PhAMA

'Innovative Medicines for Malaysia'

Overview Of Intellectual Property And The Pharmaceutical Industry :

PART 1

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Executive Summary

Intellectual Property ("IP") rights are defined by the World Trade Organization as "rights given to people over the creations of their minds". As a developing country, a strong IP regime is critical for Malaysia to boost its competitiveness, especially to attract foreign direct investment ("FDI") while at the same time encouraging technological advancement and innovation. In order to become a high-income nation, Malaysia must focus on attracting high quality FDI with more research and development ("R&D") expenditure and value added exports.

The pharmaceutical industry regards patents as the most important amongst all the legal instruments of protection that are available for IP. This is because patents allow the pharmaceutical industry to protect for a limited time the commercial rights of the drugs and medicines that are invented by them. The R&D efforts that are undertaken by innovator pharmaceutical companies are high-risk and costly ventures with no guarantee of positive returns.

Once a drug has been successfully created, it is susceptible to being copied by third parties through reverse engineering as pharmaceutical compounds can be easily imitated once they have been discovered. Hence, a patent would prevent a third party from exploiting another person's invention and unjustly benefiting from it without any legal consequences. The patents granted to pharmaceutical companies have allowed them to flourish, and in the process have also enabled these companies to continuously innovate in the field of health and science, improving the quality of life of the average human being.

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

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

It is definitely possible for generics companies to thrive in a strong IP rights regime. Countries such as the United States and Germany are home to some of the biggest innovator companies in the world and yet they have a thriving generics industry existing in parallel. Contrary to popular belief, a weak IP regime does not necessarily strengthen the generics industry or facilitate access to medicine. It is worth noting that generics companies are highly dependent on the innovator pharmaceutical companies in order to come up with new products because a copy cannot exist without the invention.

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

- hinder access to newer drugs
- result in the emigration of local talents
- enable the flourishing of counterfeit medicines

In the United States, the Hatch-Waxman Act was enacted to address the competing interests of the innovator companies and the generics manufacturers by granting each, the following rights:

Table 1 Rights Granted to Innovator Pharmaceutical Companies and Generic Manufacturers by the Hatch-Waxman Act

Rights Granted to Innovator Pharmaceutical Companies by the Hatch-Waxman Act	Rights Granted to Generics Manufacturers by the Hatch-Waxman Act
Data exclusivity	Reliance on clinical trial data of the innovator after the data exclusivity period
Patent term restoration	Right to conduct clinical trials during the patent term (Bolar exemption)
Patent linkage	

PhAMA would highlight that the two "gains" by generics manufacturers in the Unites States pursuant to the Hatch-Waxman Act, i.e., Bolar exemption and the reliance on innovator clinical trial data are already rights granted to and enjoyed by generics manufacturers in Malaysia. However, innovator companies in Malaysia are given only one out of the three rights granted to innovator companies by the Hatch-Waxman Act, namely, data exclusivity and even then, that right is in a more limited form.

PhAMA has identified the following "gaps" in the existing IP regime as being the most compelling in terms of need to be addressed if Malaysia hopes to have a chance to be a leading nation not only in the pharmaceutical industry but also related industries such as healthcare, hospital services and medical tourism:

(1) **Patent Term Restoration ("PTR")**

PhAMA strongly recommends the implementation by Malaysia of a PTR system to compensate for marketing time lost while developing the product and awaiting approval by the regulatory authority.

(2) **Patent Linkage**

The adoption and implementation of a patent linkage system similar to the system in the United States is recommended.

(3) **Data Exclusivity ("DE")**

DE by way of a directive rather than through legislative enactment

PhAMA would urge the Government to have DE enacted as part of the law, possibly, through the new Pharmacy Act.

Eligibility for DE Conditional on Application Filed Within Limited Time

PhAMA strongly urge an amendment of the law so that DE eligibility shall not be conditional upon making the application for marketing authorization within any time limit.

Calculation of DE Period From the Date of First Registration in the World

The calculation of the period of DE should made from the date of local registration approval, allowing innovator companies to enjoy the full period of DE from when the drug product is approved for marketing locally.

(4) **Second Medical Usage / Indication And Dosage Regimen**

PhAMA is of the firm position that there is no validly persuasive reason to exclude new and non-obvious Second Medical Use or a new, non-obvious dosage regime from patent protection, indeed, there are good reasons to allow such patents for the benefit of society at large.

(5) **Compulsory Licensing**

Local Working Requirement

PhAMA urges further amendment of the Patents Act to remove any imposition of local working requirements.

Compulsory Licensing Under Section 84 of the Patents Act 1983 (Rights of Government)

PhAMA's position is that compulsory licenses should only be resorted to in exceptional circumstances of genuine necessity as how it was originally intended.

(6) **Administrative Enforcement Of IP Rights**

Penalties for offences related to counterfeit medicines

PhAMA strongly recommends amendments to the relevant statutes to prescribe minimum penalties that must be imposed upon conviction of an offence. The minimum fine per counterfeit item found and minimum jail terms are to replace the current provisions which prescribe only the upper limits. This will remove judicial discretion that has, often, resulted in inadequate and non-deterrent sentences.

Pharmacy Bill

PhAMA fully supports the proposals of the Pharmacy Bill. PhAMA also strongly recommends that the new Pharmacy Act provides for a rebuttable presumption relating to offences so that the possession, custody or control of three or more quantity of the same counterfeit drug is deemed (until proven otherwise) to be for the purposes of sale, trade or commerce where it is absent in the relevant legislation.

It is further strongly recommended that the new Pharmacy Act makes it an offence to print, import, produce, reproduce, publish, sell, issue, circulate, distribute or be in possession of any publication, label, printed materials or insert relating to pharmaceutical products which reproduces or substantially reproduces, closely copies or imitates the trade mark, brand, package get-up and/or copyrighted material of another without licence or consent.

