctrine of exhaustion was already permitted under case law.³⁴⁶ However, in order to market a product, rules of the drug regulatory agent have to be complied with. According to the Malaysian NPCB's drug registration guidance document, application for the registration of medicines by an applicant who is not the product owner has to be accompanied with a letter of authorisation from the product owner.³⁴⁷ This requirement is capable of working against the effect of parallel importation as it is unlikely that a parent company would supply the trader with a letter of authorisation when it has appointed its own sole distributor in the country.³⁴⁸ The Health Ministry is said not to support parallel importation and hence, multi-national pharmaceutical companies in Malaysia are not affected by the measure at all.³⁴⁹ Here, national rules rather than TRIPS work to a disadvantage of the flexibility provided.

b) Revocation of Patents

Article 32 states that 'An opportunity for judicial review of any decision to revoke or forfeit a patent shall be available'. The provision implies that

³⁴⁵ Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines*, 233.(note 166 above)

³⁴⁶ See *Smith Kline & French Laboratories Ltd v Salim (M) Sdn Bnd* [1989] 2 CLJ 228

³⁴⁷ National Pharmaceutical Control Bureau and Malaysia Ministry of Health, Drug Registration Guidance Document, Revised January 2016 http://bpfk.moh.gov.my/images/Drug-Registration-Guidance-Documents/2016/Jan2016/Complete_DRGD_JAN_2016.pdf (accessed 22 March 2016).pg 539

³⁴⁸ Local Pharmacy News, Drugs on the Side - Choose Our Medicines With Care, 2 November 2000, Malaysian Pharmaceutical Society <http://www.mps.org.my/newsmaster.cfm?&menuid=36&action=view&retrieveid=98> (accessed 22 March 2016).

³⁴⁹ Ibid.

revocation and forfeiture of a patent should be made available but did not list the grounds for revocation or forfeiture of a patent. As 5A(3) of the Paris Convention permits forfeiture of patents when grant of compulsory licenses is insufficient to prevent the abuse of rights granted to patent owners, Hestermeyer inferred that such would also be applicable under TRIPS.³⁵⁰ The Malaysian Patents Act does not provide for the possibility of revocation and forfeiture of patents.

C) Transition Periods

Article 65 and 66 of TRIPS give developing and least developed countries (“LDCs”) longer transition periods to meet its obligations under TRIPS. While developed countries were only afforded a one-year transition period, developing countries were afforded five years, and LDCs were given a ten-year transition period, which was subsequently extended twice in 2002 for pharmaceutical products until 1 January 2016, and in 2005 for all products (other than Articles 3, 4 and 5) until 1 July 2013.³⁵¹ The transition period is of practical relevance to countries that are primarily generic drug manufacturers. Before the implementation of TRIPS, India was tasked to produce generic versions of antiretroviral drugs and this brought down prices of antiretroviral medicines drastically. These transition periods have now expired for all countries except the LDCs. The TRIPS Council further extended the transition period for all products and pharmaceutical products until 1 July 2021 and 1 January 2033 respectively.³⁵²

³⁵⁰ Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines*, 254.(note 166 above)

³⁵¹ Joint United Nations Programme on HIV/AIDS (UNAIDS) and United Nations Development Programme (UNDP), *TRIPS Transition Period Extensions for Least-Developed Countries*.(note 9 above)

³⁵² World Trade Organization (WTO), *Responding to Least Developed Countries' Special Needs in Intellectual Property* https://www.wto.org/english/tratop_e/trips_e/ldc_e.htm (accessed 22 March 2016).

D) Compulsory Licences

Perhaps the core of the flexibility provision lies in Article 31 TRIPS, which permits the government or third parties authorised by the government to issue compulsory licences to produce generic versions of a patented medicine without the consent of the patent owner. It is perhaps the most effective and immediate method in lowering the prices of medicines. As such, it was an issue of contention between the developed and the developing countries during TRIPS negotiation. Developing countries is said to have emerged victorious in matters related to the TRIPS compulsory licence provision as it was stronger and clearer than that provided under the Paris Convention.³⁵³ Under Article 5 of the Paris Convention, compulsory licences can only be applied after a fixed period of time and application can be refused if the patentee could justify his inactions with a legitimate reason. Article 31 TRIPS did not put a fixed time frame on the application of compulsory license and it permits the application of compulsory licences for other use than those permitted under Article 30. In Malaysia, compulsory licence and use by the government are provided under Section 49 and Section 84 of the Patents Act 1983. After the implementation of TRIPS, the Section 49 is revised to tighten the requirements for application of compulsory licences. It now reflects both the requirements of TRIPS and the Paris Convention in granting compulsory licences. As mentioned above in Chapter III, application could only be made under few circumstances: where the patented product is not produced without any legitimate reason and where the patented product is sold at an unreasonably high price or it does not meet the public demand without any legitimate reason.

TRIPS seems to offer more flexibility as it does not contain any explicit

³⁵³ Jerome H. Reichman, "Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options," *The Journal of Law, Medicine & Ethics* 37, no. 2 (2009): 247-263; doi: 10.1111/j.1748-720X.2009.00369.x.

limitations on the grounds compulsory licences may be granted. It did however, subject the applicant to make efforts in obtaining authorisation from the patent owner under ordinary circumstances; this is waived in cases of ‘national emergency or other circumstances of extreme urgency or in cases of public non-commercial use’. An equivalent of this is provided under Section 84 of the Malaysian Patents Act. Needless to say, granting compulsory licensing on public health grounds is allowed provided the limitations are fulfilled. Members may provide for such ground directly in the legislation. Malaysia explicitly provided health to be a ground for the government use of patents. Although TRIPS permit usage of a patented product without the consent of the owner, adequate remuneration to the patent owner has to be provided.

A further limitation is provided under subparagraph (f), which provides that such usage has to ‘authorized predominantly for the supply of the domestic market’. The implication of such provision is severe for Members who lack the capacity to manufacture pharmaceutical products. Although TRIPS provided Members with the compulsory licensing flexibility, it is meaningless if a country is incapable of manufacturing the said patented pharmaceutical product for its domestic market. These Members have to source the product from another Member. The whole process is rather cumbersome given that the exporting Member has to agree to issue a compulsory licence, manufacture the product and export it. Furthermore, such action is prohibited under Article 31(f).

2. The Doha Declaration

TRIPS flexibilities presented lots of ambiguities due to its vague language. Ultimately, the more flexibilities the provision attempt to offer, the vaguer the language has to be for Members to implement TRIPS according to

their national policies. The developed countries prefer a stricter and narrower interpretation of the flexibilities but the opposite is preferred by the developing countries. There were concerns over the implication of TRIPS on access to medicines. In particular, there were disputes over the extent of a Member's rights in issuing a compulsory licence. Pharmaceutical companies protested to the South African Government's measure to implement an open-ended parallel import and compulsory licence on antiretroviral drugs and the US brought a complaint to the WTO with regards to Brazil's threat to apply compulsory licence. The obstacles met in utilising TRIPS flexibilities had the developing countries addressing public health issues at the TRIPS Council.³⁵⁴ This culminated in the adoption of the Declaration on the TRIPS Agreement and Public Health ("Doha Declaration") in November 2001. Under the Declaration, Members recognized the gravity of public health problems in developing countries and LDCs as well as the concerns about IP protection's effect on prices of medicines.³⁵⁵

