PhAMA

'Innovative Medicines for Malaysia'

Intellectual Property Rights And Access To Medicines:

PART 3

CONTENTS

PhAMA
'Innovative Medicines for Malaysia'

Executive Summary

Over the last decade, there have been increasing concerns expressed that the push for better protection of patent and related rights for pharmaceutical inventions will compromise access to medicines. This part of the Position Paper seeks to debunk the myth that a strong patent regime drives higher prices of medicines and hinders access to medicines. The price of medicines is caused by a number of factors, and has no direct correlation to the strength of a patent system in the country.

This Position Paper will also state that strengthening the patent system in a country will neither hinder access to medicines nor stifle the growth of the generics industry. On the contrary, it is advocated that a strong patent regime:

- improves access to medicine by encouraging higher level of availability of medicines in the country,
- promotes investments and job opportunities; and
- creates a more robust generics industry in the long term.

Affordability of medicine is a factor which is commonly cited for the lack of access to medicine in developing countries. Innovator companies being the creators of Innovator Brand drugs are often accused of pricing their products higher than generics companies for more profits. This is untrue because in order to maintain financial viability, innovator companies have to price their products higher in order to recoup the massive investments that they have sunk into the development of an Innovator Brand drug.

Generics companies are no different to innovator companies in their commercial goals because they also focus their efforts on where demand is the greatest so as to maximize their profits. They are also least likely to copy Innovator Brand drugs that are not profitable. Innovator companies are often criticized for patenting something which they had innovatively created. However, the profit-oriented choices that generic companies make are seldom commented upon. As such, there is a misconception that patents are the culprits whenever there is no generic competition in a drug market when such is demonstrably not true.

Most pharmaceutical critics often use retail prices as a reference in their criticism of patents without any consideration that retail prices are actually the combination of many other costs that are incurred along the supply chain. Other financial issues that affect Malaysia as a nation such as inflation, the weakening of the Ringgit as a currency or increase in oil prices can play some part in affecting the affordability of medicine. The implementation of the Goods and Services Tax (GST) in April 2015 would have also have an impact on the price of medicine in Malaysia. Patents play only a minor role compared to other non-IP related factors that affect the affordability of medicine in Malaysia.

It is perfectly possible for generics companies to thrive in a strong IP rights regime. Countries such as the United States (US) and Germany are home to some of the biggest innovator companies in the world and yet they have a thriving generics industry existing in parallel.

Contrary to popular belief, a weak IP regime does not necessarily strengthen the generics industry or facilitate access to medicine. It is worth noting that generics cannot exist on their own because they are essentially identical

copies of Innovator Brands drugs. Generics companies are highly dependent on the innovator pharmaceutical companies in order to come up with new products because a copy cannot exist without the invention.

Hence, there will be consequences on generic companies when innovator companies are affected by adverse anti-IP decisions which discourage innovation. In addition, the response of the innovator companies to these adverse decisions that affect them will have an impact on public health and well-being as a whole.

A weak IP regime will eventually:

- ***Hinder*** access to newer drugs - A weak IP regime would inevitably cause a longer delay in the launch of new drugs in a developing country because innovator companies are not assured that their latest inventions are protected. For Malaysia, the lack of availability of the latest drugs would also mean that patients would need to travel to neighbouring countries with strong IP laws such as Singapore in order to obtain the latest drugs and better medical treatment. If IP laws are weakened in Malaysia, there will be consequences to the medical tourism industry in Malaysia.

- ***Result*** in the emigration of local talents - It is possible that the failure of the government to implement a strong IP rights regime would eventually prompt many bright and talented innovators to leave Malaysia in favour of countries that have better IP laws that will protect their inventions.

- ***Enable*** the flourishing of counterfeit medicines - When the IP rights regime of a country is weak, it would be difficult for pharmaceutical and generics companies to take action against counterfeiters.


Concept
IDEA
Product
WORK
SUCCESS

3.1 Introduction

Healthcare is a topic of high concern to any country in the world. The health of a nation's citizens depends on unobstructed access to medicine which is vital in combating diseases. With the pharmaceutical industry being the originator and inventor of most medicines which are available in the world, pharmaceutical companies are key players in any discussion on access to medicine.

Access to medicine is a major problem in many developing countries. Low and middle income countries bear the majority burden of diseases compared to high income countries. A 2005 World Health Organization (WHO) Report revealed that 58% of malaria cases occur in the poorest 20% of the world's population and 82% of rotavirus deaths occur in the world's poorest countries[1]. Despite bearing the burden of diseases, patients in many developing countries are not able to secure access to medicine for a variety of reasons.

The four factors that influence access to medicine, as identified by the World Health, are:

- rational medicine selection;
- affordable prices;
- sustainable financing from the government; and
- reliable health and supply systems.

Failure in any one of these factors jeopardizes access to medicine.

Under the Agreement on the Trade-Related Aspects of Intellectual Property (TRIPS), signatories to the Agreement have the obligation to provide patent protection to pharmaceutical products by 1 January 2005. The exception is given to least developed countries through the Doha Declaration where these countries are given until 1 January 2016 to allow pharmaceutical patents. Better and more comprehensive protection of patent and related rights concerning pharmaceutical inventions over the last few decades has prompted concerns that access to medicine will be compromised. Much attention is given to the IP rights that are held by pharmaceutical companies over their products because they are perceived by certain NGOs to be an obstacle to access to medicine. This is due to the widely-held and misguided perception that patents lead to high prices of medicines.

This part of the Position Paper seeks to debunk the myth that a strong patent regime drives higher prices of medicines and hinders access to medicines. The price of medicines is established by a number of factors, and has no direct correlation to the strength of a patent system in the country. Access to medicine hinges on making medicines widely available to countries and people in need and data has shown that countries with weak IP and patent regime also tend to be victims of low access to medicines[2].

This Paper will also state that strengthening the patent system in a country will neither hinder access to medicines nor stifle the growth of the generics industry. On the contrary, it is advocated that a strong patent regime:

- improves access to medicine by encouraging higher level of availability of medicines in the country,
- promotes investments and job opportunities; and
- creates a more robust generics industry in the long term.

[1] World Health Organization, Public Health, Innovation and Intellectual Property Rights (2006) page 4

[2] Ernst R. Berndt and Iain M. Cockburn, "The Hidden Cost Of Low Prices: Limited Access To New Drugs In India" (2014) 33(9) Health Aff page 1567-1575

3.2 Understanding Innovator and Generic Drugs

For the purposes of this Paper, innovative pharmaceutical products that are patented will be referred to as "Innovator Brand" drugs. The innovator pharmaceutical company that discovers and creates the Innovator Brand drug holds the right to market it exclusively for a period of time before another party can market a copy of the Innovator Brand Drug.

On the other hand, generic drugs or generics are the chemical equivalents of the Innovator Brand drugs that are usually manufactured without a licence from the innovator company. The WHO defines a generic drug as *"a pharmaceutical product, usually intended to be interchangeable with an innovator product, that is manufactured without a licence from the innovator company*[3] *and marketed after the expiry date of the patent or other exclusive rights"*[4].

Generics can enter the medicine market under different conditions such as the expiration of patents, non-enforcement of patents, absence of patent system for pharmaceutical products in certain countries or compulsory licensing. The speed of the entry of generics into a market can be affected by the strength of the IP laws in that particular country. A weak regime of IP rights will enable free entry of generics into the medicine market subject to the ability of the generics company in replicating the Innovator Brand drug. On the other hand, a strong regime of IP rights is perceived to slow down the entry of generics into the medicine market. A country that allows pharmaceutical products to be patented will have to engage in a balancing exercise to ensure that the IP rights of the innovator companies and the entry of the generics into the medicine market are equally respected.

[3] Management Sciences for Health, "Managing Access to Medicine and Health Technologies" (2012) paras 3.1

[4] World Health Organization, "Generic Drugs", <*http://www.who.int/trade/glossary/story034/en/*> accessed 28 September 2014

3.3 Are Patents Barriers To Access To Medicines?

Affordability of medicine is a factor which is commonly cited for the lack of access to medicine in developing countries. When individuals do not have the financial means, access to medicines can become limited. Many proponents of generic drugs often argue that the IP rights, particularly, patents that are owned by innovator companies are the main causes of the high prices of drugs. The commercial exclusivity that is possessed by an innovator company during the patent term of its Innovator Brand drugs is often viewed in an uneasy manner by anti-IP activists and public health advocates.

Critics of pharmaceutical companies of Innovator Brands often state that pricing of medicine should be determined by a competitive market and the commercial exclusivity granted by a patent should be abolished. Innovator companies are viewed with suspicion because their monopolistic position gives them the power to reduce output of medicine in order to maximize profit.