Practical Issues

PhAMA strongly reiterates the need to address the weaknesses which have been identified in the current prosecution framework and processes. PhAMA fully supports the need for a more streamlined approach as has been highlighted by Point 16 of the Online Public Engagement document, which drew attention to the need to reduce bureaucracy by integrating the processes of the appointment of Drug Enforcement officers, as currently, officers are appointed by different authorities depending on subject matter.


idea

1.1 Introduction of Intellectual Property (IP)

Intellectual property (IP) is a multi-faceted field which covers a wide range of areas. The World Intellectual Property Organization (WIPO) describes IP as "creations of the mind, such as inventions; literary and artistic works; designs; and symbols, names and images used in commerce[1]." The World Trade Organization (WTO) defines IP rights as "rights given to people over the creations of their minds[2]."

Although IP may seem to be abstract or intangible, IP rights have much in common with the rights associated with real property. Most IP rights can be assigned or transferred to another person. Ownership of IP generally gives an exclusive right to exploit the property or to give others a license to do so in a variety of ways. Those who infringe on another person's IP right can be held accountable.

Over the course of history, a variety of legal instruments had emerged to protect IP. The traditional core of IP originally consisted of:

- copyright,
- patents,
- designs,
- trade marks, and
- protection against unfair competition.

These instruments differ in their subject matter, extent of protection, and field of application. A summary of each area is provided below.

Copyright protects original works of authorship and it typically lasts for the life of the author plus 50 years (in Malaysia and numerous jurisdictions). Literary and artistic works are common subjects of copyright. Copyright can also be given to those who are authors of secondary works such as broadcasting organizations and performers. It is not necessary to register copyright for the author to enjoy protection.

Patents are legal titles that grant the owner the exclusive right to make commercial use of their invention. The term of protection is limited to 20 years from the date of application of the patent and on the expiry of the term, the invention becomes available in the public domain for exploitation by others. Patent is one of the oldest and most traditional forms of IP. The pharmaceutical industry regards patents as the most important amongst all the legal instruments of protection that are available for IP. This is because patents allow the pharmaceutical industry to protect for a limited time the commercial rights of the drugs and medicine that are invented by them. ***Patent will thus be the focus of this paper.***

[1] WIPO, "What is Intellectual Property"?(WIPO Publication No. 450(E) <*http://www.wipo.int/about-ip/en/*> accessed 3 September 2014

[2] WTO, "Frequently asked questions about TRIPS" <*http://www.wto.org/english/tratop_e/trips_e/tripfq_e.htm*> accessed 3 September 2014

Industrial Design deals with the appearance of products which are commercially mass-produced. It protects the decorative and ornamental features of consumer goods such as cars, bags and furniture. The visual aspect of a product makes it more attractive aesthetically when it is marketed and as such, industrial design serves to prevent the visual aspect of the product from being copied by third parties and competitors. Registration of industrial design confers exclusive rights on the owner to make, import, sell or hire out any article to which the design is applied for.

Trade Marks are signs that identify a certain product or company. They function to enable customers to distinguish goods that are offered on sale by different companies. Trade marks also play a role in protecting a product or a firm's reputation for quality. Almost all commercial industries rely on trade marks to identify their goods and services. Trade marks are capable of being registered. Registration confers on the proprietor the presumption of validity of the trade mark and provides rights and remedies to the registered proprietor beyond that under common law. Trade marks are territorial in nature and are protected only in the territory that they are registered in. However, many countries have legislation that provides protection to well-known trade marks although they may not be registered locally or for a particular class of goods.

1.2 The Role of IP in Encouraging Development and Progress

IP has played an important part throughout history in encouraging development and progress of human civilization. This section will explore the role of IP as one of the driving factors of technological advancement in the world and how it has contributed to some of the progress of the pharmaceutical industry.

The concept of rewarding innovators or creators can be traced back to the ancient period of 4th Century B.C. where the famous philosopher Hippodamus of Miletus advocated honours for men who had benefited the state by making a discovery that was in public interest[3]. It is clear that at least by that time, individuals from different civilizations had recognised the importance of protecting human thought or intellectual property as opposed to divine religious knowledge which could not be owned[4].

The systematic protection of IP only started to gain momentum when Venice enacted the first known general patent statute in 1474. It was essentially the foundation of all future patent statutes. Patents were used to protect local craft guilds and to reward strangers who brought new knowledge to Venice[5]. The patent system in Venice enabled innovation to flourish in the city. Subsequently, the migration of Venetian artisans and craftsmen encouraged the use of patents to spread throughout Europe[6].

The first of the Northern European countries to follow the footsteps of Venice is the United Kingdom (UK). During the Industrial Revolution, the patent system made massive contributions to the innovation process and technological progress in the UK. Inventing was a risky activity and patent protection was the only realistic way to obtain a return sufficient enough to cover the cost of producing and developing inventive output[7]. The patent system functions like 'insurance' for investors and assures them that they have an avenue for compensation for inventions that are unfairly copied by third parties.

In the 20th century, IP continued to encourage development and progress of companies in the scientific field and this is especially true for the pharmaceutical industry. IP has enabled small pharmaceutical companies to flourish through innovation.

> In the late 1970s, Azithromycin was discovered by a team from Pliva, a small pharmaceutical company from Croatia. A patent application for Azithromycin was filed by Pliva in 1981 in the former Yugoslavia and subsequently patented worldwide. The patenting initiative by Pliva was the key to the commercial success of Azithromycin. Scientists from pharmaceutical multinational Pfizer Inc. came across Pliva's patent while searching the database of the US Patent and Trademark Office (USPTO) and realized the great potential of the antibiotic. As one of the largest drug makers in America with an international presence, Pfizer was able to offer Pliva the channel to commercialize its antibiotic. In 1986, talks between Pliva and Pfizer eventually led to a licensing agreement. Under the agreement, Pfizer acquired the right to sell Azithromycin worldwide while Pliva maintained the right to sell the product in Central and Eastern Europe and would earn royalties on Pfizer's sales[8].