The most important yet controversial provision is paragraph 4 on which Members 'agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health' and that TRIPS 'can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.' The provision is further fortified with Members reaffirming 'the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.' It affirms that Members should be able to utilize TRIPS flexibilities without fear of pressure and opposition. Article 8.1 TRIPS provided that Members may take measures to protect public health, provided it is consistent with the

³⁵⁴ Carlos M. Correa, Implications of the Doha Declaration on the TRIPS Agreement and Public Health, June 2002, World Health Organization WHO/EDM/PAR/2002.3 <http://apps.who.int/medicinedocs/pdf/s2301e/s2301e.pdf> (accessed 25 March 2016).pg 2

³⁵⁵ Paragraph 1 and 3 of the Doha Declaration

Agreement. The effect of paragraph 4 was reportedly to suggest that Article 8.1 does not prevent a Member from derogating from its obligations under the Agreement if necessary to take measures to protect public health.³⁵⁶ Subparagraph 5(b) reiterates the Members' right to grant compulsory licences and freedom to determine the grounds to grant such licences. Subparagraph 5(c) clarifies that it is the Members' 'right to determine what constitutes national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency...' Subparagraph 5(d) settled the debate of whether international exhaustion of intellectual property rights is allowed or not under TRIPS. It stated that Members are allowed to establish its own regime of exhaustion. Clearly, it is legal for Members to apply an international exhaustion regime if they wish to.³⁵⁷

Paragraph 6 instructs the Council for TRIPS to come up with a solution for Members who lack pharmaceutical manufacturing capability to be able to utilise compulsory licensing. The General Council in August 2003 decided to waive Article 31(f) under certain circumstances. Both exporting and importing members are subject to strict formal rules of notification to the Council and conditions regarding quantity and packaging of pharmaceutical products were also imposed. Remuneration to the patent holder was to be paid in the exporting state and the importing member is waived from paying the remuneration. Safeguards against trade diversion and abuse of the system were also provided for. The Decision can be found under the Annex to the

³⁵⁶ Carlos M. Correa, *Implications of the Doha Declaration on the TRIPS Agreement and Public Health*, pg 11.(note 354 above); Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines*, 258.(note 166 above)

³⁵⁷ Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines*, 260.(note 166 above); Carlos M. Correa, *Implications of the Doha Declaration on the TRIPS Agreement and Public Health*, pg 18.(note 354 above)

Protocol Amending the TRIPS Agreement with the insertion of Article 31*bis*. The decision remains in effect until it is replaced by the amendment. In accordance with Article X:3 of the WTO Agreement, the amendment will only take effect pending its acceptance by two thirds of the Members. The deadline for the acceptance has now been extended to 31 December 2017.³⁵⁸

There have been debates regarding the legality of the Doha Declaration. The Declaration though attempts to provide clear interpretation of the TRIPS Agreement did not amount to ‘authoritative interpretations’, which are considered to be binding under Article IX:2 of the WTO Agreement. The Declaration made no reference to the Article and the procedure was not adhered to.³⁵⁹ There are arguments that the non-invocation of Article IX:2 does not indicate the lack of legal basis for the Declaration; that the requirement of three-fourths majority only has to be fulfilled if a consensus cannot be reached; and the defect of not passing the Declaration pursuant to the recommendation of the Council of TRIPS can be overcome.³⁶⁰ Yet some interpreted the Declaration as a ‘decision’ under Article IX:1 of the WTO Agreement as it was adopted by consensus of the Ministers and this decision appears to be a substantive agreement on the interpretation of the TRIPS Agreement in accordance with the meaning of Article 31(3)(a) of the Vienna Convention on the Law of Treaties.³⁶¹ As Abbott pointed out, the ‘Ministers

³⁵⁸ General Council, Amendment of the TRIPS Agreement - Fifth Extension of the Period for the Acceptance by Members of the Protocol Amending the Trips Agreement, 2 December 2015, World Trade Organization Doc. WT/L/965 https://www.wto.org/english/tratop_e/trips_e/amendment_e.htm (accessed 25 March 2016).

³⁵⁹ Article IX:2 requires a Ministerial Conference to exercise its authority on the basis of a recommendation by the Council for TRIPS and interpretations of a multilateral trade agreements shall be adopted by a three-fourths majority of the Members. The Doha Declaration was not passed pursuant to the recommendation of the Council for TRIPS and the Declaration was passed on consensus.

³⁶⁰ Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines*, 281.(note 166 above)

³⁶¹ Frederick M. Abbott, "The Doha Declaration on the TRIPS Agreement and Public Health:

in Doha should be assumed to have acted with a purpose. The only apparent purpose for agreeing on a method of application of the TRIPS Agreement is to have an effect on the way in which the agreement is implemented by WTO Members.³⁶²

3. Effectiveness of TRIPS Flexibilities

Despite the reaffirmation of the TRIPS flexibilities in Doha Declaration, there were practical difficulties in implementing these measures. Procedural requirements are complicated and developing countries are met with retaliation from pharmaceutical companies.³⁶³

However, there are ample of evidences that these flexibilities have in practice been applied. For instance, India and the Philippines exclude from patentability new forms of known substances unless they are significantly more efficacious and new or second uses and combinations of the known substances; Article 27 has been utilised to limit evergreening tactics.³⁶⁴

Under TRIPS, Members also have the discretion to establish opposition and revocation procedures, which allow stakeholders, including civil society groups to oppose the grant of patents.³⁶⁵ This assists patent office in

Lighting a Dark Corner at the WTO," *Journal of International Economic Law* 5, (2002): 469-505; Dr Henning Grosse Ruse-Khan, "Proportionality and Balancing within the Objectives for Intellectual Property Protection," in *Intellectual Property and Human Rights*, ed. Paul L.C. Torremans(Kluwer Law International, 2008), 184. Article 31(3)(a) provides that a treaty should be interpreted together with the context of 'subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions'.

³⁶² Frederick M. Abbott, "The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO," 469-505.(note 361 above)

³⁶³ See Dina Halajian, "Inadequacy of TRIPS & the Compulsory License: Why Broad Compulsory Licensing is Not a Viable Solution to the Access to Medicine Problem," *Brooklyn Journal of International Law* 38, no. 3 (2013): 1191-1231; Human Rights Council, *Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health*, Anand Grover.(note 14 above)

³⁶⁴ Human Rights Council, *Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health*, Anand Grover.para 35.(note 14 above)

evaluating whether a product or process is genuinely patentable.³⁶⁶ Examples of such success include India and Thailand, where patent applications for crucial HIV medicines have been successfully opposed.³⁶⁷

After the Doha declaration, Malaysia was the first in 2004 to issue a compulsory licence for importation of generic versions antiretroviral drugs from India after lengthy failed priced negotiations.³⁶⁸ Given the high prices of antiretroviral drugs, approximately 75% of the HIV positive patients could not afford treatment.³⁶⁹ Despite an offer of thirty to forty percent price reduction by GlaxoSmithKline and Bristol-Myers Squibb, the discounts were insufficient to meet the needs of Malaysia's HIV treatment programme.³⁷⁰ Negative consequences followed after the issuance of compulsory licence. The affected pharmaceutical companies filed complaints with the government immediately after the approved government use of the patented medicines, prompting negative implications for foreign investment.³⁷¹ Nevertheless, Article 31 TRIPS proved effective. Prices of the antiretroviral drugs reduced by 81%, the number of people that could be treated nearly tripled from 1500 to 4000 and further price concessions with the pharmaceutical companies were prompted.³⁷² In November 2005, the authorisation of government use expired and Malaysia is still struggling over the high costs of health

³⁶⁵ Ibid. para 50

³⁶⁶ Ibid.

