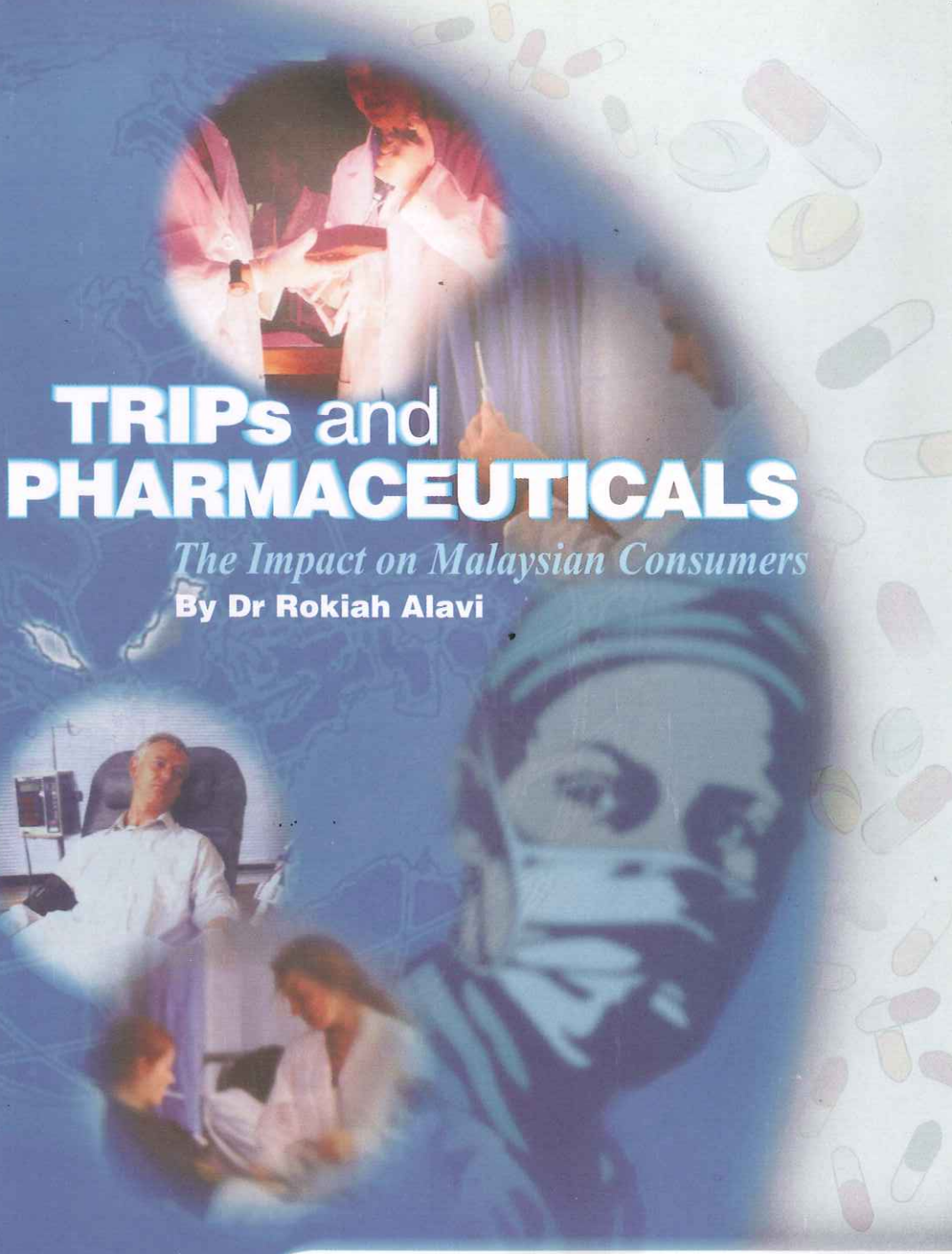

TRIPs and PHARMACEUTICALS

The Impact on Malaysian Consumers

By Dr Rokiah Alavi

Edited by:
T. Indrani

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ERA CONSUMER MALAYSIA

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[Education And Research Association for Consumers, Malaysia]

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ERA CONSUMER is a voluntary, non-political and non-profit organization. ERA focuses on issues ranging from food security, human rights, environment and consumer rights to women's rights for a socially just and equitable society.

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FOREWORD

Debate rages today all over the world over the pricing of essential drugs for the ill and afflicted, and their availability. The row over the drugs to treat or keep in check HIV and AIDS needs special mention, for it proves the heartlessness of pharmaceutical companies in an environment where millions of people are dying from the disease every year across Africa and Asia.

While pharmaceutical companies have a strong case for guarding their patent rights over products on which they spent millions of US dollars to develop, consumers and consumer advocates are increasingly concerned over the blatant theft of the age-old remedies of indigenous traditional healers and from ancient societies like India and China, and genetic modification of tropical herbal plant varieties by multinational pharmaceuticals for commercial sale as proprietary drugs.

It is often argued, and has even been proven, that the monopoly protection of a commercially successful drug can provide huge returns that more than make up for the required investment in its discovery or research and development. Hence, the great pressures MNCs exert on the governments of developing countries to disallow the local manufacture of successful, essential drugs or the import of cheaper generic versions.

In recent times, as the debate over the high cost of AIDS drugs to the Africans (and to people outside the developed world as well) rages, two large pharmaceutical companies offered to sell their AIDS drugs in Africa at below their profit or production costs. However, the prices still remain high and NGOs have argued that it would still be cheaper to allow the drugs to be copied for local manufacture.

ERA Consumer is pleased to come out with this publication in the midst of this raging debate, with focus on the situation in Malaysia and to try contribute positively to the role the TRIPs Agreement can play in public health, with some recommendations for policy decisions. It is our hope that cool heads will prevail in this heated debate, and that the right of consumers to good health is not trampled upon.

MARIMUTHU NADASON
President
ERA Consumer Malaysia

TRIPs AND PHARMACEUTICALS: THE IMPACT ON CONSUMERS

Introduction

The Agreement on Trade-related Intellectual Property Rights or TRIPs is an integral part of all the agreements that come under the World Trade Organisation (WTO). TRIPs prescribes the minimum levels of protection in various areas that a WTO member country must have, and lays down the constraints which the holder of intellectual property rights (IPRs) has in the exercise of the rights.

IPRs are legal and institutional devices to protect creations of the mind such as inventions, works of art and literature, and designs. They also include marks on products to indicate their difference from similar ones sold by competitors. Over the years, the concept of IPR has been widened to include not only patents but also copyright, industrial designs and trademarks, trade secrets, plant breeders' rights, geographical indications and rights to layout designs and "undisclosed information".

Patents, copyright and trademarks are arguably the most significant in terms of their economic importance, their historic role in the industrialisation of Europe and North America, and their current standing as pillars of the international law of intellectual property rights. For example, patents provide inventors with legal rights to prevent others from using, selling or importing their inventions for a fixed period.

All WTO members must enact national laws that subscribe to the provisions of the TRIPs Agreement and implement these laws, or amend existing laws to comply with the TRIPs provisions. The countries must also ensure that their laws permit effective action against any act of infringement of intellectual property rights.

This study intends to evaluate the impact of the TRIPs Agreement on the protection of patents in the pharmaceutical sector in Malaysia. Patents are considered the most complicated and problematic area under TRIPs. Malaysia presents an interesting case because patents have been granted to pharmaceutical products and processes since the introduction of such laws in the then Malaya.

In fact, the Malaysian standard is considered high; going by the international standard, even before the advent of the TRIPs Agreement. For many developing countries, patents were not granted for pharmaceutical products mainly to ensure the accessibility of essential drugs to the large majority of the population. This was because product patents have a direct impact on prices of drugs. The introduction of product patents in the TRIPs Agreement

therefore became one of the most controversial issues in the WTO, and its inclusion was persistently rejected for many years. Social policy commitments to provide people access to inexpensive drugs were responsible for many countries adopting lenient patent laws (Vohra, 1998:2).

IPRs have never been more economically and politically important or controversial than they are today. Patents, copyrights and trademarks are frequently mentioned in discussions and debates on such diverse topics as public health, education, agriculture, trade, industrial policy, biodiversity conservation, biotechnology, information technology and the entertainment and media industries.

Drug companies have been widely accused of taking advantage of their patent rights by charging exorbitant prices for essential medicines such as AIDS drugs. Indigenous peoples and advocacy groups supporting their rights condemn multinational companies for being "biopirates" by making money out of their knowledge and claiming patent rights for "inventions" that were actually stolen from these communities.

Concerns are raised that patenting plants, animal genes and gene fragments is not only unethical but may also be stifling innovation. Developing countries complain that they are being pressured, under the WTO, to introduce Western-style IPR regimes even before they are ready to adopt them, and worry that this situation puts them at a serious disadvantage in this era of rapid technological change.