It is posited that patents are not direct obstacles to access to medicine in developing countries. Attaran in 2004 revealed that only 19 out of 319 items on the WHO Essential Medicine List have basic patents post-dating 1 April 1982. In the 65 countries studied in Attaran's report with the majority of them being developing countries, patents and patent applications exist only in respect of 1.4% of the essential medicines of the time (300 instances out of 20,735 combinations of essential medicines and countries)[5]. Hence, it cannot be said that patents are a barrier in many developing countries to affordable medicines because they do not exist in 98.6% of the cases for essential medicines according to Attaran's report. In fact, some drugs not covered by patents can be inaccessible for most people, even at an economical and efficient price[6].

INNOVATOR COMPANIES CONTINUE TO INCUR ADDITIONAL COSTS EVEN AFTER DEVELOPING THE DRUG.

There are reasons other than patents why access to medicine remains out of reach for some communities. This Paper will also explore the reasons behind higher priced Innovator Brand drugs, the profit motivation of generics companies and additional factors affecting the affordability of medicines.

3.3.1 Why Are Generics Cheaper Than Innovator Brand Drugs?

The market for a drug with generics is highly competitive because buyers can choose from several sources of chemically identical medicines[7]. Generics are generally manufactured and marketed by many different companies. Since generics are usually priced lower than the Innovator Brand drug that it is imitating, they are regarded to be cheaper substitutes for the treatment of diseases. Patients who are price-sensitive would switch to the purchase of generics instead of Innovator Brand drugs.

[5] Amir Attaran, "How Do Patents And Economic Policies Affect Access to Essential Medicines in Developing Countries?" (2004) 23(3) Health Affairs 155, page 157

[6] Ester Ferrera, " Access to Medicine: Patent, Price Regulation and Prizes" ILSP 13, page 16

[7] Supra Note 3

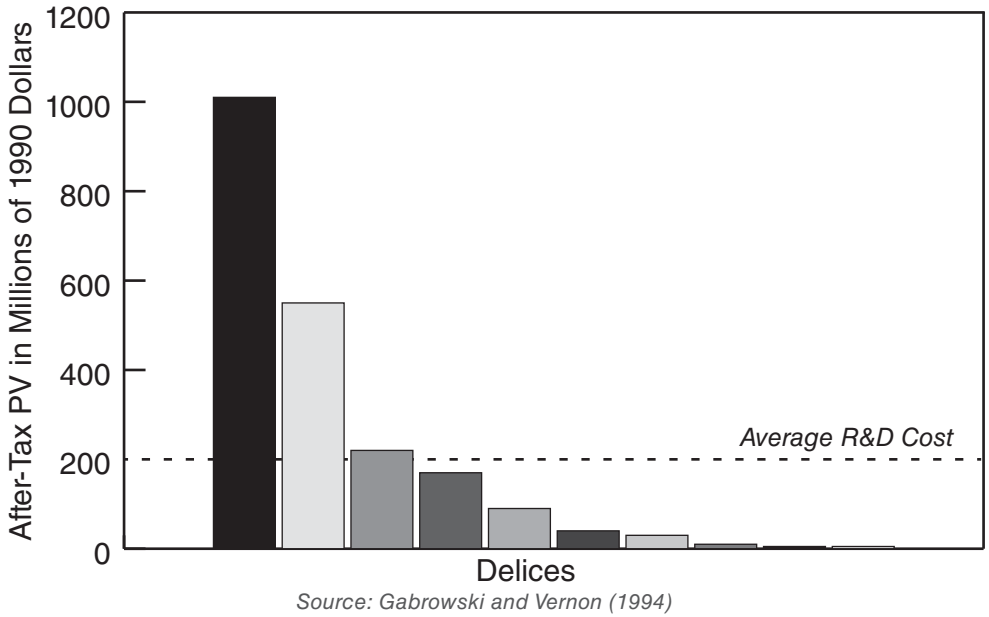
There is a need to understand the reason for the higher price of Innovator Brand drugs compared to generics as innovator companies. The reason is certainly not due to for mere profits. As stated, innovator companies face a high cost when they engage in R&D and a study in 2014 estimated the cost of developing a drug to be US$2.56 billion[8].

Innovator companies continue to incur additional costs even after developing the drug. Expenses are incurred for the stringent quality control measures that are implemented to sustain and maintain the production of Innovator Brand drugs. The R&D efforts do not stop after the launch of the Innovator Brand drugs[9]. Funds are invested in additional R&D to find potential benefits of the same molecule. Innovator companies also commit resources for post-marketing surveillance to ensure the continuous safety of the Innovator Brand drugs in the market[10].

The vast disparity in production costs allows generics companies to price the generic products lower than Innovator Brand drugs. Generics companies did not invest in the R&D that is required to discover and develop the drug; they merely copy an established product. In addition, they face much less hurdles with regulatory authorities. Instead of having to conduct lengthy and complex clinical trials that the innovator companies are subjected to, generics companies are required only to demonstrate "bioequivalence". A generic drug satisfies this if it is demonstrated that the active ingredient is absorbed into the body at the similar rate and amount as the Innovator Brand drug. Bioequivalence tests are much cheaper to be conducted compared to complex clinical trials.

A sample of New Chemical Entities (NCEs) from 1980 to 1984 revealed that only 3 out of every 10 drugs obtained returns above the average cost of R&D and these findings are summarized in Graph 1 below[11].

Graph 1 Returns to R&D on New Drug Introductions in the 1980s



Source: Gabrowski and Vernon (1994)

[8] Sandra Peters and Peter Lowy, "Cost to Develop and Win Marketing Approval for a New Drug Is $2.6 Billion", *<http://csdd.tufts.edu/news/complete_story/pr_tufts_csdd_2014_cost_study>* accessed 24 November 2014

[9] US Food Drug and Administration, "Abbreviated New Drug Application (ANDA): Generics" *<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/>* accessed 1 October 2014

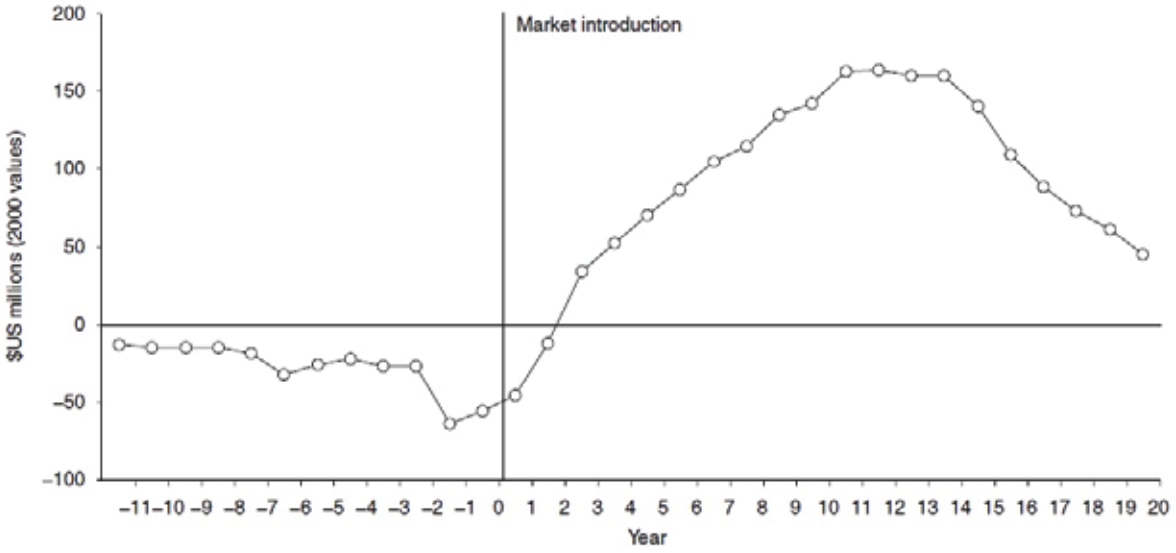
[10] Henry Grabowski and John Vernon, "Longer Patents for Lower Imitation Barriers: The 1984 Drug Act" (1986) 76(2) R&D, Innovation and Public Policy 195

[11] Henry Grabowski and John Vernon, " Returns to R&D on new drug introductions in the 1980s" (1994) 13 Journal of Health Economics 383, p.399

The data in the Graph 1 shows that the top two drugs with the highest figures account for 70% of the total returns of all the drugs. Clearly, there is a vast gap between drugs that are successful commercially and drugs that fail to generate the required amount of sales to justify its commercialization and business continuity to produce and supply. Drugs with smaller amount of sales are not necessarily failed products as these drugs may be targeted at a niche market. Nevertheless, the cost of R&D for a smaller niche market can still be the same as those which cater to a larger market. Since generics companies do not conduct the kind of R&D which innovator companies do, their pricing policies do not take into consideration the need to recoup the high R&D costs.

