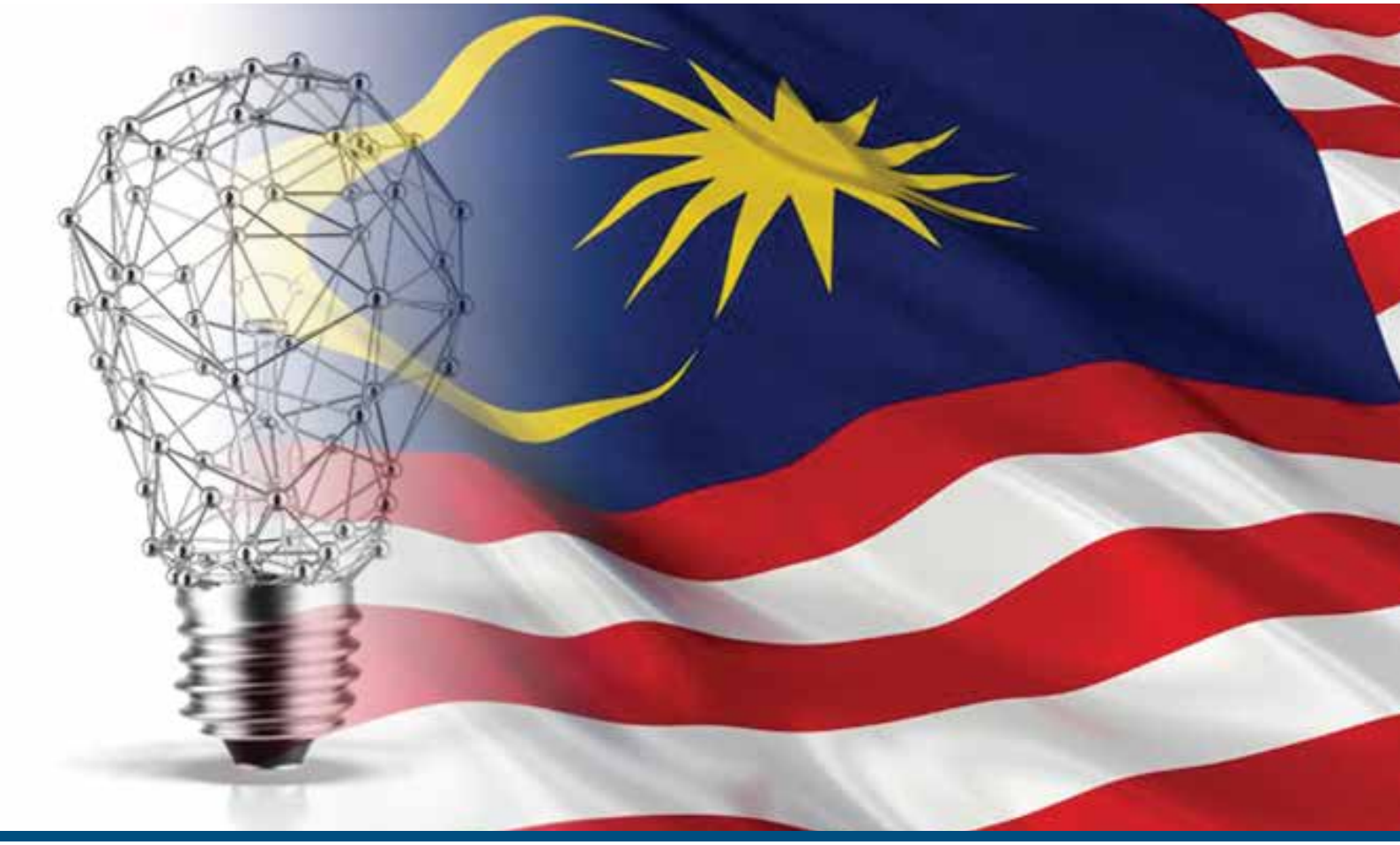
PhAMA

'Innovative Medicines for Malaysia'



Protection Of Pharmaceutical Innovations: Gaps In Malaysia's Intellectual Property Regime :

PART 4

CONTENTS

PhAMA
'Innovative Medicines for Malaysia'

Protection Of Pharmaceutical Innovations: Gaps In Malaysia's Intellectual Property Regime

Innovation is the reason why intellectual property ("IP") is protected. Innovation is valued because history shows that a society strong in innovation will flourish and thrive far better than one which isn't. A strong and robust IP protection regime must thus be in place if the Government is to motivate not only innovative behavior but, more importantly, investments in innovation.

The business of drug development in the pharmaceutical industry is characterized by unusually large spending on research when measured by the standards of other industries[1]. It is also an area in which empirical studies have found that patents and related IP protection really matter when decision-makers contemplate spending money on R&D, in contrast with other industries that rate other factors not related to patents or IP, as more important[2].

The role of a country's IP regime is therefore broader than providing administration and registration protection for IP rights. It has a more critical underlying role, which is to motivate investments in innovation that will lead to innovative activities beneficial to the country.

Malaysia's IP regime has existed for a while and has undergone a number of developments and changes over the years. This part of the Position Paper aims to highlight "gaps" in the existing regime which have contributed to Malaysia losing out when competing with other countries for R&D spend or being omitted altogether from the list of destinations for investments in innovative pharmaceutical activities. It also seeks to offer some considered proposals to narrow the gaps so that Malaysia's position will be rendered more competitive and balanced. All these would be necessary if Malaysia is to truly transform itself to a high-income, knowledge-based, developed economy and country.

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")

(2) Patent Linkage

(3) Data Exclusivity

(4) Second Medical Usage / Indication And Dosage Regimen

(5) Compulsory Licensing; And

(6) Administrative Enforcement Of IP Rights

IT IS WORTH NOTING THAT THE INTENTION OF THE HATCH-WAXMAN ACT WAS "TO BALANCE TWO CONFLICTING POLICY OBJECTIVES: TO INDUCE NAME-BRAND PHARMACEUTICAL FIRMS TO MAKE THE NECESSARY RESEARCH AND DEVELOP NEW DRUG PRODUCTS, WHILE SIMULTANEOUSLY ENABLING COMPETITORS TO BRING CHEAPER, GENERIC COPIES OF THOSE DRUGS TO MARKET."

Calls by PhAMA and innovator pharmaceutical companies to address the above "gaps" have always been met with resistance, if not, a cautious response by the Government. The resistance, as perceived by PhAMA, appears to be tied to concerns that if those "gaps" are narrowed, they will help innovator companies drive out generic competitors for longer or somehow hinder the Malaysian public's access to cheaper versions of generic drugs. If those are the concerns, there is no basis for them. In this regard, one needs only to look at how patent term restoration ("PTR"), patent linkage and data exclusivity came to be implemented in the United States to understand that they pose no threat to the development of a thriving generics industry.

In the United States, prior to the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act), innovator companies could rely on the United States Food and Drug Administration (FDA) to treat the clinical trial data submitted as confidential, therefore, generic competitors could not rely on those data to gain marketing approval, and further, during the patent period, generic competitors could not conduct clinical trials without risk of infringing the patent[3]. This situation made entry of generic drugs into the market after the expiry of originator patents difficult and led to Congress passing the Hatch-Waxman Act to remedy the situation. It is worth noting that the intention of the Hatch-Waxman Act was "to balance two conflicting policy objectives: to induce name-brand pharmaceutical firms to make the necessary research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market[4]." These competing interests that were addressed by the Hatch-Waxman Act are at the heart of the discussions in this part of the Position Paper.

The Hatch-Waxman Act enabled innovator companies to rely on data exclusivity protection[5] for their clinical trial data, patent term extensions to compensate for the delay caused by regulatory review[6] (PTR) and the approval of generic drugs contingent upon the absence of valid patents[7] (patent linkage). In exchange for these rights, generic competitors under Hatch-Waxman Act were allowed to conduct the necessary clinical trials during the patent term[8] (also known as "Bolar provision" or "Bolar exemption") and also, apply for FDA approval of a bioequivalent product through the abbreviated new drug application ("ANDA") procedures that do not require the duplication of clinical trials, thus, significantly speeding up the entry of generic drugs into the market[9].

1 Rebecca S. Eisenberg, "The Role of the FDA in Innovation Policy", (2007) 13 Mich. Telecomm. Tech. L. Rev. 345, page 350
2 Wesley M. Cohen et al., "Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (Or Not) 1-31 (National Bureau of Econ. Research, Working Paper No. 7552, 2000), < *http://www.nber.org/papers/W7552.pdf* >
3 Supra Note 1 at page 357 to 359
4 Abbott Labs v Young 920 F.2d 984, 991(D.C. Cir 1990)
5 21 U.S.C. § 355
6 35 U.S.C. § 156
7 21 U.S.C. § 355(b), (c), (j)
8 35 U.S.C. § 271 (e)
9 21 U.S.C § 355 (j)

The Hatch-Waxman Act thus addressed the competing interests of the innovator companies and the generics manufacturers by granting each, the following rights –

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.

A generics manufacturer runs the risk of infringing the innovator's patent if it conducts, during the patent term, bioequivalence and stability trials for purposes of obtaining regulatory approval, even if it only plans to enter the market after the patent expires[10]. The Bolar exemption makes it non-infringement for generics manufacturers to conduct such trials. This allows them to enter the market earlier than they would have been able to if they could only carry out trials after the patent expires. In Malaysia, this exemption, in force since 1 August 2001, is found in section 37(1A) of the Patents Act 1983 and is similar to the Bolar provision in the United States:

> ***"The rights under the patent shall not extend to acts done to make, use, offer to sell or sell a patented invention solely for uses reasonably related to the development and submission of information to the relevant authority which regulated the manufacture, use of sale of drugs."***

Similar to the situation in the United States where generic companies are able to rely on the innovator's clinical trial data through the abbreviated ANDA procedure, the latest Drug Registration Guidance Document ("DRGD")[11] provides that generics manufacturers in Malaysia are not required to submit non-clinical data to support the safety of the product or clinical data to support product safety and efficacy[12], although a bio-equivalence study is required for generics drugs (scheduled poisons)[13].

Hence, all the rights granted to generics manufacturers by the Hatch-Waxman Act in exchange for the concessions made by the innovator companies are granted 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 as will be discussed later in this part of the Position Paper. PhAMA will venture to say that the law as it stands creates a playing field which is inequitably skewed in favour of generics manufacturers.

[10] Antony Tridico and Jeffrey Jacobstein "Facilitating generic drug manufacturing: Bolar exception worldwide" (WIPO Magazine, June 2014,) < http://www.wipo.int/wipo_magazine/en/2014/03/article_0004.html > accessed 20 October 2014

[11] National Pharmaceutical Control Bureau, Ministry of Health Malaysia, "Drug Registration Guidance Documents", (1st ed, November 2014)

[12] Supra Note 11 at page 151

[13] Supra Note 11 at page 166

The Hatch-Waxman Act has been in force since 1984 and for more than 30 years now, innovator companies have fully enjoyed rights of data exclusivity, PTR and patent linkage. Have these rights stunted or hindered growth and development of the generics industry in the United States? Not at all. In an investor report published in October 2013[14], it was reported that the Hatch-Waxman Act shook up the generics drugs business in 1984, and almost 30 years later, it was safe to say that the law had its desired effect. About 84% of the four billion prescriptions written each year are for generic drugs, saving patients and government program billions of dollars annually. Despite innovator companies fully enjoying the rights of data exclusivity, PTR and patent linkage as part of the "bargain" under the Hatch-Waxman Act, the generics industry in the United States has not only flourished but has overtaken the market share of innovator companies, filling up a high majority of the prescriptions for drugs in the United States each year.

Instead, the Hatch-Waxman Act has attracted criticisms that the benefits given to generic companies are too great compared to the benefits given to innovator companies, thus resulting in an increase in prices for brand name drugs as innovator companies struggle to recoup R&D costs and make a profit[15].

[14] FiercePharma, "Top 10 generics makers by 2012 revenue" (October 21, 2013), *http://www.fiercepharma.com/special-reports/top-10-generics-makers-2012-revenue*

[15] Jaclyn L. Miller, "Drug Price Competition and Patent Term Restoration Act: The Elimination of Competition between Drug Manufacturers" (2002) 5 DePaul J. Health Care 91, page 95

1. Patent Term Restoration ("PTR")

A brief introduction to patent term restoration may be found in Part 1 of this Position Paper.

An innovator company is extremely dependent on the protection given by patents. During the patent term is the only time when an innovator company may recoup its investments[16] or make a profit as there will be a sharp decline in earnings when generic competition begins[17] after the patent expires. Although patents are typically granted for a term of 20 years from the date of application, the effective period when the patented innovative pharmaceutical products (referred to in this Paper as "Innovator Brand" drugs) enjoy monopoly position in the market is significantly less that the full patent term due to the time taken to obtain marketing approval from the authorities.

