# Parallel Importation and Compulsory Licensing – Impact On Drug Prices in Malaysia.

**By**
**Rodziah Ahmad**
**Corporate Masters in Business Administration**
**Universiti Malaysia Sarawak**
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## ABSTRACT

Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement provision on parallel importation and compulsory licensing had been major issue discussed among World Trade Organization country members to promote access to essential medicines in low-income country. This paper presented both legislation and its impact on drug prices in Malaysia. It is found that the Government has provision on parallel importation and compulsory licensing in the Patent Act 1983. Consumers in Malaysia will be better off with parallel import of patent drugs from India as price of the same drugs imported from India is lower than those imported directly from original manufacturing country. However, compulsory licensing does not actively utilized by the local manufacturer and the study shows that compulsory licensing does not reduce the price of patent drugs in Malaysia.

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## Section 1: Overview

Health care is universally considered as basic human rights. Pharmaceutical industry has been an active subject of numerous economics study for the past few decades. In the 60's, the subject area was relationship between marginal cost and prices of drugs. The 70's theme was comparison of profit rate from one pharmaceutical's manufacturing firm to another. Then people tend to relate the impact of generic competition in terms of prices and market share of patented (original) drugs as generic drugs flooded the market after the original drugs reached their expiry dates. Beginning the last decade, as the needs of newly founded drugs, which is an essential medicines, has become crucial among developing and least developed countries, in addition with emerging of global competitive trade, major studies on pharmaceutical has concentrating on the prices of newly developed patented drugs (differential pricing).

Expenses related to health have become a major issue to consumer in Malaysia as well. The medical and health costs include hospitals and clinic expenses; medical aid appliances and mostly for medicine and drugs prescribed for patients.

Consumer Price Index (CPI) for medical care and health expenses in Malaysia has been increasing for the last decade. In 1990, CPI for medical care and health expenses was 88.9 and 110.7 in the year 1997[1] (an increase of 19 percent in seven years and average annual increment of 3 percent). In 1998 the CPI was 95.1 compared to 103.4 in August 2001[2] (an annual average increase of 8 percent). It indicates consumer expenses on medical care and health increases over time.

One of the reasons noted for the increment in the CPI was the increasing price of medicine and drugs in the retail market that is heavily depended on imported and patented medicines (Alavi, 1999). In conjunction with TRIPS[3] Agreement, patent holders that manufactured new-life saving drugs are given 20-year protection

[1] Base year 1994.
[2] Base year 2000.
[3] Trade Related Aspects of Intellectual Property Rights

whether on the product and process. They have the exclusive monopoly for manufacture, distribution and sales of the patented drugs (Balasubramaniam, 2000).

TRIPS agreed by 136 country members in the 1994 World Trade Organisation (WTO) Agreement establishes minimum universal standards in all areas of intellectual property and the intention is to implement these standards globally through a strong enforcement mechanism established in WTO. These affect pharmaceuticals, which many countries had previously excluded patent protection in order to produce generic drugs at lower prices and thereby contribute to the improvement of public health.

However, there are some exceptions for member governments to comply with the TRIPS agreement to protect public health and, in particular, to promote access to medicines for all such as provision for parallel imports and compulsory licensing.

Since Malaysia is a member of WTO, the objectives of this study are to review the impact of the compulsory licensing and parallel importation in the pharmaceutical sector, particularly on the local drugs pricing.

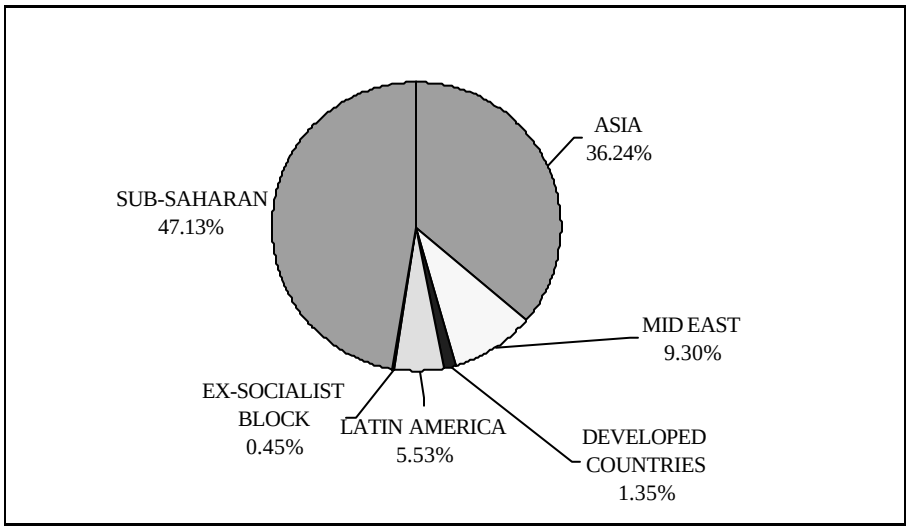
This paper is organized into five sections. The second section takes up some explanation on patents, TRIPS Agreement and its impact on pharmaceuticals. A brief discussion from theoretical background to the impact of parallel importation and compulsory licensing on drug prices in Malaysia is presented in section three and four respectively. A conclusion of the findings appeared in the final section of the paper.

## Section 2: Patents, TRIPS and Impact on Drug Pricing

### Introduction

The World Bank reported 84% of those infected with all types of infectious and parasitic diseases come from Asia and Sub-Saharan countries (Figure 1). While 53% of cancer patients are from Asian countries (Figure 2). More than 95% of all HIV-infected people in the year 2000 live in the developing world, which has likewise experienced 95% of all deaths are due to AIDS[4].

**Figure 1: World's Infectious and Parasitic Disease[5] Patients (2000)**

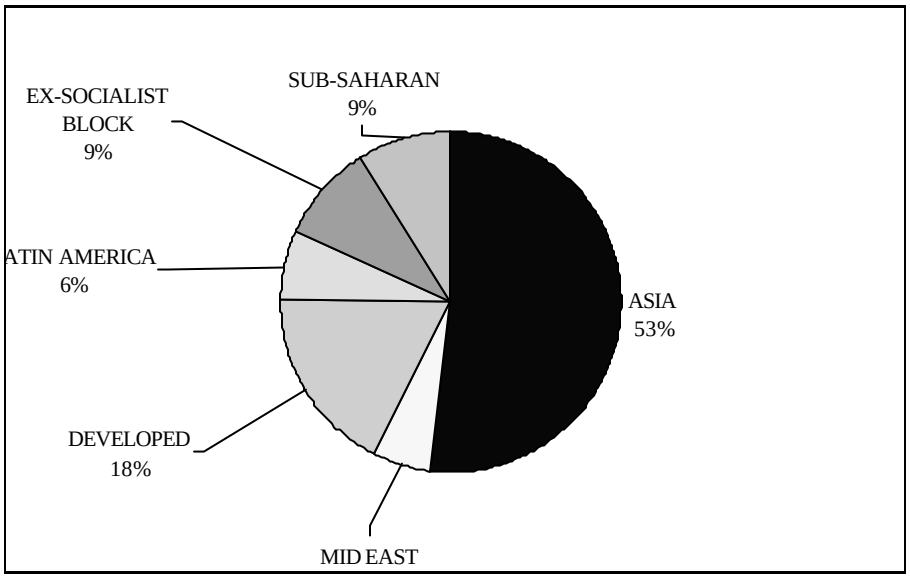



Source: Health, Nutrition and People Statistic, World Bank (2001)

4 Source WHO Report, 2001

[5] Tuberculosis, STD, Diarrhoeal, Childhood cluster, Bacterial meningitis, Hepatitis B &C, Malaria, Tropical Cluster Diseases, Leprosy, Japanese encephalitis, Trachoma, Intestinal nematode infections

**Figure 2: World's Cancer Patients (2000)**



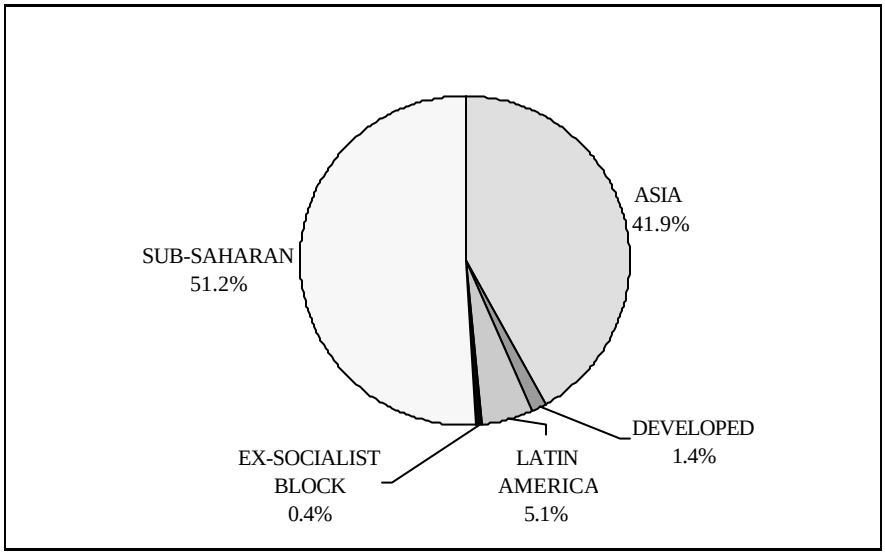

Source: Health, Nutrition and People Statistic, World Bank (2001)

It is expected that the number of parasitic-type diseases will infected 3.9% of world population[6] in 2010. 52% and 42% of these patients are from developing and least developed Sub-Saharan and Asian due to less access to antiretroviral treatment (Figure 3). Without a proper treatment of cancer, in 2010, it is expected number of world's cancer patients is increasing 24% from year 2000 with the majorities is Asian (Figure 4).