Critics of IPRs argue that the way the TRIPs Agreement is worded allows multinational companies (MNCs) to raise prices of essential drugs to levels that are too high for the poor to afford, limit the availability of educational materials to school and university students in developing countries, legitimise the piracy of traditional knowledge and undermine the self-reliance of resource-poor farmers.

According to a study conducted by the United Nations Conference on Trade and Development (UNCTAD) and the International Centre for Trade and Sustainable Development (ICTSD), it is impossible, with any certainty, to calculate the long-term impacts of TRIPs on developing countries and their populations. However, the study maintains that the developing and least developed countries will incur short-term costs in the form of administration and enforcement, and rent transfers, and that these will outweigh the benefits.

The cost-benefit balance will vary widely from one country to another, but in many cases the costs will be "extremely burdensome". The World Bank, in its report *Global Economic Prospects and the Developing Countries 2002,* states that if TRIPs were fully implemented, rent transfers to the major technology-creating countries – particularly the United States, Germany and France – in the form of pharmaceutical patents, computer chip designs and other intellectual property would amount to more than US20 billion a year.

In the year 2001, multinational pharmaceutical companies initiated legal proceedings against the Government of South Africa, arguing that the laws it had presented to Parliament would permit parallel import of generic versions of patented drugs, and therefore in breach of the TRIPs Agreement. However, the massive adverse publicity the action generated resulted in the corporations dropping their suit.

While relaxing international patent rules that restrict the manufacture and sale of generic drugs is one way of increasing the availability of essential drugs, another option is to widen access to treatments for the poor, provide incentives for research into diseases that most afflict the poor and even establish a global fund to make available for the poor essential drugs at affordable costs.

Recent Developments

With all countries outside the developed block teaming up on the issue of affordable essential drugs for their peoples, the United States led the developed nations in blocking the efforts of the developing and least-developed countries at the meetings on the TRIPs Agreement and Public Health at the Fourth Session of the WTO Ministerial Conference held in Doha from Nov 9-14, 2001.

The African Group fought hardest against the US-led minority at the deliberations and in the end saw its language watered down, despite all the efforts at mediation put by, to a certain extent, the European Commission. The Doha Declaration nevertheless "recognised the gravity of the public health problems affecting developing and least developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics".

However, the ministers stressed the need for the WTO Agreement on TRIPs "to be part of the wider national and international action to address these problems". How? By affirming that the Agreement "can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines to all. In this connection, we affirm the right of WTO Members to use, to the full, the provisions in the TRIPs Agreement, which provide flexibility for this purpose".

Developing and least-developed countries do not think that the agreement is flexible where their needs and concerns matter. The Ministers further declared that "we recognise that these flexibilities inclcude ... in applying the customary rules of interpretation of international law, each provision of the TRIPs Agreement shall be read in the light of the object and purpose of the Agreement ..."

Paragraph 6 of the Doha Declaration has raised particular concern. The paragraph states that the WTO Ministers "recognise that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of licensing under the TRIPs Agreement". The Ministers therefore instructed the TRIPs Council "to find an expeditious solution to this problem and to report to the General Council before the end of 2002".

At the on-going meeting of the TRIPs Council in June 2002, 13 developing countries – Bolivia, Brazil, China, Cuba, the Dominican Republic, Ecuador, India, Indonesia, Pakistan, Peru, Sri Lanka, Thailand and Venezuela formally submitted proposals on access to affordable, essential medicines.

Arguing that access to public health-related products is not limited to countries with insufficient or no pharmaceutical manufacturing capabilities, the 13 countries argued that Article 30 of the TRIPs Agreement should be interpreted so as to "recognise the right of WTO Members to authorise third parties to make, sell and export patented public health-related products without the consent of the patent holder to address public health needs in another country".

Therefore, the acts of making, selling and exporting public health-related products under this circumstance could be recognised as "limited exceptions to the exclusive rights conferred by a patent". The countries also argued that the spirit of the limited exceptions in Article 30 does not unreasonably conflict with the normal exploitation of the patent and does not unreasonably prejudice the legitimate interests of the patent owner".

We will have to wait for the close of the year, to find out what the WTO Council on TRIPs and Public Health will decide, but going by how the developed nations have always had the edge in WTO deliberations, the developing and least-developed nations may have to, in the end, find more drastic solutions to their problems on their own, despite and in spite of the TRIPs Agreement.

THE SCENARIO IN MALAYSIA

From the very beginning, foreign MNCs owned more than 95% of the patents in Malaysia. This only goes to prove that patents have hardly been a policy tool for encouraging local inventive activities. The main role of patent protection is to exclude competitors from using foreign patented inventions and innovations. This is in contrast to its role in the developed countries, where the pharmaceutical industry is highly research intensive and patent protection plays a very crucial role in the development of the industry.

The importance of patent protection in the pharmaceutical industry is increasing and therefore it is useful to study the impact of strengthening protection for patents in Malaysia, in line with the TRIPs Agreement on the pharmaceutical sector.

Two main parties will be negatively affected by patent protection: the local producers and the consumers. Evidence from some developed and developing countries shows that patent protection is a hindrance to the development of local producers and has impeded domestic scientific and technological advancement. Patent protection can also adversely affect consumers, particularly in terms of drug pricing and access to drug therapy. Patented drugs are very expensive and therefore many users may not be able to get access to these drugs, with the poor being the worst affected.

All this while, Malaysians have not truly felt the burden of expensive drugs because the national health system had been heavily subsidised. However, recent developments in Malaysia, such as the privatisation of the health sector, the currency crisis as well as the "merger mania" among the large international pharmaceutical firms have alerted relevant authorities and people at large that there is a need to review the drug pricing policy and to re-examine relevant TRIPs provisions to minimise the impacts of a strengthening TRIPs regime under the WTO rule.

This review is done in three sections, with the first section providing a general overview of the TRIPs Agreement. This involves a brief evaluation of the framework of the agreement and the comparison to the standards of IPR protection in Malaysia. The discussion in section two aims to evaluate the implications of patent protection on consumers. The impact of patent protection on producers will not be addressed here. Some recommendations and policy suggestions are laid out in the last section.

TRIPs AGREEMENT AND MALAYSIA'S GENERAL POSITION

Features of the TRIPs Agreement

The TRIPs Agreement came into force on Jan 1, 1995. It has seven parts and 73 articles (Vohra, 1998:6). The structure of the Agreement on TRIPs is as given in Table 1.

Table 1 : Salient features of the TRIPS Agreement

Part I	General provisions and basic principles
Part II	Standards concerning the availability, scope and use of intellectual property rights: I. Copyright and related rights II. Trademarks III. Industrial designs IV. Geographical indications V. Patents VI. Layout-designs (topographies) of integrated circuits VII. Protection of undisclosed information VIII. Control of anti-competitive practices in contractual licences
Part III	Enforcement of intellectual property rights: I. General obligations II. Civil and administrative procedures and remedies III. Provisional measures IV. Special requirements related to border measures V. Criminal procedures
Part IV	Acquisition of maintenance of intellectual property rights and related inter-parties procedures
Part V	Dispute prevention and settlement
Part VI	Transition arrangements
Part VII	Institutional arrangements: final provisions

Source: GATT (1 994: 365). Taken from Vohra (1998:6).

The TRIPs Agreement has been referred to as a "minimum standards agreement", and the WTO has emphasised that it is not intended to be a harmonisation of agreement. This means that WTO member countries must conform to the minimum requirements established by the agreement and members are free to provide more extensive protection of intellectual property within their own legal systems. The minimum standards are set at a level broadly comparable

with that in the main industrial countries. The agreement sets the standards by requiring the members first, to comply with the obligations of the main conventions of the World Intellectual Property Organisation (WIPO), the Paris Convention and the Berne Convention. Secondly, the TRIPs Agreement adds a substantial number of additional obligations on matters where the pre-existing conventions are silent or are seen as being inadequate. Therefore, this agreement is sometimes referred to as the Berne-and-Paris-plus agreement.

TRIPs gives all WTO members transitional periods so that they can meet their obligations under it. However, there are two important substantive obligations that have been effective since TRIPs came into force on Jan 1, 1995. One is the so-called "non-backsliding" clause in Article 65.5 which concerns changes made during the transitional period, and the other the so-called "mail box" provision in Article 70.8 for filing patent applications for pharmaceutical and agricultural chemical products during the transitional period.

The transitional period, which depends on the level of development of the country concerned, is defined in Articles 65 and 66. Developed countries were given a one-year transition period, meaning that they had to comply with all the provisions under TRIPs by Jan 1, 1996. Developing countries were given a general transitional period of five years until Jan 1, 2000 while those countries on the United Nations list of least-developed nations were given 11 years from Jan 1, 1995 to comply.