Drug regulatory approval is mandatory in almost all countries and is a necessary step towards safeguarding consumer health and safety. In Malaysia, pharmaceutical products cannot be marketed without regulatory approval[18] and prior clearance from the Drug Control Authority ("DCA"). The time taken for approval by the DCA may take up to 245 working days as stated in the Guidelines, or 12 to 18 months as reported by PhAMA members. This approval period by the local DCA must be viewed in conjunction with the fact that approval from a regulatory body in the drug's country of origin must be attained beforehand. If the country of origin is the United States, which is not uncommon, the approval process by the United States Food and Drug Administration takes approximately 7.5 years for standard review, and 5.1 years for expedited review[19].

INNOVATOR PHARMACEUTICAL COMPANIES MUST ACHIEVE SIGNIFICANT REVENUE THROUGH SALES AND MARKETING OF THE INNOVATOR BRAND DRUGS TO BREAK EVEN AND RECOUP COSTS BEFORE THEY CAN HOPE TO SEE PROFITS. IF THEY CANNOT DO SO, THERE WILL BE LOSSES TO BEAR AND IF LOSSES ARE NOT CONTROLLED, THE SURVIVAL OF THE COMPANY WILL BE THREATENED.

Thus, by the time the Innovator Brand drug enters the market, blessed with the necessary regulatory approvals, the 20 years patent term is almost halved or may well be more than halved. Within the remaining patent period, the innovator company must recoup its significant costs incurred in the long process from lab to market, with some profits to spare. Unless it is able to do so, there will be little incentive to innovate and little will be available to plough back to finance further R&D necessary for the discovery of new or better drugs. The following data may aid in illustrating the point and to set in context the reality faced by innovator companies:

R&D Investments by Members of US PhRMA Research and Manufacturers of America in 2013[20]	US$ 51.1 billion
Total percentage of sale re-invested in R&D by members of the Pharmaceutical Research and Manufacturers of America in 2013[21]	17.8%
Average R&D cost for a drug in the 2000s[22]	US$ 1.2 billion
Estimate cost to develop and win marketing approval for a new drug in the United States in 2014[23]	US$ 2.6 billion

The amounts involved are considerable. Innovator pharmaceutical companies must achieve significant revenue through sales and marketing of the Innovator Brand drugs to break even and recoup costs before they can hope to see profits. If they cannot do so, there will be losses to bear and if losses are not controlled, the survival of the company will be threatened.

The longer the regulatory approval process, the shorter the remaining patent period available to market the Innovator Brand drug and the higher the chances of failing to recoup the significant costs and investments which have been sunk in.

The loss of patent exclusivity has a direct correlation with the level of R&D which the innovator company will undertake. A case in point was when the Osaka-based pharmaceutical company, Takeda, lost the patent rights to its diabetes drug Actos®, which accounted for 18% of the company's global sales[24]. This loss in revenue forced Takeda to scale down its R&D to fewer areas of research, thereby limiting the prospect of innovation[25].

The system of patent term restoration ("PTR") resulted from efforts to find balance between the need for a drug to undergo approval process by the regulatory authority and the significantly reduced time to work the pharmaceutical patent due to prohibition against marketing prior to regulatory approval. Many countries have implemented a PTR system and they include the European Union[26], United States[27], Australia[28], Japan[29], Republic of Korea[30] and Singapore[31]. It is also in the pipeline for Canada, following the Comprehensive Economic and Trade Agreement ("CETA") in 2013, potentially increasing the drug patent term by up to two years[32].

THE SYSTEM OF PATENT TERM RESTORATION ("PTR") RESULTED FROM EFFORTS TO FIND BALANCE BETWEEN THE NEED FOR A DRUG TO UNDERGO APPROVAL PROCESS BY THE REGULATORY AUTHORITY AND THE SIGNIFICANTLY REDUCED TIME TO WORK THE PHARMACEUTICAL PATENT DUE TO PROHIBITION AGAINST MARKETING PRIOR TO REGULATORY APPROVAL.

Underlying the countries' implementation of the PTR system is the clear recognition that there is inequity resulting from the time taken up by the drug approval process (especially if it's a long one) and that this inequity needs to be addressed, not only to encourage but to enable innovator pharmaceutical companies to continue to innovate because continued innovation is critical to the well-being and health of society.

The PTR system of the United States, European Union, Japan and Australia allows the patent term to be restored up to a maximum of five years to compensate for delays in marketing approvals by the regulatory authorities. PTR is usually granted upon the approval of an application by the patent holder.

In some countries, the PTR system stipulates that the total patent life with PTR may not exceed a maximum number of years from the product's approval date, that is, the potential marketing time is limited to a specified maximum number of years. If the patent life of a product after approval already enjoys that maximum number of years or exceeds it, then, it becomes ineligible for PTR. In the United States, the specified maximum is 14 years.

There is no PTR system in Malaysia. This is known by PhAMA to be one of the factors consistently operating against Malaysia when innovator companies decide on which countries to locate innovative activities and R&D spending. It has also contributed to make Malaysia less attractive as a base country to local inventors of pharmaceutical innovations.

PhAMA's Position and Recommendation

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.

Indeed, certain commentators lament that their respective countries *"may witness a steep decline in innovator companies establishing their grounds in this volatile market due to the absence of statutory provisions for data exclusivity and patent term extension* [emphasis ours].[33]*"* For innovator companies, even a year of extended patent life for a drug can translate into much needed profits[34] that can then be reinvested into more R&D to discover novel or better drugs. Studies and empirical evidence have established a positive correlation between higher drug profits and greater R&D investments and efforts[35].

16 Thomas F. Poche, "The Clinical Trial Exemption from Patent Infringement: Judicial Interpretation of Section 271 (e) (1)" (1994) 74 B.U.L Rev. 903 cited in Jaclyn L. Miller, "Drug Price Competition and Patent Term Restoration Act: The Elimination of Competition between Drug Manufacturers" (2002) 5 DePaul J. Health Care 91, page 95

17 Henry Grabowski, John Vernon and Joseph A. DiMasi," "Returns on Research and Development for 1990s New Drug Introductions" (2002) 20 Supp Pharmacoeconomics 3, page 20 (Please refer to page 9 of Part 3 of this Position Paper)

18 Regulation 7(1) Control of Drug and Cosmetic Regulations 1984

19 Thomas J Moore and Curt D. Furberg "Development Times, Clinical Testing, Postmarket Follow-Up and Safety Risks for the New Drugs Approved by the US Food And Drug Administration, The Class of 2008" (2014) JAMA Inter Med 174, page 90-95

20 Pharmaceutical Research and Manufacturers of America "2014 Biopharmaceutical Research Industry Profile" (Washington DC, PhRMA, April 2014)

21 ibid

22 J. Mestre-Ferrandiz, J. Sussex, and A.Towse. "The R&D Cost of a New Medicine." (London, UK: Office of Health Economics, 2012); S.M. Paul, et al. "How to Improve R&D Productivity: The Pharmaceutical Industry's Grand Challenge." (Nature Reviews Drug Discovery 2010; 9: 203–214).cited in Pharmaceutical Research and Manufacturers of America "2014 Biopharmaceutical Research Industry Profile" Washington DC, PhRMA, April 2014

23 Tufts Center for the Study of Drug Development "Cost to Develop and Win Marketing Approval for New Drug is US $ 2.6 billion," (18 November 2014) *<http://csdd.tufts.edu/news/complete_story/pr_tufts_csdd_2014_cost_study >* assessed on 24 November 2014

24 Anon, "Takeda Pharmaceutical – 10 largest U.S. Patent Losses", (24 October 2011) *< http://www.fiercepharma.com/special-reports/10-largest-us-patent-losses/takeda-pharmaceutical-10-largest-us-patent-losses >* assessed on 17th September 2014

25 Anon "Takeda Announces Reorganization to Propel Continued Growth", (16th September 2014) *<http://www.fiercepharma.com/press-releases/takeda-announces-reorganization-propel-continued-growth>* accessed on 17th September 2014

26 5 year extension in the form of a Supplementary Protection Certification (SPC) - Article 13 REGULATION (EC) No. 469/2009 (Supplementary Protection Certificates for Medicinal Products) [European Union]

27 5 year extension – Section 201 Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Act), adding in Section 156 to 35 U.S.C. [United States of America]

28 5 year extension – Section 77 Patents Act 1990 (consolidated as of 1 January 2011) [Australia]

29 5 year extension – Article 67(2) Patent Act (Act No. 121 of April 13, 1959, as last amended by Act No. 16 of April 18, 2008) [Japan]

30 5 year extension – Article 89(1) Patent Act (Act No. 950 of December 31, 1961, as amended up to Act No. 9985 of January 27, 2010) [Republic of Korea]

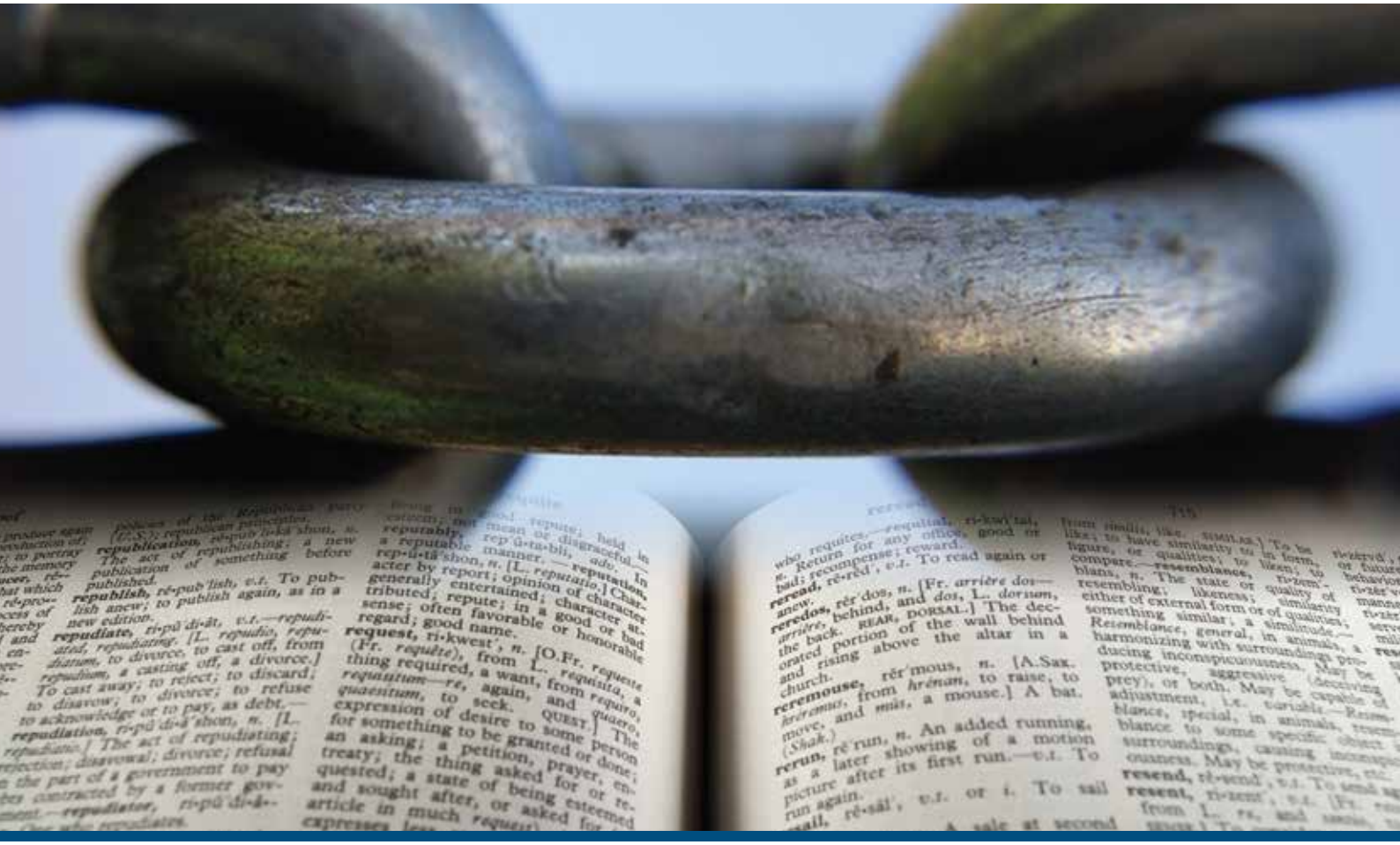
31 5 year extension – Section 36A(4) Patents Act 1994 [Singapore]

32 Noel Courage , "Giving Canadian Drug Exclusivities a Shot in the Arm", (Bereskin & Parr Intellectual Property Law, 2013) *< http://www.bereskinparr.com/News/id428 >* assessed on 15 December 2014

33 Gandhi T "Patent Term Extension and Data Exclusivity in India", (American Intellectual Property Law Association, 2014)

34 Jacobsen and Wertheimer "Modern Pharmaceutical Industry: A Primer"(Jones and Bartlett Publishers, 2010) cited in Tessensohn and Yamamoto "Patent Term Extensions for Biologic Innovators in Japan" (2011) 29 Nature Biotechnology , page 32-37

35 Henry Grabowski and John Vernon, " The determinants of pharmaceutical research and development expenditures" (2000) 10 J Evol. Econ 201, page 213



2. Patent Linkage

The patent linkage regime which began in the United States with the Hatch-Watchman Act in 1984 is a form of legal ordering that ties patent protection for marketed pharmaceuticals to the drug approval process[36]. A system of patent linkage is now adopted in many countries[37] including in Australia[38], Mexico[39], Singapore[40], China[41], Chile, Peru, Bahrain and Oman. A brief introduction to patent linkage may be found in Part 1 of this Position Paper.