In another study, a closer examination of the pattern of cash flows for some NCE as shown by Graph 2 below reveals that an innovator company will only start earning a net profit from selling its products after the second year of marketing. The first 12 years are comprised of negative cash flows because of the R&D costs. The first 2 years of marketing are also characterized by negative cash flows because of the heavy promotion and advertising expenditures during the product launch period. After that, cash flow rises to a peak on the 12th year and then begins to decline. The decline becomes even steeper as the patent expires and generic competition begins[12].

Graph 2 Pattern of Cash Flow for Some NCEs



Source: Grabowski, Vernon and DiMasi (2002)

Statistics show that Innovator Brand drugs are priced based on the costly nature of its R&D and production. Hence, patents are not obtained for the sake of reaping profits but to ensure that innovator companies can still survive financially in light of the risky and high cost of R&D that they have undertaken in the creation of new drugs that ultimately save lives and benefit the public.

[12] Henry Grabowski, John Vernon and Joseph A. DiMasi," Returns on Research and Development for 1990s New Drug Introductions" (2002) 20 Supp Pharmacoeconomics 3, p.20

3.3.2 The Profit-oriented Decisions Of The Generics Industry

Although their business models are different, generics companies and innovator companies still share the common financial motivation of serving the interests of their shareholders[13]. The pricing decisions of generics are tied to market forces depending on the number of companies involved in the market.

Generics companies too may focus their efforts on where demand is the greatest so as to maximize their profits. The decision to copy which Innovator Brand drug is not done with altruistic intentions and like all companies, the eventual aim is still to make a profit.

Generic companies are least likely to copy Innovator Brand drugs that are not profitable. Statistics from Grabowski and Kyle in 2007 confirm that greater market sales within the first year of generic sales draw more generic entrants.

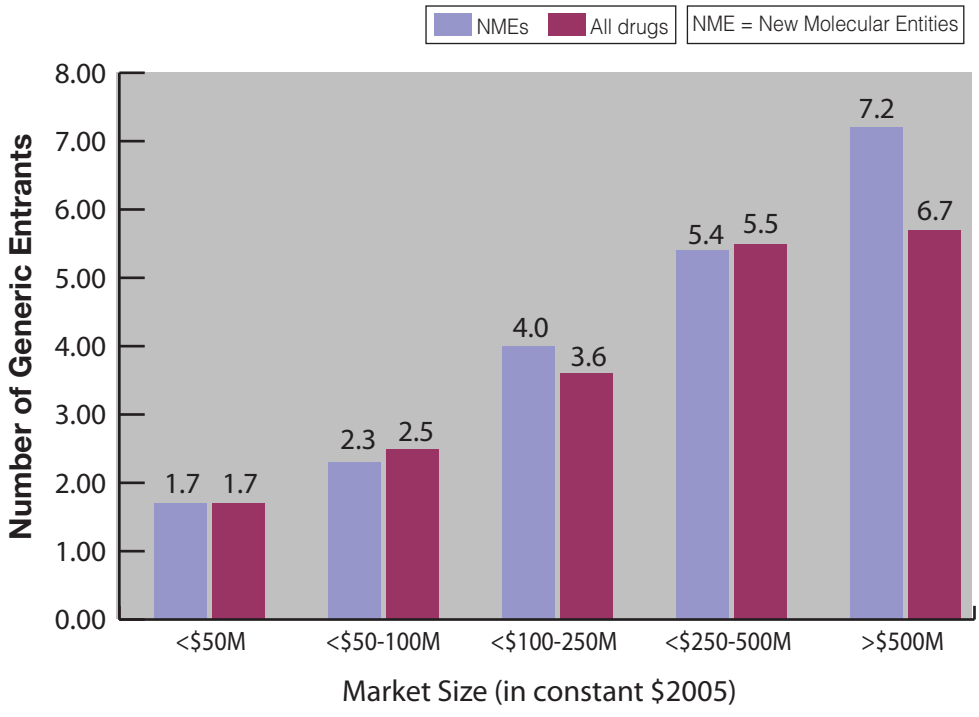
Graph 3 shows the average number of generic entrants in relation to the market value of the drugs. In 2012, the global market share of the generics industry was reported to be $269.8 billion[14].

GENERICS COMPANIES TOO MAY FOCUS THEIR EFFORTS ON WHERE DEMAND IS THE GREATEST SO AS TO MAXIMIZE THEIR PROFITS.

GENERICS COMPANIES ARE LEAST LIKELY TO COPY INNOVATOR BRAND DRUGS THAT ARE NOT PROFITABLE.

VOLUME OF PRODUCT SALES IS A KEY DETERMINANT OF GENERIC ENTRY AND COMPETITION.

Graph 3
Average number of generic entrants within 1 year, by market size



Source: Grabowski and Kyle (2007)

[13] World Health Organization, 'Public Health, Innovation and Intellectual Property Rights" (2006) page 120

[14] BCC Research, "Global Markets for Generic Drugs"
< *http://www.bccresearch.com/market-research/pharmaceuticals/generic-drugs-markets-phm009g.html*> accessed 10 October 2014

The analysis demonstrates that markets with less than $50 million in market sales have less than two generic competitors after the first year of generic competition, whereas markets with sales greater than $500 million for New Molecular Entities (NME) have more than seven generic competitors. However, even markets with sales of $50–100 million averaged between two and three generics within one year of generic entry. The results from the Grabowski and Kyle research are consistent with several studies by economists which point to product sales being a key determinant of generic entry and competition[15].

Grabowski and Kyle also examined 24 pharmaceutical products that were introduced from 1980 to 1989 but still do not have generic competition as of 2005. They noted several interesting facts from the sample they examined:

- 20 out of 24 of them do not have any patent protection in 2005
- only 5 out of 24 of them have sales in excess of $50 million in 2004
- 15 out of 24 of them have sales below $10 million in 2004

From the above information, the authors attributed the lack of generic competition primarily to economic reasons rather than patents considering that IP rights were not present for 20 out of 24 of the pharmaceutical products. Hence, it was a profit-oriented decision behind the absence of generic competition in the market for the drugs mentioned above[16]. Access to medicines is thus not hindered by a patent regime, and the lack of generics is seen for many drugs even after the patents have expired.

Innovator companies are often criticized for patenting something which they had innovatively created. However, the decision of the generics companies not to enter into a particular drug market after patent expiration and the profit-oriented choices that generic companies make are seldom commented upon. Instead, proponents of generics often prefer to drive the misconception that patents are the culprits whenever there is no generic competition in a drug market when such is demonstrably not true.

ACCESS TO MEDICINES IS THUS NOT HINDERED BY A PATENT REGIME, AND THE LACK OF GENERIC DRUGS CAN BE SEEN IN MANY INSTANCES EVEN AFTER THE EXPIRATION OF THE PATENTS.

3.3.3 Non-patent factors that affect the affordability of medicines

The rising price of medicine is a major concern to Malaysians as it affects the affordability of medicines. The rising cost of medicine cannot however be attributed solely to the presence of patents because there are other factors that have a bigger impact on the affordability of medicine such as the marking up of retail prices due to cost factors in the supply chain and government taxes.

A major factor frequently overlooked by critics is the commercial reality of selling drugs which involves the marking up of prices by retailers. It is important to note that drugs, like other commodities, go through a supply chain before the end product is received by the customer.

[15] Henry Grabowski and Margaret Kyle, "Generic Competition and Market Exclusivity Periods in Pharmaceuticals" (2007) 28 Manage. Decis. Econ. 491, page 494

[16] Supra Note 15 at page 500

Innovator pharmaceutical companies do not sell their products directly to customers. Innovator Brand drugs are first sold in bulk to wholesalers. The pharmacies, clinics and hospitals will then buy the Innovator Brand drugs at wholesale prices from the wholesalers before selling them to customers at retail prices. The retail price is the final price which consumers have to pay for the drugs and it can be influenced by a whole range of costs which the manufacturer, wholesaler and retailer have to bear including:

- transportation
- marketing
- importation costs
- operating expenses (for e.g. rent, electricity)
- labour (employee's salaries)

ACCESS TO MEDICINES IS THUS NOT HINDERED BY A PATENT REGIME, AND THE LACK OF GENERIC DRUGS CAN BE SEEN IN MANY INSTANCES EVEN AFTER THE EXPIRATION OF THE PATENTS.