Malaysia's compliance with the provisions under TRIPs

Malaysia has complied with most of the provisions under the TRIPs agreement. Areas that require changes or formulation of new legislation are under review, with the assistance of the experts from the WTO and WIPO. Table 2 shows comparison between the TRIPs Agreement standards and the existing Malaysian intellectual property protection legislation.

The standards of the Malaysian intellectual property laws are at an equal level compared to that of the TRIPs Agreement, except in a few areas. The Malaysian government is seriously looking into this matter and a TRIPs Working Committee has been formed under the Ministry of Domestic Trade and Consumer Affairs to come up with new legislations on:

1. Plant varieties
2. Layout-designs of integrated circuits
3. Geographical indications
4. Performers' rights
5. Neighbouring rights

In addition, a number of changes and amendments to the existing legislation are being

prepared to ensure compliance with the TRIPs Agreement. They are:

1. An amendment to the Patents Act – the term for patent protection will be amended to 20 years from the filing date, instead of 15 years from date of grant of the patent as provided under the Malaysian Patents Act.
2. An amendment to the Trademarks Act to include protection for well-known marks.

Table 2: Malaysia's General Position on Norms and Standards of TRIPs Agreement

DE FACTO TRIPS STANDARD	MALAYSIA'S POSITION
Patents	**Patents**
• Members shall comply with provisions of the Paris Convention of 1967.	• The requirement of TRIPs provisions on Patents are generally covered by the Malaysian Patents (Amendment) Act 1993.
• A minimum patent duration of 20 years from filing.	• A minimum patent duration of 15 years from date of grant of patent (the amendment will be made).
• The term of protection is counted from the date of filing.	• The term of protection is counted from the date of grant (the amendment will be made).
• Extension of the protection of a patented process to the products directly obtained by that process.	• Same
• No discrimination against certain fields of technology or against foreign inventions.	• Reservations against Israel (Malaysia does not have diplomatic relations with Israel). There are efforts to resolve this matter.
• Use of compulsory licence only in exceptional cases.	• The compulsory licensing provisions in the Patent Act are under consideration to meet the requirement of Article 31 of the TRIPs Agreement.
• Biotechnological – excluded from patent protection may be: plant and animals other than micro-organisms, and essentially biological processes for the production of plants and animals, other than non-biological and micro-biological processes. Plant varieties should be protected either by patents and/or an effective *sui generis* system.	• There are reservations on the issue relating to the protection of plant and animal varieties. Discussions on protection for plant varieties are in progress to decide on whether to protect them through the amendment of the Patents Act or through the enactment of a specific law on Plant Varieties.

Trademarks	**Trademarks**
• Members shall comply with the provisions of the Paris Convention.	• The Trademarks (Amendment) Act 1994 complies with the provisions of the Paris Convention.
• Service marks to be protected in the same way as marks distinguishing goods.	• The provisions on service marks were well covered by the amendment of the Act in 1994, which provides for registration and protection of service marks.
• Well-known marks to be protected as well.	• There is no provision for well-known marks in the Malaysian law, but consultations are going on with WIPO on how to recognise well-known marks.
• Cancellation of a mark on the grounds of non-use cannot take place before three years of uninterrupted non-use has elapsed, unless valid reasons based on the existence of obstacles to such use are shown by the trademark owner.	• Same.
• Initial registration, and each renewal of registration, of a trademark shall be for a term of no less than seven years. The registration shall be renewable indefinitely.	• Same.
Copyright	**Copyright**
• Members shall comply with Articles 1 through 21 of the Berne Convention of 1971.	• The Copyright (Amendment) Act 1990 complies with the provisions of the Berne Convention (1971) as well as the TRIPs Agreement.
• Computer programmes (software) are to be protected under copyright laws as literary works which can be protected for at least 50 years.	• Computer programmes (software) are protected under the Copyright Act.
• Compilation of data or other materials, whether machine readable or other form, which by reason of the selection or arrangement of their contents constitute intellectual creations, shall be protected under copyright law.	• Compilation of data is also protected under the Act.
	• The Act also provides for rental rights to all eligible works.
• The authors of computer programmes and cinematographic works are provided with exclusive rental rights.	• Malaysia has always accorded protection to producers of sound recordings and broadcasts under its copyright law.
• Producers of phonograms shall enjoy the right to authorise or prohibit the direct or indirect reproduction of their phonograms. Broadcasting organisations shall have the right to prohibit the following acts when undertaken without	• Malaysia is not a party to the Rome Convention and therefore performers are not protected under the current act. However, Malaysia is in the process of coming up with a legislation for the protection of performers.
	• Same.

their authorisation: the fixation, the reproduction of fixation, and the re-broadcasting by wireless means of broadcasts, as well as the communication to the public of television broadcasts of the same.

- Performers shall also have the possibility of preventing the following acts when undertaken without their authorisation: the broadcasting by wireless means and the communication to the public of their live performance.
- Term of protection shall be no less than 50 years.

Geographical indications

- Geographical indications which identify goods as originating in a particular territory, or a region or locality in that territory, where a given quality, reputation or other characteristics of the goods are essentially attributable to their geographical origin. There is a special law for geographical indications.
- The registration of a trademark which contains a geographical indication shall be refused or invalidated.
- Additional protection for geographical indications for wines and spirits are still being negotiated under TRIPs.

Geographical indications

- Malaysia does not have a specific law on this. There are on-going consultations with WTO and WIPO on this matter.

Neighbouring rights

- Malaysia does not have any law to cover neighbouring rights.

Industrial designs

- Independently-created industrial designs that are new or original shall be protected. Designs that are not new or original may be provided protection if they do not significantly differ from known designs or combinations of features of known designs.
- Each member shall ensure that requirements for securing protection for textile design, in particular in regard to

Industrial designs

- Industrial design protection in Malaysia is currently accorded by virtue of registration under the Registered Designs Act 1949 of United Kingdom.
- Malaysia is in the process of promulgating a law on industrial designs which will generally conform with the Paris Convention and the TRIPs Agreement.

any cost, examination or publication, do not unreasonably impair the opportunity to seek and obtain such protection. Members shall be free to meet this obligation through industrial design law or through copyright law.

- A minimum total duration of protection of at least 10 years.

Layout-designs of Integrated Circuits

- Protection to the layout-designs of integrated circuits is provided in accordance with Articles 2 through 7 and paragraph 3 of Article 16 of the Washington Treaty on Intellectual Property in respect of Integrated Circuits.
- Protection term of 10 years.
- Protection covers also equipment containing a protected chip.
- Compensation in case of innocent infringement.
- Use of compulsory licence only in exceptional cases.

Layout-designs of Integrated Circuits

- Malaysia does not have specific law to cover this subject matter, though the layout designs can be protected as artistic works under the Copyright Act or under the Industrial Design Act.
- Malaysia does not foresee any problem complying with the agreement.

Sources:

** *Sources on TRIPs Standards:*

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- WIPO (1996), "Agreement on Trade-Related Aspects of Intellectual Property Rights", Annex IC

** *Sources on Malaysian Position:*

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- Hafisah Mustaffa (1995), "Malaysia's Perspective on the TRIPS Agreement - The View from the Malaysian Government", paper presented at WIPO/ASEAN National Seminar on The Agreement on TRIPS and Its Implications for Business Enterprises, July 27-28 1995, Kuala Lumpur.
- Interviews with officers at the Ministry of Domestic Trade and Industry, Malaysia.

Enforcement of the IPRs Protection

WIPO in 1996 highlighted that the major problem in the international law of intellectual property has been on the issue of enforcement. A substantive and high standard of protection of intellectual property is of little use if rights cannot be effectively enforced. Thus, a major set of obligations in the TRIPs Agreement requires members to provide domestic procedures and remedies so that rights holders can enforce their rights effectively. The provisions on enforcement have two basic objectives:

1. to ensure that effective means of enforcement are available to rights holders;
2. to ensure that enforcement procedures are applied in such a manner as to prevent the creation of barriers to legitimate trade and to provide for safeguards against their abuse.

The provisions on enforcement contained in Part III of the agreement are divided into five sections. The first section lays down general obligations that all enforcement procedures must meet. The second requires that civil judicial procedures must be available in respect of any activity infringing intellectual property rights covered by the agreement. The third section deals with provisional measures each country must take to ensure that its judicial authorities have the authority to order prompt and effective provisional measures, both to prevent infringing activity from occurring and to preserve relevant evidence.

The fourth section deals with border measures that must be applied, at least in respect of imports of counterfeit and pirated goods, and in respect of goods infringing other intellectual property rights as well as provides corresponding procedures concerning infringing goods destined for export. The final section deals with criminal procedures. Provision must be made in cases of willful trademark counterfeiting or copyright piracy on a commercial scale. Sanctions must be sufficient to provide a deterrent, consistent with the level of penalties applied for crimes of corresponding gravity. Criminal remedies in appropriate cases must also include seizure, forfeiture and destruction of the infringing goods and of materials and instruments used to produce them. A further general point concerning enforcement is that, in joining the TRIPs Agreement, countries will commit themselves to establish contact points in their national administrations and be ready to exchange information with one another on trade in infringing goods.