In general, the system of patent linkage establishes a relationship between the market approval process of generics and the patent status of the originator product. Marketing approval will not be granted to a generics manufacturer before the patent expires unless it can show that the patent is expired or it has been authoritatively determined that the patent will not be infringed or is invalid. The national regulatory authority may not register or approve for marketing a generic drug if the drug for which approval is sought remains patented.

In the United States, patent linkage system is applied through the publication of "Approved Drug Products with Therapeutic Equivalents and Evaluations", commonly known as the "Orange Book". It identifies the drug products which have been approved by the Food and Drug Administration ("FDA") and lists the approved drugs, discontinued drugs and provides patent and exclusivity information. Applicants of the pioneer drug must file with the FDA the number and expiration date of any patent the subject matter of which is the drug which has received marketing approval. If a generic producer wishes to register a generic bioequivalent, it would have to certify that:

(a) there is no competing patent (the drug has not been patented);
(b) the patent has expired;
(c) the date on which the patent will expire and that the generic drug will not be marketed until after the expiry date; or
(d) the patent is invalid or would not be infringed[42].

If the generics manufacturer makes a certification based on (d) above, it must notify the patentee of its application. Within 45 days of the notification, the patentee may file an infringement action and if so, the application for marketing approval of the generic drug will automatically be stayed for 30 months. If the patent expires within that 30 months period or if the court declares the patent invalid or is not infringed, the FDA may grant approval immediately. Otherwise, approval may only be granted after the patent expires.

The patent linkage regimes in most countries mirror that of the United States, although the Chinese have implemented their own version of a patent linkage system outside of any bilateral treaty obligation[43].

AT NO POINT IS THE REGULATORY BODY BURDENED WITH THE TASK OF ASSESSING PATENT VALIDITY OR INFRINGEMENT QUESTIONS OR REQUIRED TO ENFORCE THE PATENT ON BEHALF OF THE PATENTEE.

Critics of patent linkage often argue that it places an undue burden on the national drug regulatory body to assess and enforce patent rights when it is traditionally concerned with drug safety and efficacy issues. Such criticisms are somewhat misguided. The patent linkage system in the United States (with most countries having a similar system) places the onus squarely on the generics manufacturer applying for marketing approval to certify that the originator's patent is either expired or is invalid or not infringed. If the applicant certifies it to be invalid or not infringed, the patentee, who must be notified by the applicant, must then file infringement action in court within a specified time to enforce its patent. The applicant may then move the court to invalidate the patent.

At no point is the regulatory body burdened with the task of assessing patent validity or infringement questions or required to enforce the patent on behalf of the patentee. Just as it is the applicant's duty to verify and check when making the certification for marketing approval, it is the patentee's duty to sue in court for infringement if it wishes to enforce the patent and invoke the system to stay the approval application until after the infringement and/or validity questions have been determined by the court.

THE PATENT LINKAGE SYSTEM THEREFORE OFFERS NO PRESUMPTION OF PATENT VALIDITY OTHER THAN WHAT IS ALREADY PROVIDED BY THE COUNTRY'S PATENT LAW. IT ALSO DOES NOT PREVENT OR DELAY COMPETITION FROM THE GENERICS MANUFACTURERS. COMPETITION DURING THE PATENT TERM FROM NOT ONLY THE GENERICS MANUFACTURERS BUT ANY OTHER THIRD PARTY IS PROHIBITED BY THE PATENTS ACT 1983 AND NOT BY ANY PATENT LINKAGE SYSTEM WHICH IS IMPLEMENTED.

Critics also often argue that patent linkage leads to a presumption of validity of the patent and prevents or delays competition from the generics manufacturers. In responding to such criticisms, it is worthwhile reiterating that the patent linkage system is simply a procedural safeguard to ensure that the regulatory body does not inadvertently approve the marketing of an infringing product. Unless and until a patent granted in accordance with the Patents Act 1983 is expired or declared invalid by the court, the exclusive rights of the patentee to exploit the patented invention is secured by law (s. 36 Patents Act 1983). The drug regulatory body has no authority or power to contravene or to aid another to contravene this provision of the law. Approval for marketing granted to a generic drug will not excuse infringement if it comes within the claims of the patent in suit. It is not a defence to infringement recognised by the Patents Act 1983. This is well illustrated by the case of **Ranbaxy (Malaysia) Sdn Bhd v El Du Pont De Nemours and Company [2011] 1 AMCR 857.** The plaintiff, a generic company, took up action for a declaration by the High Court that the regulatory approval granted to it by the National Pharmaceutical Control Board (NPCB) when the defendant's patent was still subsisting, meant that the manufacturing and sale of its products do not constitute patent infringement. The Court, per Azahar Mohamed J, disagreed with the plaintiff, ruling that there is no connection between drug regulations and patent rights. His Lordship also pointed out that *"NPCB does not concern itself with any patent protection aspects of the drug nor does it purport to grant any authorization to work the patent."* His Lordship went on to hold that the plaintiff did infringe the defendant's patent.

Thus, the criticisms which have been levelled against the patent linkage system lack sound basis. The patent linkage system is simply an administrative system and cannot add to or take away what is conferred by the Patents Act 1983. The criticism is hardly one against patent linkage, but a blanket criticism against patents in general, although PhAMA is confident that the overall consensus is that patents are necessary and exist for very good reasons.

PhAMA would add that a patent linkage system that allows generic manufacturers to obtain information on existing patents has a beneficial role to play in allowing them to better plan their production schedules and to assess whether to wait for the patent to expire or to challenge its validity if there is good basis to do so. A patent linkage system will also avoid confusion in the marketplace caused by having infringing products enter the market and then withdrawn because of infringement action by the patentee. And, it may also minimise the need for litigation over the amount of damages to be paid for the patentee's loss suffered due to the generic drug being marketed during the patent term.

The patent linkage system therefore offers no presumption of patent validity other than what is already provided by the country's patent law. It also does not prevent or delay competition from the generics manufacturers. Competition during the patent term from not only the generics manufacturers but any other third party is prohibited by the Patents Act 1983 and not by any patent linkage system which is implemented.

Critics harp on generics being delayed from entering the market. PhAMA would highlight that what critics fail to appreciate is that more patent time is lost during the originator drug's regulatory approval process, as the approval time for generics is undoubtedly shorter than that of new indications[44]. Yet, as it stands, originator pharmaceutical companies get no respite from the IP regime which is currently in place in Malaysia, not only is there no patent linkage system, there is no PTR as well. When, both rights came into being as rights given to originator companies in exchange for allowing use of their clinical trial data by generics manufacturers in the marketing approval process and for Bolar exemption. As mentioned, generics manufacturers in Malaysia are fully enjoying these rights yet PTR and patent linkage remain denied to originator companies.

PhAMA's Position and Recommendation

With the global pharmaceutical market calculated to be worth nearly US$1.6 trillion by 2020[45], there is every compelling reason for Malaysia to amend existing laws to be in line with international standards so that our country may optimally enjoy a share of this growing industry. The adoption and implementation of a patent linkage system similar to the system in the United States is recommended. PhAMA strongly reiterates here that the existing law is inequitably skewed in favour of the generics manufacturers as they enjoy all the "gains" which originated from the Hatch-Waxman Act whereas the innovator pharmaceutical companies are given a limited form of only one of the three "gains" granted by the Hatch-Waxman Act in exchange for the "gains" enjoyed by the generics manufacturers. Implementing PTR and patent linkage would be a step towards restoring fair equity and balance between the competing industries.

[36] Ron A. Bouchard et al, "Empirical Analysis of Drug Approval-Drug Patenting Linkage for High Value Pharmaceuticals" (2010) 8 Nw. J. Tech. & Intell Prop 174, page 176

[37] Liu BP "Fighting Poison with Poison? The Chinese Experience with Pharmaceutical Patent Linkage" (2012) 11 J. Marshall Rev. Intell. Prop. L. 623

[38] Section 26(B) Therapeutic Goods Act 1989 [Australia]

[39] Article 167-bis of the Health Law Regulations (RIS) [Mexico]

[40] Section 12A Medicines Act 1975 [Singapore]

[41] Article 18, Provisions for Drug Registration, SFDA Order No. 28 [China]

[42] Section 355(b)(2)(A), (j)(2)(A)(vii) Federal Food, Drug, and Cosmetic Act (FD&C Act) 21 U.S.C. [United States of America]

[43] Yahong Li, "Imitation to Innovation In China: The Role of Patents in Biotechnology and Pharmaceutical Industries" (23 Edward Elgar Pub., 2010) cited in Benjamin P. Liu, " Fighting Poison with Poison? The Chinese Experience with Pharmaceutical Patent Linkage" (2012) 11 J. Marshall Rev. Intell. Prop L. 623 at page 629

[44] Supra Note 11 at page 97

[45] PricewaterhouseCoopers "Pharma 2020: From vision to decision", (PwC, 2011)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3. Data Exclusivity

This part of the Position Paper is a follow-up to the Position Paper on Data Exclusivity Implementation in Malaysia by PhAMA dated 16 August 2010 to the Ministry of Health ("MOH"). Since that Position Paper, the Directive on Data Exclusivity (Directive No. 2 of 2011) ("Directive") has been issued by the Director of Pharmaceutical Services under Regulation 29 of the Control of Drugs and Cosmetics Regulations 1984.

The Directive mandates the protection of undisclosed, unpublished and non-public domain pharmaceutical test data, the origination of which involves considerable effort, submitted to the MOH for the purpose of scientific assessment in consideration of the quality, safety and efficacy of any new drug product containing a New Chemical Entity ("NCE") or approval for a second indication of a registered drug product.

Any person may apply for data exclusivity ("DE") protection and DE may be granted for:

(i) A new drug product containing NCE if an application is made in Malaysia within 18 months from the date the product is first registered or granted marketing authorization and is granted DE in the country of origin or any other country recognized by the Director of Pharmaceutical Services

(ii) Second indication of a registered drug product if an application is made in Malaysia within 12 months from the date the second indication is approved and is granted DE in the country of origin or any other country recognized by the Director of Pharmaceutical Services

The Directive provides for the maximum period of DE protection which shall not be more than 5 years for a new drug containing NCE and 3 years for a second indication of a registered drug product (in respect of the data concerning the second indication only). The DE period is calculated as follows:

(a) new drug containing NCE – period runs from the date the product is first registered or granted marketing authorization AND granted DE in the country of origin or in any country recognized by the Director of Pharmaceutical Services

(b) second indication of a registered drug product – period runs from the date the second indication is first approved AND granted DE in the country of origin or any country recognized by the Director of Pharmaceutical Services

Article 39.3 of the TRIPS Agreement provides for DE Protection and it stipulates:

> *"Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public or unless steps are taken to ensure that the data are protected against unfair commercial use."*

In the pharmaceutical industry, the public may only get the benefits of an innovative drug or a new or second indication of a drug after data has been generated to prove the drug's safety, quality and efficacy to the satisfaction of regulatory requirements[46]. As the generation of such data requires significant time and financial costs, the protection of such data from unfair commercial use is therefore necessary. Otherwise, there will be commercial and economic inequity caused to the innovator pharmaceutical companies that have had to generate the data at first instance[47].

PhAMA lauds the Government and MOH for fulfilling Malaysia's obligations under TRIPS by implementing DE in Malaysia through the Directive. Nevertheless, it remains of concern to PhAMA that the DE protection afforded by the Directive falls short of the general standard of protection granted by many other developed and developing countries worldwide.