A joint report by World Health Organization (WHO) and Health Action International (HAI) pointed out that the Manufacturer's Selling Price (MSP) is simply one of the price components that are paid by consumers for medicine. As medicine moves along the supply chain, additional costs are added to the MSP[17]. The report divided the supply chain of medicines into 5 stages and they are illustrated in Figure 1.

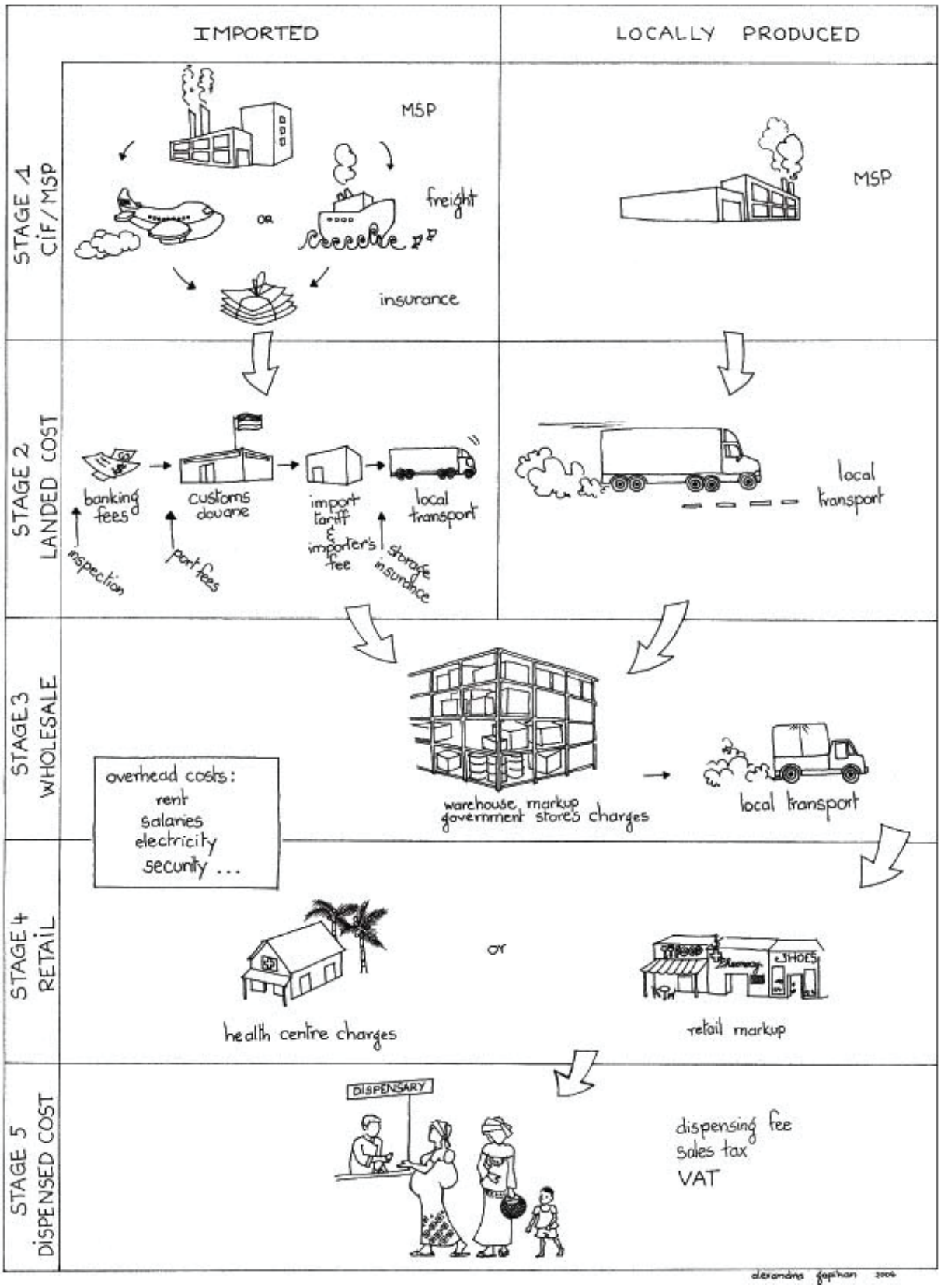
Critics often use retail prices as a reference in their criticism of patents without any consideration that retail prices are actually the combination of many other costs that are incurred along the supply chain. These costs would have been added on regardless and independently of any existing patents. Patents play only a minor part as compared to other non-IP factors that build up the retail price of a drug. Figure 1 shows that there are significantly more transactions involved when a drug is imported, which is often the case with Innovator Brand drugs. Transactions such as freight charges, insurance payments and custom inspection fees are beyond the control of the manufacturer. If the cost of any of the transactions were to increase, the extra cost will be passed down through the supply chain to be borne by the consumers.

OTHER FINANCIAL ISSUES THAT AFFECT MALAYSIA AS A NATION SUCH AS INFLATION, THE WEAKENING OF THE RINGGIT AS A CURRENCY OR INCREASE IN OIL PRICES CAN ALSO CONTRIBUTE TO MAKING MEDICINE LESS AFFORDABLE.

Other financial issues that affect Malaysia as a nation such as inflation, weakening of the Ringgit or increase in oil prices can also contribute to making medicine less affordable. Such financial factors can reduce the purchasing powers of Malaysians and decrease the affordability of medicine.

[17] World Health Organization and Health Action International, "Measuring medicine prices, availability, affordability and price components" (2nd edn, 2008) page 129

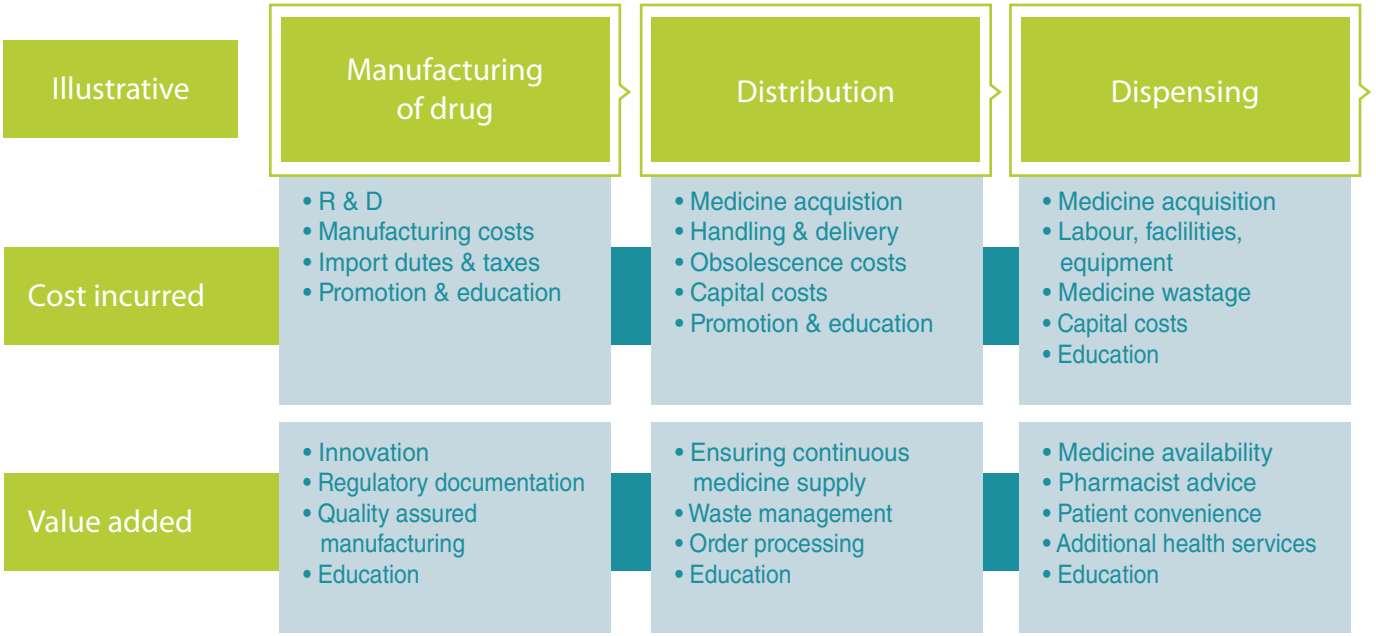
Figure 1 Supply Chain of Medicines



Source: WHO and HAI (2008)

A 2014 paper by IMS Health provides an alternative illustration of the variety of costs that have to be factored into the price of a pharmaceutical drug. The paper also highlights that the cost of a drug may come from value-added initiatives of the parties that are involved in the supply chain[18]. These value-added initiatives are additional efforts which go beyond the basic standard required and they benefit the end consumers. Figure 2 is a summary of the breakdown of the costs covered by the price of a drug.