In developed countries, the introduction of highly active antiretroviral treatment and the availability of drugs for opportunistic infections and malignancies lead to a less number of people infected with these two major killing-diseases. In developing countries, however, access to these drugs is seriously lacking.

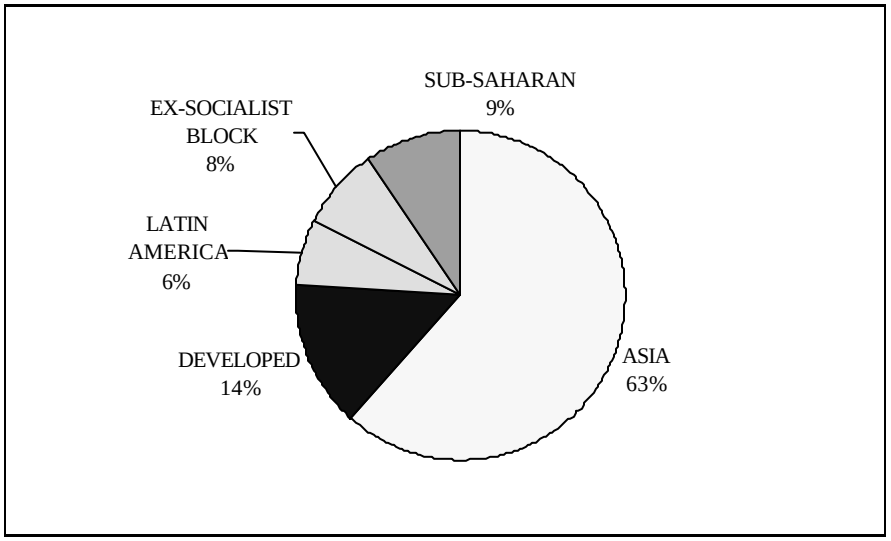
[6] Based on World Bank projection on world population (7,084.3 million)

**Figure 3: World's Infectious and Parasitic Disease Patients (2010)**




Source: Health, Nutrition and People Statistic, World Bank (2001)

**Figure 4: World's Cancer Patients (2010)**




Source: Health, Nutrition and People Statistic, World Bank (2001)

Several interrelated factors determine access to essential drugs, including drugs to treat HIV and opportunistic infections. Among them are appropriate to use, supply management, economic issues, drug selection, legislation and regulation, manufacturing, research

and development decisions. As these parasitic disease and cancer are quite recent in medical history, most of the drugs created especially to treat the diseases are under patent. This renders the treatment less affordable than drugs for which generic alternative exits. Since patent protection allows exclusive rights to an invention and prevents generic competition, it is seen as one of the major reasons for limited availability and affordability of drugs.

**What is Patent?**

A patent is a title granted in a specific country that gives exclusive rights over the manufacture and use of an invention to the owner of this invention in that country, in exchange of the disclosure of the invention to the public. Patent is national policy and must be filed in every country where protection is desired for a specific invention.

The objective of the patent system is to encourage inventive activity as well as technology transfer and activities associated with the commercialization or marketing of an invention.

The criteria for a patent to be granted is that the invention must be new, involve an inventive step and be capable of industrial application. Because of this novelty criterion, a system was instituted under the Paris Convention (1883, as revised- now managed by the World Intellectual Property Organization, WIPO) to allow companies to protect the same invention in various countries.

Once a patent is granted, the patentee has the right to prevent others from "using, offering for sale, selling or importing" the invention without his permission.

In the pharmaceutical sector, patents may be granted for different kinds of inventions. The invention may concern on:

- Product, i.e. new pharmaceutical substance or formulation;
- Process, i.e. new manufacturing process for a known pharmaceutical substance;

**Theoretical Explanation on Monopolistic Criteria of Patent**

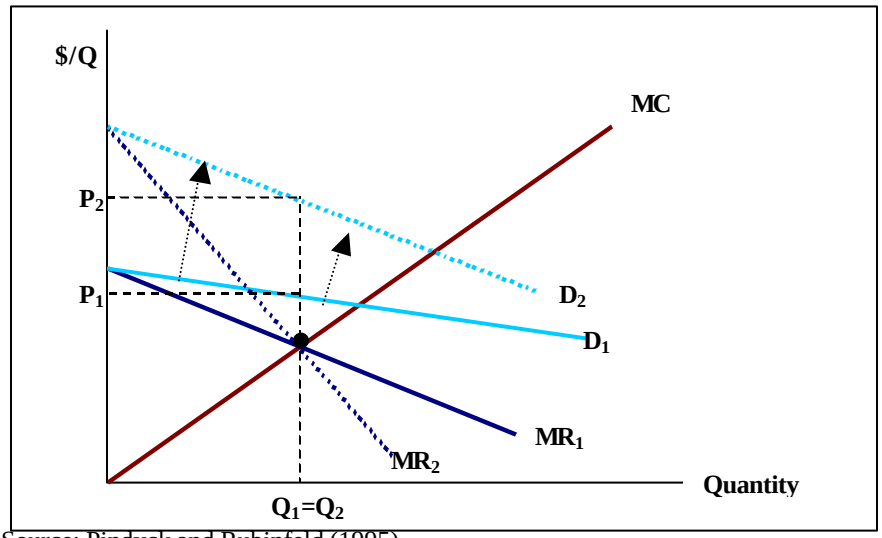
Commonly, whenever a patent is granted to a pharmaceutical manufacturer, a patentee will be the sole supplier of a certain drug or in a simpler term, a monopolist. A monopolistic market has no supply curve; therefore, there is no one-to-one relationship between price and the quantity produced. The monopolist's output decision depends not only on the marginal cost but also on the shape of the demand curve. As a result, shift in demand will not trace out series of prices and quantities, instead leads to change in prices without changes in output (quantities). This is illustrated in Figure 5.

The demand curve $D_1$ shifts to new demand curve $D_2$. However, the new marginal revenue $MR_2$ intersects marginal cost MC at the same point that the old marginal revenue curve $MR_1$ did as the profit maximizing output remains the same ($Q_1 = Q_2$). Therefore, a monopolist will increase price to a new price $P_2$ from $P_1$ to maximize profits.

This model is supported by Bala and Sagoo's (1999) study on patent and drug prices. It was found that ratios between the lowest and highest retail prices for selected monopoly drugs[7] are up to 1:4 in developing countries. The variety of demands among countries leads to these price differences. The guiding principal for the proprietor of these monopoly drugs in fixing prices is simply to set the limits according to what the market can bear. Differential pricing will be elaborated further in the next section.

[7] Drugs still under patents in some countries – ceftriaxone sodium, indinavir sulphate, lamivudine, simvastatin and zivoduvine.

**Figure 5: Shift in Demand Leads to Change in Price but Same Output**




Source: Pindyck and Rubinfeld (1995)

However, theoretically, there are three general ways of system rules that will increase social welfare with application of patent:

i) Incentive Theory. Norhaus (1969) observed that each increase in the duration of patents stimulate an increase in inventive activity, Ideally, patent duration should be increased up to the point where the marginal benefits (inclusive of to the producer and society) equal to the marginal cost.

ii) Optimizing patterns of productivity. Sales of patented goods will ensure that goods get into the hand of people who needs them and able to pay for them.

iii) Rivalrous invention. Its objective is to eliminate/reduce duplicative activity of intellectual work.