The licensing agreement meant a huge breakthrough in terms of annual revenues and allowed Pliva to fund expansion in Europe and the United States. Zithromax, Pfizer's branded version of Azithromycin was one of the best-selling branded antibiotics in the United States and worldwide with total sales peaking at US$2 billion in 2005. Pliva's utilisation of its IP rights enabled it to commercialize the results of its R&D and opened the way to distant markets which would otherwise have seemed inaccessible. Society at large also benefited from this arrangement as Pfizer's international network meant that Pliva's useful invention would be able to reach many parts of the world instead of being restricted to Croatia, the home of Pliva. This success story had shown that even a relatively small pharmaceutical company can benefit from strong patent protection with a sound business policy[9].

IP is not only beneficial to innovator pharmaceutical companies as generics companies can also grow and progress by utilising IP rights.

Dr Reddy's Pharmaceutical Company ("Dr. Reddy's") started out as a small generics company in 1984 but it quickly grew into a large corporation. In 1992, Dr. Reddy's Research Foundation (DRF) was created to facilitate the company's drug discovery program. Over the years, the company had built a significant portfolio of IP rights to enable it to gain an important competitive advantage. The company filed its first international patent in 1995. By 2010, Dr. Reddy's alone made 267 international patent applications with DRF filing an additional 56 international patent applications. In addition, to protect the company's image as a strong brand name and to instill customer confidence, Dr. Reddy's also filed trade mark registrations for many of its products in major markets[10].

With IP, Dr Reddy's business model moved from imitator to innovator where it no longer restricts itself to the generics market but it is also breaking new grounds in the innovative medicine sector. The successful utilization of IP which brought financial success has enabled the Dr. Reddy's to become the first Indian pharmaceutical firm to be listed on the New York Stock Exchange. In addition, the company's revenue rose at an average of 23% between 2000 and 2010 with earnings of US$ 1.56 billion in 2009[11].

[3] Lily Ross Taylor, "Party Politics in the Age of Caesar" (University of California Press 1971) page 113

[4] Carlos A. Primo Braga, Carsten Fink and Claudia Paz Sepulveda, "Intellectual Property Rights and Economic Development" (Technet Working Paper) page 5

[5] Ibid.

[6] Craig Allen Nard and Andrew P. Moriss, "Constitutionalizing Patents: From Venice to Philadelphia" (2004) Review of Law and Economics 2(2), page 257

[7] H.I. Dutton, The Patent System and Inventive Activity during the Industrial Revolution, (Manchester University Press 1984) page 151

[8] WIPO, "Azithromycin: A world best-selling Antibiotic", *<http://www.wipo.int/ipadvantage/en/details.jsp?id=906>* accessed 4 September 2014

[9] Ibid.

[10] WIPO, "Innovating India's Pharmaceutical Industry", *<http://www.wipo.int/ipadvantage/en/details.jsp?id=2659>* accessed 4 September 2014

[11] Ibid.

1.3 The IP Law System in Malaysia

All the core areas of IP are protected domestically in Malaysia under several pieces of legislation. **Table 2** summarises the main areas of IP and their scope of protection in Malaysia.

Table 2 Summary of Main Areas of IP and Scope of Protection in Malaysia

Instrument of Protection	Definition	Subjects of Protection	Registration	Period of Protection
Trade Marks Act 1976	Any mark that is used for the purpose of indicating a connection between the proprietor of the mark and the relevant goods or services in the course of trade	Logo, brand, label, signature, word, letter, numeral, colour or any combination of them	Yes	10 years and renewable every 10 years
Industrial Design Act 1996	Features of shape, configuration, pattern or ornament applied to an article by any industrial process or means	Textile patterns, furniture designs, architectural structures, bottle shapes, car designs, tablet shapes and designs	Yes	Maximum of 25 years
Patents Act 1983	An exclusive right granted for an invention (product or process) that permits in practice the solution to a specific problem in the field of technology	Any new and inventive invention excluding scientific theories, mathematical methods, business schemes, methods of medical treatment for humans and animals	Yes	20 years only
Copyright Act 1987	An exclusive right granted to authors, artists and other creators for the protection of their literary, musical and artistic works, film and sound recordings	Novels, poems, films, musical, drama, paintings, photographs, sculptures, songs, newspapers	No	Life of author and 50 years after death of author, 50 years after first publication of film or sound recording

The Malaysian Intellectual Property Corporation (MyIPO) is the current statutory body that is responsible for the administration of IP matters in Malaysia including:

- the registration of IP rights
- maintenance of the IP registry and
- IP prosecution proceedings

Enforcement of IP rights can either be done through the judicial process or by the Enforcement Division of the Ministry of Domestic Trade, Cooperatives and Consumerism (MDTCC).

IP rights are not merely protected domestically in Malaysia as there is an international dimension to them. The World Intellectual Property Organization (WIPO) is one of the specialized agencies established by the United Nations to "encourage creative activity" and "to promote the protection of intellectual property throughout the world[12]." Malaysia is a member of WIPO since 1989.

INTERNATIONAL IP TREATIES

The domestic IP framework in Malaysia takes into consideration the International Treaties and Conventions that Malaysia is a party to. One of the first International IP treaties signed by Malaysia is the Paris Convention for the Protection of Industrial Property. Malaysia also acceded to the Patent Cooperation Treaty (PCT) which allows the application of a patent to be filed in different member countries through a single process.

By virtue of its membership of the World Trade Organization (WTO), Malaysia has an obligation under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) to ensure that its laws and regulations provide the minimum standard of protection for IP rights as prescribed by the Agreement in its own territory. The TRIPS Agreement is the most comprehensive international IP agreement to date which takes into account almost all of the IP rights that are in existence at the time of its signing.

[12] Preamble of the Treaty establishing the WIPO 1967


Patent Law

1.4 The Patent Law System in Malaysia

As patents are regarded as the most important and strategic IP rights to the pharmaceutical industry, a clear understanding of the genesis of the patent law system and how it operates in Malaysia is important towards understanding the need for a strong IP system and the adjunct protection unique to the industry.

An inventor who wants to patent his invention in Malaysia has to fulfil the requirements of patentability under the Patents Act 1983.
The four requirements of patentability can be summarized as:

a) New
b) Involves an inventive step
c) Industrially applicable
d) Does not fall under any exclusions in the Act

The conditions for patentability under the Patents Act 1983 are strict and it ensures that only deserving inventions are protected under the Act.