Figure 2 Summary of the Breakdown of the Costs Covered by the Price of a Drug



Source: Aitken, Machin and Troein (2014)

Another factor which further increases the overall costs of medicine is tax. The implementation of the Goods and Services Tax (GST) in April 2015 would have an impact on the price of medicine in Malaysia. The Ministry of Health confirms that although medical services are exempted from GST, not all medical products will be exempted from GST. Only medical products that are on the National Essential Medicine List (NEML) are exempt from GST. Despite the exemption of GST for the drugs on the NEML, the average medical expenditure of a Malaysian is still expected to increase when the GST comes into force. In December 2014, the Health Minister was reported to have stated that medical costs may rise by around 1%-2% when GST is implemented[19].

The factors that are highlighted above are elements which affect the affordability of medicine. When all the relevant factors are considered as a whole, it is clear that patents and IP rights play a very minor role in determining the final retail price of medicine. As such, there is little basis to conclude that patents and IP rights are the reasons for the high cost of medicine and therefore, are a cause for barriers to access to medicine.

[18] Murray Aitken, Claire Machin and Per Troein, "Understanding the pharmaceutical value chain" (IMS Institute for Healthcare Informatics, 2014), page 2-3 *<http://www.imshealth.com/imshealth/Global/Content/Corporate/IMS%20Health%20Institute/Insights/Understanding_Pharmaceutical_Value_Chain.pdf>* accessed 10 December 2014

[19] World Health Organization, "The World Medicine Situation" (2004) page 37

3.4 Mutual Coexistence Of A Strong Patent Regime And The Generics Industry

As debates on access to medicine are mostly fixated on the price of drugs, it is easy to slip into the misconception that IP rights and generics are in conflict and that one must be curbed for the other to thrive. Sound evidence has suggested otherwise. It is, in fact, perfectly possible for generics companies to thrive in a strong IP rights regime. Countries such as the United States (US) and Germany are home to some of the biggest innovator companies in the world. However, they also have a strong, thriving generics industry. Table 1 below shows the top 10 countries with the highest sales value of generics in the year 2000 [20].

Table 1 Value of Generics Market in 2000

Country	Value (US$ billion)
USA	31.7
Germany	5.7
France	4.4
UK	4.5
Italy	3.0
Brazil	2.4
Spain	2.2
Argentina	2.0
Mexico	2.0
Canada	1.9

Source: IMS customized study (value and generic share in total value)

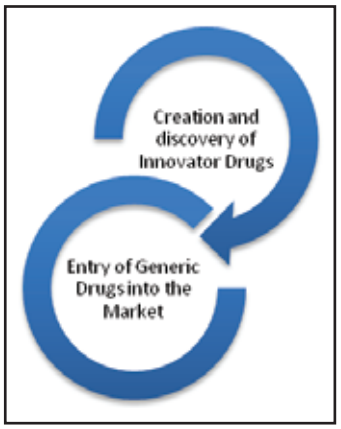
Table 1 shows USA and Germany as the top two countries with the highest value of generics sale although they also have strong IP rights regime.

The 1984 Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Act) in the US is a prime example of a legislation which took into consideration the interests of the pharmaceutical and generics companies. It was designed to encourage generic competition and strengthen the rights of patent owners at the same time. In the words of Senator Hatch in his speech introducing the legislation, "the public receives the best of both worlds - cheaper drugs today and better drugs tomorrow".

Through the Hatch-Waxman Act, the rules pertaining to the approval of generic drugs in the US Food and Drug Administration were relaxed. Generics companies were allowed to rely on the safety and efficacy data submitted for the Innovator Brand drugs instead of conducting them on their own. Furthermore, they only need to demonstrate the bioequivalence of their products for regulatory approval. This significantly lowered the barriers to entry for generics companies.

[20] Henry Grabowski and John Vernon, "Longer Patents for Increased Generic Competition in the US" (1996) 10 PharmacoEconomics 110, page 121

On the other hand, the Act ensures that there is a balance of interests by providing incentives to innovate in anticipation of increased generic competition. Innovator companies were given the benefit of patent term restoration to compensate for the time lost whilst waiting for regulatory approval. Provisions for patent linkage were also introduced in the Act to ensure that the regulatory approval of a generic drug is not granted whilst the relevant patent is in force.



In the early 1980s, the level of generic drugs dispensed in the US was around 10%. Since the passing of the Hatch-Waxman Act, this number increased to 40% by the mid-1990s[21]. Currently, 8 out of 10 prescriptions that are filled in the US are for generic drugs[22]. For the innovator companies, the average effective patent life for new drugs coming to the market in the 1991 to 1993 period was 11.8 years with an average extension of 2.3 years[23]. Thus, although the effective patent term has been extended for pharmaceutical products, the growth of generics has not been impeded. A win-win situation is possible where both pharmaceutical and generics companies benefit and thrive under a strong IP rights regime.

ALTHOUGH THE EFFECTIVE PATENT TERM HAS BEEN EXTENDED FOR PHARMACEUTICAL PRODUCTS, THE GROWTH OF GENERICS WAS NOT IMPEDED.

This win-win situation is possible because the IP legal framework can be structured to balance and take into consideration the interests of both the competing industries. In the case of the US, provisions that favour innovator companies such as patent term restoration are balanced with apro-generics provisions of easier regulatory approvals[24]. This balance of interests is also exercised on a global scale as demonstrated by the allowance of compulsory licensing provisions in the TRIPS agreement in light of the obligation of WTO member states to permit patents for pharmaceutical products[25].

[21] Henry Grabowski and John Vernon, "Longer Patents for Increased Generic Competition in the US" (1996) 10 PharmacoEconomics 110, page 121

[22] US Food Drug and Administration, "Facts about Generic Drugs" *<http://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/understandinggenericdrugs/ucm167991.htm>* accessed 8 October 2014

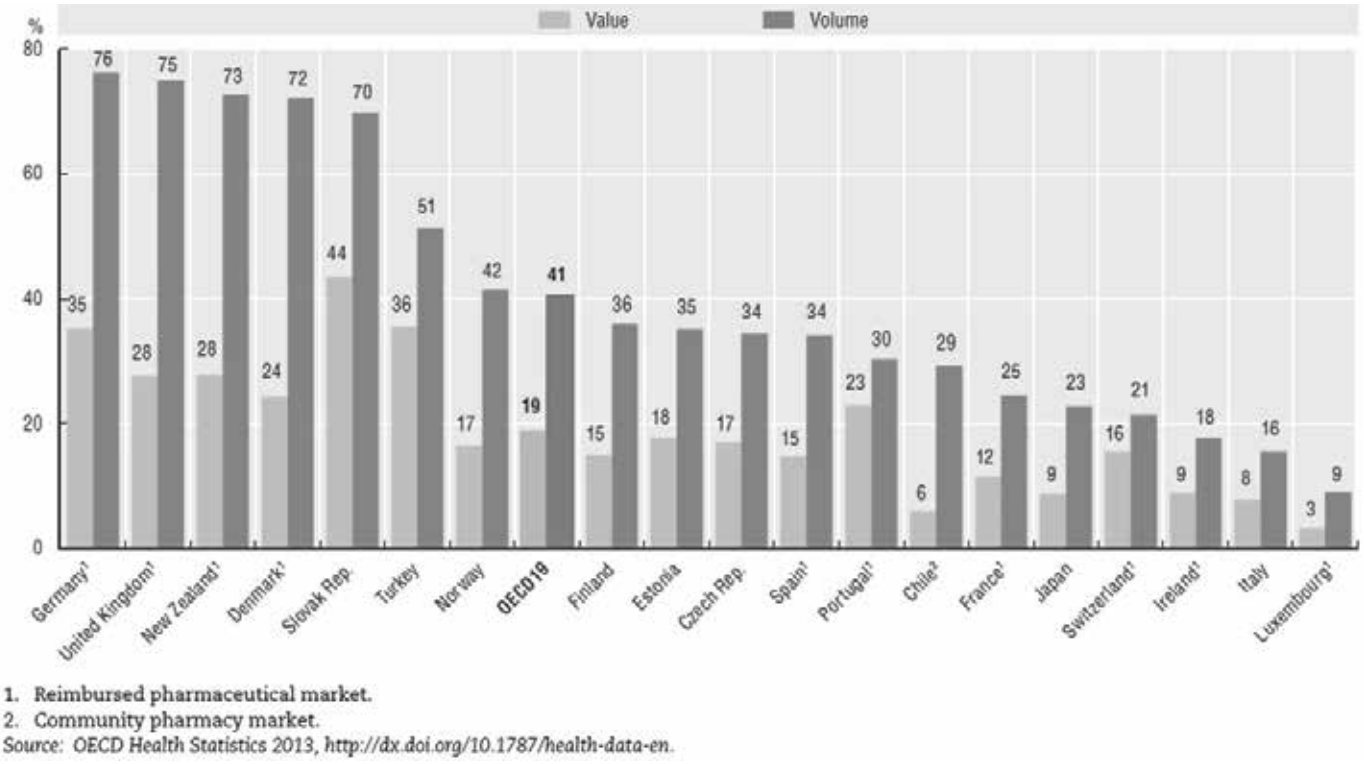
[23] Supra Note 21

[24] Daniel E. Troy, Chief Counsel of United States Food and Drug Administration, "Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments)" (Statement before the Senate Committee on the Judiciary, 1 August 2003) *<http://www.fda.gov/newsevents/testimony/ucm115033.htm>* accessed 8 October 2014