In Malaysia, intellectual property is a new area for the Customs, the Enforcement Division of the Ministry of Domestic Trade and Consumer Affairs and for the judiciary. No study has yet been undertaken to evaluate compliance with the enforcement provisions under TRIPs and its costs. However, surveys on systems of intellectual property rights by taking US standards as the basis for analysis tend to list a large number of enforcement inadequacies in developing countries (US International Trade Commission, 1988; Gadbaw and Gwynn, 1988). Problems often mentioned include the slowness of the enforcement processes;

discrimination against foreigners; biased court decisions; inadequate civil and or criminal remedies and corruption.

It can be very costly to have an efficient and up-to-date enforcement system, and therefore many developing countries encounter an enormous financial burden to keep up with the standards demanded by the TRIPs Agreement. The United States, for example, spends more than US$300 million each year to operate the Patent and Trademark Office (Sherwood, 1990b: 181). Furthermore, the enforcement component of a "mature" intellectual property rights system is much more difficult for developing countries to emulate (Primo Braga, 1990).

The Malaysian government perceives the provisions on enforcement as "too detailed" and according to it, among the provisions that could pose some difficulties are:

1. The requirement that procedures for IPRs should not entail unreasonable time limits or unwarranted delays – this surely will mean extra workload for the enforcement authorities;
2. The requirement that decisions on the merits of a case shall be in writing and reasoned. This is not the norm in Malaysia and the need for the decisions to be made available without undue delay also amounts to additional obligations;
3. The provision on border measures – at present only the copyright law provides for border prevention. The Trade Descriptions Act may have to be amended to cater to border prevention for trademarks;
4. The provision on the duration of suspension – the time limit imposed could pose a problem to the Customs;
5. Increasing staff and financial allocations for the enforcement authorities to implement the existing and new legislation (including additional staff for the judicial and legal services); and
6. Additional financial allocation for the purchase of equipment and machinery as well as for skills improvement in the enforcement capabilities of the enforcement officers.

Hafisah (1995b) noted that intellectual property would require more attention from the enforcement unit of the Ministry of Domestic Trade and Consumer Affairs, judicial and Customs authorities like never before because the volume of international trade in intellectual property is expected to increase in the near future. This will surely increase the workload of the enforcement unit, judicial and Customs authorities, and it is expected that they will be burdened by pressure from importers and exporters to comply strictly with TRIPs requirements. Therefore, it is imperative that the judicial and Customs authorities be knowledgeable in this subject as well as be sufficient in staff strength and related facilities.

Pharmaceutical Patents

A report by the United Nations, (1993:6) states that product patents and trademarks are the two most important forms of protection for the pharmaceutical industry (see Table 3). According to Wijk and Junne (1993), the pharmaceutical industry particularly has become very sensitive about the legal protection for its products in recent years, because of three major developments.

First, the industry has been experiencing a growing R&D expenditure. Pharmaceutical firms spend a higher percentage of their sales revenue on research than any other high-technology industry, and three times as much as other chemical and related industries (WIPR 1991:336). They invest a minimum of 10% of their sales revenue on R&D (Wijk and Junne 1993:28). The US International Trade Commission noted that between 1976 and 1990, the cost of taking a drug from discovery to marketing approval in the United States increased from US$54 million to US$231 million (WIPR 1991:336).

Table 3: Subject matter and main fields of application of intellectual property rights

Types of intellectual property rights	Subject matter	Main fields
Patents	new, non-obvious, indigenous applicable inventions	chemicals, drugs, plastics, engines, turbines, electronics, industrial, control and scientific equipment
Trademarks	signs or symbols to identify goods and services	all industries
Copyright	original works of authorship	printing, entertainment (audio, video, motion pictures) software, broadcasting
Integrated circuits	original layout designs	microelectronics industry
Breeders' rights	new, stable, homogeneous,	agriculture and food industry
Trade secrets	secret business information	all industries
Industrial designs	ornamental designs	clothing, automobiles, electronics etc.

Source: UNCTAD (1993) Table 2 p.9

The second factor is increasing competition from the generic drugs industry. Generic drugs are neither protected by patents nor brand names and are mostly based on compounds of which the patent protection has expired (Wijk and Junne 1993:28). As the price of generic drugs is usually low compared with that of patent-protected drugs, the use of generics has been encouraged by many public authorities in most OECD countries in order to reduce the

cost of healthcare. This also has been the case in many developing countries, for example, India, Sri Lanka, Argentina, Brazil, Indonesia and Thailand.

Another development which put enormous pressure on the pharmaceutical industries is the copying of protected drugs in the developing countries. Most of the drugs that have been marketed in the world can be easily copied and pirated by competitors, just by knowing the active ingredients in the formulation of a particular drug. Such information is public knowledge.

It has been estimated that 23% of the market for patented drugs in the mid-1980s in Argentina, Brazil, India and Mexico, valued around US$5.9 billion, was supplied by domestic companies copying protected drugs (Noques 1990:86). It takes 12 years to discover and develop a new drug, at an average cost of US$359 million, and statistics show that only 30% of the drugs sell well enough for the average research and development costs for a new drug to be recouped (Lewis 1996). The high cost demonstrates the value of intellectual property rights to pharmaceutical companies. A good example is the piracy of Feldene, Pfizer's best-selling anti-arthritic drug. It took 10 years of research and a budget of US$125 million to develop the drug and a 1987 survey found that 12 Thai companies were producing generic products based on the Feldene formula.

The introduction of patents for pharmaceutical products was the most controversial aspect of the TRIPs Agreement. The right to a patent is defined as "the right to secure the enforcement power of the state in excluding unauthorised persons, for a specified number of years, from making commercial use of a clearly identified invention" (Machlup 1). For an invention to be protected by a patent, it must provide a novel solution to a technological problem, involve an inventive step and be industrially applicable (Blakeney 1996:12).

There are two major types of patent protection for pharmaceuticals, i.e product patent and process patent. The product patent refers to the chemical structure defining a chemical compound. In pharmaceuticals, the product patent is the most useful patent because it grants protection regardless of the method used to produce the compound or the intended use of the compound (Lewis 1996). Patent protection granted to a pharmaceutical product is given the following privileges under the provisions of Article 5A of the Paris Convention (Balasubramaniam, 1988):

1. An exclusive right to manufacture, import and distribute the pharmaceutical product in that country. However, there is no obligation that the drug should be manufactured locally.
2. Prevent others from manufacturing, importing and distributing that pharmaceutical product in that country.

Process patents, on the other hand, are directed at protecting the "means of obtaining" an end result (Lewis 1996). Process patents protect two things: the process of making the product and the process of using the product to treat a disease. The protection given by process patents is regarded as rather weak and relatively easy for a competitor to violate (Azmi and Alavi, 1999). This is mainly because alternative processes of manufacture are relatively easy to devise and it is impossible for the innovator to patent all possible routes. In addition, it will be extremely difficult to determine which process is being used by a copier, and this facilitates piracy and infringement.

Malaysia provides both product and process patents under its Patents Act 1983. In Malaysia, the life of patent is as long as 15 years from the date of the granting of the patent. To ensure compliance with the TRIPs Agreement, this provision is in the process of review and will be changed to 20 years from the date of filing. There are four exceptions given in the Patents Act of Malaysia:

1. The exclusion of methods of human and animal treatment;
2. The exclusion of discovery and scientific theories;
3. The discovery of biological processes for the production of plants or animals, as opposed to microbiological processes, and;
4. Plant or animal variety.

Methods for the treatment of human or animal body are not patentable in Malaysia, and this is contained in section 13(1) of the Patents Act 1983. This exclusion is confined only to methods of treatment and does not extend to the products, particularly substances and compounds, and the apparatus that are used in such a method (Azmi and Alavi, 1999). Medicinal plants are not patentable in Malaysia. However, Malaysia is in the process of adopting the International Union for the Protection of New Varieties of Plants (UPOV) model law on plant and animal variety to comply with the TRIPs Agreement.

In Malaysia, foreign patents constitute a large proportion of the total number of patents applied for and granted (see Table 4). Between 1986 and 1998, foreigners owned 96% of the total patents applied for and 97% of all the patents granted. Patent ownership among Malaysians is therefore very low compared with patent ownership in the developed countries. In comparison, residents in Japan and the US owned 87% and 56% respectively of the total patents granted in 1996. Even in Thailand, the local patent ownership figure was much higher, at 31%.