However, there may be some minor inventions which are new but do not satisfy the strict requirement of an inventive step. Nevertheless, the idea was that minor inventions should still be protected to encourage creative thinking and innovative activities. This led to the introduction of the second tier protection system or utility model system in these countries. The alternative system is devised in such a way that they are normally cheaper and faster to obtain than a standard patent. The duration of protection is also generally shorter to compensate for the lower level of invention. In Malaysia, the second tier protection system is known as utility innovation. There are several differences between a patent and a utility innovation and they are summarised in **Table 3** below:

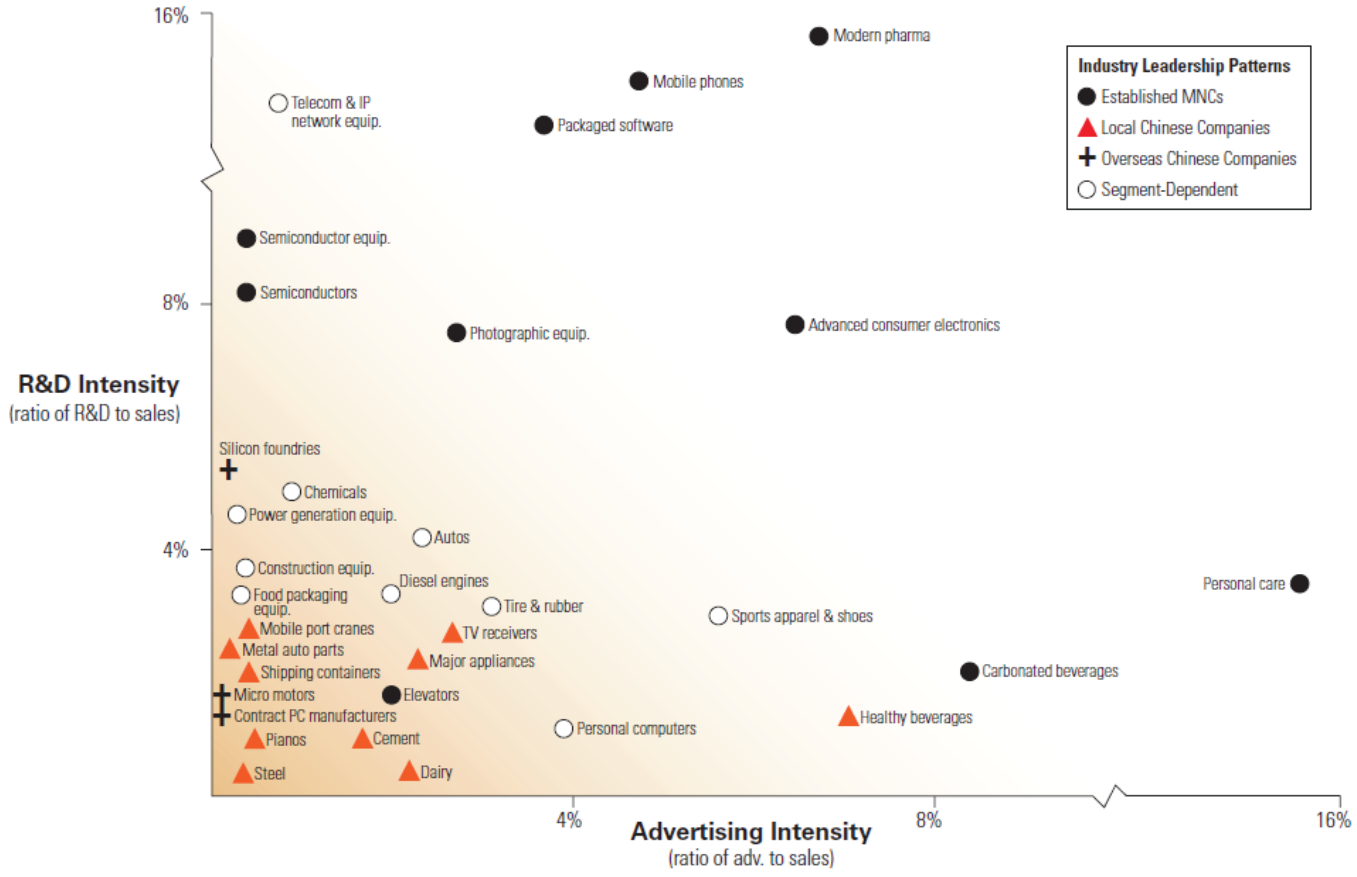
Table 3 Differences between Patent and Utility Innovation

	Patent	Utility Innovation
Duration	20 years	10 years with a possibility of being renewed for two additional five years period
Novelty	Yes	Yes
Inventive Step	Yes	No
Industrial Application	Yes	Yes
Excluded List	Yes	Yes
Number of Claims	Multiple	One

1.5 The Importance of IP Protection to the Pharmaceutical Industry

Innovation is the engine that drives the pharmaceutical industry and it is an industry that relies heavily on research and development (R&D) for its survival and progress. The pharmaceutical industry spends approximately 16%-17% of its sales on R&D as compared to the computer industry which spends around 8%, the electronics industry at 6% and the aviation industry at less than 4% of its sales[13]. A brief overview of China's industry landscape by the Harvard Business Review in 2008 also reveals the pharmaceutical industry as the most research-intensive industry in the country as compared to the other industries (See **Graph 1**).

Graph 1 Overview of China's Industry Landscape by the Harvard Business Review



Source: Harvard Business Review, November 2008, page 84

[13] Thomas B. Cueni, "Industrial Property Protection – Lifeline for the Pharmaceutical Industry" cited in Thomas Cottier and Peter Widmer (eds), "Strategic Issues of Industrial Property Management in a Globalizing Economy" (Hart Publishing 1999) page 14967

The R&D efforts that are undertaken by pharmaceutical companies are high-risk and costly ventures with no guarantee of positive returns. Over an estimated period of 12 years, the R&D of a new drug would require more than 10,000 substances tested before 1,000 compounds can be isolated for advanced testing. Only 1 out of the 1000 compounds will eventually become an effective drug which can be made available for patients in the commercial market. With each new drug also comes the incremental depletion of long-established chemical possibilities which in turn raises the bar for further chemical discovery[14].