Practically, Subramanian(1994) estimates changes in prices, profits and social welfare arising from increase patent protection for pharmaceuticals for two developing countries via Argentina and India; concluding that these are sensitive to assumptions about pre-patent market structure and price elasticity of demand (cited in Watal and Mathai, 1995). Using detailed market share in India for the year 1993, it has been shown that the average price rise resulting from a move from the present oligopolistic market structures to patent

monopoly would be in the range of about 50 per cent, with range from 0 to 75 per cent (Watal, 1995)

Given the social welfare of patent, monopolistic theory of patentee in determining prices for their products and death tolls arising from lack of access to the patented drugs, the question is now whether a patent protection is of significant importance for drugs procurement.

**Trade-Related Aspects of Intellectual Property Rights (TRIPS)**

TRIPS is not only institutionalized the General Agreement on Trade and Services (GATT) but also has international legal status and a large number of matters relating to international trade will fall within its jurisdiction. Effective on 1 January 1995, TRIPS date the most comprehensive multilateral agreement on intellectual property. The areas of intellectual property that it covers are:

- Copyright and related rights i.e. the right of performers, producers of sound recordings and broadcasting organizations;
- Trademarks including service marks;
- Geographical indications including appellations of origin;
- Industrial design;
- Patents including the protection of new varieties of plants;
- Layout-design of integrated circuits
- Undisclosed information including trade secrets and test data.

The objectives of the TRIPS Agreement are essentially aimed at strengthening certain aspects of the protection of intellectual property at global level. The developed and developing countries had applied to provisions in TRIPS Agreement by 1 January 1996 and 1 January 2000 respectively (Article 65.2, 65.3 and 65.1) but least-developed countries have at least until 1 January 2006 and this may be extended (Article 66.1).

The WTO's Agreement on TRIPS attempts to strike a balance between the long term social objective of providing incentive for future invention and creation, and the short term objective of allowing people to use existing inventions and creations.

The balance philosophy of TRIPS works in three ways:[8]

- Invention and creativity in themselves should provide social and technology benefits. Intellectual property protection encourages private sectors' inventors and creators for new inventions, which the development cost could be extremely high, because they can expect to earn some future benefits from their creativity by not restricting in their product pricing.
- The way intellectual property is protected can also serve social goals. Patented inventions have to be disclosed to public (Article 29,30), allowing others to do a further study on the invention while its patent is being protected. This helps technological progress and transfer (Article 7). After a patent protection lapse, a new invention become available for others to use.
- There are certain conditions TRIPS agreement that allow government to make exception for the protection granted in order to meet social goals (Article 8) such as in national emergencies or if the right-holder do not supply the invention after a patent is granted.

The main issue with respect to pharmaceuticals is the obligation to grant patent protection (Article 40.1) to pharmaceutical products and process inventions (Article 27).

As the Agreement comes into force in a member state, any inventions of a pharmaceutical product or process that fulfills the established criteria of novelty, inventiveness and usefulness (Article 27.1), will be under patent for minimum of 20 years (Article 33). Prior to the TRIPS Agreement, without the patent protection on process, the local companies could develop the drugs through difference process than those patented and could make locally developed cheaper versions of the product.

There are some impacts of the TRIPS Agreement on prices and availability of pharmaceutical products:

- A twenty-year monopoly on pharmaceutical product will enable the patent holder to keep the prices of the patent drugs high.

[8] http://www.wto.org/English/tratop_e/trips_e/factsheet_pharm01_e.htm

- Copies of the drugs under patent either produced locally or imported should be banned from the market.

- The generic equivalents would come onto market only after the expiry of the patent of a patented drug. During this period of patent protection, there will be no cheaper alternatives.

However, to secure public interest, a system of parallel importation (Exhaustion of patent, Article 6) and compulsory licensing (Article 31) may be applied by member states to counteract the impact of the TRIPS on drug prices.

In a WTO Ministerial Conference in Doha, Qatar (November 2001), member countries recognized the needs for intellectual property protection for the development of new medicines and its effect on prices. It was also understood that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Therefore, WTO members should make the most of the provisions' flexibility in TRIPS Agreement.

World Health Organization (WHO) has its own view related to the TRIPS Agreement. This is summarized below:

- Patent. WHO supports government's legislation on patent protection as an incentive for research and development, and at the same time protect the rights of the public.

- R & D. As priority setting for research and development in the pharmaceutical market is imperfect, WHO is actively encouraging public sector financing for critical public health problems and neglected tropical diseases such as malaria and tuberculosis.

- Price. Lower income countries cannot be expected to pay the same price for essential drugs as the wealthier countries. Therefore, WHO strongly supports the development of mechanisms for preferential low prices for essential drugs in lower-income countries.

- Generic Drugs. Experience from countries that permitted production of generic drugs demonstrates the market

competition increases affordability of medicines and stimulates true innovations within the pharmaceutical industry. Hence, WHO supports the implementation of the TRIPS Agreement to ensure prompt availability of generic drugs upon patent expiration.

- Standard. WHO norms, standards and guidelines represent international consensus in the area of pharmaceuticals as TRIPS in the area of trades.

## Section 3: Parallel Importation

### Definition and Theoretical Explanation

Parallel imports or parallel trade, which are sometimes referred to as "Grey Market" imports, are cross border trade in a product, without the permission of the manufacturer or publisher (cited in Ducket, 1999). The incentives for its occurrence is a sufficient difference in prices between the two nations to cover shipping and transaction costs and still offer gains to both shipper and the buyer. It is therefore, a form of arbitrage.

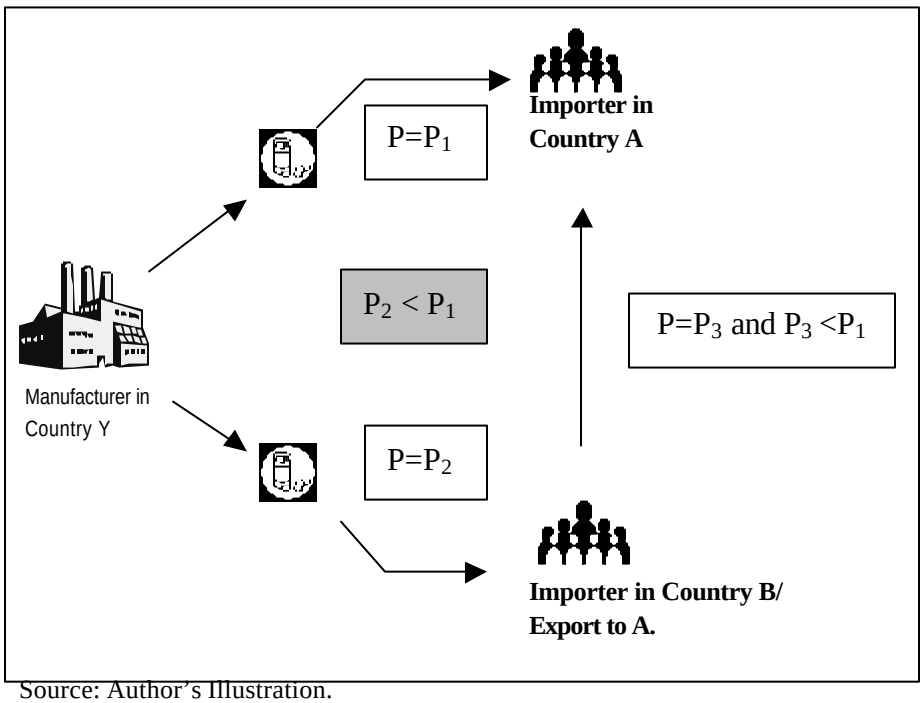
In general, there are three prerequisites for the evolution of gray markets (Chaudry and Walsh,1995):

- gray marketers must have a source of supply;
- trade barriers between countries must be low enough to provide easy access from one market to another; and
- price differentials must be large enough to appeal to the profit motives of gray marketers.

The flow of goods in parallel trade is illustrated in Figure 6.

Manufacturer in origin country Y selling its patent drugs to country A and B with different prices of $P_1$ and $P_2$ respectively, due to market imperfections through a strategy of price discrimination. Importer in country A has an alternative to import the same patented drugs from country B at price $P_3$ ($P_2$ plus shipping and handling cost) which is lower than $P_1$.

**Figure 6: General Flow of Parallel Trade.**




Source: Author's Illustration.

Economic theory demonstrates that the welfare tradeoffs in regulating parallel imports are complex and depend on circumstances. Price differs between two identical nations except in incomes per capita is due to income effect. The demand curve in the rich nation is steeper and less price-elastic that the demand curve in less affluent nation. Assuming similarity of production and distribution cost functions, this difference in demand curve elasticities leads a profit maximizing firm with some monopoly power to charge a higher price in the rich nation than in the poor nation.