IMPOSING SUCH TIME RESTRICTION AS A CONDITION FOR DE AVAILABILITY IS UNUSUAL RATHER THAN THE NORM WHEN COMPARED WITH THE CONVENTION IN MANY COUNTRIES.

PhAMA's Position and Recommendation

3.1 Eligibility for DE Conditional on Application Filed Within Limited Time

DE will only be considered if the marketing authorization application is filed within the time specified by paragraph 4.2 of the Directive. In respect of a new drug product containing NCE, the time limit is 18 months from the date the product is first registered or granted marketing authorization and for a second indication of a registered drug product, 12 months from the date the second indication is approved. Failure to observe the time limit will cause DE to be denied and forfeited.

Feedback from PhAMA's members since the implementation of the Directive on 1 March 2011 is that it is challenging, if not impossible, to meet the time limit if the first worldwide registration is not in the European Union or the United States as both are relied upon for the Certificate of Pharmaceutical Product (CPP), required to be submitted with the application. Currently, the submission of the regulatory dossier without the CPP is allowed only on a case-by-case basis. This causes hardship to PhAMA's members and they stand to lose DE if the application cannot be filed within time due to delay or factors beyond their control. The current regime is therefore unsatisfactory and unfair because innovator companies can unjustly be deprived of DE.

Imposing such time restriction as a condition for DE availability is unusual rather than the norm when compared with the convention in many countries as can be seen from **Table A**. A more detail comparison table can be found in Annexure-A to this Position Paper. PhAMA therefore strongly urge an amendment of the Directive so that DE eligibility shall not be conditional upon making the application for marketing authorization within any time limit.

46 International Federation of Pharmaceutical Manufacturer Associations (IFPMA) , " Encouragement of New Clinical Drug Development: The Role of Data Exclusivity" (Geneva, 2000)

47 ibid

Table A Conditions of Granting Data Exclusivity in Various Countries

Country	DE is automatically granted together with NCE / New Indication (NI) approval	DE implementation date is granted based on approval in the country of origin	DE will only be granted to new products if the application is made within a stipulated time from the date the product is registered in any country / NI is approved in any country
Australia	Yes	No, it is based on local registration approval	No time limit for application
Canada	Yes	No, it is based on local registration approval	No time limit for application
China	Yes	No, it is based on local registration approval	No time limit for application
European Union	Yes	No, it is based on local registration approval	No time limit for application
Japan	Yes	No, it is based on local registration approval	No time limit for application
Singapore	Yes	No, it is based on local registration approval	No time limit for application
Taiwan	Yes	No, it is based on local registration approval	Within 3 years from marketing approval in any country
USA	Yes	No, it is based on local registration approval	No time limit for application

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

The calculation of the DE period under the Directive is another point which PhAMA strongly urge re-consideration and change. Paragraph 4.6 calculates the DE period in Malaysia from the date the new drug product containing NCE is first registered or granted marketing authorization in the world and for a second indication of a registered drug, from the date the second indication is first approved in the world.

This is again unusual rather than the norm when compared with the convention in many countries as can be seen from Table A. Almost all countries calculate the period of DE 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. Here, unless the innovator companies seek marketing approval in Malaysia first, it is not possible that they get to enjoy the full period of DE. Furthermore, the local regime does not include any mandatory time limit for the grant of marketing approval after submission and also does not provide that if that time is not met, the DE period is to be correspondingly extended by the period after the mandatory time limit and the eventual grant. Although MOH gave notice in November 2010 of their intention to streamline the approval process to 210 working days, PhAMA's members continue to report lengthy delays. The result is that the existing regime unjustly penalizes innovator companies because they choose to seek marketing approval in other countries first.

PROGRESS, SUCCESS AND FAIR COMPETITION THRIVE WHEN THERE IS FAIR BALANCE, NOT WHEN THE INTERESTS OF ONE INDUSTRY, THE GENERICS, IS PLACED FIRST, OVER AND ABOVE THE COMPETING INTERESTS OF THE INNOVATIVE PHARMACEUTICAL INDUSTRY. ESPECIALLY, WHEN BOTH THE INDUSTRIES RELY ON PRODUCTS WHICH THE INNOVATOR COMPANIES HAVE TO FIRST INVEST FUNDS, EFFORT AND TIME TO DISCOVER AND PRODUCE.

As earlier highlighted, DE is one of the three rights granted to innovator companies in exchange for the "gains" to generics manufacturers as first crafted under the Hatch-Waxman Act. In Malaysia, generics manufacturers fully enjoy all the "gains" but DE, which is the only "gain" given to originator companies is unjustly restricted by paragraphs 4.2 and 4.6 of the Directive. This creates further inequity and hardship to innovator companies.

It is also disappointing that the Government thought it sufficient to confer DE by way of a Directive rather than through legislative enactment. This, again, departs from the practice in most other countries which is to have DE conferred as a statutory right. This would have been preferred as it would better secure DE's status and position in Malaysia. PhAMA would urge the Government to have DE enacted as part of the law, possibly, through the new Pharmacy Act.

ALMOST ALL COUNTRIES CALCULATE THE PERIOD OF DE 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.

Progress, success and fair competition thrive when there is fair balance, not when the interests of one industry, the generics, is placed first, over and above the competing interests of the innovative pharmaceutical industry. Especially, when both the industries rely on products which the innovator companies have to first invest funds, effort and time to discover and produce.

PhAMA has the same aspirations for Malaysia as the Government: for our nation to achieve world class status as a hub for advanced health innovations and healthcare delivery. Making changes to the existing regime to address the "gaps" highlighted so far will, at minimum, be required before Malaysia can begin to start on the journey to our common aspirations.

4. Second Or Subsequent Medical Usage Or Indication And Dosage Regime

This discussion on second or subsequent medical usage or indication and dosage regimen is in response to the recommendations in the consultancy project on issues relating to patent law and policy in Malaysia vis-à-vis the domestic pharmaceutical industry by the International Centre for Law and Legal Studies (I-CeLLS). This consultancy project was commissioned by the Performance Management and Delivery Unit (PEMANDU) in 2011. Amongst others, I-CeLLS recommended amending the patent law to disallow patent rights for second or subsequent medical usage, but to allow such inventions to be certified only as utility innovations. In the same project, I-CeLLS also recommended that patents for dosage regimens be disallowed totally.

The debate on new (whether second or subsequent) medical usage or indication for known drugs is not new. However, due to the recent rising costs in R&D spend[48] and the plethora of existing drugs with potential for repositioning, there has been realization that the repositioning of existing drugs can be advantageous.

Drug repositioning is the process of finding new uses outside the indication for existing drugs, and is also known as redirecting, repurposing or reprofiling[49]. For convenience, reference to "Second Medical Usage" or "Second Medical Use" in this paper will also include reference to subsequent medical usage or indication.

Strong patent protection is available for Second Medical Use in most of the developed and developing countries including the United States of America, Australia, Canada, Japan, South Korea, New Zealand, Singapore, Europe, China, Indonesia, Mexico, Nigeria, Philippines, Russia, Taiwan and Ukraine[50].

In Malaysia, our Patents Act 1983 similarly permits protection for Second Medical Use. By section 13(1)(d) Patents Act, "methods for the treatment of human or animal body by surgery or therapy, and diagnostic methods practiced on the human or animal body," are not patentable. However, the products used in any such methods remain patentable. Thus, patent claims for pharmaceutical products used for the methods as stated in section 13(1)(d) are made in a "Swiss-type" claim format as opposed to a direct claim for the method[51].

Section 14(4) Patents Act further reads as follows:

> *"The provisions of subsection (2) shall not exclude the patentability of any substance or composition, comprised in the prior art, for use in a method referred to in paragraph (d) of subsection (1) of section 13, if its use in any such method is not comprised in the prior art."*

Associate Professor of International Islamic University of Malaysia, Ida Medieha Abdul Ghani, concludes that "the policy of allowing the patenting of second medical use has been incorporated in the Patents Act" via s. 14 (4) of the Patents Act[52].

Although there is nothing in MyIPO's Guidelines for Patent Examination ("Guidelines") which deals expressly with patent claims for Second Medical Use, there is indication that an application for Second Medical Use in the "Swiss-style" format would be accepted[53].

Section 14 (4) is nearly identical to Article 54(4) of the European Patent Convention ("EPC") [formerly Article 54 (5) of the EPC 1973] and in the United Kingdom, there is a similar provision in the form of s 2(6) of the Patents Act 1977.

There is as yet no judgment by a Malaysian court on the interpretation of s. 14(4). It may thus be helpful to look at the decisions of the Enlarged Board of Appeal of the European Patent Office ("EPO") on this provision, since s. 14(4) is nearly identical to Article 54(4) EPC. In Re Eisai Co Ltd[54], the European Board of Appeal, referring to the former Article 54 (5) of the EPC 1973, which corresponds to the current Article 54(4), stated that:

> *"…It should be added that the Enlarged Board does not deduce from the special provision of Article 54(5) EPC that there was any intention to exclude second (and further) medical indications from patent protection other than by a purpose-limited product claim. The rule of interpretation that if one thing expresses the alternative is excluded (expressio unius (est) exclusion alterius) is a rule to be applied with very great caution as it can lead to injustice. No intention to exclude second (and further) medical indications generally from patent protection can be deduced from the terms of the European Patent Convention…"*

As s. 14(4) of our Patents Act is fashioned after Article 54(5) EPC, the ruling of EPO's Enlarged Board of the Appeal would serve as credible confirmation of the position in Malaysia that the product, substance or composition of a Second Medical Use is patentable if the use is novel. The Patents Act has already placed Malaysia in line with international standards in so far as a new second or subsequent medical use is concerned.

With regard the patentability of a new form or dosage of a known pharmaceutical product, patent offices and the courts have, in the beginning, generally taken a conservative and cautious approach. However, with greater understanding and awareness of the subject-matter, more and more countries have since allowed patent rights and have also acknowledged the need for it to be protected by patent.

In Abbott Laboratories[55], the Enlarged Body of Appeal, which is the EPO's highest judicial body, set out the following non-exhaustive list of potentially patentable subject matter which included a "new and inventive dosage regime":

(a) new and inventive dosage regime
(b) new and inventive mode of administration
(c) treatment of the same disease by targeting a different aetiology
(d) new patient group, which can be treated by the known substance or composition

The patent offices of many developed countries have granted protection for new dosage regimes, including the United States of America, Japan, Russia, Australia and New Zealand[56]. Prior to Abbott Laboratories, the EPO's Enlarged Board of Appeal stated in Re Eisai Co Ltd that:

> *"Where the medicament itself is novel in the sense of having novel technical features – e.g. a new formulation, dosage or synergistic combination – the ordinary requirements of Article 54(1) to (4) EPC will be met and there will in principle be no difficulty over the question of novelty……"*

Despite Re Eisai Co Ltd, the Court of Appeal of England & Wales in its earlier decision in Bristol-Myers Squibb v Baker Norton[57] held that a new dosage regime for the treatment of the same disorder did not fulfill the novelty requirement of a patent and is also contrary to the method of treatment exclusion. However, in its later decision in Actavis v Merck[58], the Court of Appeal reversed itself by going the other way and held that new dosage regimes were patentable, and in the words of Jacob LJ:

> *"Research into new and better dosage regimes is clearly desirable – and there is simply no policy reason why, if a novel non-obvious regime is invented, there should not be an appropriate patent reward. Such a reward cannot extend to covering the actual treatment but a Swiss form claim which specifies the new, inventive, regime is entirely in accordance with policy.*[59]*"*

In so far as Malaysia is concerned, there is no express prohibition in the Patents Act to disallow patent for a novel, non-obvious dosage regime. Instead, s. 14(4) would permit the patenting of any product, substance or composition used in a novel, non-obvious dosage regime, in line with the current position of an increasing number of developed and developing countries.

As the world population grows larger, there is a more pressing and urgent need to keep epidemics and antimicrobial resistance in control, in addition to the general need for quality and affordable health care for all. As pharmaceutical products resulting from the R&D conducted by pharmaceutical companies is a huge part of the provision of health care, the discovery of drugs for new and existing diseases is critical to ensure advancement in healthcare. Despite huge R&D investments to discover new drugs, increasingly fewer drugs have been discovered[60]. As Chong and Sullivan states:

> *"The current costly and time-consuming paradigm of drug discovery is ill equipped to combat rapidly emerging diseases, such as avian flu, drug-resistant pathogens and diseases that have a small financial market. One solution is to identify new uses for existing drugs. As the pharmacologist and Nobel laureate James Black said "the most fruitful basis for the discovery of a new drug is to start with an old drug.*[61]*"*

IMPOSING SUCH TIME RESTRICTION AS A CONDITION FOR DE AVAILABILITY IS UNUSUAL RATHER THAN THE NORM WHEN COMPARED WITH THE CONVENTION IN MANY COUNTRIES.