Table 4: Patent and Utility Innovation Applications Received and Granted (Oct 1, 1986 to July 31, 1998)

Country/Year	1986	1987	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	Total
Applications														
Malaysian (%)	11.1	2.2	4.5	4.5	4.0	4.4	6.7	6.9	6.2	4.4	4.0	2.8	3.1	4.3
Foreign (%)	88.9	97.8	95.5	95.5	96.0	95.6	93.3	93.1	93.8	95.6	96.0	97.2	96.9	95.7
Total Number of Patents	262	3266	1620	1887	2305	2427	2410	2882	3587	4177	5575	6451	3534	40383
Granted														
Malaysian (%)	-	-	0	8.3	3.9	2.8	0.9	1.1	1.3	1.7	4.4	6.6	3.5	12.7
Foreign (%)	-	-	100	91.7.	96.1	97.2	99.1	98.9	98.7	98.3	95.6	93.4	96.5	97.3
Total Number of Patents	-	-	6	132	518	1050	1134	1284 1	629	1753	1801	789	461	10557

Source: Calculated from statistics obtained from the Ministry of Domestic Trade and Consumer Affairs, Malaysia.

The number of patents granted to pharmaceutical manufacturers is not known because the Patents Office does not record its data according to the Malaysian Industrial Classification system. The classification of patents granted is done according to the field of technology and they are divided into eight categories as listed in Table 5. Pharmaceuticals fall under the "Human Necessities" category. As can be observed from the Table 5, this category had the second largest number of patents that were granted between 1988 and 1997.

However, checks with pharmaceutical firms in Malaysia indicate that local manufacturers do not own any patent because they are not involved in R&D activities and innovations. All pharmaceutical patents in Malaysia are owned by foreign multinational companies. There were 62 multinational firms operating in Malaysia in 1998. Smithkline Beecham is the major player in the pharmaceutical market in terms of sales, while the other dominant firms are Glaxo, Wellcome, Merck Sharp and Dohme Division, Roche (M) Sdn Bhd and Novartis Corporation. The market share of these firms in terms of annual turnover (see Table in Appendix 1) seems to imply that there is a strong competition between them. However, this is not necessarily the case because these firms actually concentrate on a few therapeutic segments and therefore enjoy monopoly power.

It can therefore be concluded that the level of IPRs legislation in Malaysia is of a high standard and is in compliance with most of the provisions stipulated in the TRIPs Agreement. Patent rights have been granted to pharmaceutical products and processes long before Malaysia's political independence, and it is apparent that patents granted to foreign MNCs in Malaysia are being used to protect their imports. As a result, MNCs gain opportunities to dominate the entire Malaysian market for a particular therapeutic segment, thus effectively becoming monopolists. Theoretically, a monopolist can and will charge a higher price and produce less in order to maximise profits. This is how consumers will be adversely affected.

Table 5: Malaysian patents based on field of technology
(Oct 1, 1986 – Aug 31, 1997)

Field of Technology	1988-92		1993		1994		1995		1996		1997		Total	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
Human Necessities	727	26	215	17	260	16	336	19	285	16	105	19	1928	20
Performing Operation; Transportation	553	19	169	13	267	16	268	15	323	18	95	18	1675	17
Chemistry; Metallurgy	818	29	503	39	505	31	542	31	483	27	146	27	2997	30
Textiles; Paper	42	1	15	1	12	1	27	2	31	2	9	2	136	1
Fixed Constructions	154	5	37	3	71	4	48	3	76	4	19	4	405	4
Mechanical Engineering; Lighting; Heating; Weapons; Blasting	174	6	52	4	79	5	61	3	103	6	34	6	503	5
Physics	186	7	155	12	192	12	194	11	178	10	49	9	954	10
Electricity	186	7	138	11	243	15	277	16	322	18	84	16	1250	13
Total	**2840**	**100**	**1284**	**100**	**1629**	**100**	**1753**	**100**	**1801**	**100**	**541**	**100**	**9848**	**100**

Source: Intellectual Proprty Division, Ministry of Domestic Trade and Consumer Affairs, Malaysia, unpublished

THE IMPACT OF TRIPs ON CONSUMERS

The main concerns of consumers about healthcare are costs of treatment and access to the prescribed drugs. If the prescribed drugs for certain illnesses are branded and patented, the cost of medical treatment can be extremely high. Even though the drug market in many developing countries has seen increasing sales of generic drugs, there are some illnesses, however, that require the use of patented drugs. This is mainly because the drug therapy discovered for these illnesses is relatively new and drugs are protected under product and process patents for 20 years.

For example, Ceredase, the only drug therapy for Gaucher's Disease[1], costs more than US$100,000 for a year of treatment (Fisch, 1994, 296). Other examples include the tissue plasminogen activator for heart attack victims, priced at US$2,800 a dose, and Retrovir, an anti-viral drug for HIV and AIDS patients, priced at US$2,400 for a year of treatment[2]. Undoubtedly, patent protection, which provides pharmaceutical firms with the exclusive rights necessary to control the output and pricing of new drugs, is the main reason that the prices of these drugs are excessively high.

Malaysia relies heavily on imported medicines, with 70% to 80% of its drug requirements being imported (Ministry of International Trade and Industry, 1998:169). Some 60% of these imports are patented. The ratio of imports of drugs to consumption rose from 87% in 1996 to 92% in 1998, implying an increasing need for imported drugs and the inability of domestic producers to cope with rising demand for drugs in a domestic scenario where the per capita income rose over the years (see Table 6).

Table 6: Imports, production and local demand of pharmaceuticals, 1996-1998

Year	Imports (RM million)	Production (RM million)	Local Demand (RM million)	Ratio of production to consumption[a] (%)	Ratio of imports to consumption[a] (%)
1996	838	334	960	35	87
1997	1000	34	1142	30	88
1998 *(estimate)*	1004	353	1087	32	92

Source: Data for production, imports and local demand are obtained from MIDA (1998), MIDA Industry Brief April, unpublished.

Note: [a] consumption is equivalent to local demand.

[1] *Gaucher's Disease (Glucosyl Cerebroside Lipidosis) is a genetic disorder that causes the body to under produce the enzyme required to break down glycolipids. The excessive amounts of glycolipids lead to intense pain, and in younger patients, sometimes death (Fisch, 1994).*

[2] *Please refer to Fisch (1994) for sources of these prices.*

This is in sharp contrast with the situation in the US and the European Union nations, where the ratio of imports to consumption was only 2.7% and 17.5% respectively in 1989 (see Balance et al. 1992: 52). On the other hand, the ratio of production to consumption in these countries was 99.5% and 108.7% respectively in the same year. In Malaysia, the ratio was only 30% to 35%.

In 1995, the balance of trade in pharmaceutical products was in deficit of almost RM400 million. The figures on exports and imports also show that the rate of growth in exports is much slower than imports, thus widening the trade deficit over the years (see Table 7).

In Malaysia, patented drugs are imported directly by local subsidiaries of MNCs which own the patent or by their licensed agents. The operations of the multinational pharmaceutical companies in the country are mainly restricted to marketing their products which are imported, while inbound logistics, outbound logistics, inventory control, warehousing, order processing and distribution are handled mostly by their distributors. The two largest pioneers in pharmaceutical distribution in Malaysia are Diethelm and Zuellig. Diethelm handles the distribution for companies such as Abbot, Hoechst, Bayer, Boehringer Ingelheim, Bristol Meyers Squibb, Johnson and Johnson, Roche, Sandoz and Sterling Drugs. On the other hand, Zuellig handles the distribution for companies such as Astra, Ciba, Eli Lilly, Glaxo-Wellcome, E. Merck, Reckitt and Coleman, Rhone Poulenc, Schering Plough, Seven Seas, Smithkline Beecham and Upjohn.

Table 7: Balance of Trade in Pharmaceuticals, 1988-1995

YEAR	EXPORTS (RM'000)			IMPORTS (RM'000)			BALANCE OF TRADE (RM'000)		
	SITC 541	SITC 542	TOTAL	SITC 541	SITC 542	TOTAL	SITC 541	SITC 542	TOTAL
1988	2151	33070	35221	68526	17477	96003	-66375	15593	-50782
1989	22520	38227	60747	72657	228299	301056	-50137	-190172	-240309
1990	29422	40217	69639	79891	232856	312747	-50469	492639	-243108
1991	33652	46729	80381	81945	273681	355626	48293	-226952	-275245
1992	2409	52092	54501	81713	345141	626854	-79304	-293049	-372353
1993	30698	49507	80205	82454	283700	366154	-51756	-234193	-285949
1994	41592	63780	10537F	91943	328780	420723	-50351	-265000	-315351
1995	59284	74787	134071	1198918	412381	532195	-60530	-337594	-398124

Source:Malaysia, Department of Statistics, various years
Note: SITC 541: Medicinal and Pharmaceutical Products
SITC 542: Medicaments (Including Veterinary Medicaments)

Such a heavy dependence on imported and patented medicines will clearly have a significant impact on the cost of healthcare. The impact of such a dependence is apparent from the

consumer price index (CPI) for medical care and health services in Malaysia, which rose steadily in the 1990s. Between 1994 and 1997, the cost of healthcare was increasing at about 3% to 4% annually (Ministry of Finance, 1998). In 1998, the CPI for the health sector rose by 6%. The impact of increasing medical bills is reflected in the government expenses as well. The government budget for healthcare has increased significantly from RM2.2 billion in 1994 to RM3.3 billion in 1996. It increased further to RM3 .6 billion in 1999 (Ministry of Finance, 1998), despite the privatisation efforts.