³⁶⁷ Ibid.

³⁶⁸ Sara Germano, "Compulsory Licensing of Pharmaceuticals in Southeast Asia: Paving the Way for Greater Use of the TRIPS Flexibility in Low- and Middle-Income Countries," *76 UMKC Law Review* 273, 286-87, (2007).

³⁶⁹ Chee Yoke Ling, Malaysia's Experience in Increasing Access to Antiretroviral Drugs: Exercising the 'Government Use' Option, 2006, Third World Network <http://www.twn.my/title2/IPR/pdf/ipr09.pdf> (accessed 17 June 2016).

³⁷⁰ Sara Germano, "Compulsory Licensing of Pharmaceuticals in Southeast Asia: Paving the Way for Greater Use of the TRIPS Flexibility in Low- and Middle-Income Countries." (note 368 above)

³⁷¹ Ibid.

³⁷² Ibid.

financing.³⁷³

In November 2005, Taiwan issued a compulsory licence for the Roche avian influenza drug, "Tamiflu".³⁷⁴ In 2001 and 2005, Brazil successfully used the threat of compulsory licence to obtain significant price discounts on needed medicines.³⁷⁵ In 2007, after failed agreement on price concessions, Brazil issued compulsory licence for a type of antiretroviral drug.³⁷⁶ Between 2006 and 2007, Thailand issued two compulsory licences on antiretroviral drugs and one on a medicine for major cardiovascular treatment.³⁷⁷ Rwanda was the first to trigger the waiver provisions to Article 31(f) TRIPS when it issued a compulsory license for a antiretroviral drug that it is incapable of manufacturing locally and applied for assistance from Canada in 2007.³⁷⁸ Post-Doha, by the end of 2007, 52 developing countries and LDCs have issued compulsory licences, giving Article 31 the much desired effect contemplated in the Declaration.³⁷⁹ The use of TRIPS flexibilities and implementation of Doha Declaration have also been encouraged by international funds and donors such as the Global Fund, UNITAID and the World Bank.³⁸⁰

There are however, concerns regarding the adverse effects of implementing the flexibilities. Usage of compulsory licences is generally low³⁸¹ and most involved LDCs that do not have to provide pharmaceutical

³⁷³ Ibid.

³⁷⁴ Riadh Quadir, "Patent Stalemate? The WTO's Essential Medicines Impasse between Pharmas and Least Developed Countries," *61 Rutgers Law Review* 437, (2009).

³⁷⁵ Ibid.

³⁷⁶ Ibid.

³⁷⁷ Jerome H. Reichman, "Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options," 247-263.(note 353 above)

³⁷⁸ Ibid.

³⁷⁹ Ellen FM 't Hoen, *The Global Politics of Pharmaceutical Monopoly Power: Drug Patents, Access, Innovation and the Application of the WTO Doha Declaration on TRIPS and Public Health*.pg 44.(note 245 above)

³⁸⁰ Ibid.pg 63-64

patents.³⁸² These licences also mainly relate to antiretroviral drugs.³⁸³ Members should exercise caution when choosing the best legal mechanism to ensure access to medicines as measures such as compulsory licence are sure to elicit economic, political pressures and trade sanctions from developed countries. As seen in the case of Malaysia, there was concern that the issuance of a compulsory licence would put the country at risk of diminished foreign direct investments and patent owners will seek a more business-friendly legal environment. Pharmaceutical companies also retaliated by filing complaints. In the case of Thailand, the European Union Commissioner for External Trade intimidated Thailand's Minister for Commerce that issuance of compulsory licences for Abbott Laboratories' Kaletra, an antiretroviral drug in 2007 could lead to Thailand being isolated from the global biotechnology investment community.³⁸⁴ Similarly, the Office of the United States Trade Representative ("USTR") placed Thailand on its 'Special 301' Priority Watch List on the reason that Thailand lacked transparency and due process when issuing compulsory licence.³⁸⁵ According to an article, the USTR also threatened to terminate Thailand's privileges to export certain products to the US at low or no tariffs.³⁸⁶ Abbott Laboratories responded by announcing withdrawal of applications to market seven new drugs in Thailand.³⁸⁷ The

³⁸¹ TG Agitha, "TRIPS Agreement and Public Health: The Post Doha Crises," *Journal of Intellectual Property Rights* 18, (2013): 287-293; Dina Halajian, "Inadequacy of TRIPS & the Compulsory License: Why Broad Compulsory Licensing is Not a Viable Solution to the Access to Medicine Problem," 1191-1231.(note 363 above)

³⁸² Ellen FM 't Hoen, *The Global Politics of Pharmaceutical Monopoly Power: Drug Patents, Access, Innovation and the Application of the WTO Doha Declaration on TRIPS and Public Health*.pg 60.(note 245 above)

³⁸³ *Ibid.*; Dina Halajian, "Inadequacy of TRIPS & the Compulsory License: Why Broad Compulsory Licensing is Not a Viable Solution to the Access to Medicine Problem," 1191-1231.(note 363 above)

³⁸⁴ TG Agitha, "TRIPS Agreement and Public Health: The Post Doha Crises," 287-293.(note 381 above)

³⁸⁵ *Ibid.*

³⁸⁶ Jerome H. Reichman, "Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options," 247-263.(note 353 above)

generation of such extreme oppositions were surprising given that the government use orders issuance fulfilled all national and international legal procedural requirements.³⁸⁸

On the other hand, implementation and use of the Doha Declaration flexibilities by the LDCs in sub-Saharan Africa were hardly challenged; the explanation of which most likely lies in the small pharmaceutical market share of these regions.³⁸⁹ Another reason for the extreme opposition is that use of the flexibilities by the developing countries is primarily used to import generics rather than producing the originator's medicines.³⁹⁰ Overall, the experience to increase access to medicines via the implementation and use of TRIPS flexibilities is generally mixed.³⁹¹

Strictly speaking, TRIPS provisions achieved its dual goals of balancing protection of IPRs with access to medicines when viewed in isolation without regards to economic and political pressures exerted from developed countries. In all cases of compulsory licensing, prices of medicines were significantly reduced to increase access. Despite the difficulties faced, these countries successfully utilised the compulsory licensing flexibility. The Doha Declaration also encouraged a number of non-WTO Members to make use of flexibilities to allow use of generic medicines regardless of its patent status.³⁹² There are also positive effects from the practice of countries in issuing compulsory licences. For instance, after Malaysia issued the government use order, pharmaceutical companies have since become more co-operative and

³⁸⁷ TG Agitha, "TRIPS Agreement and Public Health: The Post Doha Crises," 287-293.(note 381 above)

³⁸⁸ Ellen FM 't Hoen, *The Global Politics of Pharmaceutical Monopoly Power: Drug Patents, Access, Innovation and the Application of the WTO Doha Declaration on TRIPS and Public Health*.pg 48.(note 245 above)

³⁸⁹ *Ibid*.pg 65

³⁹⁰ *Ibid*.pg 60

³⁹¹ *Ibid*.pg 65

³⁹² *Ibid*.pg 62

began to demonstrate a willingness to decrease prices.³⁹³ Pharmaceutical companies who felt threatened by the use of compulsory licence have since offered their products to developing countries on a cheaper basis and some have even offered voluntary royalty-free licences.³⁹⁴ Even though Members seldom use the flexibilities afforded under TRIPS, the inclination to negotiate is higher due to the availability of legal tools that Members may use to lower prices.³⁹⁵ With regard to trade sanctions taken against countries that use compulsory licensing, from a legal perspective, imposing countries rather than governments issuing compulsory licences in conformity with TRIPS are said to be at greater risk of being in violation of the WTO rules for launching unilateral retaliatory actions.³⁹⁶ The exertion of such pressures is said to amount to the extraterritorial breach of human rights obligations.³⁹⁷