The cost of R&D that is incurred by pharmaceutical companies is high. At the start of the 21st century, the cost of R&D per drug that is incurred by a pharmaceutical company is estimated to be US$802 million (in 2000 dollars). In 2013 dollars, this figure translates approximately to US$1.04 billion. According to the latest study that is released in 2014 by the Tufts Center for the Study of Drug Development, the new estimated cost of developing a new drug is now US$2.56 billion, an increase of almost 145% between the two study periods. According to DiMasi, rising drug development costs have been driven mainly by increases in out-of-pocket costs for individual drugs and higher failure rates for drugs tested on human subjects.

Given the high cost of pharmaceutical R&D, there is a need to safeguard the investments of time, manpower and finance by the pharmaceutical companies into their inventions which comprised primarily of drugs. Once a drug has been successfully created, it is susceptible to being copied by third parties through reverse engineering as pharmaceutical compounds can be easily imitated once they have been discovered.

The solution adopted by pharmaceutical companies to protect the expensive investments that had been poured into their inventions is through the utilisation of IP rights which they had gained as creators of their inventions. In the field of IP protection, pharmaceutical companies regard **patents** as the most important IP right for their commercial activity. Patents provide the protection that pharmaceutical companies need for their inventions and the commercial activities that are associated with them.

ONCE A DRUG HAS BEEN SUCCESSFULLY CREATED, IT IS SUSCEPTIBLE TO BEING COPIED BY THIRD PARTIES THROUGH REVERSE ENGINEERING AS PHARMACEUTICAL COMPOUNDS CAN BE EASILY IMITATED ONCE THEY HAVE BEEN DISCOVERED.

WITHOUT PATENT PROTECTION, AN INVENTOR WOULD BE RELUCTANT TO REVEAL HIS INVENTION BECAUSE ANYONE WOULD BE ABLE TO COPY HIS INVENTION AND UNJUSTLY BENEFIT FROM HIS INVENTION WITHOUT ANY LEGAL CONSEQUENCES.

[14] D. Wayne Taylor, "Pharmaceutical Access in Least Developed Countries: on-the-ground barriers and industry successes" , Cameron Institute Report Fall '10, page 8

[15] Joseph A. DiMasi, Ronald W. Hansen and Henry G. Grabowski, "The price of innovation: new estimates of drug development costs" (2003) Journal of Health Economics 22, page 180

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

[17] Supra Note 4 at page 28

The Concept of A Patent

A patent is essentially a grant of a limited monopoly by a government to an inventor for his new invention. This limited monopoly provides the inventor with exclusive rights over his invention which includes exclusive commercial exploitation for a period of time. At the end of the patent term, the invention falls into the public domain and anyone is legally free to make use of it.

Without patent protection, an inventor would be reluctant to reveal his invention because anyone would be able to copy his invention and unjustly benefit from his invention without any legal consequences. As a result, the public will not benefit from any new advances that his invention may offer. Patent protection therefore rests on the basis of a social contract between the inventor and the state whereby the inventor agrees to disclose the scientific and technical knowledge contained in his invention to the public in exchange for the guarantee of a limited monopoly to benefit exclusively from his invention.

With the disclosure of inventions through patents, society in general will be able to increase its pool of knowledge. This social contract also reflects the balance of interests between the inventor's right to profit from his invention and the advancement of technical knowledge in society.

That the patent system is pivotal to the pharmaceutical industry has been affirmed in numerous surveys undertaken throughout many decades. A 1973 survey by Taylor and Silberston revealed that the pharmaceutical industry is critically and almost uniquely dependent on patent protection. Surveys conducted by Mansfield from 1981 to 1983 in the United States of America showed that pharmaceutical companies have a very high likelihood of resorting to patents to protect their invention. The survey revealed that pharmaceutical companies had patented 82% of their inventions and they have one of the highest rates of patent filings compared to other industries (see **Table 4**).

[14] D. Wayne Taylor, "Pharmaceutical Access in Least Developed Countries: on-the-ground barriers and industry successes" , Cameron Institute Report Fall '10, page 8

[15] Joseph A. DiMasi, Ronald W. Hansen and Henry G. Grabowski, "The price of innovation: new estimates of drug development costs" (2003) Journal of Health Economics 22, page 180

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

[17] Supra Note 4 at page 28

Table 4 Percentage of Patentable Inventions that were Patented, Twelve Industries, 1981-83

Percentage of Patentable Inventions That Were Patented, Twelve Indutries, 1981-83[a]		
Industry Group or Industry	All Firms	Firms with 1982 Sales Exceeding $1 Billion
Industry groups: Industries (Pharmaceutical, Chemical Petroleum, Machinery and Fabricated Metal Products) where patents are relatively important	84	86
Industries (Primary Metals, Electrical Equipment, Office Equipment, Instruments, Motors, Motor Vehicles, Rubber and Textlies) where patents are relatively unimportant	66	66
Individual industries:		
Pharmaceuticals	82	83
Chemicals	81	84
Petroleum	86	87
Machinery	86	97
Primary Metals	50	49
Electrical Equipment	83	83
Office Equipment	75	77
Office Equipment and Instruments[b]	75	77
Motor Vehicles	65	65
Other[c]	85	d

Source: Edwin Mansfield, Management Science, Vol. 32, No. 2 (Feb 1986) p.177

Mansfield's surveys also showed that pharmaceutical companies would also have a high likelihood of refraining from developing or introducing new inventions if patent protection for pharmaceutical products could not be obtained (see **Table 4** below)[22].