Drug repositioning allows a reduction in the pharmaceutical R&D timeline. Develop ment risks are also reduced as known drugs would typically have known safety and pharmacokinetic profiles. It is a research and production strategy that offers a shorter route to patients due to the many stages of drug development that can be bypassed[62]. All-in-all, repositioning offers a better trade-off compared to other drug development strategies[63]. Thus, research into further uses of known drugs has considerable health and economic importance. Disallowing patent protection for Second Medical Use or a new, non-obvious dosage regime would be detrimental to society as there would then be no incentive by innovator companies to invest in R&D of existing drugs. The prejudice and harm to society should this occur would be immense. However, if protection is given to repositioned drugs, it will undoubtedly drive innovation in this area of R&D as there is incentive for pharmaceutical companies to invest in the repositioning of drugs. Society will then have the chance of benefiting from a new use or a new, more effective dosage regimen of a known drug.

Although repositioning offers a better trade-off compared to other R&D strategies, this does not mean that the development of a new use for an existing drug or a new dosage regimen is investment-free or does not come with challenges. There is still a need to test the potential new indications in clinical trials to keep the public safe[64], and sometimes even the most basic data collected for the original indication is no longer acceptable due to the changes in regulatory standards[65]. Prior to that, the substance or compound will have to be identified and the idea of repositioning will have to be validated, and subsequently, there is a need to conduct a market analysis of the potential candidate's product profile[66]. Consider the repositioning of ceftriaxone from an antibiotic to a potential treatment for amyotrophic lateral sclerosis[67] - this required a laborious screening of 1040 different compounds from the National Institute of Neurological Disorders and Stroke's custom collection[68]. The R&D efforts and funding that are funnelled into second medical usage or drug repositioning are certainly not a trivial matter. In the United States, the cost of phase II clinical trials alone for a second medical use is approximately US$ 17 million and lasts on average two years[69].

It is no different when it comes to new, non-obvious dosage regimes (including dosage forms and mode of administration). Testing is important as the wrong dosage can cause loss of drug action[70]. R&D costs are frequently increased[71] to make the drugs suitable and safe for its target market, for example, formulations for children. Traditional tablets may be accepted by children of school going age[72], but is generally not acceptable by patients younger than that. Creating a liquid formulation involves dealing with a number of challenges[73] as the dose and volume of liquid medicines may be limited by the solubility of the known drug compound, thus requiring research into the necessary volume and type of co-solvent and surfactant excipients to be added. Stability has to be ensured with buffering agents, antioxidants and preservatives. Indeed, sometimes, more sophisticated formulations are required such as encapsulation of drug particles. These complex procedures all pose difficult technical challenges and *"consequently, research and development will be more lengthy and costly."*[74] Unfortunately, as it stands, many drugs currently have no available liquid formulation for patients[75]. Denying patent protection will serve only to retard progress in this area by removing any incentive for R&D.

Developing new forms of formulations such as fast-dispersing dosage forms ("FDDFs")[76], not just for children, but geriatric and bedridden patients[77], require particular technology, which, more often than not are proprietary to third parties, for example, Zydis™ (Scherer), OralSolv™ (Cima), WOWtab™ (Yamanouchi) and oral thin films (LTS Lohmann). Thus, there may need to be licensing agreements in place which will drive up the cost of R&D even further. As a result, *"development costs [for FDDFs] are higher than for conventional oral dosage forms"*[78].

Further, contrary to common belief, the pharmaceutical company that runs the research for the repositioning may not be the proprietor of the patent for the original indication. Indeed, 15 out of 26 of the drugs with a second medical usage as identified by Ashburn and Thor have different originators and re-positioners[79]. Thus, there will be IP licensing issues and the financial implications arising from them that will need to be settled before R&D may even commence.

With all the heavy investments into R&D and the development of existing technology, bringing about overall improved healthcare benefits and advancement, there is no justifiable case to deny patent protection for any of these innovations. This would be a regressive step for Malaysia and we will be worse off for it. Not only will

innovator companies shy away from R&D investments and innovative activities in Malaysia, we can also expect to find only older generations of dosage regimens and medical uses, which undoubtedly, will be less effective and beneficial compared to the latest new dosage regimens and medical uses protected elsewhere by patent.

The presumption that denying patent protection to these innovations (as proposed by the International Centre for Law and Legal Studies (I-CeLLS)) will allow generics manufacturers to freely market them in Malaysia is overly simplistic and not a sound one. Unless generics manufacturers are willing to undertake the costs and effort to generate safety and efficacy data of their own, they will not have access to such data to support marketing approval if the innovator companies do not first market the drug in Malaysia.

[48] Ted T. Ashburn and Karl B Thor, "Drug Repositioning: Identifying and Developing New Uses for Existing Drugs" (2004) 3 Nature Reviews 673, page 673
[49] ibid
[50] Ravi Srinivasan and Alastair Newman "Patent protection for new uses of known drugs" (International J A Kemp, Building and Enforcing Intellectual Property Value, 2013) *<www.iam-magazine.com >* accessed 10 October 2014
[51] Intellectual Property Corporation of Malaysia "Guidelines for Patent Examination in the Intellectual Property Corporation of Malaysia" (2011) at page 23
[52] Ida Medieha bt Abdul Ghani Azmi, " Pharmaceutical Patents in Malaysia" [2002] 2 MLJ i at xxvi
[53] Intellectual Property Corporation of Malaysia "Guidelines for Patent Examination in the Intellectual Property Corporation of Malaysia" (2011) at page 23
[54] Decision Gr 05/83 (Second Medical Indication/Re Eisai Co Ltd)
[55] Decision G2/08 (Dosage Regime/ Abbott Laboratories) cited in Ravi Srinivasan and Alastair Newman "Patent protection for new uses of known drugs" (page 17, International J A Kemp, Building and Enforcing Intellectual Property Value 2013) *<www.iam-magazine.com >* accessed 10 October 2014
[56] Ibid
[57] Bristol-Myers Squibb v Baker Norton [2001] RPC 1
[58] Actavis UK Ltd v Merck & Co Inc [2008] EWCA Civ 444
[59] ibid
[60] Peter Landers, "Drug industry's big drug push into technology falls short" (Wall Street Journal, 2004) *<http://www.wsj.com/articles/SB107758348388437255>* accessed on 15 January 2015
[61] Curtis R. Chong and David R. Sullivan, "New uses for old drugs" (2007) 448 Nature 645, page 645
[62] Supra Note 48 at page 673 and 674

[64] Benjamin N. Roin, " Solving the Problem of New Uses", (1 October 2013) *< http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2337821 >* assessed on 26 September 2014
[65] Supra Note 48 at page 677
[66] Supra Note 48 at page 676
[67] Rothstein et al. "Beta-lactam antibiotics offer neuroprotection by increasing glutamate transporter expression" (2005), Nature 433(7021):73-77 cited in Chong CR and Sullivan Jr. DJ "New uses for old drugs", (2007), Nature 448(9): 645, page 645
[68] Ibid
[69] Di Masi JA, Hansen RW, Grabowski HG , "The price of innovation: new estimates of drug development costs"(2003), Journal of Health Economics, 22:151-185; cited in Chong CR and Sullivan Jr. DJ , "New uses for old drugs"(2007), Nature 448(9): 645, page 645
[70] Schirm et al. , "Lack of appropriate formulations of medicines for children in the community" (2003) Acta Paediatr 92
[71] Nunn T and Williams J , "Formulation of medicines for children" (2004), British Journal of Clinical Pharmacology 59(6): 674-676
[72] Ibid.
[73] Ibid.
[74] Ibid.
[75] Nahata MC , "A lack of paediatric drug formulations", (1999) Paediatrics 104(3) Suppl 607
[76] Ibid.: Examples include Calpol Fast Melts (Pfizer), Nurofen Meltlets (Crookes Healthcare) and Benadryl orodispersable tablets (McNeil)
[77] Seager H, "Drug-delivery Products and the Zydis Fast-dissolving Dosage Form" (1998) Journal of Pharmacy and Pharmacology 50: 375–382
[78] Supra Note 71
[79] Supra Note 48 at pages 677 to 681

PhAMA's Position and Recommendation

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.

There is also no valid or reasoned justification to limit inventions for a new, non-obvious second medical usage to protection as utility innovations. Unlike patent inventions which must be both novel and inventive, utility innovations do not need to satisfy the requirement of inventive step or non-obviousness. The reason why the Patents Act has provisions for utility innovations is to provide protection for innovations of a rather incremental character which may not meet the patentability criteria. The objective of the Patents Act in this regard is to encourage and promote innovation, if the invention does not meet the higher criteria for patent protection, the law will still protect it as a utility innovation if it is new. In practice, protection as utility innovation is generally considered suited for SMEs that make minor improvements to and adaptations of existing products.

WHETHER INVENTIONS OF A SECOND MEDICAL USAGE OR DOSAGE REGIMEN IS TO BE PROTECTED AS INVENTIONS OF PATENTS OR UTILITY INNOVATIONS MUST BE DETERMINED IN ACCORDANCE WITH PATENT LAW AND BE GIVEN THE SAME, EQUAL TREATMENT AS ALL OTHER INVENTIONS.

To artificially confine new, non-obvious second medical usage to protection as utility innovations throws the whole patent regime under the Patents Act into disarray. If it is new and non-obvious, it is deserving of patent protection just like all other inventions. If it is new but does not meet the inventiveness requirement then, it may only be protected as a utility innovation just like all other inventions which do not meet this requirement. To make an exception with respect new, non-obvious second medical usage as recommended by I-CeLLS demonstrates intent to deny patent protection and confine such inventions to protection as utility innovations, regardless that the invention may be new and non-obvious and would have been granted patent protection if it wasn't an invention in the nature of a second medical usage.

I-CeLLS's recommendation is a blanket discrimination against second medical usage inventions and renders them less worthy than other inventions. PhAMA is strongly against the recommendations of I-CeLLS. Whether inventions of a second medical usage or dosage regimen is to be protected as inventions of patents or utility innovations must be determined in accordance with patent law and be given the same, equal treatment as all other inventions. Permitting exceptions to be made as recommended by I-CeLLS is a dangerous position to take. It introduces uncertainties to Malaysia's patent system, with all the attendant negative consequences. Innovation will suffer. If the category of second medical usage inventions can suffer a "downgrade" and be treated worse off than other patentable inventions, innovators and investors will be left to wonder what other inventions will next suffer a downgrade. The uncertainty and ever present threat of being stripped of eligibility for full patent rights will not augur well for innovation in Malaysia, our business standing, economy and country.


3. Limits on Confidential Information
deemed proprietary, and the Recip
such information where the infor
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Information from
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5. Compulsory Licensing

A compulsory license is a license granted by a competent national authority allowing the exploitation of a patent without the consent of the patentee. Broadly speaking, compulsory licenses are granted in the following situations[80]:

(a) Non-working of a patent
(b) Other, more broadly defined abuses
(c) Public interest

On the international front, Article 5 of the Paris Convention for the Protection of Industrial Property 1883 ("Paris Convention") allows countries to provide legislative provisions for the grant of compulsory licenses to prevent abuses which might otherwise arise from the patentee's exclusive right to exploit the patent. Article 31 of the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS Agreement") also gives recognition to compulsory licensing; allowing the use of a patent without the patentee's authorization provided certain conditions are satisfied.

In Malaysia, compulsory licensing is provided for under Part X and section 84 of the Patents Act 1983. Compulsory licensing under Part X deals mainly with instances when a patent is not worked in Malaysia, or where a compulsory license is issued on the basis of interdependence of patents. Section 84 provides for compulsory licensing pursuant to a national emergency or where the public interest requires it or where the patentee is found by a judicial or relevant authority to have exploited the patent in an anti-competitive manner. In this discussion, the law, both domestic and international, in relation to both types of compulsory licenses will be set out separately, followed by a discussion on the current state of the law in relation to economic and commercial reality.

5.1 Compulsory Licensing Under Part X of the Patents Act 1983 Local Working Requirements and Interdependence of Patents

Whilst the concept of compulsory license and the need for it are generally accepted as can be seen from the provisions of the Paris Convention, TRIPS Agreement and our Patents Act, the conditions stipulated by national laws as to when compulsory licensing may be invoked have been the subject of heated debates and challenge. In this regard, PhAMA would highlight Article 27.1 of the TRIPS Agreement, which prohibits a compulsory license regime which discriminates as to the place of invention, field of technology and whether products are imported or locally produced.

In 2000, the United States requested for a consultation with Brazil at the WTO Dispute Settlement Body to discuss the legality of Article 68 of Brazil's Law No. 9,279 of 14 May 1996, which establishes that the local working requirement for patents can only be satisfied by local production of the patented invention[81]. However, the consultation was not carried through and the United States, due to increasing pressures from a public backlash, opted to reach a mutually agreeable solution with Brazil and withdrew its WTO complaint[82].