The Special Rapporteur on the Right to Health, Anand Grover did not explicitly rule that TRIPS is in conflict with the human rights obligation of right to health, rather he found that TRIPS does have a negative impact on prices and availability of medicines.³⁹⁸ He stressed on developing countries and LDCs to make full use of the flexibilities when implementing national laws and policies.³⁹⁹ Indeed, the will to balance the economic interests of the

³⁹³ Sisule F. Musungu and Cecilia Oh, *The Use of Flexibilities in TRIPS by Developing Countries: Can They Promote Access to Medicines?* pg 26.(note 218 above); Ellen FM 't Hoen, *The Global Politics of Pharmaceutical Monopoly Power: Drug Patents, Access, Innovation and the Application of the WTO Doha Declaration on TRIPS and Public Health.*pg 51.(note 245 above)

³⁹⁴ Sarah Joseph, *Blame It on the WTO?*, 226.(note 186 above); Subhasis Saha, "Patent Law and TRIPS: Compulsory Licensing of Patents and Pharmaceuticals," *Journal of the Patent and Trademark Office Society* 91, (2009): 364-373.

³⁹⁵ Jerome H. Reichman, "Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options," 247-263.(note 353 above)

³⁹⁶ Ibid.

³⁹⁷ Sarah Joseph, *Blame It on the WTO?*, 229.(note 186 above)

³⁹⁸ See generally Human Rights Council, *Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover.*and para 94.(note 14 above)

³⁹⁹ Ibid.para 96 and 97

state and the public interests of right to health lies on the State. The regulatory discretionary enjoyed by States in the light of TRIPS when implementing their patent system is also pointed out by the ‘Declaration on Patent Protection – Regulatory Sovereignty under TRIPS’ which is published on 15 April 2014 to commemorate the 20th year since the creation of the WTO.⁴⁰⁰ It reinforces that necessary and reasonable curtailment of a patent owner’s exclusive right in the light of socio-economic interests does not transpire into non-compliance with the TRIPS Agreement.⁴⁰¹

A major part of the Declaration referred to Article 27 TRIPS. In *Canada – Pharmaceutical Patents*, the most contested part of the Panel’s decision concern the non-discrimination rule in Article 27(1). The provision prohibits discrimination of patents as to the ‘place of invention, field of technology and whether products are imported or locally produced’. Canada argued that the non-discrimination rule is exempted under Article 30 (limited exceptions to rights conferred) and separate rules for the pharmaceutical industry could be established. The Panel rejected such argument and was of the opinion that the rule applied to both Article 30 and 31 (compulsory licensing). The Declaration is supportive of Canada’s view that the non-discrimination principle does not apply to Article 30 and 31 and explicitly contradicted the Panel’s decision.⁴⁰² As every technology is unique and differences may

⁴⁰⁰ Matthias Lamping, Opinion: Declaration on Patent Protection - Regulatory Sovereignty under TRIPS, 22 August 2014, Max Planck Institute for Innovation and Competition, Munich.doi: 10.1007/s40319-014-0243-6
http://download.springer.com/static/pdf/248/art%253A10.1007%252Fs40319-014-0243-6.pdf?originUrl=http%3A%2F%2Flink.springer.com%2Farticle%2F10.1007%2Fs40319-014-0243-6&token2=exp=1459217243~acl=%2Fstatic%2Fpdf%2F248%2Fart%25253A10.1007%25252Fs40319-014-0243-6.pdf%3ForiginUrl%3Dhttp%253A%252F%252Flink.springer.com%252Farticle%252F10.1007%252Fs40319-014-0243-6*~hmac=4ac988d4c81cc4513d4ca4a3f64082d5930c74352581c96471b1a1dbcea5ac22 (accessed 29 March 2016).

⁴⁰¹ Paragraph 5 of the Declaration on Patent Protection - Regulatory Sovereignty under TRIPS

⁴⁰² See paragraph 8 of the Declaration on Patent Protection - Regulatory Sovereignty under TRIPS

occur ‘with regard to its exposure to market failure, its susceptibility to patent protection and its socio-economic implications’, the demand for patent protection and the attainment of public policy should also differ according to the technology at issue.⁴⁰³ Accordingly, states have the discretion to define patentable invention as Article 27 does not require states to provide protection for subject matter that they classify as discoveries or inventions they do not consider to be of a technical nature.⁴⁰⁴ States may for instance, deny patents for biological material, derivatives of known products or substances, new uses of known substances such as a second use of pharmaceutical substances, and selection of elements from patented compounds.⁴⁰⁵

Patent protection also should not be granted when an invention is not effectively disclosed under Article 29.⁴⁰⁶ Furthermore, Article 27 and 28 does not hinder states from limiting patent protection only to the uses, purposes or functions disclosed in an application whose range is particularly wide and unpredictable such as chemical compounds and gene sequences.⁴⁰⁷ Such specific protections constitute a legitimate differentiation rather than discrimination within the meaning of Article 27.1.⁴⁰⁸

Article 6 TRIPS also allowed states to select whether or not to apply international exhaustion and that Article 27 does not prevent states to apply the exhaustion doctrine to different fields of technology.⁴⁰⁹

⁴⁰³ Paragraph 7 of the Declaration on Patent Protection - Regulatory Sovereignty under TRIPS

⁴⁰⁴ Paragraph 10 of the Declaration on Patent Protection - Regulatory Sovereignty under TRIPS

⁴⁰⁵ Paragraph 11 of the Declaration on Patent Protection - Regulatory Sovereignty under TRIPS

⁴⁰⁶ Paragraph 12 of the Declaration on Patent Protection - Regulatory Sovereignty under TRIPS

⁴⁰⁷ Paragraph 17 of the Declaration on Patent Protection - Regulatory Sovereignty under TRIPS

⁴⁰⁸ Paragraph 17 of the Declaration on Patent Protection - Regulatory Sovereignty under TRIPS

⁴⁰⁹ Paragraph 18-19 of the Declaration on Patent Protection - Regulatory Sovereignty under TRIPS

The Declaration also explicitly contradicted the Panel’s decision in the *Canada – Pharmaceutical Patents* case that stated that the three criteria in Article 30 must be established cumulatively for the exception to rights conferred to patent owners to apply.⁴¹⁰ Authors of the Declaration were of the opinion that a limited exception should not necessarily be narrow in its effect; it is limited within the meaning of Article 30 as long as the scope of the exception is reasonably proportionate to its objective as well as purpose and does not unduly curtails the innovation rewards provided by the market.⁴¹¹ Therefore, even *prima facie* ‘unlimited’ stockpiling of generic medicines prior to the expiration of patent protection exception is compatible with Article 30 if it is proportionate and all affected interests are taken into consideration.⁴¹²

With regard to compulsory licences, the Declaration reaffirmed that Article 31 does not restrict grounds on which the licence may be issued.⁴¹³ Compulsory licences ensures patent protection remains properly balanced with socio-economic interests and states are therefore, free to grant compulsory licence if the patent owner fails to work the patent within the territory since Article 27’s non-discrimination rule does not apply to Article 31.⁴¹⁴ The authors in the Declaration on Patent Protection argue that TRIPS do provide a solution via compulsory licensing under circumstances where the patent holder fails to work the patent within the territory of protection.⁴¹⁵ The