[18] Ida Madieha bt Abdul Ghani Azmi, "Patent Law in Malaysia: Cases and Commentary" (Sweet and Maxwell Asia, 2003) page 2

[19] Tay Pek San, Intellectual Property Law in Malaysia, (Sweet and Maxwell Asia 2013) page 499

[20] C.T. Taylor and Z. A.SIlberston, The Economic Impact of the Patent System (Cambridge University Press 1973)

[21] Edwin Mansfield, "Patents and Innovation: An Empirical Study" (1986), Management Science, Vol. 32, No.2, page 177

[22] Supra Note 21 at page 175

Table 5 Percent of Developed or Commercially Introduced Inventions that Would Not Have Been Developed or Commercially Introduced if Patent Protection Could Not Have Been Obtained, Twelve Industries, 1981-83

Percent of Developed or Commercially Introduced Inventions That Would Not Have Been Developed or Commercially Introduced if Patent Protection Could Not Have Been Obtained, Twelve Industries, 1981-83[a]		
Industry	**Percent That Would Not Have Been Introduced**	**Percent That Would Not Have Been Developed**
Pharmaceuticals	**65**	**60**
Chemicals	**30**	**38**
Petroleum	**18**	**25**
Machinery	**15**	**17**
Fabricated metal products	**12**	**12**
Primary metals	**8**	**1**
Electrical equipment	**4**	**11**
Instruments	**1**	**1**
Electrical equipment	**1**	**1**
Office equipment	**0**	**0**
Motor vehicles	**0**	**0**
Rubber	**0**	**0**
Textiles	**0**	**0**

Source: Edwin Mansfield, Management Science, Vol. 32, No. 2 (Feb 1986) p.175

Although patents are the most important form of IP for pharmaceutical companies, the other forms of IP are also utilised by them to enhance their business.

- Trade marks are used to protect the strong reputation of a pharmaceutical company and helps consumers to differentiate the various types of drugs and medicines that they are buying in the market.
- Copyright helps to protect the written contents of the packaged drug and databases that are produced by the company.
- Increasingly, industrial designs have been utilized to protect unique shapes and designs of tablets and packaging for drugs.
- Information regarding marketing strategies and distribution networks is protected under confidential information and trade secrets.

THE HIGH COST OF INVESTMENT IN THE R&D OF ITS PRODUCTS AND THE LOW COST OF THE REPRODUCTION OF THE R&D EFFORTS BY ITS COMPETITORS CHARACTERIZE THE MALAISE OF THE PHARMACEUTICAL INDUSTRY.

A combined utilisation of IP protection instruments by pharmaceutical companies presents a powerful platform towards commercial success which would in turn spur greater re-investment into new inventions and improved products and services.

It is important to note that the high value of the pharmaceutical industry does not reside in the cost of manufacturing the physical product but in the bulk of the R&D that precedes the creation of a physical product. The high cost of investment in the R&D of its products and the low cost of the reproduction of the R&D efforts by its competitors characterize the malaise of the pharmaceutical industry. Furthermore, pharmaceutical companies are required to fulfil high levels of health and safety standards as their products could potentially be the difference between life and death for its consumers. There are many regulatory barriers that pharmaceutical companies have to cross before the final launch of their products.

Given the distinctive nature of the pharmaceutical industry, some countries have adopted and implemented additional protection and safeguards in parallel to their patent law system to accommodate the unique challenges that pharmaceutical companies face. These safeguards are notably patent term restoration, data exclusivity and patent linkage. An overview of each of these protection measures or safeguards is set out below.

Patent Term Restoration

Pharmaceutical companies have to obtain approval from the relevant regulatory body before they can market their products. The approval process is notoriously lengthy because the regulatory body has to examine and review the data that are submitted by the pharmaceutical companies and evaluate whether the products in question are safe for human consumption.

The lengthy approval process means that pharmaceutical companies suffer a significant reduction of the 20 years patent term that was originally granted to them. In order to compensate for such a loss in patent term due to the time taken by the regulatory process, the United States, Australia and Japan have adopted legislation to enable a patent to extend its life beyond its original expiry date. Patent term restoration is not an automatic given right and it must be applied by the patent owner. Certain countries like the US impose a restriction of a maximum of 14 years for the remaining term of the restored patent[23].

[23] Li Yahong, "Intellectual Property and Public Health: Two sides of the same coin" 6 AJWH 389, page 393

Data Exclusivity

Data exclusivity is a type of protection accorded to pharmaceutical companies to protect the data that is generated from clinical trials for a certain number of years before they can be used by another party. During the period of exclusivity, no applicant can rely on the data to apply for marketing approval from the authority.

The data that is generated from clinical trials are valuable not only to the pharmaceutical companies that conduct them but also to their competitors which comprise mainly of companies that produce generic versions of their inventions. Pharmaceutical companies devote a lot of resources to produce the data that is required for marketing approval. The very same data could be obtained by generic drug companies and reproduced at almost zero cost for the purpose of obtaining marketing approval for their products. Generic drug companies do not have the same amount of resources as pharmaceutical companies to conduct similar clinical trials because of the immense cost. As such, they are largely dependent on the pharmaceutical companies for the data that is required to be submitted to the regulatory authorities.