[25] World Trade Organization, "Obligations and Exceptions", *<http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm>* accessed 8 October 2014

The other example of a thriving generics industry with a strong IP rights regime is Germany. In a report by the Organisation for Economic Cooperation and Development (OECD), the generics industry accounted for 76% of the pharmaceutical market share in Germany in 2011. This is the highest generics market share compared to other OECD countries. The United Kingdom, another country with strong IP rights regime, comes in at second place with a generics market share of 75%. The OECD data demonstrates that the presence of strong IP rights does not prevent generics from occupying a majority share of the pharmaceutical market in a country. In contrast, in some countries with weaker IP rights protection such as Chile, generics account for less than 50% of the pharmaceutical market share. The OECD data also suggests that a weaker IP rights regime does not necessarily result in a bigger share of the market for generics companies. Graph 4 below illustrates:

Graph 4 Share Of Generics In The Total Pharmaceutical Market, 2011 (Or Nearest Year)



1. Reimbursed pharmaceutical market.
2. Community pharmacy market.

Source: OECD Health Statistics 2013, http://dx.doi.org/10.1787/health-data-en.

Source: OECD Health Statistics 2013

Pro-generics advocates who attack the existence of patents fail on a fundamental premise; in that patents are also the lifeblood of generics companies. In fact, generics companies usually refer to patents as a source of information in developing new products. The disclosure function of a patent provides the information which generics companies need in order to produce an identical copy of the Innovator Brand drug. Without patents, the information that generics companies need would have been kept secret because there is no incentive for innovator companies to reveal anything about its Innovator Brand drug [26].

Hence, generics companies will do better to acknowledge the need for innovator companies to have adequate rights of protection for their inventions and that the generics industry will thrive in an environment of strong patents and IP regime, as shown by actual experience and data.

[26] World Health Organization, "Public Health, Innovation and Intellectual Property Rights" (2006) page 20

3.5 Consequences Of A Weak IP Rights Regime

Contrary to popular belief, a weak IP regime does not strengthen the generics industry or facilitate access to medicine. An environment that does not respect IP rights undermines the pharmaceutical industry and this would in turn create rippling effects on the pharmaceutical industry regardless of the nature of the development of the medicines and will ultimately, impact access to medicine.

GENERICS COMPANIES ARE HIGHLY DEPENDENT ON THE INNOVATOR PHARMACEUTICAL COMPANIES IN ORDER TO COME UP WITH NEW PRODUCTS BECAUSE A COPY CANNOT EXIST WITHOUT THE INVENTION.

Generics cannot exist on their own because their products are identical copies of Innovator Brands drugs. Generics companies are dependent on the innovator companies to come up with new products because a copy cannot exist without the original. Hence, there will be consequences on generics companies and the health sector as a whole when innovator companies are affected by adverse decisions which does not appreciate or which lowers the ability to innovate via an inadequate patent and related rights regime.

A weak IP regime will eventually hinder access to newer drugs, result in the emigration of local talents and enable the flourishing of counterfeit medicines. Each of the consequences of a weak IP regime will now be discussed.

3.5.1 Delay In The Launch Of New Drugs

A society's health can only be at an optimum level when its members have access to new, more effective and better drugs. For instance, in the treatment of infectious diseases, there will always be a need for new drugs because viruses are capable of becoming drug-resistant over time. New, better drugs, better treatment dosage or new medical use all require discovery and development by innovator companies. For this, innovator companies need to invest heavily in building laboratories and facilities, purchase equipment and human capital and fund a multitude of related costs. R&D is an exercise of trial and error towards finding the most suitable or workable solution to a problem. It thus undergoes a lethargic cycle of failures before success. All of these considerations demand a strong commitment to healthy and sustainable financial resources. Hence, any company will be required to profit in order to be able to reinvest into this commitment.

Generics companies operate on copying an innovator and as such, they are highly unlikely to engage in any groundbreaking discoveries and can afford a less demanding business margin. Hence, specialized technical capabilities that are required to manufacture biologic therapies for medical fields such as oncology are likely to be beyond the reach of many generics companies [27].

In countries with weak IP laws, innovator companies may choose not to introduce their latest drugs there to prevent their drugs from being exploited by generics companies through reverse engineering. A country with a weak IP regime would inevitably see a longer delay in the launch of new drugs in the country because innovator companies are not assured that their latest inventions will be protected. Without effective protection, there is every possibility of unfair exploitation by generics companies and third parties that did not contribute to the cost of the drug development.

A further significant point to consider is that a study by Pécoul in 1999 found that only 13 of the 1223 drugs licensed worldwide between 1975 and 1997 were for tropical diseases endemic to developing countries. It is no coincidence that during the years between 1975 and 1997, IP protection for pharmaceutical products was almost non-existent in many developing countries[28]. Innovator companies will rarely enter into a market that has no effective IP protection because they would be left vulnerable and helpless against unfair exploitation of the fruits of their innovativeness. There will be no means of enforcement.

Patent rights are the incentives for the development of medicines as they ensure reward by way of commercial exclusivity for a finite period of time. The profits generated by innovator companies during the patent term can kick-start a chain reaction which ultimately benefits the public and society at large:

The innovator companies' profits serve to fund the R&D necessary to create and bring new pharmaceutical products to the market in the future

↓

Larger research budgets will open up possibilities to treat otherwise untreatable conditions

↓

Availability of newer and more effective products in the market will in turn put price pressure on established products that are already on sale[29]

There is data[30] showing that countries with higher levels of patent protection obtain a larger share of first launches for new drugs over the period from 1982 to 2002. **Table 2** below shows a selection of the number of first launches in several countries ranging from high income countries to low income countries.

Table 2 Number of First Launches in High- to Low- Income Countries

Country	Number of first launches (between 1982-2002)
Japan	231
United States	163
Germany	74
United Kingdom	72
Switzerland	36
Spain	23
Mexico	16
Austria	12
Canada	10
Venezuela	6
Malaysia	5
Philippines	4
Brazil	3
Thailand	2
Peru	1
Pakistan	1

Source: Jean O. Lanjouw (2005)

It is no surprise that countries such as Japan, the United States, Germany and the United Kingdom were frequently chosen by innovator companies for a first launch of their new products. The high level of IP protection in those countries no doubt factored in the decisions taken by the innovator companies. An interesting observation from Table 2 is that Mexico, a developing nation, had 16 first launches. Mexico's number of first launches was even higher than that enjoyed by some of the high income nations such as Austria and Canada. The fact that Mexico is recognized as one of the few developing nations to have implemented a robust IP regime certainly contributed to this privilege. Countries that do not have a good track record in the protection of IP rights such as Thailand, Peru and Pakistan had only 1 or 2 first launches as seen by their occupation at the bottom three positions of **Table 2**.

A recent 2014 report by Berndt and Cockburn further reinforces the observation that countries with weak IP protection encounter substantial delays in having access to newer medicines. The report revealed that out of the 184 new drugs that were approved by the US Food and Drug Administration from 2000 to 2009, 50% of them went on sale in India only after lags of more than five years from their first worldwide introduction [31]. The report highlighted the 'hidden cost' of India's façade of low priced medicines and weak IP protection policy, in particular, patents, which have brought on the result of patients in India receiving old versions of less effective medicine.