⁴¹⁰ Paragraph 22 of the Declaration on Patent Protection - Regulatory Sovereignty under TRIPS

⁴¹¹ Paragraph 23-25 of the Declaration on Patent Protection - Regulatory Sovereignty under TRIPS

⁴¹² Paragraph 26 of the Declaration on Patent Protection - Regulatory Sovereignty under TRIPS

⁴¹³ Paragraph 28 of the Declaration on Patent Protection - Regulatory Sovereignty under TRIPS

⁴¹⁴ Paragraph 29-30 of the Declaration on Patent Protection - Regulatory Sovereignty under TRIPS

⁴¹⁵ Paragraph 30 of the Declaration on Patent Protection - Regulatory Sovereignty under

Declaration asserts that Article 27 non-discrimination rule – the prohibition to discriminate as to whether products are imported or locally produced does not apply to Article 31’s compulsory licensing provision and states are free to implement local working requirements into national laws. The perspective is in line with Article 5A(2) of the Paris Convention which allow members to grant compulsory licences when patent holders fail to work the patents. Furthermore, TRIPS provided that none of the IPRs shall derogate from existing obligations Members may have under the Paris Convention. Malaysia has implemented the local working requirements under Section 49 of its Patents Act 1983.

Findings of the Declaration are not new and it confirms Anand Grover’s view that states are able to fulfil both its human rights obligation and duties under TRIPS as long as states take full advantage of the TRIPS flexibilities. The Declaration on Patent Protection may not be legally binding but it does carry the opinions of more than 40 patent experts from 25 countries. Certainly some weight should be attached to it. To conclude, in accordance with Doha Declaration, it is undeniable that TRIPS causes an adverse impact on access to medicines but these may be balanced by the full application of the flexibilities in support of the Members obligation of right to health.

I. Conclusion

The global pharmaceutical production, consumption and trade are heavily concentrated in the developed region of the world. Although the protection of IPRs is available under certain international conventions, the law is fragmented and disharmonized. Large multinational pharmaceutical companies lobbied for a minimum standard patent protection obligation under the auspices of GATT’s strict and effective dispute settlement mechanism due

TRIPS

to huge sums of expenditure incurred in the R&D process of medicines and competition produced by generic medicine manufacturers. TRIPS was incorporated under a single package as an annex to the WTO Agreement, introducing pharmaceutical patents and an effective enforcement mechanism. However, the implementation of TRIPS resulted in price increment from patented medicines and consequently, created a barrier to access to medicines in low- and middle-income countries. Proponents of TRIPS retorted that the justification of implementing a more stringent patent protection in developing countries is dictated by increased R&D activities globally and locally, as well as the facilitation of technology transfer. The reality however, reflects a different circumstance as patent protection does not lead to more R&D in neglected diseases of the developing region as it is uneconomical to do so whether abroad or locally. The protection of IPRs is also only one of the factors a company take into account when considering whether to invest in a developing country. The ability of the destination country to absorb the technological development process also limits the effect of technology transfer from developed countries. IPRs may act as an incentive to increase R&D and technology transfer to a certain extent, nevertheless, empirical evidence suggests that stringent patent protection in Malaysia does not justify the impediment of access to medicines. Quite to the contrary, it is found that private entities are driven by economic benefits and powerful developed countries by their greed to keep a competitive edge when advocating stringent patent protection under the guise of so-called undistorted and balanced free trade regime.

In the international human rights sphere, access to medicines is protected as a right to health. However, the protection offered does little with the non-participation of the WTO and some of its members. TRIPS attempt to balance the interests of both the producer and consumer of pharmaceuticals by providing certain flexibilities for Members to consider national health care

policy when implementing patent protection. These flexibilities when used to the full advantage are capable of having states fulfil both its human rights obligation and duties under TRIPS. However, a country's capacity to utilise such flexibilities may be limited by its own trade interests and implementation of other IP protection agreement. For instance, in spite of the high reliance Malaysia placed on imported patented drugs, it went ahead to sign the Trans-Pacific Partnership ("TPP"), in the hope of bolstering domestic exports. Malaysia also has to abide by the provisions of the Paris Convention in which, its Patent Act reflected. Therefore, a country may be restricted in its ability to apply TRIPS flexibilities when it has to consider its internal economics, political interests and maintain diplomatic relations with other states as well as simultaneously having to comply with several other international agreements.

1. Possible Solutions

While Malaysia's legislation incorporated almost all the flexibilities made available under TRIPS, it did not take full advantage of the flexibilities and there are rooms for further enhancement. Amendments can be made to legislations as well as rules and regulations to accommodate more of TRIPS' flexibilities. First, to follow after the footsteps of India and the Philippines, Malaysia should also set its own definition of patentability criteria, which is not defined under Article 27 TRIPS. A further pharmaceutical use derived from a product with already known pharmaceutical use(s) should be excluded from the grant of patent. As mentioned above, 'me-too' drugs with slight modifications made to an original drug are abundant and breakthrough innovative discoveries on the other hand, are rare.⁴¹⁶ This could be used to limit evergreening and in the case of Malaysia, patent clustering that has been

⁴¹⁶ Sisule F. Musungu and Cecilia Oh, *The Use of Flexibilities in TRIPS by Developing Countries: Can They Promote Access to Medicines?*(note 218 above)

identified to create barriers on the local production of generics.

Second, parallel imports should be encouraged in the country. Although parallel imports are allowed under the law, the drug registration rule has effectively hindered its usage. The rule that application for the registration of medicines by an applicant who is not the product owner has to be accompanied with a letter of authorisation from the product owner should be removed to make parallel imports a possible and viable option.

Third, under Article 30 TRIPS limited exceptions to patent protection, full application of the Bolar exemption should be adopted. Although the Panel decision's in *Canada – Pharmaceutical Patents* also allows the use, import and manufacture of a patented product for the purpose of seeking regulatory approval, it is not as commonly found as the 'research and experimental use' exception.⁴¹⁷ Malaysia could perhaps look into extending the application of Bolar exemption if it is not hindered to do so under current laws.

Apart from legislative amendments, changes can be made to procedural aspects of patent examination as TRIPS is silent on the relevant issue. Successful examples include India and Thailand who permits opposition procedures against patent applications; and Brazil who requires obtainment of the National Sanitary Supervision Agency ("ANVISA")'s prior consent when reviewing a patent application relating to medicine.⁴¹⁸ These procedures subject patent examination to higher levels of scrutiny⁴¹⁹ and provide an added protection against cumbersome and frivolous patent applications. For instance, the involvement of concerned stakeholders such as civil society organizations and patient groups in the opposition of an application or grant of a patent could assist a patent office which is often understaffed and

⁴¹⁷ Human Rights Council, *Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover*.(para 48-49)(note 14 above)

⁴¹⁸ Ibid.(para 50)

⁴¹⁹ Ibid.

overburdened with work load.⁴²⁰

Changes could also be made within internal national policies. Malaysia currently has no price regulation mechanism in place to control the prices of medicines.⁴²¹ The government believes that pure market forces of a free market economy dictates fair and reasonable pricing, acting as a price control mechanism on its own.⁴²² However, the government fails to comprehend or take into consideration the heterogeneity of patented medicines, where substitutes are unlikely to be found. A free market does not exist when medicinal products are protected by the patent regime, eliminating almost all sorts of competition and manufacturers are at liberty to fix different prices in different countries. Medicine prices in Malaysia are regarded to be high in terms of international pricing.⁴²³ Although generic drugs are found to be much cheaper in Malaysia with most innovator drugs being 29%-90% more expensive⁴²⁴, it was also found that retail pharmacies mark up prices of medicines by 100%-140% for generics and 25%-38% for innovators, mark-ups that were considered comparatively high as opposed to other countries where the WHO-HAI surveys have been published.⁴²⁵ Research

⁴²⁰ Ibid.