The relationship between patents and drug prices

There is a direct relationship between patent protection and the prices of drugs. Patent rights accord the patentee with a monopoly power. With this, the firm earns an opportunity to dominate the drug market, and consequently, to charge high prices. It is important to note that patent protection creates monopolists because of the weaknesses in the patent system itself.

Balasubramaniam (1998) suggests a few factors that made patent protection a source of monopoly power. Firstly, patents provide the patentee the exclusive right to exploit the innovation commercially for a certain length of time. Second, a patent can be used to prevent the importation of cheaper products even though the cheaper substitutes are available in the international market. Third, the patent may prevent a local manufacturer from starting the production of similar products, even if the patentee does not set up production facilities in that country. During this period of time, no other drug company is allowed to manufacture the patented drug, while the import and distribution of the patented pharmaceutical product is done either by the company which own the patents or by a licensed agent. Producing, importing or distributing the drug without the permission of the owner means violating the patented drug company's rights. Thus, it is this market power which grants patent owners the opportunity to charge high prices for their products.

When a new product is launched, the manufacturer will be the sole source of that particular drug (refer to graph in Appendix). During the first stage (A-B), the pioneer drug has no competitor and claims monopoly power in the market. Patent protection provides the pharmaceutical company the authority to evade any possible competition, thus enhancing further its market power. The price of the drug will be at its highest level during this period, as the producer attempts to recoup the high costs incurred in developing the drug as fast as possible[3].

After a period of time, rivals enter the market, with molecular modified drugs, and take away some of the inventor's market share. However, the patent protection for the pioneer drug exists throughout the period AE, despite the therapeutic competition from rival innovators. Once the patent expires, competitors can legally use the same active ingredients as the originating firm and competition from generic drug producers begins.

[3] *The discussions in this paragraph are substantially from Balance et al. (1992).*

In practice, pioneer drug producers continue to sustain their market power and keep their prices high by instilling confidence and manipulating the perception of consumers and doctors about the superiority of their drugs. Heavy investment in advertising and effective marketing strategies are carried out to ensure users would eventually associate brand names with a particular disease or illness. Hence the importance of trademarks in this industry.

Non-working of patents

During the early period of the patent system, patent owners were obliged to exploit patents by producing in the country granting the patent (Wijk and Junne, 1998). In addition, imports of patented products were allowed and parallel importation was not considered as forfeiting the legal rights of the patent owner. However, revisions to Article 5A of the Paris Convention have resulted in a progressive weakening of the patent-working requirements. Consequently, current patent laws give patent owners a legal right which does not require them to utilise their patents in production [4].

Developing countries raised their concerns about the importance of imposing more stringent working obligations on foreign patent holders and they argued that the import of patented products does not constitute the working of an invention (Wijk and Junne 1993). Industrialised countries, on the other hand, argued that it may be uneconomical for a company to exploit its patent in all countries where the patent is recognised. They perceive the prevention of the unauthorised copying of a patented product or process in the importing country as one of the core functions of the patent. Therefore they asserted that the definition of working a patent also includes importing the product.

As a result, most of the patents granted in the developing countries are not being exploited in production. Katz (1998) found that in Argentina, out of 102 patents granted, only 15 were actually under exploitation, 29 covered current imports and the remaining 58 patents were not under present exploitation. A certain fraction of those 58 patents were "abandoned", i.e. the maintenance fees had not been paid regularly to keep them "active", while yet another fraction were being kept active, either for future utilisation or for the protection of future imports. This is clearly in contrast with the US data, where 50% to 60% of the patents granted in the US were commercially exploited (UNCTAD, 1997). Katz therefore states that the role of patents as instruments for import protection is quite apparent in Argentina.

A survey done in 1998 on foreign owned multinational companies in Malaysia shows that 100% of the patents granted (both process and product patents) have not been used for production (see Table 8). Almost all patents have been utilised for covering imports. However, there are some companies granted patent protection which did not utilise the patents for production, nor to cover their imports.

[4] *Most countries have compulsory licensing provisions where by if a patent if not 'worked' within a stipulated period of time, the patent holder may be obliged to license the patent right to another person in return for compensation (Blakeney, 1996)*

Table 8: The usage of patent protection granted to MNCs in Malaysia, 1998

No.	Company	No. Of Patent Granted	Type Of Patent	Usage		
				Locally exploited for production	Utilised for covering present import	NOT being presently used in production nether for covering the present import
1	Multinational involved in production of generic drugs, packaging imported products, marketing distribution of imported products	23	product	×	✓	×
2	Multinational involved in marketing and distribution of imported products	100	product	×	✓	×
3	Multinational involved in marketing and distribution of imported products	more than 50	product and process	×	✓	✓
4	Multinational involved in marketing and distribution of imported products	1	petty patent	×	✓	×
5	Multinational involved in marketing and distribution of imported products	31	product and process	×	✓	✓
6	Multinational involved in marketing and distribution of imported products	15	product and process	×	✓	×
7	Multinational involved in marketing and distribution of imported products	27	product	×	✓	×
8	Multinational involved in marketing and distribution of imported products; producing generics	many	product and process	×	✓	✓
9	Multinational involved in marketing and distribution of imported products	more than 30	product and process	×	✓	×
10	Multinational involved in marketing and distribution of imported products, and producing generic drugs	6	process	×	×	✓
11	Multinational involved in marketing and distribution of imported ported products	18	product	×	✓	×

Source: Based on questionnaires and interviews.

Since almost all patents granted to MNCs in Malaysia have never been exploited for domestic production, we can expect this to have an adverse effect on the prices of patented drugs. This is clearly evident in the Malaysian drug market.

Drug prices in Malaysia

It has been found that price differences between a patented drug and its alternative with the same pharmacological classification can be as high as 219,000% (Ministry of Health, 1996). The significant contrast between prices of generic drugs and branded (or original) drugs are as shown in Table 9. For example, the cost of the branded anti-rheumatic drug Voltaren (Diclofenac Na) 25mg is RM0.27 a tablet, which is 900% higher than the generic equivalent which costs only RM0.03 a tablet. Similarly, the price of one tablet of the generic anti-histamine, Terfenadine 60mg, is RM0.119, compared with its branded equivalent which is priced at RM0.42 a tablet. The price difference is 221%. Such contrast is more notable for the antibiotic Amoxycillin Oral Suspension 125mg/5ml, that is 1,044%.

Table 9: Price comparison between local generic products and the original (branded) products (1996)

Therapeutic categories	Chemical Entity	Unit dose/pack size	Average local generic price (RM)	Original (Branded Price (RM)	Difference in Price between Generics and Branded (%)
Antirheumatics	Naprosyn 250mg Diclofenac Na. 25 mg	1 tab 1 tab	0.19 0.03	0.48 0.27	253% 900%
Antiulcerants	Cemetidine 200 mg Cimetidine 400 mg	1 tab 1 tab	0.11 0.21	0.20 0.40	180% 190%
Antiasthmatics	Ketotifen Syrup 1 mg/5ml Ketotofen Tab 1 mg	100 ml 1 tab	4.82 0.15	15.00 0.72	311% 80%
Antihistamines	Terfenadine Tab 60 mg	1 tab	0.19	0.42	221%
Antibiotic O.S.	Amoxycillin O.S. 125 mg/5 ml	60 ml	1.14	11.9	1044%
Topical Steroids	Clobetasol Propionate 0.05% cream	450	32.22	151.43	470%

Source: Malaysian Organisation of Pharmaceutical Industries, as reported in the Molt Press Release dated Feb.16, 1996, obtained from http://prn.usm.my/edl/esentia2.html

The situation worsens because there is no law in Malaysia to control the prices of drugs sold in the market. This is surprising because many other developing countries, and most of the developed countries, have some sort of price controls on pharmaceuticals. In developing countries, the main reasons for imposing price control have been to restrain possible market

exploitation by foreign multinationals, medicines being a "basic need", and the low level of purchasing power of consumers in general. However, the reason why the Malaysian government takes the stand of not controlling the prices of drugs is that the government believes that market competition among drug companies alone is sufficient to ensure fair and reasonable prices. However, the drug industry is not as homogeneous as it seems (Ng, 1994), and therefore the absence of price control has had an adverse effect on the prices of drugs in Malaysia.