Parallel imports take place when there is underlying monopoly power or market imperfections such as difference in political, social, economic, legal and regulatory regimes (Rozek and Rapp, 1992), among which patent protection figures most prominently, exploited by the original seller through a strategy of price discrimination. The strategy that the firms undertake in price determination is the Ramsey Pricing rule or the inverse elasticity rule.

Ramsey's (named after British Economist, Frank P. Ramsey, 1903-1930) rule specifies that goods whose demand is inelastic should be taxed (priced) more heavily than those whose demand is elastic, or sensitive, to price changes. Hence, the lower the demand elasticity of the goods, the higher the tax(price) should be.

The price discrimination started when the research and development (R&D) is taken into account by the innovator firms. Danzon (2000) noted that cost of (R&D) is relatively high i.e. 30 percent of total cost, including forgone interest and it is 13-20 percent of sales of US pharmaceutical firms. These R&D cost is a fixed cost, invariant to volume and will sunk at launch of a drugs, and accepted as "common cost" which serves patients worldwide. Hence, R&D costs cannot rationally be allocated to specific countries or patients. As a result, price cannot be set at the marginal cost, as theorized in earlier study as it will not covers the fixed cost of R&D.

As competition and free entry of generics will force the prices down to marginal cost, patent is used to permits innovator firm to bar generic products. With Ramsey pricing, the fixed cost can be recovered with the smallest feasible reduction of the total surplus retained by consumer and producers. Constrained Ramsey pricing would leads to price just enough to ensure recovery of the desired fixed cost. On the other hand, unconstrained Ramsey pricing allows prices charges more than marginal cost, maximizing funds to induce future R&D. In the end, the former could charge higher prices in order to break even, including the cost of R&D.

There are certain conditions whereby Ramsey pricing would or would be likely to fail (Scherer, 2001) and this involves parallel trade.

- Parallel trade arbitrage prices from low-price to high-price markets. This will leads to two adverse consequence:1) erode profits in higher price market that further reduce probable fund for future R&D; 2)Firm will reduce or stop the supplies or increase price of drugs in a low-price market. To avoid this, some legislation should prevent parallel exportation of pharmaceutical product at low priced market.

- If market in low income nation can be segmented to two (or more) groups: 1) minority with health insurance coverage will be the one with low price elasticity of demand; 2) majority with less

ability to pay for a higher drug prices. Firms may decide to serves the minority groups with price charged higher than one would expect with Ramsey theory (in the poor nation). To promote access cheap medicine for all, the less income nation shall be allowed to do parallel importation.

- Low-priced drugs in one nation may be due to national price control policy, not due to Ramsey pricing rationale. Therefore, consumers might pay less than Ramsey optimal price. As a result of this, firms may reduce supply to price-controlled nation and welfare benefits is reducing by product shortage. In order to encourage welfare benefits, parallel import from nation subject to price control strategy shall be prohibited.

However, Maskus and Chen (2000) advanced a model that analyzes parallel imports as a response to vertical pricing arrangements between a rights holder (manufacturer) and a foreign distributor. In the model, if markets were segmented, the manufacturer would charge a wholesale price to its foreign distributor to ensure an efficient (profit-maximizing) retail price. On the other hand, if markets were integrated by parallel trade, the distributor could purchase the good at a wholesale price and resell to other markets at the local retail price. If the transport cost were low enough, this would be profitable, but would diminish the return to the manufacturer and waste resources in costly trade.

The welfare: if the costs of engaging in such trades are low, there would be gains from permitting it; if the costs are high, it would be more sensible to ban it. Countries with low trade barriers might prefer an open regime of parallel trade.

The tradeoff: parallel imports will benefit consumers in the high-price country but hurt consumers in the low-price country as such trade forces the manufacturer to set an inefficient wholesale price to limit its extent (Danzon (1998), Towse (1998), cited in Gyldmark, (1999); Markus and Chen, (2000)). It also found that parallel trade increases the profitability of pharmaceutical wholesalers and retailers and may not totally lower the prices for drugs in the high-priced country.

The cost and benefits of parallel importation is summarized in Figure 7.

**Figure 7: Cost and Benefits of Paralell Importation**

| Parallel Importation (PI) | |
|---|---|
| Benefit | Cost |
| • A reduction of brand-name drug prices in poor countries<br>• As complement to price control program<br>• Source of technology transfer to the importer<br>• To avoid counterfeit products. | • Reducing supply at small markets<br>• Transport and repackaging cost takes up on price advantage<br>• Parallel importation firms 'free ride' on original manufacturer's marketing and R&D expenses<br>• Reduce original manufacturer's profit<br>• Offset any incentive to more R&D by manufacturer<br>• Weaken the Intellectual Property Rights of innovators |

Source: Maskus (2001), Danzon (2001), Ducket(1999), Bale(2000); Rozek and Rapp, 1992, Schrer (2001), Supakakunti et. al., 2001.

## Experiences of Other Countries

The legal principal of parallel importation is "exhaustion". Once the company Y has sold its product to Country B, its patent is exhausted and it no longer has any rights over what happens to that product (refer to Figure 6).

Member countries of TRIPS Agreement are not bounded to ban parallel importation. The TRIPS Agreement simply says that none of its provisions can be used to address the issue of exhaustion of intellectual property rights in a WTO dispute (Article 6) unless fundamental principles of non-discrimination are involved.

Parallel imports of pharmaceuticals are common in the EC to promote a common market, and the savings can be substantial. Firms like Informedica track parallel prices for clients seeking to minimize the expenditure on medicines. In a recent analysis, Informedica compared the UK list and best UK contract prices to the prices charged by five parallel importers for eight important drugs for HIV.

The UK list price for a 270 capsule package of Roche's Inversae is £331, but the drug was available form a parallel imported for £203. This is £95 less than the best UK contract price. A package of

Bristol-Myers Squibb's Videx, a drug licensed from the US, is listed in the UK at £88 and available from a US parallel importer for £50. Bristol-Myers Squibb's Zerit is listed at £172 in the UK but the Spannish parallel import is available for £66. The best European price for Glaxo's Retrovir is £54 compared to a UK list price of £125.[9]

In a study by Maskus and Chen in Sweeden, price of pharmaceutical products subjected to parallel importation were found reduced at 4 percent in 1998 from the previous year compare to those which do not have parallel import competitors that rose 1 percent in the same period. That is why parallel import is said to be one of the preventive steps in drugs price control.

US's banned policy on parallel importation resulted Glaxo, Ciba-Geigy and Pfizer charged from 43 to 69 times as much for the same drug in the country as they did in India.

Due to parallel importation competition, Tamoxifen used in breast cancer treatment, in Canada, is priced at a tenth of price charged in the US[10] while a month's supply of an osteoporosis drug sold for $170 in the United States but only $45 in Canada and $51 in Mexico.

In a survey by Bala (1995), prices for SmithKline Beechman's version of Amoxil was $8 in Pakistan, $14 in Canada, $16 in Italy, $22 in New Zealand, $29 in the Philippines, $36 in the USA, $34 in Malaysia, $40 in Indonesia, and $60 in Germany[11]. Glaxo's prices for Zantac and Voteran were lower in the UK than in Indonesia, for example, despite Indonesia's low income.

Even though the variation of prices seems to benefit consumers in low-income countries, there are some disputes by US pharmaceutical manufacturer over parallel trade in these countries. Among low-income countries that faced pressure from PhRMA[12] were South Africa, Kenya, Ghana, Philippines and Thailand.

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[9] Cited in http://www.cptech.org/pharm/sa/sa-10-97.html

[10] "Re-import and Save", The Washington Post, 29th September 2000.

[11] All prices are in US Dollar.

[12] Pharmaceutical Research and Manufacturers Association

With these examples, it is interesting to study whether Malaysia permits parallel importation and how would the legislation effect the drug prices in Malaysia.

**Parallel Importation in Malaysia**

The purpose of Patent Act 1983 (Act 291) is to give legal protection to patent holders together with exclusive rights which includes the exploitation of the patents, to assigned or transferred the rights and signing license contract. This Act is effective from 1st October 1986.

Non-patentable inventions include the following: discoveries, scientific theories and mathematical methods; plant or animal varieties or essentially biological processes for the production of plants or animals, other than man-made living micro-organism processes; schemes, rules or methods for doing business, performing purely mental acts or playing games; methods for the treatment of the human or animal body by surgery or therapy, and diagnostic methods practiced on the human or animal body (Patents Act 1983, Sect.13).

Two revision had been made to this Act ever since. The first revision, Patent Act (Revision) 1995, is effective from 1st August 1995 to speed up the processing and granting the patents in accordance with Paris Convention and to extend the protection of patents.

The second and latest revision is Patent Act (Revision) 2000, which is effective from 1st August 2001[13]. Among others, the Act allows parallel import of the products that has been patented after the product has been marketed at overseas.