Malaysia has the same "local working" requirement. Section 49(1) of the Patents Act provides that an application for a compulsory licence may be made by any person at any time after the expiration of three years from the grant of a patent, or four years from the filing of a patent application, whichever is the later, if:

(a) there is no production of the patented product or application of the patented process in Malaysia without any legitimate reason (emphasis added); or

(b) there is no production of the patented product in Malaysia for sale in any domestic market, or if there are some but are sold at unreasonably high prices or do not meet the public demand without any legitimate reason (emphasis added)

There is a surprising dearth of published literature on the motivation and rationale for imposing the "local working" requirement in Malaysia. The words "in Malaysia" were inserted pursuant to amendments to the Patents Act in 2001[83], making a patent eligible for compulsory licensing in Malaysia if the claimed product is not produced or the claimed process is not applied in Malaysia. Importation into Malaysia of the patented products will no longer suffice to avoid compulsory licensing[84].

Section 49A of the Patents Act deals with the situation when patents are inter-dependent and allows grant of a compulsory license to the extent necessary to avoid infringement, if the invention claimed in a later patent cannot be worked in Malaysia without infringing an earlier patent and the invention of the later patent constitutes an important technical advance of considerable economic significance in relation to the invention of the earlier patent.

Upon grant, the Malaysian Intellectual Property Office will determine[85] the scope and time period of the license as well as the amount and conditions of royalty payments to the patentee.

THERE IS NO BASIS TO REQUIRE LOCAL PRODUCTION IF THE PATENTED GOODS ARE ALREADY FREELY SOLD AND COMMERCIALLY AVAILABLE IN MALAYSIA BY WAY IMPORTATION.

PhAMA's Position and Recommendation

The local working requirement imposed by section 49 of the Patents Act is absent in countries with strong patent rights, for example, Singapore and the United States. Such a requirement is inconsistent with and contradicts Article 27.1 of TRIPS which prohibits a compulsory licensing regime which discriminates based on place of production. Some learned authors have taken the position that Article 27.1 of TRIPS does not allow any country to invoke a local working requirement[86]. In the European Union, the European Court of Justice has held that the local working requirements in one member state are satisfied by the importation of products manufactured in another member state of the European Union[87], which was the position in Malaysia prior to the amendment of the Patents Act to insert the words "in Malaysia".

In relation to working requirements in general, it has been observed that the non-working of a patent might not always be negative, as "sleeping patents" may occur as a result of market uncertainty or low speed of discovery – a company may choose not to invest at a time when the market conditions are unsuitable for entry. A working

requirement might actually cause a forward looking company to delay the research activity, causing considerable social and private detriment[88].

PhAMA urges further amendment of the Patents Act to remove any imposition of local working requirements which are inconsistent with Article 27.1 of TRIPS. In a highly globalized and mobile world, it is not possible, from an economic or logistical perspective for patentees to have local production in every country which imposes "local working requirements". The production location or the place of application of a patented process is a very commercially driven decision – where a myriad of factors are at play and weighed including availability of raw materials, costs, local talent pool, tax incentives and others. The imposition of local working requirements is thus unlikely to cause or motivate a patentee to locate production facilities locally or to apply the claimed process here if from its financial and business considerations, Malaysia is not a top choice in terms of suitability. There is no basis to require local production if the patented goods are already freely sold and commercially available in Malaysia by way importation. In permitting compulsory licensing in such a situation, section 49(1) of the Patents Act in effect, compels the patentee to permit a licensee to produce the patented goods locally in competition with the patentee's goods which are already sold in the local market.

PHAMA THEREFORE REITERATES THE NEED TO AMEND THE PATENTS ACT TO REMOVE ANY IMPOSITION OF LOCAL WORKING REQUIREMENTS WHICH ARE INCONSISTENT WITH ARTICLE 27.1 OF TRIPS.

The existing provisions of the Patents Act permit the compulsory licensing scheme to be unjustly exploited against the patentee. In short, it allows the Government to intervene in patent matters against the wishes and consent of the patentee without an extremely good and valid reason. This is a dangerous power and could bring about unexpected consequences for Malaysia if unjustifiably exercised. PhAMA therefore reiterates the need to amend the Patents Act to remove any imposition of local working requirements which are inconsistent with Article 27.1 of TRIPS.

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

The controversy surrounding the cost of drugs to treat AIDS and the number of HIV cases and deaths in Africa[89] led to the Declaration on the TRIPS Agreement and Public Health[90] during the Ministerial Conference in Doha in 2001 ("Doha Public Health Declaration"). It was declared that the TRIPS Agreement does not prevent measures to protect public health. In particular, paragraph 6 of the Doha Public Health Declaration states:

> *"We recognize that WTO Members with insufficient or no manufacturing capabilities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and report to the General Council before the end of 2002."*

Article 31(f) of the TRIPS Agreement provides that the use of the patent subject matter is allowed only if such use is authorized "predominantly for the supply of the domestic market of the Member authorizing such use", thereby preventing the export of generics to countries that do not have the ability and infrastructure to manufacture the drugs themselves[91]. Following paragraph 6 of the Doha Public Health Declaration, the General Council of the WTO issued the decision entitled "Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health[92]" ("2003 WTO Decision") which waived the obligations of an exporting member under Article 31(f), provided that:

(a) The eligible importing member has made a notification to the Council for TRIPS specifying the names and expected quantities of the products needed and has established that it has insufficient or no manufacturing capabilities for the products and confirms that the pharmaceutical product is patented in its territory. The notification should also confirm that the importing country intends to grant or has granted the compulsory license in accordance with Article 31 of the TRIPS Agreement and the provisions of the 2003 WTO Decision

(b) The compulsory license issued by the exporting member contains the following conditions:

  (i) Only the amount necessary to meet the demands of the importing member may be manufactured under the license and the entire production will be exported to the particular importing member

  (ii) The products produced under the license has to be clearly identified as being produced under the 2003 WTO Decision, and the supplier should distinguish the products through special packaging, special colouring and/or shaping of the product

  (iii) Prior to the shipment of the products, the licensee shall post on a website the quantities to be supplied to the importing member, as per (i) above and the distinguishing features of the products as per (ii) above.

(c) The exporting member shall notify the Council for TRIPS of the grant of license and the conditions attached to it.

Following the 2003 WTO Decision, a member country may now export generics to countries with insufficient or no manufacturing capabilities. The conditions attached to the compulsory license as stated in the declaration are to prevent abuse or unfair compromise of the exclusive rights of the patentee. The compulsory license is to be issued in good faith to protect public health and not be used as an instrument to pursue industrial or commercial policy objectives. In fact, the then General Council chairperson, Carlos Perez del Castillo, Uruguay's ambassador, left no room for doubt about this in his statement[93]:

> *"...Second, Members recognize that the purpose of the Decision would be defeated if products supplied under this Decision are diverted from the markets for which they are intended. Therefore, all reasonable measures should be taken to prevent such diversion in accordance with the relevant paragraphs of the Decision…… Third, it is important that Members seek to resolve any issues arising from the use and implementation of the Decision expeditiously and amicably……Fourth, all information gathered on the implementation of the Decision shall be brought to the attention of the TRIPS Council in its annual review..."*

On 6 December 2005, a decision was made by the General Council[94] to amend the TRIPS Agreement by inserting Article 31 bis ("Protocol Amending the TRIPs Agreement"), which states that Article 31(f) shall not apply in respect of compulsory licenses granted for the purposes of production of pharmaceutical products and its export to eligible importing members. This corresponds with the 2003 WTO Decision which envisages exportation by an exporting member to the eligible importing member.

The WTO's website which provides guidance on how to accept the Protocol Amending the TRIPS Agreement is helpful reference and makes it clear that a member country may accept the Protocol without implementing it domestically:

> *"Can a Member accept the Protocol without implementing the Paragraph 6 System?*
>
> *Accepting the Protocol is clearly distinct from implementing the Paragraph 6 System in Members' domestic legal frameworks. In other words, the Protocol can be accepted independently from adopting domestic implementing legislation…. The legal act of acceptance of all WTO Member's entitlement to use the System is not dependent upon and is therefore distinct from a Member's domestic implementation of the System in the accepting Member in the event it decides itself to take advantage of the System….."*[95]

Section 84 of our Patents Act allows a patent to be exploited by a Government agency or a third party designated by the Government, including importing the patented drug into Malaysia, without the patentee's consent in the following circumstances:

> *"(a) where there is a national emergency or where the public interest, in particular, national security, nutrition, health, or the development of other vital sectors of the national economy as determined by the Government, so requires; or*
>
> *(b) where a judicial or relevant authority has determined that the manner of exploitation by the owner of the patent or his licensee is anti-competitive,"*

The exploitation of the patent shall be limited to the purpose for which it was authorized. The patentee must be paid adequate remuneration, taking into account the economic value of the Minister's authorization and where a decision is made to correct anti-competitive practices, the need to correct such practices. And, by section 84(8), the exploitation of the patent by the Government agency or a person designated by the Government shall be predominantly for the supply of the market in Malaysia.

Section 84 is not an uncommon provision – in fact, the grant of compulsory licenses for reasons of public health interests has been heavily utilized in Brazil and Thailand[96]. The Malaysian government has also previously invoked section 84 to allow the importation of antiretroviral drugs from India[97].

There have however been proposals and calls recently to extend section 84 to allow for compulsory licenses to export pharmaceutical products to least developed nations that are incapable of producing pharmaceutical products[98], as promulgated by the 2003 WTO Decision.

Although several countries including the European Union[99], China[100] and South Korea[101] have legislatively adopted the 2003 WTO Decision, thus far, only Canada has successfully shipped drugs manufactured under a compulsory license to Rwanda in 2008. An application by India's NatcoPharma Ltd for a compulsory license to manufacture cancer drugs to be exported to Nepal was subsequently withdrawn[102].

Prior to any discussion on whether our patent law should be amended to allow compulsory licenses to be granted for the export of drugs to least developed nations in accordance with the 2003 WTO Decision, it would be instructive to take a look at the Canadian experience in evaluating the feasibility of this.

In Canada, an application for a compulsory license to manufacture pharmaceutical products for export may be made pursuant to its Access to Medicines Regime (CAMR). Apotex Inc., a generics manufacturer, first made such an application to manufacture and export HIV drugs to Rwanda[103]. The entire process, originally initiated by the non-governmental organization Medicins San Frontieres (MSF), took about four years, from the initiation of the CAMR process to the first shipment of the drugs. MSF subsequently withdrew its participation due to time and financial constraints[104]. After its experience, Apotex labelled CAMR as "unsuccessful"[105] and was unwilling to use the process again, citing the high costs and the lengthy time as the reasons for its reluctance[106].

IN THEORY, GRANTING A COMPULSORY LICENSE FOR THE EXPORT OF PHARMACEUTICAL PRODUCTS TO LEAST DEVELOPED NATIONS IN NEED MIGHT SEEM LIKE A NOBLE AND GOOD IDEA. WHEN PUT INTO PRACTICE, THE SCHEME WAS NOT WORKABLE FOR A MYRIAD OF REASONS AND IT REINFORCES THE POINT THAT PATENTS ARE NOT THE BARRIER TO ACCESS TO MEDICINES IN POOR COUNTRIES IN THE FIRST PLACE. IN GENERAL, ONLY A SMALL SUBSET OF THE DRUGS WAS PATENTED. THE PRESENCE OF PATENTS HAS NOT UNIFORMLY DETERRED GENERIC PURCHASING.

In theory, granting a compulsory license for the export of pharmaceutical products to least developed nations in need might seem like a noble and good idea. When put into practice, the scheme was not workable for a myriad of reasons[107] and it reinforces the point that patents are not the barrier to access to medicines in poor countries in the first place. In a survey conducted by Attaran and Gillespie-White on antiretroviral drugs in African countries, it was found that generally, only a small subset of the drugs were patented[108]. Even if the drugs were patented, they were not being strictly enforced by the innovator companies in poor countries and the presence of patents has not uniformly deterred generic purchasing[109].