⁴²¹ Zaheer Ud Din Babar et al., "Evaluating Drug Prices, Availability, Affordability, and Price Components: Implications for Access to Drugs in Malaysia."(note 139 above); Zaheer-Ud-Din Babar et al., "Pharmaceutical Industry, Innovation and Challenges for Public Health: Case Studies from Malaysia and Pakistan," 193-204.(note 56 above); Richard D Smith et al., "Trade, TRIPS, and Pharmaceuticals," 684-691.(note 259 above)

⁴²² Zaheer Ud din Babar et al., "Medicine Utilisation and Pricing in Malaysia: The Findings of a Household Survey," 47-61.(note 339 above); Mohamed Izham Mohamed Ibrahim and Salmah Bahri, "Drug Policies and Pricing Mechanism: The Malaysian Perspective."(note 147 above)

⁴²³ Zaheer Ud Din Babar et al., "Evaluating Drug Prices, Availability, Affordability, and Price Components: Implications for Access to Drugs in Malaysia."(note 139 above)

⁴²⁴ Asrul Akmal Shafie and Mohamed Azmi Hassali, "Price Comparison between Innovator and Generic Medicines Sold by Community Pharmacies in the State of Penang, Malaysia," *Journal of Generic Medicines: The Business Journal for the Generic Medicines Sector* 6, no. 1 (November 2008): 35-42; doi: 10.1057/jgm.2008.25.

⁴²⁵ Zaheer Ud Din Babar et al., "Evaluating Drug Prices, Availability, Affordability, and Price Components: Implications for Access to Drugs in Malaysia."(note 139 above)

has also suggested that increasing the availability of generic choices does not bring down prices.⁴²⁶ These impose a severe burden on consumers especially where health expenditures are privately financed. All literatures reviewed thus far supports and recommend some price monitoring and regulatory mechanisms to cap sky-rocketing prices of medicines.⁴²⁷ Criticisms arose within the public health sector as well. The public procurement system lacks transparency and is 'attributed to crony capitalism whereby privileges are awarded to firms close to the government.'⁴²⁸ Bidding for tenders should be opened to the participation of foreign firms and a more transparent evaluation as well as awarding of tenders is needed as pressed by the USTR during the US-Malaysia Foreign Trade Agreement ("FTA") negotiation.⁴²⁹

More assistance and support of legal and technical expertise should also be rendered to developing countries when incorporating and implementing the TRIPS flexibilities in national policies due to widespread misconceptions.⁴³⁰

Another option to promote access to medicine is the purchase of medicines at bulk so that it could be sold at a cheaper price to the developing countries. Patent owners may also come together and make patents available on a non-exclusive basis to manufacturers and distributors of medicines in return for royalty payments known as patent pool. Generic manufacturers would only have to deal with the pool when seeking a licence to manufacture

⁴²⁶ Zaheer Ud din Babar et al., "Medicine Utilisation and Pricing in Malaysia: The Findings of a Household Survey," 47-61.(note 339 above)

⁴²⁷ See *ibid.*; Zaheer Ud Din Babar et al., "Evaluating Drug Prices, Availability, Affordability, and Price Components: Implications for Access to Drugs in Malaysia."(note 139 above); Zaheer-Ud-Din Babar et al., "Pharmaceutical Industry, Innovation and Challenges for Public Health: Case Studies from Malaysia and Pakistan," 193-204.(note 56 above); Mohamed Izham Mohamed Ibrahim and Salmah Bahri, "Drug Policies and Pricing Mechanism: The Malaysian Perspective."(note 147 above)

⁴²⁸ Mohamed Azmi Hassali et al., "TRIPS, Free Trade Agreements and the Pharmaceutical Industry in Malaysia."(note 37 above)

⁴²⁹ See *ibid.*

⁴³⁰ Richard D Smith et al., "Trade, TRIPS, and Pharmaceuticals," 684-691.(note 259 above)

patented medicines in the pool and companies may avoid the proliferation of compulsory licences.⁴³¹

Above all, a more sustainable option is needed and possessing the ability to manufacture pharmaceutical products locally tops the list of being the most important factor in promoting access to medicines. Malaysia is recognised to have ‘significant generic drug manufacturing capacity’ and is able to produce active ingredients and finished products.⁴³² The production of active ingredients however, is only to a very limited extent and Malaysia relies heavily on imports of both raw materials and finished products.⁴³³ Case studies in parts of developing countries and LDCs reveal that local pharmaceutical production promotes access to medicines as it may increase price-based competition and fill the gap for the developing countries needs in the future - local firms in more advanced developing countries produce new products that meet both local and international needs; and an efficient as well as widespread supply-distribution pharmaceutical network by many local firms enhance access to medicines.⁴³⁴ The study also finds that local pharmaceutical production in these countries is feasible and technology transfer plays an important role in making production feasible and competitive.⁴³⁵

⁴³¹ Cynthia M. Ho, *Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights*, 360.(note 82 above)

⁴³² Economic and Social Commission for Asia and the Pacific United Nations, *Development of Health Systems in the Context of Enhancing Economic Growth Towards Achieving the Millennium Development Goals in Asia and the Pacific* (United Nations Publication, 2007), 116.

⁴³³ Sauwakon Ratanawijitrasin, *Drug Regulation and Incentives for Innovation: The case of Asean*, Commission on Intellectual Property Rights, Innovation and Public Health http://www.who.int/intellectualproperty/studies/drug_regulation/en/ (accessed June 13 2016).

⁴³⁴ UNCTAD Secretariat, *Local Production of Pharmaceuticals and Related Technology Transfer in Developing Countries*, 2011, UNCTAD/DIAE/PCB/2011/<http://apps.who.int/medicinedocs/documents/s19062en/s19062en.pdf> (accessed JUne 13 2016).pg 13-14

⁴³⁵ Ibid.

Needless to say, local R&D should be actively pursued as well but the lack of resources may mean that a more viable solution is needed. The Malaysian government only devotes 4% of its GDP on R&D and it is not discernible how much of that portion is devoted to pharmaceutical R&D. The small Malaysian market meant that local firms have to look to exports abroad in order to grow in the industry.⁴³⁶

Malaysia has to search for ways to acquire an enabling technology transfer environment. Technology transfer from the North has not been very successful as gleaned from above in Chapter IV. To this end, it is suggested that developing countries should rely on the South-South cooperation in sharing and exchanging information, expertise and technology to facilitate growth in the area.⁴³⁷ Such cooperation works to the benefits of developing countries as it may lead to economies of scale.⁴³⁸ Baker (2004) said that with the exception of a few countries such as Brazil and India, local pharmaceutical production in small domestic markets meant ‘diseconomies of scale’ and encourages South-South cooperation.⁴³⁹ The cooperation is also imperative because these countries are more likely than not to share similar social-economic problems such as the HIV pandemic.⁴⁴⁰

The cooperation however is subject to the openness and will of the countries to collaborate. A long-term sustainable and more substantive

⁴³⁶ The Edge Newspaper, Remedy Lies in Export, 2000 <http://www.mps.org.my/newsmaster.cfm?&menuid=36&action=view&retrieveid=123> (accessed June 13 2016).