The impact of parallel importation on drug prices can be evaluated by comparing prices of patented (branded) drugs obtained from local retailers, which is imported directly from the original manufacture by its agent or sole distributor, and prices of the same patented drugs obtained from international market.

The drug selections are based on the National Essential Drugs List. The patent expiry date is referred to "List of Products with Malaysian

[13] Source: Ministry of Domestic Trade and Consumer Affair (last updated on 17th October 2001)

Patent Registration List (Azmi and Alavi, 2001)". The selected drugs are those with available patented drugs as at year 2001. The usage of each drug is also noted.

For every drugs sold, it will be priced according to dosage and packaging of drugs. The most available package will be recorded and used for evaluation of price variations. Prices for comparison will be based on a unit of each selective active ingredient.

For the purpose of this research, all the prices gathered are retail prices. Local retail prices of branded and generic drugs are obtained from several retail pharmacies located in Klang Valley and recommended retail price compiled by National Pharmaceutical Control Bureau (NPCB), Ministry of Health.

International retail prices are gathered from different pharmaceutical retailers in India, Thailand, Australia, Hong Kong and New Zealand. These retailers are certified retailers in their country and also provide the services through the internet.

It is important to note that the prices studied are retail prices and meant for personal usage. The original prices obtained from these retailers are in US dollars and inclusive of freight charges from the particular third party country to Malaysia. International prices are recorded in the US dollar and then converted to Ringgit Malaysia as at 1st January 2002[14].

Due to the limited time frame, the findings of this study are based on a small market sample, i.e. for local price, the based is a Kuala Lumpur market and for international, it is based on whatever available on the net. The selection of branded drugs is limited as certain drugs are not available in all countries understudy. It is due to differences in disease pattern, local dominant generic drugs that makes selling of branded drugs would be unprofitable or smaller demand in the particular country. The price of drugs are assumed does not affected by other factors such as inflation, income per capita, currency exchange or other economical and social factor.

[14] USD1 = RM3.80

## Descriptive Findings

The patented drugs are newly developed drugs to treat newly discovered disease or infection. Most of the drugs do not have generic substitute. These monopolized drugs are listed in Table 1. Three of the drugs are originated from US where patent is most protected.

Comparison of prices on each patent drugs is listed in Table 2 to Table 9 and discussion on each finding is appended after each related tables.

**Table 1: Patented Drugs without Generics**

| Drug Usage | Active Ingredients | Manufacturer (Origin Country) | Drug's Name | Patent expiry |
|---|---|---|---|---|
| Prevents nausea and vomiting caused by cancer treatment. | Ondansetron | Glaxo Wellcome Operations (UK) Ltd., (UK) | Zofran® | 31-Jan-07 |
| Lowers high level of cholesterol | Simvastatin | Merck & Co. Inc. (US) | Zocor® | 27-Nov-05 |
| Decreases the size of an enlarged prostate, which helps urination problems. | Finastride | Merck & Co. Inc. (US) | Proscar® | 11-Nov-13 |
| Treats infections. Belongs to a group of drugs called macrolide antibiotics | Azithromycin Dihydrate | Pfizer, Inc (US) | Zithromax® | 30-Mar-08 |
| Treats rashes, skin irritation, and other types of skin problems. | Mometasone Furoatet | Schering Corp. (South Africa) | Elomet ® | 24-Jan-02 |

**Table 2: Patented Drug – Price Differences between Originator and Selected Third Party Countries (Zofran®)**

| Selling Country | Packaging | Price per unit (RM) | Ratio to Originator's Price |
|---|---|---|---|
| *4 mg* | | | |
| UK(originator) | x 30's | 36.00 | 1:1 |
| India | x 10's | 10.26 | 0.3:1 |
| Thailand | x 10's | 50.16 | 1.4:1 |
| *8 mg* | | | |
| UK (originator) | x 30's | 51.47 | 1:1 |
| India | x 10's | 15.96 | 0.3:1 |
| Thailand | x 10's | 60.42 | 1.2:1 |

Indian price for Zofran® used as a supplement drugs in cancer treatment is 70 percent lower than those imported directly from the originator's country, UK, but Thailand's price is 20 percent to 40 percent higher. Parallel importation shall be used to make cancer treatment more affordable to patients in Malaysia.

**Table 3: Patented Drug – Price Differences between Originator and Selected Third Party Countries (Zocor®)**

| Selling Country | Packaging | Price per unit (RM) | Ratio to Originator's Price |
|---|---|---|---|
| US (orginator) | 10 mg | 3.80 | 1:1 |
| Thailand | 10 mg | 9.50 | 2.5:1 |
| New Zealand | 10 mg | 6.59 | 1.7:1 |

Third party country's prices are higher in between 70 percent to150 percent than those imported from the originator country. Parallel importation would not help much in getting cheaper Zocor® for Malaysian market.

**Table 4: Patented Drug – Price Differences between Originator and Selected Third Party Countries (Proscar®)**

| Selling Country | Contents | Price per unit (RM) | Ratio to Originator's Price |
|---|---|---|---|
| US (originator) | 5 mg | 5.63 | 1:1 |
| Thailand | 5 mg | 9.75 | 1.7:1 |
| New Zealand | 5 mg | 11.40 | 2:1 |

As per previous drug, Proscar® if imported from third party country is higher between 70 percent to 100 percent , Thailand and New Zealand respectively, than those imported directly from the originator country. Once again, as the retail price from original county is lower, parallel importation would not help in reducing the price of branded Proscar®.

**Table 5: Patented Drug – Price Differences between Originator and Selected Third Party Countries (Zithromax®)**

| Selling Country | Packaging | Price per unit (RM) | Ratio to Originator's Price |
|---|---|---|---|
| US (Originator) | 500 mg | 17.32 | 1:1 |
| Thailand | 500 mg | 10.76 | 0.6:1 |
| New Zealand | 500 mg | 23.05 | 1.3:1 |

For Zithromax®, consumers in Malaysia have an alternative to a cheaper drugs when parallel importation takes place from Thailand as the prices are lower than the one that imported directly from the originator country, US. However, the drug will cost more of 1.3 times of the original price if imported from New Zealand.

**Table 6: Patented Drug – Price Differences between Originator and Selected Third Party Countries (Elomet®)**

| Selling Country | Packaging | Price per unit (RM) | Ratio to Originator's Price |
|---|---|---|---|
| *0.1% 15 g (ointment)* | | | |
| South Africa (originator) | 0.1% 15 g (ointment) | 27.60 | 1:1 |
| US | 0.1% 15 g (ointment) | 41.04 | 1.5:1 |
| *0.1& 30 ml (lotion)* | | | |
| South Africa (Originator) | 0.1% 30 ml (lotion) | 45.30 | 1:1 |
| US | 0.1% 30 ml (lotion) | 102.60 | 2.3:1 |

There is no advantage for the end consumer in Malaysia to do parallel trade for Elomet® as the third party country prices, in this sample, US are higher than the originator country at 50 to130 percent.

**Table 7: Patented Drug – Price Differences between Selected Countries (Prozac®)**

| Selling Country | Packaging | Price per unit (RM) | Ratio to Originator's Price |
|---|---|---|---|
| *20mg* | | | |
| US (Originator) | 20 mg x 28's | 7.10 | 1:1 |
| India | 20 mg x 60's | 3.17 | 0.4:1 |
| New Zealand | 20 mg x 30's | 5.70 | 0.8:1 |
| Thailand | 20 mg x 28's | 11.81 | 1.7:1 |
| Hong Kong | 20 mg x 60's | 15.14 | 2.1:1 |

Originator's price are still lower if compared to those imported from Thailand and Hong Kong. Given parallel importation is not permitted in Thailand, no reason could be verified for a higher price in Hong Kong. As usual, India and New Zealand offer more competitive price, if parallel importation came into practice, at a discount rate of 60 percent and 20 percent respectively.

It is noted that the drug's patent expiry is in March 2002. It may cause variation of prices between third party countries.