The many implications and consequences of compulsory licensing must be carefully considered before granting any compulsory license and before any amendment of the law to broaden the powers to grant compulsory licence. Jon Matthews explains:

> *"Imagine you are the owner of a large pharmaceutical company in the United States. You have spent enormous amounts of money and time in developing a new and useful drug. Patent ownership provides protection for your business so that as your company grows, you have more money to invest in research and development of new drugs. To your surprise, you find that you are slowly losing your patents because you are forced by foreign governments to allow others to use your patented products without your consent. As a result, profits are diminished and control of your product weakened."*[110]

In granting and dealing with compulsory licenses, whether pursuant to Part X or section 84 of the Patents Act, it is imperative that the government considers a long-term, "big picture" view of the matter and the impact it has on the patentee as well as the message it is sending to innovator companies. The threat of a compulsory license will affect the drive to innovate in the country, not only generally as stated in Part 2 of this Position Paper, but it will also bring about consequences which are specifically related to the threat of compulsory licensing. In situations where the patents involved are for drugs to treat diseases endemic to the developing region[111], the threat of compulsory licensing of these types of drugs will have increased negative consequences on the innovator companies than drugs which are also in demand in rich, developed countries, as there would be an even more limited market to recoup R&D and other costs associated with the drug development. If such costs cannot be recovered, innovator companies will be discouraged or unable to continue further R&D on such types of drugs and this will only result in a lack of newer and better drugs to combat those endemic diseases.

Bird and Cahoy in their study on the relationship between FDI and compulsory licensing came to the conclusion that whilst the issuance of compulsory licenses by a least-developed country might not affect FDI decisions of multi-national companies, the issuance of compulsory licenses in middle developed countries (such as Malaysia) can trigger the loss of significant FDI[112].

BIRD AND CAHOY IN THEIR STUDY ON THE RELATIONSHIP BETWEEN FDI AND COMPULSORY LICENSING CAME TO THE CONCLUSION THAT WHILST THE ISSUANCE OF COMPULSORY LICENSES BY A LEAST-DEVELOPED COUNTRY MIGHT NOT AFFECT FDI DECISIONS OF MULTI-NATIONAL COMPANIES, THE ISSUANCE OF COMPULSORY LICENSES IN MIDDLE DEVELOPED COUNTRIES (SUCH AS MALAYSIA) CAN TRIGGER THE LOSS OF SIGNIFICANT FDI.

There have been examples in practice such as when in 2007, the Thai government issued a compulsory licence for Kaletra, a drug to combat AIDS owned by Abbott although it did not encounter any public health emergencies as defined under TRIPS. Abbott later announced that it was planning to withdraw registration of half a dozen of new drugs in Thailand even after the Thai Government issued its explanatory report. The U.S. Trade Representative Office also listed Thailand as a priority watch country following the issuance of the compulsory licenses[113]. Thailand might have also suffered broader economic losses as a result of its compulsory licensing.

In considering compulsory licensing in Egypt, Bird and Cahoy suggested that the current state of the law of compulsory licensing there could have contributed to the decline in FDI despite the Egyptian government's aggressive efforts to attract FDI[114]. What is striking from the discussion by Bird and Cahoy are the similarities between the compulsory licensing schemes applicable in Malaysia and Egypt (Egypt's Article 23(4) of Law No. 82 of 2002 Pertaining to the Protection of Intellectual Property Rights allows the grant of compulsory license if the patentee does not exploit the patent in Egypt[115]. This provision is similar to Malaysia's section 49 of the Patents Act). Further, Cottier et al in their study on the impact of local working requirements on technology transfer, concluded that such requirements generally weaken IP rights, which is ironically associated with technology transfer[116].

PhAMA's Position and Recommendation

PhAMA's position is that compulsory licenses should only be resorted to in exceptional circumstances of genuine necessity as how it was originally intended. Compulsory licenses allow competitors to enter into a market when the patent is still valid – this destroys the fundamental principle of patents, which is exclusivity to compensate for innovation expenses[117]. Patent protection is of fundamental importance to innovator companies as the R&D work required to be carried out carries with it high risks of failure and the costs to be recouped are not only the costs associated to the patent itself, but the R&D costs of other inventions that failed[118]. Lawmakers in the United States have acknowledged the pharmaceutical sector's unique reliance on investment-backed expectations[119]. The compulsory licensing scheme which is in place and the exercise of power to grant licence under the scheme must always carefully consider the innovator company's position as patentee before forcing it to give up exclusivity of rights.

The urgings by the generics sector to amend the law to permit compulsory licensing to manufacture to export outside Malaysia contrary to section 84(8) of the Patents Act cannot be rushed into but require further careful deliberation and thought. The Government must first consider Malaysia's suitability as a producer of generics to least developed countries and whether such locally produced generics will be able to compete with generics produced elsewhere. Interested licensees wishing to produce generics for export to least developed nations will still have to offer prices that are sufficiently competitive. Generic companies too are driven and motivated by profits and the licensing venture will have to be a profit-making one to be sustainable.

In the Canadian experience referred to earlier, Apotex who had obtained a compulsory licence to produce for export to least developed countries, had initially priced the drug at $0.39 per tablet and could not make a sale. It lost out to Indian generic companies who offered the drug at $0.36 per tablet. Apotex was forced to reduce the price to $0.195 per tablet and at this pricing, Rwanda bought a batch. Apotex stopped selling altogether after a short time, the lack of profitability at this low pricing no doubt contributing to its decision to discontinue[120].

It is worthy also to note that the implementation by other countries of the Protocol Amending the TRIPS Agreement into their legislations did not result in a rush by generic companies to apply for compulsory licenses to export in accordance with the Protocol. The Protocol is to serve the real and genuine needs of least developed nations for very competitively priced medicines and is certainly not intended as a means for generics companies to use compulsory licence for a profit-making venture at the expense of innovator companies. The Government will be misguided if the Protocol is implemented as law to satisfy such motivation and purpose of the generic companies.

IT IS WORTHY ALSO TO NOTE THAT THE IMPLEMENTATION BY OTHER COUNTRIES OF THE PROTOCOL AMENDING THE TRIPS AGREEMENT INTO THEIR LEGISLATIONS DID NOT RESULT IN A RUSH BY GENERIC COMPANIES TO APPLY FOR COMPULSORY LICENSES TO EXPORT IN ACCORDANCE WITH THE PROTOCOL.

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[84] Lim Heng Gee, " The Compulsory Licensing in the Patents Act 1983 – A Potent Weapon or an Emasculated Deterrent?" [2004] 1 MLJ 70, page 77

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[120] Supra Note 103 at page 154


LAW

6. Enforcement Of Intellectual Property Rights

This part of the Position Paper examines some of the relevant legislative and practical issues concerning enforcement of IP rights by the pharmaceutical industry in Malaysia.

6.1 Counterfeit Medicines in Malaysia

The World Health Organisation (WHO) defines a counterfeit medicine as one, which is deliberately and fraudulently mislabeled with respect to identity and/or source[121]. The counterfeiting of medicines can occur both in relation to branded as well as generic products. Counterfeit products may include products with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging.

It is estimated that counterfeit medicines account for nearly 10% of the world's supply of medicine or US$22 billion and will grow to become 16% of the aggregate size of the legitimate industry. This growth is faster than the legitimate trade. It is also estimated that counterfeit medicines sales will grow 13% annually through 2010, compared to just 7.5% estimated annual growth for the legitimate global pharmaceutical trade[122].

In Malaysia, a survey conducted in 1997 by the Ministry of Health disclosed that 5.8% of the drugs sampled in urban and rural areas were fakes. PhAMA ran a survey of its own almost a decade later in 2005 where 289 samples of 3 prescription medicines were purchased from a total of 196 pharmacies and clinics. The result turned in by the PhAMA survey was that approximately 5% of the prescription medicines were fakes. During the almost 10-year period between the two surveys, it appears that the rate of counterfeit medicines in Malaysia did not decrease but had remained largely constant.

In 2005, the Government was moved to introduce the use of Meditag security labels on all packaging of medicines, not only as an added "tool" to curb counterfeit and unregistered medicines but also, to better safeguard public health. Officially enforced from 1 May 2005, its use is now mandatory for all products registered with the Drug Control Authority.

The Meditag security label is a hologram with a serial number issued by the Ministry of Health (MOH). All private pharmacies are supplied with a decoder to verify the originality of the Meditag label affixed on packaging so that consumers can themselves check to verify the authenticity of the security labels prior to purchase. Nevertheless, counterfeiters have not been deterred and were still able to copy the labels with the help of their counterparts in China[123]. This required the Government to revise the Meditag hologram to incorporate more sophisticated features. On 1 November 2012 the third version of the hologram (Meditag III) was approved for use. Tapping into the current widespread use of multimedia communication, the MOH also released a smart phone application to allow consumers to compare the Meditag label on a particular pharmaceutical product with the authentic features of the Meditag hologram.

The volume and value of unregistered products (which included counterfeit medicines) seized by the authorities during enforcement raid actions have been increasing over the years as reflected by the data shown in Table 1[124]:

Table 1 Value of Unregistered Products Seized by Authorities During Enforcement Raid Actions

Year	Market Value of Unregistered Products Seized (RM)
2003	6.5 Million
2009	10.4 Million
2011	22.5 Million
2012	23.7 Million

What is certain is that the issue of counterfeit medicines is not one which will go away or be easily eradicated. The counterfeiting of medicines is too a lucrative business, with generally low production costs, high gross margins and sales opportunities available at both local and export markets. Counterfeited medicines purportedly produced in Malaysia have been found not only in the local market but also in Hong Kong, Thailand and Vietnam. An effective, robust and well-functioning regulatory and legal enforcement frame work is required if the problem of counterfeit medicines is to be kept controlled and curbed to a minimal level.

6.2 Applicable Legislation

There is no single consolidated piece of legislation to govern the enforcement of IP rights concerning the pharmaceutical industry. Instead, provisions are found in a number of statutes.

Section 58 of the Patents Act 1983 provides for the civil wrong of patent infringement and defines what constitutes infringing acts. Section 59 gives the patentee the right to sue in the High Court anyone who has infringed or is infringing or who has performed acts so that infringement will likely occur (imminent infringement). The exploitation of a patent without the patentee's licence is not made a criminal offence by the Patents Act. Hence, a patentee does not have the option to lodge complaints with the enforcement authority for criminal or administrative enforcement action to be taken against a person who exploits the patent without licence. The patentee's rights in relation to his patent are enforceable primarily through an infringement action in the High Court.

Other relevant statutes that may be used against counterfeit and unregistered medicines are:

(1) Trade Descriptions Act 2011

(2) Sale of Drugs Act 1952

(3) Poisons Act 1952

(4) Control of Drug and Cosmetic Regulations 1984; and

(5) Medicine (Advertisement and Sale) Act 1956

Included amongst their provisions are those which vest necessary powers of enforcement in authorized public officers (including the police) and prescribe the penalties for offences associated with counterfeit medicines.

6.3 Penalty for Offences Relating to Counterfeit Medicines

There is no minimum penalty prescribed by any of the statutes which govern offences relating to counterfeit medicines. Only the maximum penalties are prescribed. Judges thus have a wide discretion when it comes to sentencing. There is also no obligation to impose a jail term in the case of a repeat offender although the maximum limit of the penalties for such cases is generally doubled. A summary of the current sentencing provisions for offences relating to counterfeit drugs is as per **Table 2**:

Table 2 Summary of Current Sentencing Provisions for Offences Related to Counterfeit Drugs

	First Offence			Second or Subsequent Offence		
Statutory Provision	**Minimum Fine (RM)**	**Maximum Fine (RM)**	**Imprisonment Term**	**Minimum Fine (RM)**	**Maximum Fine (RM)**	**Imprisonment Term**
Sections 5 & 8 Trade Descriptions Act 2011	None	100,000 for individual; 250,000 for company	Up to 3 years	None	250,000 for individual; 500,000 for company	Up to 5 years
Section 12 Sale of Drugs Act 1952	None	25,000 for individual; 50,000 for company	Up to 3 years	None	50,000 for individual; 100,000 for company	Up to 5 years
Section 32 Poisons Act 1952	None	3,000 for normal cases; 5,000 for wilful default or culpable negligence	Up to 1 year for normal cases, up to 2 years for wilful default or culpable negligence	None	3,000 for normal cases; 5,000 for wilful default or culpable negligence	Up to 1 year for normal cases, up to 2 years for wilful default or culpable negligence
Control of Drugs and Cosmetics Regulations 1984	None	None	None	None	None	None
Section 5(1) Medicine (Advertisement and Sale) Act 1956	None	3,000	Up to 1 year	None	5,000	Up to 2 years

Although the maximum fines for the first and subsequent offences prescribed under the Trade Descriptions Act 2011 are considerably higher than the repealed Trade Descriptions Act 1972 and other related statutes, the absence of a prescribed minimum penalty deprives the 2011 Act of the "bite" it needs to be an effective deterrent to counterfeiters and repeat offenders. There is still no assurance that offenders guilty of dealing in counterfeit medicines and thereby exposing the public to all the harmful health risks which such counterfeits bring, will receive punishment sufficient to have a deterrent effect despite the higher maximum limits.