⁴³⁷ Evaristus Oshionebo, "International Patent Regime, HIV/AIDS Pandemic, and Access to Essential Medicines in Developing Countries," in *International Law, Conventions and Justice*, ed. David A. Frenkel (Athens, Greece: Athens Institute for Education and Research, 2011), 247; Rosalind Pollack Petchesky, *Global Prescriptions: Gendering Health and Human Rights* (Zed Books London and New York in association with United Nations Research Institute for Social Development, 2003), 114.

⁴³⁸ Evaristus Oshionebo, "International Patent Regime, HIV/AIDS Pandemic, and Access to Essential Medicines in Developing Countries," 248.(note 435 above)

⁴³⁹ Ibid.

⁴⁴⁰ Ibid.

solution is needed. Another view is advanced wherein things would have had been different if only the right to development codified in numerous international agreements and as well as the principle of ‘transfer and dissemination of technology’ found in Article 7 TRIPS were given the same priorities as IPRs.⁴⁴¹ Differences would have been made in developing countries’ pharmaceutical manufacturing capability and more could have had gain access to essential medicines. Claims on those principles and public health rights must be able to be raised in a legal framework. In the end, the long-term sustainable and substantive solution to developing countries’ fight in access to medicines lies in the solid foundation of a ‘normative framework and a set of procedures grounded in human rights’.⁴⁴² WTO Agreements could be amended to accommodate human right by either making references to the ICCPR and ICESCR or adding a human right agreement into the WTO regime. This is the better option given that WTO Members will have to comply with human rights obligations within the WTO setting and is bound to give human rights more teeth when in conflict with TRIPS. There is hope for a better access to medicines. Pharmaceutical companies are taking steps to fulfil its human rights responsibilities too. For instance, Merck & Co. offered patients in 11 cities in India zero-interest loans for the purchase of one of its hepatitis medicines.

2. Challenges Ahead

Even if the suggested solutions above are implemented, a bigger concern has already invaded the promotion of access to medicines. While the implication of TRIPS in introducing a high standard on the protection of IPRs may have resulted in the lack of access to medicines, the flexibilities however,

⁴⁴¹ Rosalind Pollack Petchesky, *Global Prescriptions: Gendering Health and Human Rights*, 115.(note 437 above)

⁴⁴² See *ibid.*, 116.

act as an important safeguard to public health when utilized to the fullest. Notwithstanding, the biggest implication of TRIPS was the introduction of IP in trade agreements. With the adoption of TRIPS, IP became essential in trade agreements.⁴⁴³ Developed countries, in particular, the United States have long circumvented TRIPS flexibilities by shifting negotiation focus to bilateral and regional trade agreements.⁴⁴⁴ These agreements restrict countries from implementing TRIPS flexibilities.⁴⁴⁵ They also usually require a higher standard than the minimum obligations implemented by TRIPS by imposing stricter intellectual property obligations and thus, commonly referred to as “TRIPS-Plus” though they are not in any way related to TRIPS. For instance, the recent signed deal of the TPP between 12 countries including the United States and Malaysia severely undermines TRIPS flexibilities and the Doha Declaration. Certain safeguards are provided. For instance, Article 18.6 TPP affirms the parties’ commitment to take measures to protect public health and the decision of the General Council of August 30, 2003 on the implementation of paragraph six of the Doha Declaration as well as the amendment of the TRIPS Agreement. Like TRIPS, it also provides for patent revocation, limited exceptions and permits the use of Article 31 TRIPS. However, provisions of the TPP override the flexibilities in essence.

In addition to the patentability criteria specified by TRIPS, Article 18.37 TPP adds that patents are available for new uses of a known product, new methods of using a known product, or new processes of using a known product. This effectively extends the range of patented inventions, reaffirming

⁴⁴³ Richard D Smith et al., "Trade, TRIPS, and Pharmaceuticals," 684-691.(note 259 above)

⁴⁴⁴ Frederick M. Abbott, "TRIPS II, Asia and the Mercantile Pharmaceutical War: Implications for Innovation and Access," in *Stanford Center for International Development Conference on Economic Challenges in Asia May 31-June 3, 2006* (2006).

⁴⁴⁵ Human Rights Council, *Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover*.para 71.(note 14 above)

the concern of ‘evergreening’ of patents such as the creation of ‘me-too’ drugs in the pharmaceutical industry. The term of patent protection is extended too as off-patent products may come under patent protection again if a new therapeutic use is found.

Article 18.46 provides that ‘delay in the issuance of a patent of more than five years from the date of filing’ or ‘three years after a request for examination of the application has been made, whichever is later’ shall be compensated with the extension of patent term. This effectively extends the monopoly period granted to the patent owner.

Of most concern are Article 18.50 and Article 18.52 which provide that the submission of undisclosed test or data concerning the safety and efficacy of a pharmaceutical product and biologics for marketing approval shall not be disclosed to market the same or similar product without the consent of the owner for at least five and eight years respectively from the date of marketing approval of the product. Data exclusivity hinders regulatory authorities from relying on original test data to assess the safety and efficacy of a bioequivalent generic medicine and this has the severe impact of delaying the launch of generic medicines.

Malaysia introduced data exclusivity in March 2011 under the Control of Drugs and Cosmetics Regulations. The move came in respond to mounting pressure to adopt more stringent protection of IPRs when it was placed under the US Trade Representative’s ‘Special 301 Watch List’.⁴⁴⁶ In Malaysia, the period of data exclusivity starts from the date of approval of the product in the reference country of origin and a recent study shows that such requirement essentially shortened the effective data exclusivity period to 3½ years as pharmaceutical products were not registered in Malaysia on the same date in the reference country.⁴⁴⁷ The same study also found that patent protection

⁴⁴⁶ See Mohamed Azmi Hassali et al., "TRIPS, Free Trade Agreements and the Pharmaceutical Industry in Malaysia."(note 37 above)

period tends to extend beyond the data exclusivity period by an average of 8 years and hence, that data exclusivity may have limited impact in delaying the entry of generic medicines.⁴⁴⁸ The study suggested that patent owners are simply seeking an additional layer of protection via data exclusivity given that patent protection is not absolute and may be invalidated by competitors and revoked whilst data exclusivity is difficult to be challenged or disputed.⁴⁴⁹ The study also pointed out that data exclusivity may be preferred over patent protection for products such as biologics that are often difficult to patent.⁴⁵⁰ The fatality of data exclusivity lies on the fact that it is applicable to patented, off-patent, and non-patented products.⁴⁵¹ Although there may be limited consequences on delaying the entry of generic medicines for a patented drug, the consequences may be great on the entry of generic drugs for an off-patent or non-patented drug. Given that clinical trials cost millions of US dollars, data exclusivity delays the entry of generic drugs by small pharmaceutical firms who cannot rely on original test data to gain marketing approval from the authorities.

Article 18.51 introduces the concept of patent linkage, wherein drug regulatory approval authorities have to concern themselves with the patent status of a drug. Under the TPP, the authorities, when found out that a third party is attempting to market the same patented pharmaceutical product, has to notify the patent owner and give the patent owner sufficient time to institute judicial proceedings. Another option under the TPP allows drug regulatory approval authorities to refuse marketing approval to a third party

⁴⁴⁷ Omotayo Fatokun, Mohamed Azmi A. Hassali, and Mohamed Izham M. Ibrahim, "Characterizing Pharmaceuticals on Data Exclusivity in Malaysia," *Journal of Intellectual Property Rights* 20, (July 2015): 223-229.