**Table 8: Patented Drug – Price Differences between Selected Countries (Diflucan®)**

| **Selling Country** | **Packaging** | **Price Per Unit (RM)** | **Ratio to Originator's Price** |
|---|---|---|---|
| *50 mg* | | | |
| US (Originator) | 50 mg x 7's | 17.00 | 1:1 |
| India | N/A | | |
| Thailand | 50 mg x 7's | 27.14 | 1.6:1 |
| New Zealand | 50 mg x 30's | 15.83 | 0.9:1 |
| *150 mg* | | | |
| US | 150 mg x 1's | 29.00 | 1:1 |
| India | N/A | | |
| Thailand | 150 mg x 1's | 60.80 | 2.1:1 |
| New Zealand | 150 mg x 5's | 64.60 | 2.2:1 |
| *200 mg* | | | |
| US | 200 mg x 28's | 48.86 | 1:1 |
| India | 200 mg x 40's | 19.48 | 0.4:1 |
| Thailand | N/A | | |
| New Zealand | N/A | | |

For Diflucan®, the ratio of prices differs with the contents of the active ingredients. For the lowest dosage, 50 mg, the variation of prices are not obvious, i.e. in the region of 0.9 to 1.6 of originator's price. On the other hand, for the higher dosage, i.e. 150 mg and 200 mg, there are an extreme in price. 150mg Diflucan® in selected third party country are higher of 110 to 120 percent, whereas 200mg Diflucan® are lower of 60% in India. To get the most out of it, parallel importation should be used to get the most competitive price for Diflucan®.

**Table 9 : Patented Drug – Price Differences between Selected Countries (Zantac®)**

| Selling Country | Packaging | Price per unit (RM) | Ratio to Originator's price |
|---|---|---|---|
| *150 mg* | | | |
| Australia (Originator) | 150 mg x 60's | 3.73 | 1:1 |
| Thailand | 150 mg x 50's | 2.13 | 0.6:1 |
| New Zealand | 150 mg x 30's | 5.32 | 1.4:1 |
| *300 mg* | | | |
| Australia (Originator) | 300 mg x 30's | 6.11 | 1:1 |
| Thailand | 300 mg x 50's | 2.89 | 0.5:1 |
| New Zealand | 300 mg x 30's | 8.11 | 1.3:1 |

It is found that Thailand offers a cheaper Zantac® compare to New Zealand despite of New Zealand's nearer in distance to Australia, the originator's country. The drugs are at discount of 40 to 50 percent but at premium of 30 to 40 percent of Australian's price if imported from Thailand and New Zealand respectively. By and large, parallel importation would benefits the end user in Malaysia for this drug that treats duodenal and gastric ulcer, which is a common infection to the Malaysian.

To conclude, 62.5 percent of the sample understudy support parallel importation would lead to a cheaper patented (branded) drugs.

Out of eight drugs understudy in this section, only three drugs, namely Zocor®, Proscar® and Elomet® would be cheaper to import direct from originator's country. The ratio of price from third party countries are ranged from 1.5 to 2.5 to the original prices.

Prices from originator's country for other branded drugs, i.e. Zofran®, Zithromax®, Prozac®, Diflucan®, and Zantac® are found to be in the middle among the third party countries' prices. The ratio of prices from the third party country to the price of original country is listed as follows:

**Table 10: The Range of Ratio of Drug Price from Third Party Country to The Original Price**

| Drug | Lowest ratio (Country) | Highest ratio (Country) |
|---|---|---|
| Zofran® | 0.3 (India) | 1.4 (Thailand) |
| Zithromax® | 0.6 (Thailand) | 1.3 (New Zealand) |
| Prozac® | 0.4 (India) | 2.1 (Hong Kong) |
| Diflucan® | 0.4 (India) | 2.2 (New Zealand) |
| Zantac® | 0.5 (Thailand) | 1.4 (New Zealand) |

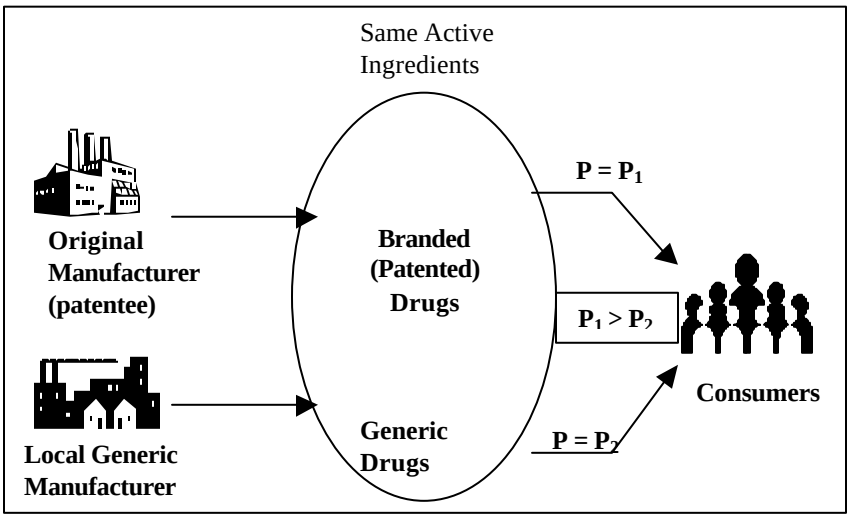
As seen, by and large, consumers in Malaysia would be better off with parallel importation allowance with cheaper branded drugs imported from India. Retailers should be aware of the current changes in our legislation system in order to provide the public with more access to cheaper medicines. As the price in this study is retail prices, it is expected wholesalers could import the drugs at a much lower cost. However, the parallel importation would be not beneficial to the society as a whole if the retailers parallel import the drugs but priced it as high as the price of original country. Then, not only the retailers, the consumers should be educated and provided with such information that they actually have an alternative to a same but cheaper drugs.

## Section 4:Compulsory Licensing

### Definition and Theoretical Explanation

Compulsory license by definition is authorizations granted to a third party to make, use or sell a patented invention without the patent owner's consent. In relation to the pharmaceutical industry, a compulsory license is granted to a third party to produce a generic drugs interchangeable with the invented, patented drugs (Eliot and Bonin, 2001), under certain conditions, while a proprietary or branded name drugs is still protected by its patent. Usually, the generic produced by local manufacturer is much cheaper that the patented drugs because they do not have an R&D cost as the patentee's. The scenario is illustrated in Figure 8.

**Figure 8: Concept of Compulsory Licensing**




Generic drugs should not be confused with counterfeit drugs. According to WHO, counterfeit medicine is one which is deliberately and fraudulently mislabeled with respect to identify and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct

ingredients, wrong ingredients, without active ingredients, with incorrect quantity of active ingredients or with fake packaging.

The birth of the concept of compulsory licensing is linked to the obligation, introduced by the UK Statute of monopolies in 1623 and recognized in many national patent laws during the 19th century. The means of compulsory licensing is to mitigate the drastic measure of direct forfeiture towards a third party how 'copy' the production of patented product or process.

A system of compulsory licensing imitated the system adopted in the UK under the Patent Act of 1883 for cases which the patent was not being worked in the UK, the reasonable requirements o the public were not satisfied, or any person was prevented from working or using the invention. This provision had influenced patent laws to the highest degree, adopted in other country as well as in the development of the International Convention for the Protection of Industrial Property (Paris Convention).

After a turbulent process of negotiation between countries that opposed compulsory licensing such as the US, the conference held at The Hague in 1925 adopted compulsory licensing as the main means to ensure the exploitation of a patent. The forfeiture of the patent would only apply where a compulsory license proved to be ineffective as a means of addressing the non-working of a patent or failed to remedy non-exploitation.

The Paris Convention, which applies to patents on inventions, utility models, industrial design, trademarks and trade-names, recognizes the right of member countries to establish compulsory licenses but with certain limitation under the Convention:

i) Member states may provide for the grant of compulsory licenses to prevent abuses of the exclusive rights conferred by the patent.

ii) Forfeiture of the patent will not be provided for except where the grant of compulsory licenses is not sufficient to prevent abuses. Forfeiture of a patent will not be instituted before the expiration of three years from the grant of the fisrt compulsory license.

iii) A compulsory license may not applied on the ground of failure to work or insufficient working before the expiration of four years from the date of application for the patent, or three years from the date of the grant of the patent whichever period expires last. It shall be refused in the patentee justifies his inaction by "legitimate reason".

The provision of compulsory licenses became a typical feature in patent laws worldwide.

In a normal market condition, when competitors introduce their generic products, the originator shall lower their prices and compete with the national firm. But this is not the case in pharmaceutical and patented drugs. As an example, patents and licensing in the chemical industry leads to higher price when there is more restrictive in licensing (Arora, 1996)[15]. Brand name drug prices increases after generic entry to capture high-end market but accompanied by large decrease in the price of generic drugs as more competitors of generic enter the market (Frank and Salkever, 1997).

Entry of generic leads to price-sensitive buyers to shift to generics, leaving only price-insensitive buyers to purchase brand-name products. This causes the brand name producers' demand function to shift inward and to become less elastic, allowing profit-maximizing brand-name firm to raise its price.

The price equation for generic product price can be written as:

$$P_g^* = P_g^*(n, P_b),$$

where $P^*_g$ is the equilibrium price of a generic product, $n$ is the number of generic producers and $P_b$ is the brand-name produce's price.