The availability of additional output of drugs and the reduction of its prices by undermining patents might seem, at first blush, to be the solution to better healthcare. However, in the long term, society will have to pay the price because of the refusal or reluctance of innovator companies to introduce their newer and more effective drugs in the country resulting in no access or late access of those drugs to the country's patients. A comparison between countries with strong and weak IP rights with respect the availability of new medicines in that country is summarized below:

Table 2 Summary of Comparison of Countries with Strong and Weak IP Rights

Countries with strong IP rights	Countries with weak IP rights
• Citizens get priority in obtaining the latest and best drugs from innovator companies	• Refusal or reluctance to introduce newer or more effective drugs in the country by innovator companies
• A plurality of treatment options for patients to choose from	• Citizens have limited choice of medicines
• Quality of health care improves in the long term	• Have to contend with inferior and older versions of pharmaceutical drugs which may be less effective or have more adverse side effects
• Cost of healthcare is reduced because effective medicine can help patients to recover faster	• Cost of healthcare increases because patients have to rely on outdated and less effective medicine

For Malaysia, the lack of availability of the latest drugs would not only have a negative impact on the quality of healthcare in Malaysia, but it would also mean that patients will need to travel to neighbouring countries with strong IP laws such as Singapore in order to obtain the latest drugs and better medical treatment. Singapore was recently ranked overall 4th among 30 countries that were surveyed in the Medical Tourism Index 2014 and it is the only Asian country in the top 5 position. Singapore was also ranked 2nd, ahead of other developed countries such as the UK and Germany, for quality of facility and services [32].

Medical tourism is a key industry sector identified by the Government to support Malaysia's economic growth. It is also a key component of the Economic Transformation Programme (ETP) which aims to transform Malaysia into a high income nation [33]. No doubt, an IP law regime which fails to adequately support the innovator pharmaceutical industry in Malaysia, will certainly not aid in promoting growth or progress of the pharmaceutical industry and related industries such as medical tourism in Malaysia.

A COUNTRY THAT RESPECTS IP RIGHTS IS ALSO A COUNTRY THAT RESPECTS AND APPRECIATES THE HIGH-LEVEL OF TECHNICAL SKILLS THAT ARE POSSESSED BY SKILLED WORKERS IN THE COUNTRY.

3.5.2 Brain Drain And Emigration Of Talents

A strong IP regime does not exist to benefit only foreign-based innovator companies but is the critical ingredient to encouraging innovation amongst domestic companies and local institutions such as universities. A strong IP regime will provide the right incentives and motivation for local talents to fill the gaps in neglected areas such as tropical diseases which remain low on the R&D agenda of foreign-based innovator companies. On the other hand, a weak IP regime will fail to motivate or incentivize local innovators to engage or invest in R&D that will form the platform for greater innovation amongst the local population.

A less than strong and robust IP rights regime might eventually force bright and talented innovators to leave Malaysia to search for countries with better IP laws that will give the due protection to their inventions and that will ensure better returns for the disclosure of their invention. It would also deter foreign innovators from coming in to Malaysia to test, create, research and develop new inventions including new medicines and drugs. As a result, the rate of technology transfer to Malaysia will inevitably slow down and not be at the desired level.

Human intellectual talent is the root of innovation activities and skilled workers are an important source of human capital to a developing country. A brain drain will result in a less progressive society and will also cost an outflow of income from the developing country itself. A clear example would be the significance of the Indian diaspora in the United States in 2001. Although a million Indians in the United States only accounted for 0.1% of India's population, they earned a remarkable share equivalent to 10% of India's national income [34].

A study by Naghavi in 2013 found links between the level of IP rights protection and the brain drain phenomena in developing countries. The study identified IP rights as one of the factors that will influence the mobility of inventors. The strength of the IP regime in a developing country is capable of affecting the stay or go decision of skilled workers once the country itself passes a certain stage of technological development. This is because the protection of IP rights increases returns to skills which attracts workers to the innovation sector. Better IP rights protection increases the probability that an inventor can enjoy market exclusivity for a finite period for his invention and this in turn increases the value of his skills. Hence, a strong IP rights regime will have the effect of retaining a part of the skilled population that would otherwise have emigrated [35].

Figure 3 Emigration Rates of Inventors 2001 - 2010

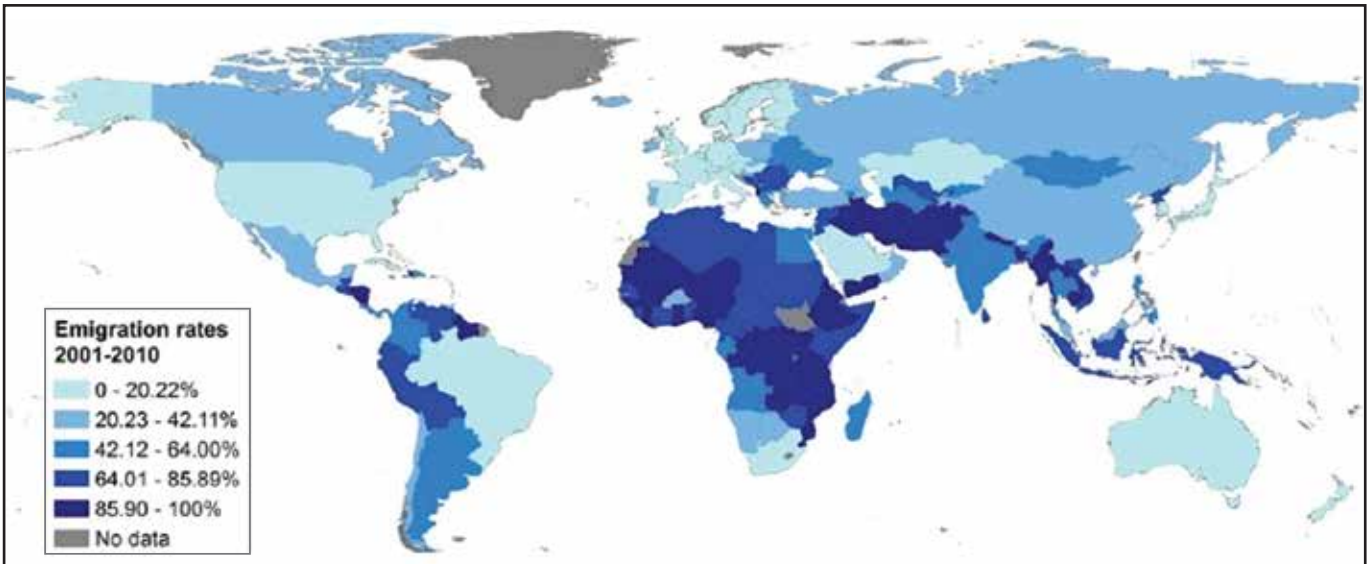


Figure 3 depicts emigration rates of inventors from 2001-2010 and it confirms that low and middle income nations and especially African countries are the most severely affected by the inventor "brain drain". It was also noted, importantly, that a majority of these countries that have high emigration rates also do not have strong IP rights regime [36].

A country that respects IP rights is also a country that respects and appreciates the high-level of technical skills that are possessed by skilled workers in the country. Not only will it retain its skilled population, it is capable of inducing a brain gain as is well demonstrated by the brain gain phenomena that has taken place in Singapore. A recent study by WIPO in 2013 on the correlation of IP and brain drain provides information of the rate of migration among inventors in Asia[37]. **Table 3** shows the largest inventor migration corridors in Asia between 1991-2000 and 2001-2010.