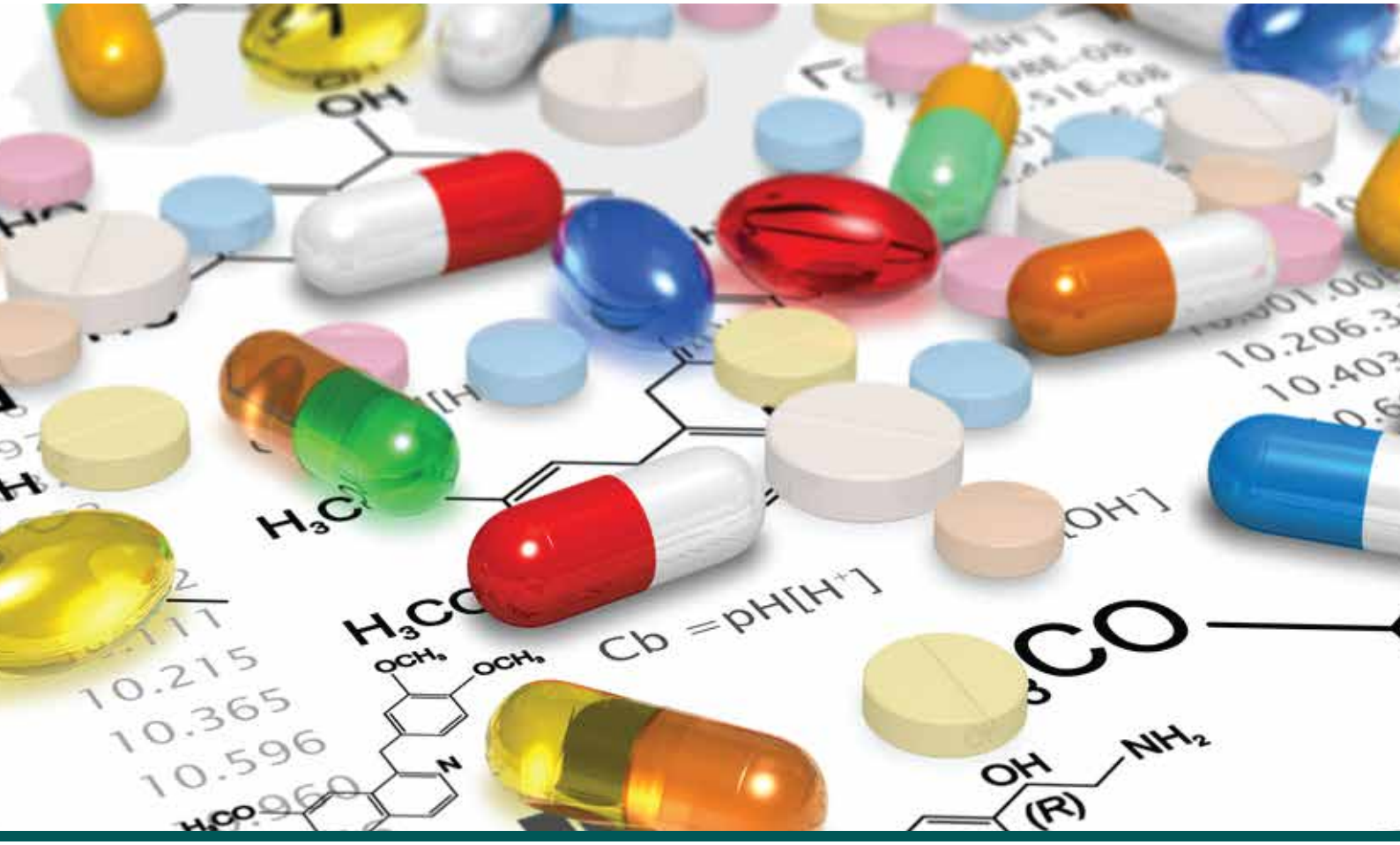
Patent Linkage

Patent linkage is an administrative and regulatory scheme whereby marketing approval for a patented drug is not granted to an unauthorized third party unless and until:
(a) the relevant patent has expired; or
(b) a determination from the judiciary or a competent authority that the patent is invalid or is not infringed.

Drug regulatory authorities and intellectual property registries are often separate administrations operating under different government ministries in many countries. The drug regulatory authority may not be aware that a generic drug that is presented for approval is in fact for a drug that is still protected by patent[24] so that if the generic version is manufactured or marketed, it will infringe the patent.

The patent linkage system therefore links the market approval process of generics and the patent status of the originator product. Marketing approval will not be granted before the patent expires unless the generics manufacturer can show that the patent is expired or it has been authoritatively determined that the patent will not be infringed or is invalid. As part of the approval process, the generics manufacturer must give certification as to the patent status of the originator drug and if it certifies that the originator's patent will not the infringed or is invalid, the patentee must be notified and if the patentee files infringement action, the application for marketing approval of the generic drug will automatically be stayed until the issue of validity and/or infringement of the patent is resolved.

[24] Benjamin P. Liu, "Fighting Poison with Poison? The Chinese Experience With Pharmaceutical Patent Linkage" (2012) 11 J. Marshall Rev. Intell. Prop. L. 623, page 650


OH
H_3C
H_3CO
Cb =pH[H+]
10.215
10.365
10.596
OCH_3
OCH_3
N
H_3CO
OH
NH_2
(R)

1.6 Misconceptions and Perceptions about IP and the Pharmaceutical Industry

In recent years, anti-IP sentiments amongst members of the public have grown and groups with anti-IP agenda have increasingly received attention. This anti-IP feeling or sometimes known as the "IP backlash" is partly fueled by several factors such as the lack of understanding of the IP system and the negative perception of IP owners as being bullies. The music and pharmaceutical industries are two industries that have been vulnerable to such negative publicity as both rely heavily on IP rights for survival.

The pharmaceutical industry is often wrongly portrayed as using patents to hinder access to medicine in developing or underprivileged countries. Such negative perception surrounding the IP system and pharmaceutical industry can be clearly seen in various forms of media and public forums. Newspaper and magazine headlines play a huge rule in shaping public opinion and the provocative language used in these publications contribute to the misconceptions about the IP system and the pharmaceutical industry. Some published headlines include "The rich world's patents abandon the poor to die[25]" and "In Africa, patents kill[26]". It is also worth noting that an initiative for compulsory licensing of an HIV/AIDS drug in a developing country such as Thailand received much publicized media coverage whilst in contrast, the grant of a compulsory licence for a cancer drug by Italy did not receive much attention at all from the press and media[27].

Alongside these accusations of corporate greed, pharmaceutical companies and the IP system are often seen as obstacles rather than partners in the global combat against diseases. Rightly or wrongly, the IP system often comes across as a tool to allow multinational companies to enrich themselves and patents are blamed for causing "death, suffering and the prevention of access to much needed pharmaceuticals, particularly in developing countries[28]". Many activists from the developing world consider the profit aspirations of pharmaceutical companies as incompatible with patients' rights and hence, there would always be a struggle between patents and patients' rights[29].

1.6.1 Patent Equals To High Cost Of Healthcare

The most common misconception held by the public is that the high cost of healthcare is due to pharmaceutical patents. The issue of the cost of healthcare dominates many of the literature and articles that are anti-IP. There is an underlying presumption that IP protection would automatically translate into higher prices. Such a presumption ignores the fact that there is a clear and established link between patent protection and the rate of innovation but there are no such links between the strength of IP protection and price levels[30].