The price equation for brand-name price can be written as

$$P_b = P_b(n,w),$$

Where $w$ is a vector of input prices. Frank and Salkever (1992) showed that $dP_b/dn < 0$ unless entry increase brand-name demand, marginal cost are decreasing or entry makes the demand curve more elastic (steeper). The reduce form brand-name price equation suggest

[15] cited in http://econpapers.hhs.se/paper/wpawuwpio/9605003.htm

that generic entry affects price through the effect of generic price on brand name demand.

Grabowski and Vernon (1992) showed brand-name prices rising relative to generic prices subsequent to generic entry. On the other hand, Caves et. al (1991) suggest that other omitted factors may have caused brand-name prices to rise over time. An example in 1982 revealed the pharmaceuticals producer price index rose sharply relative to indices of labor and material costs.

Theoretically, public could not expect the price of patented (branded) drugs will drop with the introduction of generics. It is the generics' price that will continue to reduce with entry of more generic producers. Therefore, it is important for the generics to keep a same standard of drugs but at a cheaper price to promote health for all, especially to the price-sensitive groups.

With TRIPS agreement taking effect, all member states of the WTO should provide patent protection for products and processes for 20 years. The only way national firms can initiate production is by granted compulsory licensing, which is allowed in the TRIPS agreement (Article 31). A compulsory license allows the use of an invention but only by the person that has been permitted by the government (or court) after determination that certain requirements (example: for national emergency, Article 31b) established by the law are met. Both the request and use of compulsory license may be subjected to compensation to patent holder (Article 31h), time (Article 31C) and trade border restrictions. The generic produced under compulsory license shall be authorized for the domestic market only (Article 31f). However, the compulsory licensed generic could be exported to avoid anti-competitive process (Article 31k). It does not stated the circumstances that can be concluded as national emergency or anti-competitive process and it depends on each government interpretation.

Then again, compulsory licenses should not be seen as a "magic wand" for obtaining affordable access to patented medicines in developing countries as noted in Shere and Watal (2001) due to its some basic limitations:

- Compulsory licensees must have the capability to "reverse-engineer" without the co-operation of the patent owner.

- Exports of compulsory licensed product from large markets destined for small, least-developed countries can only work where the disease patterns are common to both markets.

- Compulsory licensing will only attracted to large and profitable drug markets and on the other hand, essential medicines with small potential volumes or mostly poor patients will not attract many applicants no matter how important it is from the perspective of public health.

**Experience of Other Countries**

In conjunction of the Paris Convention, WTO countries member allow compulsory licensing after three years has lapsed of the grant to the patent holder without any proper action taken to produce the product locally, provided the licencee paying a substantial amount of royalties determined by the rulers.

Indian drug industry is a good example of what happens when companies are given the authority to produce drugs for the local market without paying daunting licensing fees. India has yet to granted a 20-year protection for patented products. Compulsory licensing permitted in the TRIPS Agreement is said mimicking the situation in India. For example, a study in 1999 shows that Lariam, a treatment for malaria costs $37 with drugs from the US but only $4 when produced in India while ZDV costs $239 per month in the US and $48 in India (Bala, 1999; also cited in Berman,1999; Ducket, 1999).

After Thailand government permits the local to manufacture a generic drugs for a high-priced foreign products, it was estimated that the compulsory licencing would reduce the price of an average month's supply of treating AIDS drugs from $92.50 to $51 per person.

Another example on how compulsory licensing would drive to a lower price of branded drugs as happened recently in Brazil. On 22nd August, 2001, Brazilian Government announced that the they would issue a compulsory license for the manufacture of the antiretroviral drug nelfinavir (sold under the brand name Viracept by Roche) to the Brazilian pharmaceutical producer Far Manguinhos. This

announcement comes after unsuccessful negotiations between the Brazilian government and Roche to cut down prices. Negotiation then continues until final agreement was made on 31st August 2001, whereby Roche will sell the drug in Brazil at a 40% discount from the original price, and Brazil will not issue the compulsory license.[16]

During the same period, Merck, Inc. formally announced a cut in the price of its product Crixivan (Indinavir) and Stocrin ( efavirenz). This is a few weeks after the launch of a Dominican Indinavir by Rowe. The price cut is significant (about 85% of the price). The retail prices now are: US$ 60.00 for the Indinavir and US$ 50.00 for the Stocrin. However, there is a condition on the price cutting, i.e. the products should not be exported to other markets. This is a condition in paper because there is no law that prohibits the export or selling of these or any other product to whoever buys it.

On January 29, 2002, members of the Treatment Access Campaign (TAC) imported a shipment of generic antiretroviral drugs from Brazil for use in a program run by Medicins Sans Frontieres (MSF) in Kayelitsha. The drugs imported were AZT, 3TC, AZT+3TC, and Nevirapine. By using generics, the cost of antiretrovirals per patient per day falls from US$3.20 to US$1.55, allowing MSF to treat more people. The anti-AIDS program in Kayleitsha shows that treatment is possible in areas with limited resrouces and challenges the South African government to provide low-cost medicine to its HIV+ citizens.

**Compulsory Licensing in Malaysia**

Part ten of this Patent Act (1983) is a special provision for compulsory licensing. Compulsory license by definition in Section 48 is the authorization to perform in Malaysia without the agreement of the owner of patent in respect of the patented invention.

Local manufacturer could produce a generic drug after the third year from the grant of a patent, with a certain royalty granted to the patent owner, (Section 49) if:

[16] "Roche Reaches Accord on Drug With Brazil", The New York Times, September 1st, 2001.

a) the price of the registered drugs are unreasonably high or do not meet the public demand,
b) no production of the patented product or application of the patented process without any legitimate reason;
c) the patented products are not available in the local market.

Under Section 52, upon the granting of the compulsory license, The Patents Board shall fix the scope and limit of the license as well as the royalty due to the owner of the patent.

The Board shall cancel the compulsory license (Sect. 54) if:
a) the ground for the grant of compulsory license no longer exist;
b) the beneficiary neither begun the working of the patented invention in Malaysia nor made serious preparation towards the working within the granted time limit;
c) the beneficiary does not respect the scope of the license as fixed in the granted decision;
d) the beneficiary is in due of the payments according to the granted decision.[17]

To study a local scenario on the impact of compulsory licensing, choice of drugs is as presented in previous section. Apart from that, Yahoo!-Health and NPCB List were referred to identify its generic competitors in international and local market respectively.

**Descriptive Findings**

There are generic drugs produced internationally and not in Malaysia (Table 11) and there are generics produced locally (Table 12).

It is depend to the government whether to import the generic in order to allow competitive market in the pharmaceutical sector.

[17] Patents Act 1983 (Act 291) and Regulations, as at 15th July 2000.

**Table 11: Patented and Generic Drugs Available in International Market**

| Drug Usage | Active Ingredients | Manufacturer (Country) | Drug's Name | Patent expiry |
|---|---|---|---|---|
| Treats depression, obsessive compulsive disorder (OCD), and eating disorders | Fluoxetin | Eli Lily & Co. (US) | Prozac® | 30-Mar-02 |
| | | (India) | Fludac | Generic |
| | | (Thailand) | Fluoxetin HCl | |
| Treats fungus infection. | Fluconazole | Pfizer Pty Ltd (US) | Diflucan ® | 22-Apr-02 |
| | | (India) | Syscan | Generic |
| | | (Thailand) | Biolab | Generic |

**Table 12: Patented and Available Generic Drugs Including Manufactured in Malaysia**

| Drug Usage | Active Ingredients | Manufacturer (Country) | Drug's Name | Patent expiry |
|---|---|---|---|---|
| Treats high blood pressure and chest pain (angina). Belongs to a class of drugs called calcium channel blockers. | Diltiazem HCl | Tanabe Seiyaku Co.Ltd. (Japan) | Herbessor ® | 13-Jul-02 |
| | | (Malaysia) | Calcizem | Generic |
| | | (New Zealand) | Dilem | |
| | | (New Zealand) | Dilcard 60 | |
| | | (India) | Masdil | |
| Treats duodenal ulcer, gastric ulcer, and other conditions. | Ranitidine | Glaxo Wellcome, (Aust.) | Zantac® | Oct. 2001 |
| | | Ranbaxy (M) Sdn Bhd (Malaysia) | Histac | Generic |
| | | Duopharma (M) Sdn Bhd (Malaysia) | Gastril | |
| | | Upha Pharm Mfg (M) S/B (Malaysia) | X'tac | |
| | | Raza Mfg Bhd, Msia (Malaysia) | Rintac | |
| | | Sunward Pharm S/B (Malaysia) | SP-Gastril | |
| | | YSP Industries (M) S/B (Malaysia) | Vesyca | |

analysis on the drug prices (branded and generic) for each class of active ingredients is presented in Table 13 to Table 16.