There are at least two distinctive categories of drug companies in Malaysia, where one is more prone to price competition while the other is more monopolistic. The generic drugs market is highly competitive and their prices are among the lowest in the world. In this market, price control may not be necessary as there are sufficient price competitors to keep the prices of the drugs in check. However, there is a lack of competition in the patented drugs market. This is because the MNCs that control this market concentrate on only a few therapeutic segments rather than the entire product category. Table 10 shows the product portfolios of selected major multinational firms in Malaysia and it clearly demonstrates the product concentration of the MNCs in a few therapeutic segments.

Table 10: Product Portfolios of Multinational Pharmaceutical Organisations in Malaysia

Name of the Company	Number of products	Major Therapeutic Segments/Product
Glaxo	30	Gastrointestinal (Zantac) Respiratory (Ventolin)
Bristol Meyer Squibbs	33	Cardiovascular (Capoten)
Pfizer	18	Anti-infectives (Zithromax, Vibranycin, Unasyn, Trosyd & Cefobid)
Roche	37	CNS (Librium, Dormicurn & Valium)
Upjohn	30	Hormones (Depo-Medrol, Depo Provera & Dalacin-C)
Wellcome	33	Anti-infective (Zovirax & Septrin) Respiratory (Actifed & Sidafed)
Zeneca	22	Anti-infective (Hibitane & Fulcin) Cardiovascular CFenormin)

Source: Haresh (1996), Table 2, page 18

Having a monopoly power would mean that MNCs will have the tendency to practice price discrimination to maximise profits. The drug market will be segmented and prices set according to what the market can bear. Balasubramaniam (1995) revealed that retail prices for 100 tablets of 150mg Zantac, manufactured and marketed by the same manufacturer, varied from US$2 (in India) to US$196 (in Chile). The prices in two least-developed countries, Mongolia and Tanzania, were found to be higher than that in advanced countries like Australia, Canada and New Zealand. Similar price discriminations are practised in Malaysia as well. Table 11 provides some examples of price discrimination between Malaysia and the United Kingdom. The price difference for the same drug in Malaysia and the UK ranges between 8% and 529%.

Table 11: Comparison between the prices of drugs in Malaysia and the UK

Brand Name	Prices in RM		Difference Between Malaysian Price Compared to the UK Price (%)
	United Kingdom	Malaysia	
Apresoline	39.40	191.40	386
Claforan	11.16	22.00	93
Catapres	6.08	38.25	529
Inderal	10.13	34.80	244
	22.50	63.65	183
	18.23	57.93	218
Adalat	16.15	22.90	42
Betaloc	37.70	148.30	293
Ternormen	30.80	35.35	25
Pirilon	20.00	33.00	65
Dermavali	33.20	41.00	24
Ceporex	66.20	79.00	19
Ventolin	24.40	27.50	13
Zantac	131.40	142.50	8
Diabenane	193.80	210.80	9
Augbritin	147.20	195.30	33
Penbritin	64.50	76.90	19
Tagamet	302.60	427.10	41

Source: Ng (1994), Table 6.2, page 125.

In addition, drug prices in Malaysia increase at a faster rate than that in the developed countries. The prices of drugs in Malaysia increased by 7% to 28% between 1990 and 1992 while prices of drugs in general remained the same in the UK during the same period (Ng, 1994:128). Out of five types of prescriptions, prices in the UK increased by 4.1% to 15.7%, but the prices of the same drugs increased by 10.2% to 30.9% in Malaysia. The average price increase for the five drugs in 1998 was 1% in UK and 20.7% in Malaysia.

The freedom to set prices has induced retailers to impose excessive mark-ups on drug prices. *Utusan Konsumer* (July 1998) highlighted that the mark-up price of drugs sold in Malaysia was between 50% and 1,500%, and this is not the usual practice in other countries. Ng (1994:130) noted that retailers charge consumers 60 to 1,000 times more than the price paid for the same drug in bulk. For example, the bulk prices of paracetamol and diazepam are both RM16 for 1000 pills or 1.6 sen each, but paracetamol is sold to consumers at five sen each and diazepam at 25 sen. There is a 200% profit margin for paracetamol and 1,460% for diazepam.

It can therefore be concluded that when there is an absence of government intervention in regulating the drug market, patent protection will emanate its worst adverse effects.

POLICY RECOMMENDATIONS

Having established that the patent system has a significant effect on the prices of drugs, we also see that even worse adverse effects arise when there is lack of government regulation of the market for medicines. This indicates that the government has an important role to play to dilute and balance the monopoly power of the huge pharmaceutical firms through the patents regime. We therefore make some policy recommendations that can bring about more sanity in the pharmaceutical market.

Price Control Policy

Prices of patented drugs in Malaysia are extremely high compared to their generic substitutes, if compared with the same drugs and brands overseas, and the prices change and increase faster compared with other countries. The main reason for this wide disparity is the absence of price supervision and control by the government. The Malaysian government cannot ignore these phenomena, for they are not only burdensome for the consumers, but also eat up the government fiscal budget and have negative repercussions on the balance of payments. Introducing a price control policy will redress the impact of the high prices of drugs and stabilise the price variations. The TRIPs Agreement does not prevent the use of price controls, so long as it is administered in a "non-discriminatory" way.

Compulsory Licensing

Vohra (1998:44) suggests that strategies to combine price controls with compulsory licensing may be an effective measure to suppress the prices of patented drugs in the market Compulsory licensing would increase output and decrease prices by creating marketplace competition within a patent-protected pharmaceutical industry (Fisch, 1994:297). A compulsory licence requires the patent owner to permit any person to manufacture, sell, or use the patented invention at an established fee. Thus, it breaks the monopoly power of the patent owner by increasing the output of the patented drug.

The TRIPs Agreement provides compulsory licensing whenever the patent holder refuses to grant a voluntary licence on reasonable commercial terms and conditions within a reasonable period. A compulsory licence is also permissible under the Malaysian Patents Act 1983. It is normally granted on two grounds, insufficient working and interdependence of patents. Under the insufficient working clause, an application for compulsory licence is normally made to the Registrar, on two grounds:

i. there is no production of the patented product or application of the patented process without any legitimate reason;

ii. there is no product produced under the patent for sale in any domestic market, or there are some but they are sold at unreasonably high prices or do not meet the public demand without any legitimate reason.

A compulsory licence granted as a result of the inter-dependence of patents takes place when an invention cannot be worked in Malaysia without infringing a patent granted on the basis of an application benefiting from an earlier patent. Correa (1999:1) noted that the provisions of a compulsory licence have become a typical feature in patent laws worldwide, and at the beginning of the 1990s, around 100 countries recognised such licences.

In Malaysia, the concept of compulsory licensing has not been invoked so far, and therefore never granted to any local manufacturer since the promulgation of the Patents Act 1983. This is despite the fact that none of the patents owned by MNCs are being worked locally. This is common in other countries as well, where the number of compulsory licences granted has been low (Correa, 1999:22).

The main reason for this is an Article 31 provision that imposes a serious burden on the compulsory licensing system, for it opens up the possibility of the licence being terminated as soon as the circumstances that led to its granting cease to exist. This condition discourages applications for compulsory licences, since the licensee may be exposed to the revocation of the right at any time (see Correa, 1999: 8).

However, a large number of compulsory licences have granted in the developed countries (see Correa, 1999: 22). As a result of this, a significant reduction in prices for medicines was reported in these countries. For example, as a result of the grant of compulsory licences in Canada, the cost of the drugs so licensed reduced by US$211 million. In 1991-92, compulsory licensed generics were priced at 55.6% of the equivalent brand name product and the savings to the consumer were estimated at US$171 million (Shondelmeyer, 1993: 3-4). Thus, the compulsory licence system is capable of mitigating the prohibitive effect of exclusive rights and striking a balance between a patent holder's interest and the social and political objectives.

In conclusion, compulsory licensing should be effectively used, for it has is already been incorporated into the Malaysian Patents Act. Correa (1999) emphasised that developing countries should seek to clarify the scope for the granting of such licences in certain cases (e.g. non-exploitation), as well as to strategise for the removal of some of the restrictive conditions imposed by the TRIPs Agreement, notably Article 31.g, in coming WTO negotiations.

Parallel Imports

Another strategy to suppress the patented drug prices is by exploiting the parallel import provision that is granted in the TRIPs Agreement. Parallel importation of patented goods is allowed in Malaysia. However, in practice, parallel importation has hardly been used, even though there is clear evidence of over pricing of patented drugs in the local market. Parallel importation means that if a patent holder charges a higher price in one market and a lower one in another, the higher price country can import from a lower-price country without the permission of the patentee (Vohra, 1998:10). The rationale of parallel importation is that the patent owners should not be allowed to segregate the market according to geographical areas and unilaterally determine and dictate the price of goods.