⁴⁴⁸ Ibid.

⁴⁴⁹ Ibid.

⁴⁵⁰ Ibid.

⁴⁵¹ Ibid.

unless the consent of the patent owner is obtained. Patent linkage effectively undermines the Bolar provision and delays the entry of generic medicines as manufacturers will not be able to conduct experiments with patented drugs to submit test data to the authorities for marketing approval. Patent linkage though allowed in the US is contrary to EU regulatory law.⁴⁵² Patent linkage also shifts early enforcement of patent protection to the drug regulatory approval authorities from the patent office, increasing the burden of the regulatory approval authorities.⁴⁵³

As Abbott accurately stated, the failure to restrain the mercantilist agenda implemented by the US and other developed countries exacerbate existing problems and raise the economic and social cost of addressing such problems.⁴⁵⁴ TRIPS imposes high standard of protection on IPRs and the consequence of impeding access to medicines was found not to be justified in developing countries. It is certain then that the further increase of such protections in the form of bilateral and free trade agreements in developing countries too is not justified.

While the Doha Declaration brought developing countries a step ahead by affirming TRIPS flexibilities, trade agreements such as the TPP brought developing countries two steps back by imposing stricter obligations and more stringent protection of IPRs. Malaysia's position on patent protection and the promotion of access to medicine seems confusing at times. Malaysia signed the TPP on one hand, and on the other hand, voted in favour of the

⁴⁵² See Article 81 of Regulation (EC) No 726/2004 and Article 126 of Directive (EC) No 2001/83 which provide that marketing of a medicinal product should not be refused, suspended or revoked except for grounds set out in the Regulation and the Directive. The status of a patent was not included in the grounds of exceptions.

⁴⁵³ PublicCitizen, Trans-Pacific Partnership Agreement: Harmful Provisions for Access to Medicines
<https://www.citizen.org/documents/specific%20provisions%20final%20draft%20w.o.pdf>
(accessed June 14 2016).

⁴⁵⁴ Frederick M. Abbott, "TRIPS II, Asia and the Mercantile Pharmaceutical War: Implications for Innovation and Access."(note 444 above)

United Nations Human Rights Council on the adoption of a resolution on access to medicine that faced opposition from the US and the EU.⁴⁵⁵ Perhaps as Maskus suggested, as nations like Malaysia develop, they become increasingly interested in tightening IPRs in order to attract modern technologies and encourage local innovation.⁴⁵⁶ Proponents of the TPP in Malaysia are convinced the deal will bring more economic development and there will be minimal effect on drug prices.⁴⁵⁷ Studies however, have shown that the net economic effects of the stringent protection of IPRs are unclear, especially with regard to developing countries.⁴⁵⁸ Meanwhile, Kirchanski suggests that the strength of a country's IP protection regime should correspond with its level of economic development.⁴⁵⁹ Perhaps Malaysia is somewhere between developing and a developed country's status and is determined to mould itself after the image of the developed countries. However, the task of balancing economic and public health interests is a difficult one and how much of this transpires remains to be seen in the future.

⁴⁵⁵ See KM Gopakumar, Access to Medicines Resolution Adopted by UN Human Rights Council, 2013 <http://infojustice.org/archives/30211> (accessed 5 April 2016).

⁴⁵⁶ Keith E. Maskus, "The Role of Intellectual Property Rights in Encouraging Foreign Direct Investment and Technology Transfer," 60.(note 279 above)

⁴⁵⁷ P. Aruna, "TPPA Crucial for Malaysia," *The Star Newspaper* 19 January 2016; Wan Saiful Wan Jan, "Prioritise Consumers in TPPA Deal," *The Star Newspaper* 19 January 2016; Tan Shiow Chin, "Minimal TPPA Effect," *The Star Newspaper* 26 January 2016.

⁴⁵⁸ Carlos Alberto Primo Braga, "The Economics of Intellectual Property Rights and the GATT: A View From the South," 243-264.(note 179 above); Ida Madiha Azmi and Rokiah Alavi, "TRIPS, Patents, Technology Transfer, Foreign Direct Investment and the Pharmaceutical Industry in Malaysia," *Journal of World Intellectual Property* 4, no. 6 (November 2001); doi: 10.1111/j.1747-1796.2001.tb00144.x.

⁴⁵⁹ Stefan Kirchanski, "Protection of U.S. Patent Rights in Developing Countries: U.S. Efforts to Enforce Pharmaceutical Patents in Thailand," *Loyola of Los Angeles International and Comparative Law Review* 16, no. 2 (1994): 569-608.

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요약(국문초록)

무역관련 지적재산권협정 (“TRIPS”: Agreement on Trade-Related Aspects of Intellectual Property Rights), TRIPS는 세계무역기구 (“WTO”: World Trade Organization)에 의해 관리되는 국제 협정이다. 이런 현상은 독특한 점이 있다. 베른과 파리 협약 등과 같은 기존 지적재산권에 대한 다자간협정의 관리는 WTO가 아니라 세계지적재산기구 (“WIPO”: World Intellectual Property Organization) 중심으로 시행되어 왔기 때문이다. TRIPS는 표준 무역 협상이 아닌 그 존재 자체가 무역 및 지적재산권과 밀접한 관계가 있다는 것을 보여준다. TRIPS는 선진국, 개발도상국과 최빈개도국의 지적재산법률을 조화 시키기 위한 시도로 WTO에 가입한 모든 회원국에게 최소 지적재산권 보호수준을 의무화하였다. 그러나 이 규정이 선진국 수준이므로 개발도상국과 최빈국의 입장에서는 상대적으로 부담스러운 수준이다. TRIPS의 도입 이전에 지적재산권은 회원국의 국내 사정이었는데 TRIPS의 도입으로 국내에 새로운 법을 제정해야 하는 실정에 이르게 되었다. 그러나 이 이면에는 지적재산권과는 전혀 관련이 없어 보이는 또 하나의 기본 권리와 충돌이 문제된다. 그것은 바로 인권이다. 지나치게 강화된 특허 보호는 인권 침해로 이어질 수 있다. 이 논문에서 다루게 될 주요 쟁점은 TRIPS가 시행된 후 의약품접근권이 인권에 어떤 영향을 미쳤는가이다. TRIPS가 시행됨으로 인해 개발도상국에서는 의약품의 특허보호가 더 강화되면서 의약품접근권에 대한 제약이 점차 심각해졌다. TRIPS에서는 지적재산권 보호와 공중보건의 균형을 맞추기 위해 특허권의 예외에 해당하는 ‘유연성’ 조항이 동반되어 있기는 하다. 그러나 이 조항 자체가 모호하여 개발도상국이 내부 공중보건관련건을 처리할 때 어려움을 겪고 있다. 이 논문에서는 말레이시아의 사례를 들어 TRIPS에 유연 조항이 있음에도 불구하고, WHO에 가입된 개도국들이 사익에 기반을 둔 공익 건강권을 위협하는 의약품 특허 보호 통일 기준을 의무적으로 시행하는 것이 정당하지 않음을 증명하고자 한다.

주요어 :TRIPS, 특허, 의약품접근권, 말레이시아, 제약업,TRIPS 유연성

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