There is also an unrealistic expectation that the pharmaceutical industry is to bear the sole burden of broadening access to healthcare. Cheap drugs through the abolition of patents are often seen by critics of the pharmaceutical industry as the ultimate answer to the problem of access to medicine. However, little attention is paid to the broader aspects of healthcare systems in which medicines need to be procured, stored, distributed, prescribed, administered and monitored[31]. The price of medicine is also affected by those broader aspects of healthcare and not just patents. Furthermore, the cost of patented medicine by pharmaceutical companies is

not necessarily higher than the alternatives that are provided by governments. A study in Argentina conducted by CAEME, the organization of multinational companies, revealed that unit prices of nationalised products in Argentina exceeded those of multinational companies by an average of 14% and 48% in the years between 1982 and 1993[32].

1.6.2 Full Market Exclusivity During A Patent Term

Another common misconception is that pharmaceutical companies enjoy 20 years of patent monopoly in the manufacturing and sale of the patented drug. As mentioned, the pharmaceutical industry is unlike other industries that rely on patents because of the need for clinical trials to obtain regulatory approval and the lengthy marketing approval process during the patent term which precludes the commercial selling and marketing of the drug pending approval.

The effective years of exclusivity vary depending on the characteristics and complexity of the drug. Studies have shown that the overall market exclusivity for new drugs has decreased over the years (see **Table 6**)[33]. For example, Inderal which was introduced in 1965 enjoyed 10 years of market exclusivity while Invirase which was introduced in 1995 had just 3 months on the market before a generic was introduced.

Table 6 Trend of Overall Market Exclusivity for New Drugs Over the Years

Product Name	Year Introduced	Term of Exclusivity from Patent
Inderal	**1965**	**10 years**
Tagamet	**1977**	**6 years**
Diflucan	**1990**	**2 years**
Invirase	**1995**	**3 months**

During the remaining patent term after marketing approval, the first few years of sale would only result in the recoupment of investments in R&D. It takes a considerable period of time before a pharmaceutical company may start to make a profit from its patented drug.

1.6.3 Patent Owners Enjoy Absolute Freedom From Competition

It needs emphasizing that an innovator pharmaceutical company does not enjoy a "pure" monopoly and absolute freedom from competition through patents as is generally perceived. Patented drugs are not free from all forms of competition. The exclusivity from patents can be eroded in several circumstances including:

- Competition from drugs which utilise a different technology to produce the same or similar result to that achieved by the patented invention. It is very much part of the operation of the patent system for third parties to try to "invent around" patent claims[34].

- Many countries including Malaysia have legislation which prohibits anti-competitive practices. As such, pharmaceutical companies are not allowed to abuse their dominant position in the market by setting unreasonably high prices. The existence of legislation that prohibits anti-competitive practices debunks the myth that pharmaceutical companies have absolute freedom in pricing their patented products.

1.6.4 Patents Automatically Prevents Infringement

Contrary to popular belief, patents that are granted to pharmaceutical companies do not automatically prevent infringement. If the patent owner is not aware of infringement, the government does not step into the shoes of patent owners to enforce the patent. It is the responsibility of the patent owner to monitor its IP rights and pharmaceutical companies spend a considerable amount of money maintaining, policing and enforcing their IP rights. A survey conducted by the Intellectual Property Owners Association in 2011 revealed that 10 out of the 20 pharmaceutical and biotechnology companies that were interviewed had spending more than US$25 million by their IP department[35].

1.6.5 A Win-win Situation

It is important to debunk these misconceptions as the shackles of negative perceptions will hinder the full realization of the potential benefits that the IP system has to offer. There is a need to demolish the mistaken notion that the IP system and public health have to be in opposition with each other. The IP system should not be viewed as a zero-sum game where the gains of the pharmaceutical industry through patents especially would transpire into the loss of benefits to public health and vice versa. In fact, the IP system provides a sustainable framework where the pharmaceutical industry could cooperate together with governments, regulatory bodies and activists. It is possible to have a win-win situation where the commercial growth of the pharmaceutical industry is followed by the advancement of public health in developing countries. The IP system can ensure this win-win situation through the quality products that are produced by innovative pharmaceutical companies and licensing deals in which technologies can be shared with developing countries[36].

[25] John Sulston, "The rich world's patents abandon the poor to die" The Guardian (London 18 February 2003) *<http://www.theguardian.com/world/2003/feb/18/aids.comment>* accessed 10 September 2014

[26] Seth Shulman, "In Africa, patents kill" (2001) MIT Technology Review *<http://www.technologyreview.com/article/400954/in-africa-patents-kill/>* accessed 10 September 2014

[27] Roya Ghafele, "Perceptions of Intellectual Property: A review", (2008) Intellectual Property Institute, page 16

[28] Supra Note 27 at page 12

[29] Supra Note 27 at page 14

[30] Supra Note 13 at page 15

[31] Gerhard Symons, "Gaining Access: Philanthropic initiatives ensure pharma a seat at the table shaping healthcare delivery" Pharmaceutical Marketing (July 2009)

[32] Supra Note 13 at page 15

[33] Wendy H. Schacht and John R. Thomas, "Patent Law and its Application to the Pharmaceutical Industry: An examination of the Drug Price Competition and Patent Term Restoration Act of 1984 ("The Hatch-Waxman Act")", CRS Report for Congress 2000, page 34

[34] Christopher Garrison, "Intellectual Property Rights and Vaccines in Developing Countries", (2004) Background paper for WHO workshop, WHO workshop, page 15

[35] Intellectual Property Owners Association, "2011 IPO Corporate IP Management Benchmarking Survey", *<http://www.ipo.org/wp-content/uploads/2013/03/corporatebenchmarking2011.pdf>* accessed 16 September 2014, page 7

[36] Sara-Jayne Adams, "Fighting back against the IP backlash", Intellectual Asset Management (September/October 2009) page 50

Innovating for a Healthier, Economically Vibrant Nation

OUR VISION

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

OUR MISSION

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

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

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