Table 12 shows the disparity in the price of Zantac in neighbouring countries in Asia and this happens mainly because parallel imports are not being practised in these countries, either due to MNC control over distribution of the drugs, or because it is not allowed under local patents laws.

Table 12: Retail prices in US$ for 100 tablets of Zantac in 11 Asian countries

Countries	Zantac (100 x 150 mg) in US$
Bangladesh	9
India	2
Indonesia	41
Malaysia	55
Mongolia	183
Nepal	3
Pakistan	22
Philippines	63
Sri Lanka	61
Thailand	37
Vietnam	30

Source: Retail Drug Prices: The Law of the Jungle, HAI News No.1000, April 1998. Taken from Balasubramaniam (2000:18)

In Malaysia, parallel importation is virtually absent because the distribution of patented drugs is controlled by the patent owners. The escalating prices of drugs in Malaysia justifies the need to practise parallel importation, particularly from India. Using Zantac as an example, importing it from India would mean that Malaysians will get access to this medicine at a very low price (US$2), compared with the existing local price of US$55.

Promoting Generic Substitutes

The government can also neutralise the impact of patents on drugs by promoting the use of locally manufactured generic drugs. This can be done by listing these drugs in the Essential

Drugs List (EDL), and educating members of the public on the advantages of using generic drugs. The use of generics has many advantages. Their use does away with trademarks, one of the major sources of market power in the industry (UNCTAD, 1981:8). As explained earlier, the potential entry into the pharmaceutical market is made more difficult because of brand loyalty on the part of consumers. Such entry barriers can be expected to be lowered once generics are introduced, and as a consequence, competition in the industry will intensify.

Increased competition in the pharmaceutical market will facilitate the bringing down of drug prices, especially prices of essential drugs that are not patented and available from multiple sources. Evidence from various countries where generics have been encouraged confirms this expectation. The earliest examples of generic-based drug procurement bringing down prices of drugs can be found in the experience of the United States in the late 1950s. Evidence from Sri Lanka and Costa Rica, which have switched to procurement based on generic names, suggests that substantial savings can be achieved in import costs once procurement tenders are invited on the basis of generic names (UNCTAD, 1981).

The Health Minister has been quoted as encouraging doctors to use generics as a cost-saving measure (*New Straits Times,* Jan 17, 1998). In early 1998, as a result of the currency crisis, the government called for the use of locally-made generics after prices of imported drugs (both generics and branded) rose sharply. As a result of this, by October 1998, procurement by Remedy from local producers increased to 60% from about 30% in 1997. This is in line with global trends. Even in countries with strong pharmaceutical industries like Britain and the US, there is a significant market penetration by generics. For example, in Germany, Denmark, the United States and the Netherlands, pharmacists are allowed to substitute generic drugs for branded ones. Though generic substitution is generally opposed by the industry in Britain, the use of generics has reportedly grown from 16% of the prescriptions in 1977 to 54% in 1994 (Dzulkifli, 1998).

However, the success of a policy to switch from branded drugs to generics depends upon its acceptance by the principal agents i.e. doctors, pharmacists and producers and importers as well as upon the existence of a government regulated system of quality control for drugs (UNCTAD, 1981). Studies have shown that doctors and patients have a preference for imported, branded drugs as a result of the aggressive and successful promotional activities of the multinational drug companies. This is not surprising, since these firms have one of the highest rates of sales promotion expenditures per value of sales. The whole objective of advertising is to convince the doctors of the importance of prescribing branded drugs (O'Brien, 1977:5). As a result, patients who are prescribed specific branded medicines can be influenced by such practices. The ignorant patient relates to the brand name and the medicine and if in future, he has the same complaint and can purchase the drug without a prescription, the chances are he will ask for the medicine of the same brand name that he had he used before. The implication of this according to, O'Brien (p.5) is that "Tetrex, Tetracyn, Tetrarco, Hostacycline, Uocycline, Ambramycin, Probacycline, Achromycin and Hycycline are all

trade names under which the antibiotics tetracycline is available. A patient with a prescription for Achromycin will go from one chemist to another and be told that the drug is out of stock whereas the chemist would have the same drug, under other brand names".

Therefore, there is a need to educate both consumers and doctors to overcome any bias or negative perception towards the use of generic products. In the US, the Federal Drug Administration (FDA) has been actively involved in providing consistent support for generics (Dzulkifli, 1998). In February 1997, the FDA was reported to have defended generic drugs for being "as good as the branded ones". In Malaysia, the Sub-Committee on Public Education Towards Quality Drug Use, formed by the Pharmaceutical Services Division of the Ministry of Health, will have to undertake a more pro-active role in this aspect. Local producers of generic drugs, on the other hand, must uphold their social responsibility by ensuring that the copies produced are of quality, of a high standard and as effective as the original.

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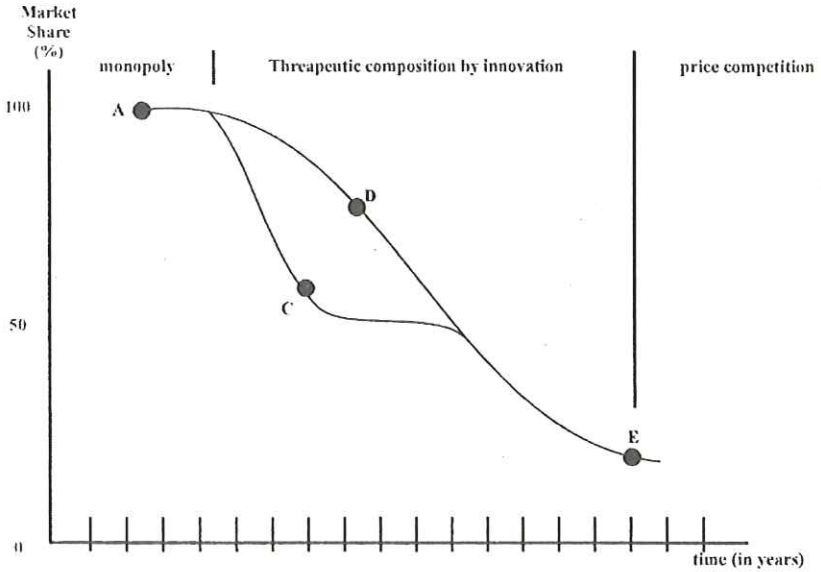
APPENDIX

Table A1: Turnover of foreign firms and their Market Share, November 1998, (RM million)

Company	Sales	Market Share*
SB International	99.3	9.1
Glaxo Wellcome	62.4	5.7
MSD	42.5	3.9
Roche	36.9	3.4
Novartis	34.6	3.2
Janssen Cilag	30.7	2.8
Pfizer	30.4	2.8
Astra	29.0	2.7
Pharmacia Upjohn	28.1	2.6
Ahott	27.4	2.5
BMS	22.7	2.1
Servier	21.0	1.9
Warner Lambert	20.5	1.9
The Boots	19.4	1.8
RPR	18.2	1.7
Schering Plough	18.2	1.7
Sanofi	18.1	1.7
Zeneca	12.2	1.1
Organon	11.6	1.1
HMR	11.1	1.0
Wyeth	10.9	1.0
Ranbaxy	10.0	0.9
Bayer	9.7	0.9
3M	9.4	0.9
Rhodia	8.9	0.8
Reckitt and Coleman	8.8	0.8
Eli Lilly	8.2	0.8
Merck	8.1	0.7
CCM Pharma	7.7	0.7
Summit	7.6	0.7
Zuellig Pharma	5.9	0.5
Synthelabo	5.9	0.5
B. Mannheim	4.3	0.4
UCB Asia Pacific	4.3	0.4
Faulding	4.1	0.4
Eisai	3.7	0.3
Nutrigen	0.3	0.0
Total	711.7	65.5
Total Local Demand	**1087**	**100.0**

Source: PhAMA, 1998 and MIDA, Industry Brief April 1999
* market share - percentage of sales to total market demand.

Figure 1: Monopoly and competition in the life cycle of a pioneer drug.



Source: UNIDO. Based on Figure 8.2 in Balance et al. (1992:207)

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The Education and Research Association for Consumers, Malaysia (ERA Consumer, Malaysia) is a voluntary, non-profit and non-political organisation that was founded in Ipoh, Perak in 1985. ERA Consumer is a registered membership organisation under the Malaysian Societies Act of 1966. It was set-up to undertake and promote the task of developing critical consciousness on public-related issues out of the larger socio-economic issues.

ERA Consumer is a dynamic institution that is constantly responding to and developing its services according to the needs and demands of the people. It aims to create awareness among the public on issues that are effecting their lives, through research and educational programmes by undertaking independent, authoritative, balanced research on public issues; carrying out public education projects; making policy recommendations to the government & international institutions; building solidarity and understanding among NGOs in Malaysia and society at large, and to increase South-South relations and North-South understanding. ERA Consumer's components and main programmes are consumer issues; human rights education; food, trade and economics.

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