**Table 13: Patented and Generic Drug Prices. (Fluoxetin)**

| Producer Country | Name | Packaging | Price per unit (RM) | Ratio to Branded Price |
|---|---|---|---|---|
| US (originator) | Prozac® | 20 mg x 28's | 7.10 | 1:1 |
| Thailand | Fluoxetin HCl | 20 mg x 28's | 5.84 | 0.8:1 |
| India | Fludac | 20 mg x 30's | 3.00 | 0.4:1 |

**Table 14: Patented and Generic Drug Prices. (Fluconazole)**

| Producer Country | Name | Packaging | Price per unit (RM) | Ratio to Branded Price |
|---|---|---|---|---|
| US (Originator) | Diflucan ® | 200 mg x 28's | 48.86 | 1:1 |
| India | Syscan | 200 mg x 4's | 0.8 | 0.02:1 |
| Thailand | Biolab | 200 mg x 1's | 1.10 | 0.02:1 |

As derived from the analysis in Table 13 and Table 14, generic drugs produced in India and Thailand are much cheaper than the equivalent in dosage branded drugs. The ratios of generic drug to the patented drug price are ranging from 0.02 to 0.4. Even though no locally produced generics for this drug are available in Malaysia, consumers in Malaysia could be better off with the imported generic drugs.

It gives some indication that if the generic could be produced locally, the price for fluconazole would be much lower than those imported from India or Thailand as locally produced drug does not incur importation cost. However, the situation may not be as expected as the local producer who obtain the compulsory license are subject to certain fees and remuneration to the patentee that may be added to the cost of the generic drugs.

As discussed earlier, new entrants of generics will not bring down the patented drugs' price to capture the high-end market that still believe in the quality of the patented (original) drugs. The prices of generics may reduce with more new entrants as competition among generic arises and this would serve the price-sensitive group.

**Table 15: Patented and Generic Drug Prices. (Diltiazem HCl)**

| Producer Country | Name | Packaging | Price per unit (RM) | Ratio to Branded Price |
|---|---|---|---|---|
| *30mg* | | | | |
| Japan | Herbessor ® | 30 mg x 100's | 0.71 | 1:1 |
| Malaysia | Calcizem | 30 mg x 500's | 0.33 | 0.5:1 |
| New Zealand | Dilem | 30 mg x 100's | 0.47 | 0.7:1 |
| India | Masdil | 30 mg x 100's | 0.20 | 0.3:1 |
| Thailand | Diltiazem - Generic | 30 mg x 100's | 1.24 | 1.7:1 |
| *60 mg* | | | | |
| Japan | Herbessor ® | 60 mg x 100's | 0.95 | 1:1 |
| Malaysia | Calcizem | 60 mg x 500's | 0.63 | 0.7:1 |
| New Zealand | Dilem | 60 mg x 100's | 0.71 | 0.7:1 |
| India | Masdil | 60 mg x 100's | 0.39 | 0.4:1 |
| Thailand | Diltiazem- Generic | 60 mg x 100's | 1.84 | 1.9:1 |

It is obvious that Diltiazem HCl generics produced locally are cheaper than the branded drugs.

However, it is not the case in generic drugs imported from Thailand whereby the generic are more expensive than the branded drugs. There is no exact reason for this. It may indicate that the original producer (Tanabe Seikayu Co. Ltd.) had been using a different pricing approach, i.e. to be priced, as near as they could, to the price of local generics to avoid competition from other imported generics.

The ratio of Malaysian generics price to a patented Dialtizem HCl (Herbessor®) is in the range of 0.5 to 0.7 depending on the packaging. Better still, India's generic has the most competitive price if we were to compare the generics manufactured in third party countries to the local manufacturer.

**Table 16: Patented and Generic Drug Prices. (Ranitidine)**

| Producer Country | Name | Packaging | Price per unit (RM) | Ratio to Branded Price |
|---|---|---|---|---|
| Australia | Zantac® | 300 mg x 30's | 6.11 | 1:1 |
| Malaysia | Histac | 300 mg x 100's | 3.80 | 0.6:1 |
| | Gastril | 300 mg x 100's | 0.84 | 0.1:1 |
| | X'tac | 300 mg x 100's | 1.92 | 0.3:1 |
| | Rintac | 300 mg x 100's | 0.80 | 0.1:1 |
| | SP-Gastril | 300 mg x 120's | 1.16 | 0.2:1 |
| | Vesyca | 300 mg x 100's | 2.00 | 0.3:1 |

Compulsory licensing is effectively used by local manufacturer to produce Ranitidine generic. The ratio of the generic drug price to the patented Zantac® are at a range of 0.1 to 0.6. The price of the branded Zantac® is still expensive even though there are competition from local generics. It shall be noted that Zantac® patent has expired in October 2001 and manufacturers listed in the table are noted as in December 2001. Verification on the production date of the generics is out of the scope of this paper; as to determine whether they are manufactured and sold to the market before or after the patent has expired.

Nevertheless, an interesting part is that all the generics are priced lower than the original drugs, and compare to the discussion on the previous drugs (Dialtizem HCl), the more generics in the market, the lower the price would be. India and Thailand

From the empirical study of this section, it is proven that compulsory licensing would be a break free for a cheaper medicines but not to reduce the price of branded (patented) drugs in Malaysia. Compulsory licensing might and might not be a tool to control branded drug prices in Malaysia. It depends solely on the marketing strategy deployed by the patentee and its distributors or selling agents.

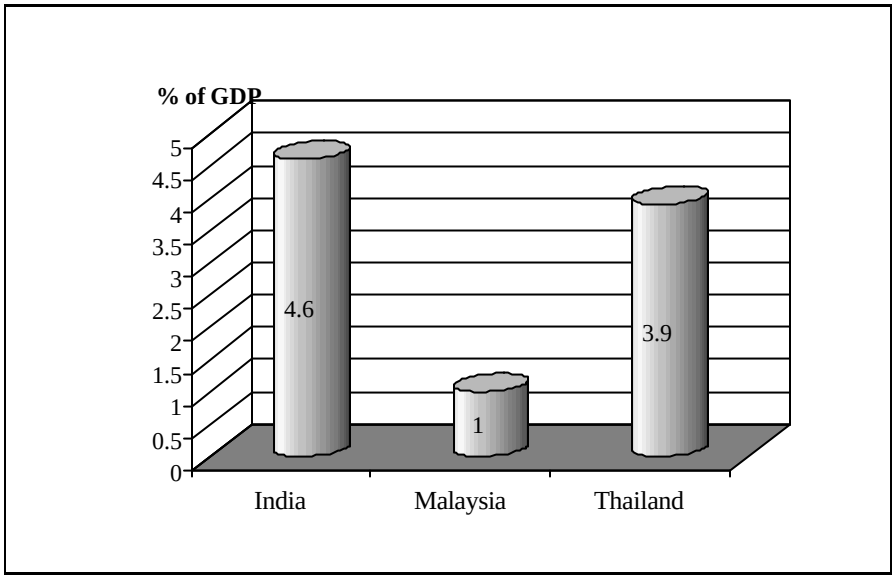
## Section 5: Concluding Remarks

This study suggests parallel importation allowance on the high priced patented drugs would be beneficial to the consumer in Malaysia. However, the Government shall control the incomings of parallel imported drugs as the handling and storage of the medicines cannot be guaranteed to be safe. As primary effect of parallel trade is that it increases the profitability of the pharmaceutical wholesalers and retailers (Heimler, 2000), it may or may not be lower the prices of the high-priced patented drugs in this country. Public should be informed and educated to differentiate the patented drugs imported directly from the original country or from a third party country.

The section of compulsory licensing in the Patent Act 1983 is seen not being fully utilized by the local manufacturer to produce generics replacement for a high priced patented drugs especially in cancer and parasitic transmittal disease treatment compare to India and Thailand. It is more further supported by comparison of health expenditure by private sector in the abovementioned countries and Malaysia. In 1997, private health sector in India and Thailand contributed to 4.6 percent and 3.9 percent of its GDP compare to the same in Malaysia which only contributed only 1 percent of our GDP (Figure 9).

As competition among generic drugs could reduce the price of among them in Malaysia, government shall issue compulsory license to local producer of generic drugs. At the same time, the demand of the patented drugs shall be taken into account, to make sure the preparation of the facilities to produce the generic drugs will not be a waste. This can be done by studying the pattern of patented drugs sales and projection of generic usage with the introduction of the substitute drugs.

**Figure 9: Health Expenditure (Private Sector) of India, Malaysia and Thailand in 1997**




Source: World Bank Report (1999)

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