27 IMS Consulting Group, "Securing IP and Access to Medicine: Is Oncology the Next HIV?" (2013) page 9 *<http://www.imshealth.com/deployedfiles/imshealth/Global/Content/Home%20Page%20Content/High-Growth%20Markets/Securing_IP_and_Access_to_Medicine_in_Emerging%20Marketjs.pdf>* accessed 9 October 2014

28 Bernard Pécoul, Pierre Chirac, Patrice Trouiller and Jacques Pinel, "Access to Essential Drugs in Poor Countries: A Lost Battle?" (1999) 281(4) JAMA 361, page 364

29 Richard A Epstein and F. Scott Kieff, "Questioning the Frequency and Wisdom of Compulsory Licensing for Pharmaceutical Patents" (2011) 78 University of Chicago Law Review 71, page 83

30 Jean O. Lanjouw, "Patents, Price Controls and Access to New Drugs: How Policy Affects Global Market Entry" (NBER Working Paper No. 11321, 2005) page 46

31 Supra Note 2 at page 1573

32 *<http://www.medicaltourismindex.com/>* accessed 12 October 2014

33 PEMANDU, "EPP4: Reinvigorating Healthcare Travel" *<http://etp.pemandu.gov.my/Healthcare-@-Healthcare_-_EPP_4-;_Reinvigorating_Healthcare_Travel.aspx>* accessed 12 October 2014

34 Mihir Desai, Devesh Kapur and John McHale, "The Fiscal Impact of High Skilled Emigration: Flows of Indians to the U.S." (2001) page 3 *<http://www.cgdev.org/doc/event%20docs/10.23.03%20GDN%20Conf/McHale%20-%20The%20Fiscal%20Impact%20of%20High%20Skilled%20Emigration.pdf>* accessed 15 October 2014

35 Alireza Naghavi, "Intellectual Property Protection and the Brain Drain" (2013) *<http://www2.dse.unibo.it/naghavi/wipo.pdf>* accessed 15 October 2014

36 Francesco Lissoni, "Study on Intellectual Property and Brain Drain – A mapping exercise" (WIPO, 2006) page 58

37 Supra Note 37 at page 65

Table 3 The Largest Inventor Migration Corridors in Asia from 1991 - 2000 and 2001 - 2010

Largest Inventor Migration Corridors, 1991-2000			Largest Inventor Migration Corridors, 2001-2010		
Origin	Destination	Counts	Origin	Destination	Counts
China	US	6,279	China	US	44,452
India	US	4,470	India	US	35,621
Japan	US	857	R. of Korea	US	7,267
Australia	US	569	Japan	US	5,045
R. of Korea	US	546	Australia	US	3,241
Israel	US	522	Israel	US	2,966
China	Japan	402	China	Japan	2,510
China	UK	328	China	Singapore	1,923
China	Germany	311	Iran	US	1,438
New Zealand	Australia	273	Malaysia	Singapore	1,090
Australia	UK	255	R. of Korea	Japan	1,080
Iran	US	233	China	UK	920
Iran	Germany	204	China	Germany	892
China	Canada	203	India	Singapore	847
China	Singapore	181	Singapore	US	775
New Zealand	US	163	Malaysia	US	729
China	Australia	135	New Zealand	US	678
India	Japan	123	China	Canada	652
India	UK	121	Pakistan	US	626
Malaysia	US	114	Australia	UK	609
R. of Korea	Japan	112	India	UK	556
China	Sweden	111	India	Germany	542
India	Canada	110	New Zealand	Australia	537
India	Singapore	108	Japan	Germany	502
Malaysia	Singapore	100	Thailand	US	494
New Zealand	UK	98	Philippines	US	450
Pakistan	US	86	India	Canada	440
Japan	Germany	83	Indonesia	US	421
Lebanon	US	82	Bangladesh	US	380
China	France	82	Lebanon	US	363

Source: WIPO (2013)

The loss of talents due to a weak system of IP rights protection brings detrimental effects not only to the innovator pharmaceutical industry but to Malaysia as a whole. When there is a smaller talent pool to tap into, it will be harder for Malaysia to achieve her ambitions and to grow, compete and expand.

WEAK PATENT LAWS IN A COUNTRY ARE OFTEN AN INDICATION OF WEAK PROTECTION FOR OTHER FORMS OF IP SUCH AS TRADE MARKS AND CONFIDENTIAL INFORMATION.

3.5.3 Counterfeit Medicine Will Become More Widespread

A weak IP regime more readily permits and encourages a third player, the producer of counterfeit medicines, to creep into the medicine supply chain and this will affect all parties, the public, generics companies and innovator companies.

Counterfeit drugs do not go through any sort of regulatory authorities. They enter the medicine market through illegal means including criminal groups, organized syndicates, corrupt government officials, rogue pharmacists and physicians. Counterfeit drugs endanger the lives and health of the general public because they

may contain toxins, contaminants, inactive substance like chalk or insufficient levels of active ingredients. The problem of drug-resistant strains of pathogens will be amplified with counterfeit medicines because the dosage of the fake drug may not be sufficient to kill or inhibit a pathogen but help instead to develop it into a drug-resistant strain. This has the potential to render the existing Innovator Brand drugs and their generic equivalent to be less effective in combating the disease[38].

When the IP rights regime of a country is weak, it will be difficult for both innovator and generics companies to take effective measures against counterfeiters. IP rights frequently are the foundation for rights that safeguard against counterfeit medicines. For instance, far from being an anti-patient or pro-corporate tool, IP rights such as trademark protection is a necessary pre-condition to brand assurance in the market, bringing with it the quality and standards ensured by that brand and the originator of the products. Some local generic companies in Malaysia such as Kotra Pharma have built up a strong brand name for itself through consistent investments in production facilities and manufacturing standards necessary to produce high quality medicine [39]. It is in the interests of all stakeholders including generics companies for Malaysia to have a strong IP rights regime.

Although much of the debate surrounding IP rights and access to medicine is centered on patent laws, the other IP rights are interrelated with each other in the legal framework. Weak patent laws in a country are often an indication of weak protection for other forms of IP as well, such as trade marks and confidential information. A strong IP rights regime will deter potential counterfeiters as strong IP laws send a clear signal that the Government does not tolerate counterfeits.

[38] Philip Stevens and Helmy Haja Mydin, "Fake medicines in Asia" (Emerging Markets Health Network Briefing No. 1, 2013)

[39] Philip Stevens, "Fake medicine in Asia: The importance of brands to medicine quality"(Emerging Markets Health Network Briefing No. 2, 2013)

3.6 Conclusion

A strong IP and patent regime does not hinder access to medicine. To the contrary, they promote access to better quality medicines and facilitate quicker access to new drugs without delay due to fears by innovator companies that they will be helpless against unfair and unwanted exploitation of their innovations. Innovator Brand drugs may be priced higher when first introduced due to the need to recoup the substantial R&D costs but ultimately, a strengthened patent system which provides the assurance to innovator companies of their ability to recoup investments in R&D and to enforce their rights against unlawful encroachment will spur greater innovation and investment in the country which will ultimately benefit the Malaysian public and the spin-off industries such as medical tourism.

ACHIEVING OPTIMUM ACCESS TO MEDICINE INVOLVES BOTH THE INNOVATOR AND GENERICS PHARMACEUTICAL COMPANIES.

The absence of patents in 98.6% of the drugs in the Essential Medicine List as reported by Attaran points to other reasons that have a more significant contribution to access to affordable medicines. High cost of medicines is attributable for instance, to taxes or the combined cost factors that are present in the supply chain of medicines such as labour, capital and transportation, and have not been shown to be due to patents per se.

Achieving optimum access to medicines involves both the innovator and generics pharmaceutical companies. A strong IP rights regime does not suppress the generics industry. The results of the United States' implementation of the Hatch-Waxman Act for the past 30 years have demonstrated that it is possible for the IP regime to reconcile both the interests of the innovator companies and generics companies. The existence of a number of successful generics companies and high market shares of generics in countries with strong IP regimes such as Germany speaks volume of the possibility of generics companies competing very successfully in an environment that upholds and respects all IP rights, including patents and related rights, equally. These countries and their strong and progressive patent laws have spurred an active pharmaceutical industry, both innovator and generics, which have considerably benefitted the country and her people.

On the surface, it seems that the generics industry will benefit from a weaker IP rights regime because of the reduction of barriers to entry into the market. However, this benefit is merely illusory and will at most bring only very short-term benefits. In the long term, the decline of the innovator companies due to unfair exploitation of patents will result in a weaker generics industry because the generic drug is entirely dependent on an originator drug being first in existence. In reality, the lack of innovation will represent an even greater barrier to access to medicines compared to high prices of medicines [40].

Malaysia must seek to strengthen its existing IP laws, particularly the patent regime and the regulatory approval process for drugs in order to promote and facilitate greater access to medicine. It will be a folly to attempt to dilute existing patent and IP laws and adopt a regressive stand towards IP protection of medicines in the country in the belief of any gain that will be short-term at best.

[40] Ester Ferrera, " Access to Medicine: Patent, Price Regulation and Prizes" ILSP 13, page 16

Innovating for a Healthier, Economically Vibrant Nation

OUR VISION

An organisation working together with key stakeholders for better health and quality of life.

OUR MISSION

Is to provide access to innovation medicines for better health and improved quality of life for all in Malaysia by:

- Promoting timely access to quality and innovative medicine
- Encouraging research and development of pharmaceutical products in Malaysia
- Forming strategic health partnership with key skateholders for the advancement of public health
- Empowering consumers for safe and responsible self-medication
- Promoting industry values and contributing to the nation
- Upgrading the skills and knowledge of industry's human resources
- Ensuring the ethical promotion of medicines in compliance with local law and a set of marketing practices

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