Based on past cases, PhAMA has reasons to be concerned in this regard. Such concerns have been expressed on numerous occasions previously and in the 2006 PhAMA Paper on Counterfeit Drugs[125], examples of some cases were also highlighted:

- In April 1999, a manufacturer was arrested for producing counterfeit Panadol and having in his possession approximately RM500,000.00 worth of goods and equipment. On a guilty plea, he was sentenced to a fine of

only RM 15,000.00, far below the maximum limit of RM 100,000.00 and/or imprisonment up to 3 years imposed by the Trade Descriptions Act 1972. It was a most lenient penalty considering that the offender was manufacturing counterfeits and was in possession of half a million Ringgit worth of goods and equipment. The sentence was hardly of any deterrent effect.

- In December 2000, the enforcement authority raided a pharmacy in Kota Kinabalu, Sabah and seized 3 units of counterfeit Ventolin inhalers. On a guilty plea, the offender was fined a mere RM 5000.00, despite the harm and danger possibly caused to a patient using the counterfeit inhalers.

In the 2011 Annual Report published by the MOH, the total value of counterfeits and unregistered drugs seized through raids, inspection and at entry points in 2011 was around RM 30,066,168. However, the total amount of fines collected from completed prosecution cases was only RM 2,172,100.00. The huge difference between the value of items seized and the amount of fines imposed and collected is further indication that the punishment handed out for offences involving pharmaceutical products does not commensurate with the gravity and seriousness of the offences[126].

In contrast, the penalties for copyright offences have a prescribed minimum that serves well to help achieve a deterrent effect. The Copyright Act 1987 was amended in 2012 to introduce heavier penalties and to prescribe minimum penalties for offences. For example, a minimum fine of RM 2,000.00 and a maximum fine of RM 20,000.00 for the sale of each infringing copy is now imposed on offenders. If the offence is repeated, the minimum and maximum penalties per each infringing copy are doubled.

Thus, the position we have currently is that an offender dealing in pirated software or music will face more severe punishment than an offender dealing in counterfeit medicines, despite the fact that counterfeit medicines can be seriously harmful, even fatal, to a consumer.

Taiwan is a good example of a country that was able to successfully reduce counterfeit medicines in the domestic market using statutorily prescribed minimum penalties. Before 2003, Taiwan was the 3rd largest market for counterfeit medicines. Enforcement was ineffective and counterfeiters enjoyed lenient punishments for the offences committed. In 2004, the Pharmaceutical Affairs Act was amended to impose stiffer penalties. Offenders who cause serious personal injury or death through the manufacture or sale of counterfeit medicines will face minimum jail sentences[127]. A summary of the penalties imposed by the amended Act are as per **Tables 3 and 4**:

Table 3 Summary of the Penalties Imposed by the Amended Act on Manufacturing of Counterfeit Medicines

Manufacturing of Counterfeit Medicines			
	Maximum Fine (NT)	Minimum Jail Term	Maximum Jail Term
Normal Case	$10 million	None	10 years
Negligence	$ 500,000	None	3 years
Resulting in Serious Personal Injury	$10 million	7 years	None
Resulting in Death	$10 million	10 years	Life imprisonment

Table 4 Summary of the Penalties Imposed by the Amended Act on Selling, Supplying, Dispensing, Transporting, Storing, Brokering, Transferring or Displaying with Intent to Sell Counterfeit Medicines

Selling, Supplying, Dispensing, Transporting, Storing, Brokering, Transferring or Displaying with Intent to Sell Counterfeit Medicines			
	Maximum Fine (NT)	Minimum Jail Term	Maximum Jail Term
Normal Case	$5 million	None	7 years
Negligence	$ 300,000	None	2 years
Resulting in Serious Personal Injury	$5 million	3 years	12 years
Resulting in Death	$5 million	7 years	None

In 2008, inter-departmental data found the estimated level of counterfeit medicines in the Taiwan market to be only 0.8% of market value[128]. This was significantly lower than in the years before amendments to the Pharmaceutical Affairs Act imposed hefty penalties on those dealing in counterfeit medicines.

The importance of punishment that will deter cannot be emphasized enough in countering counterfeit medicines. The IDEAS Report concluded that if "*the punishment meted out to producers or distributors are not sufficiently strong, some may view the benefits of counterfeiting to far outweigh the risks.*[129]" Unless the penalties imposed are sufficiently heavy and where appropriate, include a minimum jail term, any fines imposed by the Court will just be factored in as another cost of running the business in counterfeit medicines and will do nothing to deter or stop offenders.

PhAMA's Position and Recommendation

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.

For repeat offenders and offenders who are manufacturers, importers, wholesalers or distributors of counterfeit medicines, PhAMA further strongly recommends the imposition of a mandatory jail sentence for a minimum prescribed term. This will be an effective message of deterrence to would-be offenders and will clearly signal the government's firm stance against counterfeit medicines.

6.4 The New Pharmacy Act

The Pharmacy Bill was mooted by the MOH to consolidate existing legislations relating to pharmaceuticals. In 2012, the Ministry published an Online Public Engagement ("OPE") document[130] to gather public feedback on the new Pharmacy Bill. The OPE document highlighted several important proposals with respect the enforcement of IP rights in the pharmaceutical industry and the inclusion of legislative provisions that will directly address the issue of counterfeit medicines.

Point 13 of the OPE document[131] (which deals with the need for more deterrent penalties) identified some of the deficiencies of the existing legislations including:

- Low penalties
- Public safety is not taken into consideration
- Public interest is not protected
- Requirements of international conventions are not fulfilled.

The Bill then outlined some of the proposals relating to penalties for offences:

(a) Fine of RM100,000 for unregistered products

(b) Mandatory imprisonment and fine for the following cases:

⇨ Counterfeit drugs

⇨ Adulterated products

⇨ Psychotropic distribution

⇨ Precursor diversion

(c) Suggestions of General Penalties:

⇨ Individual

- Minimum imprisonment of 1 year
- Minimum fine of RM500,000

⇨ Companies

- Minimum imprisonment of 1 year
- Minimum fine of RM1,000,000

Point 18 of the OPE document[132] highlighted the lacuna of the existing laws which the Pharmacy Bill aims to eliminate. It identified some of the difficulties and weaknesses with respect the enforcement of IP rights and counterfeit medicines as follows:

- Difficulty in bringing cases of poisons possession under the Poisons Act 1952
- Restrictive interpretation of the Control of Drugs and Cosmetics Regulations 1984 compared to the principal legislation which is the Sale of Drugs Act 1952
- Cases under the Sale of Drugs Act 1952 have to be brought to Court within 60 days as required by Section 18(4) of the Act
- No provision which specifically addresses "counterfeit medicines", "trafficking of psychotropic drugs", "drug diversion", "data exclusivity" and "sampling" for big seizure items.

The OPE document further proposed that legislative provisions to adequately deal with the lacunas identified be introduced to form part of the new Pharmacy Act.

PhAMA's Position and Recommendation

PhAMA fully supports the proposals of the Pharmacy Bill. Comments, feedback and recommendations to the Pharmacy Bill have been given by industry members. PhAMA would strongly urge the Government and lawmakers to seriously consider and take them into account.

The progress of the Pharmacy Bill has remained stagnant for the past few years with little published information regarding its current status. PhAMA seeks that the Pharmacy Bill be progressed through the next stages soon and for its safe passage through Parliament without any more delay.

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. This rebuttable presumption which will aid in the prosecution of offences is now already found in the Trade Descriptions Act 2011 and the Copyright Act 1987. It remains absent in the Sale of Drugs Act 1952, Control of Drugs and Cosmetic Regulations 1984 and Poisons Act 1952.

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. This will hold those who engage in the printing, supplying and making available to counterfeiters, infringing labels, inserts, packaging and other literature relating to the original drugs, accountable and punishable as well.

6.5 Practical Issues of Enforcement

The Pharmacy Enforcement Division under the MOH and the Enforcement Division under the Ministry of Domestic Trade, Co-operatives and Consumerism (MDTCC) are the governmental agencies responsible for administrative enforcement of offences relating to pharmaceutical products. In general, the MDTCC has responsibility to enforce offences under Trade Descriptions Act 2011 while the MOH has responsibility for offences under the Sale of Drugs Act 1952, Control of Drugs and Cosmetics Regulations 1984 and Poisons Act 1952. To carry out their duties, their respective officers have powers, amongst others, to enter premises to investigate and search for relevant evidence as well as to seize and remove products, documents, equipment and any relevant evidence relating to an offence.

Whilst PhAMA lauds the co-operation and willingness of both the MOH and MDTCC to act and take enforcement actions against counterfeit cases that have been reported, there remain, however, serious weaknesses in the existing enforcement framework and processes which undermine and negate much of the efforts of industry members in this regard. Without an effective and well-structured enforcement mechanism, the most perfect legislative provisions on offences and penalties will yield little positive results.

PhAMA's concerns in this regard are borne out by the fact that the number of enforcement actions taken over the years is significantly much higher than the few cases of successful prosecution that are recorded. Some of the problems with prosecution have already been identified in the 2006 PhAMA Paper on Counterfeit Drugs[133]:

(a) There is a lack of co-operation and co-ordination between the MOH and MDTCC. Frequently, a counterfeiter may be found liable for offences under the Trade Descriptions Act as well as the Sales of Drugs Act. It is rare that a counterfeiter is charged for offences under more than one statute. Contrast the position in our closest neighbor, Singapore, where prosecutors will routinely charge a counterfeiter with all possible offences under different legislations so that when convicted, the counterfeiter will face the maximum possible penalties.

(b) Raiding officers are often found to be not sufficiently trained or experienced to conduct raid actions, resulting in poor documentation of evidence collected from the site and breaking the chain of evidence. Once the chain is broken, prosecutors will have a difficult task in successfully proving the offence.

(c) Chemists and other experts responsible for the analysis of the counterfeit drugs need to be educated and made more aware about the impact their reports will have on the prosecution case. Inadequately conducted analysis, sub-standard reports and one which fails to preserve the chain of evidence can be fatal to the prosecution. To illustrate, in Public Prosecutor v Lee Yau Ket [2008] AMEJ 0049, the chemist failed to prepare a proper description with sufficient details of the pills which she analyzed. She had given only a very general description. The High Court ruled that in cases involving pills, a comprehensive description of the subject drugs, including the size, colour, shape, length, width and depth of the pills should be set out. Mere photographs of the pills are not sufficient. This inadequacy ultimately contributed to the accused being acquitted.

(d) The investigations by the authorities after the raid action do not last very long. Valuable information necessary to uncover the mastermind and its entire organization are frequently left untouched or not followed up on.

(e) It is not uncommon to find prosecutors short on the necessary skills to prosecute the offence. A lack of knowledge and skills in court procedures, rules of evidence and admissibility of documents are frequently demonstrated. The result is particularly devastating when the prosecution is up against an experienced defense lawyer who is well familiar with all the possible weaknesses and difficulties of the prosecution's case.

Additionally, Point 16 of the OPE document[134] drew attention to the need to reduce bureaucracy by integrating the processes of the appointment of Drug Enforcement officers. Under existing legislations, officers are appointed by different authorities depending on the subject matter. For example:

- Appointment of Authority Officer for advertisement by the Minister
- Appointment of Officers and Inspectors by Chief Ministers
- Appointment of Drug Enforcement Officers by Director General of Health

PhAMA's Position and Recommendation

PhAMA is committed to fighting counterfeit medicines in Malaysia. PhAMA is also ready and willing to extend assistance within its means and to co-operate closely with the Government to achieve the common aim of successfully curbing counterfeiting activities in medicines.

PhAMA strongly reiterates the need to address the weaknesses which have been identified in the current prosecution framework and processes. It is noted with regret that the weaknesses remain problematic weaknesses today despite the same having been highlighted in the 2006 PhAMA Paper on Counterfeit Drugs. A firm commitment from the Government to overhaul the system to bring about much needed changes and improvements is long overdue.

PhAMA fully supports the need for a more streamlined approach as has been highlighted by Point 16 of the OPE document. This can only result in a simpler, more effective and more productive system. There should also be provisions in the new Pharmacy Act which can delegate enforcement powers to the police, custom officers and maritime enforcement officers.

IPHAMA STRONGLY REITERATES THE NEED TO ADDRESS THE IDENTIFIED WEAKNESSES IN THE CURRENT PROSECUTION FRAMEWORK AND PROCESSES. THEY REMAIN PROBLEMATIC WEAKNESSES TODAY EVEN THOUGH THEY WERE ALREADY HIGHLIGHTED IN THE 2006 PHAMA PAPER ON COUNTERFEIT DRUGS.

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[131] Supra Note 128 at page 6

[132] Supra Note 128 at page 8

[133] Supra Note 123 at pages 7 and 8

[134] Supra Note 123 at page 7

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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