Malaysia

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Selection, clearance and registration

Governing legislation

The Trademarks Act 1976 and the Trademarks Regulations 1997 provide for the registration of trademarks and service marks in Malaysia.

The Malaysian trademark system is substantially based on the system of the United Kingdom and thus operates in much the same way as other systems in the Asia-Pacific region, such as those in Australia, Hong Kong and Singapore.

Requirements for registration

The Trademarks Act allows the registration of any mark used or proposed to be used in relation to goods and/or services to indicate a connection in the course of trade between the goods and/or services in question and the party having the right to use the mark. In this regard, a 'mark' includes any device, brand, heading, label, ticket, name, signature, word, letter, numeral or any combination of these elements. Marks in languages other than English or Malay are also registrable, provided that a translation and transliteration are included.

To be registrable in the Trademarks Register, a mark must be inherently distinctive of the proprietor's goods and/or services. Therefore, a trademark may consist of:

- the name of an individual, company or firm represented in a special or particular manner;
- the signature of the applicant or of the predecessor of the applicant's business;
- an invented word (or invented words);
- a word (or words) which has no direct reference to the character or quality of the relevant goods and/or services and which is not, according to its ordinary meaning, a geographical name or a surname; or
- a sign that is distinctive in some other way.

The Trademarks Registry generally follows the Nice Classification of the World Intellectual Property Organization, which sets out 45 classes of goods and services.

Priority applications are accepted in Malaysia. If a trademark has been applied for in another member country of the Paris Convention for the Protection of Industrial Property, the applicant may claim the date of that application as the priority date of the corresponding application in Malaysia.

Non-traditional marks

Certain marks are distinctive due to their particular colour or combination of colours. To enhance registrability, such colour(s) may be limited to specified colour(s). However, it is usually not advisable to limit a trademark in terms of its colour(s), unless it is necessary to enhance distinctiveness, as the colour (or colours) in which a mark is used often has a bearing on whether a similar mark in different colours is an infringement or is calculated to deceive.

Shape marks are generally not registrable in Malaysia.

Application procedure
An application for the registration of a trademark is made by completing and lodging the application form with the Intellectual Property Corporation of Malaysia (IPCM). The application form must contain the filing particulars and a representation of the mark. The applicant is also required to provide a statutory declaration affirming that the applicant is the good-faith proprietor of the trademark and that the application is being filed in good faith.

Once the trademark application has been filed, it is then examined for registrability. If objections are raised, the IPCM will send an official letter giving the reasons for the objection and the applicant will be given two months to reply. If the submissions are unsuccessful, the IPCM will issue another official letter setting out its objections. Thereafter, the applicant has the opportunity of requesting a formal hearing before a senior officer of the registry. If this fails, the matter may be appealed to the High Court.

If the IPCM accepts the submissions, the application will then proceed to advertisement. Upon acceptance, the IPCM will advertise the application in the *Government Gazette*. Any party may oppose the registration of the trademark during a period of two months.

If there is no opposition, the registry will accept the mark for registration and issue a certificate of registration. Registration is effective from the date of application. A trademark registration is valid for a period of 10 years from the filing date and can be renewed indefinitely for subsequent periods of 10 years.

Parallel imports and repackaging

Parallel imports
Parallel imports are generally allowed in Malaysia. Under the Trademarks Act, if the mark is applied to the goods by the registered proprietor or if the latter expressly or impliedly consented to the use of the mark, such use will not amount to trademark infringement. Therefore, if the trademark is applied to certain products by the proprietor (or with its authorization) and the products are subsequently put on the market with the proprietor's consent, the importation and sale of those goods would not amount to trademark infringement.

As long as the parallel-imported goods sold in Malaysia are genuine and meet the quality standards of the proprietor, there does not appear to be an adverse impact on the proprietor's trademark rights, as there is no confusion as to the source of the goods. However, as consumers may not be aware of the difference between parallel imports and goods purchased through official distribution channels, the proprietor's goodwill in Malaysia may be damaged if the products are of inferior quality. In such a case, a trademark owner may seek to restrain the goods from entering Malaysia under the tort of passing off.

Repackaging
If the goods are placed on the original market with a notice restricting any alteration to their state, condition, get-up, packaging or trademark, any act of a third party (including a parallel importer) that contravenes these restrictions would amount to infringement, unless the third party:

- bought the goods in good faith without being aware of the notice of restriction; or
- became the owner of the goods by virtue of a title derived from another party.

In view of the above and subject to the exceptions, should the original packaging or the goods contain an express restriction against repackaging, refurbishing or modification of the goods, any subsequent alteration by a third party may amount to trademark infringement.

Anti-counterfeiting and enforcement

Current situation
The Ministry of Domestic Trade and Consumer Affairs (MDTCA), the Ministry of Health (MOH) and the Pharmaceutical Association of Malaysia (PhAMA) are especially concerned about the rise in counterfeiting and have recently participated in an industry roundtable to increase the efforts to combat counterfeit pharmaceuticals in Malaysia. In 2007 the value of seized counterfeit medicines amounted to M$35.8 million, in comparison to M$25.9 million in 2004. In addition, a survey carried out in 2005 by a member of PhAMA found that nearly 5% of the sample prescription medicines purchased from pharmacies and clinics were counterfeit.

Criminal offences
Offences relating to counterfeit medicines are provided under:

- the Trade Descriptions Act 1972;
- the Copyright Act 1987;
- the Sale of Drugs Act 1952;
- the Control of Drugs and Cosmetics Regulations 1984; and
- the Poisons Act 1952.

Such offences carry a maximum penalty of M$250,000 and imprisonment for up to 10 years for the first offence. The enforcement offices of the MDTCA and the MOH are responsible for carrying out raids and prosecuting offenders. There are calls to amend the legislation so as to:

- provide for minimum fines and jail sentences for each counterfeit item; and
- empower the courts to revoke or suspend the business licence of offenders, as recent cases have shown that the penalties imposed by the courts have been minimal and non-deterrent.

Holograms
As an additional measure, since May 2005 the MOH has mandated that all registered pharmaceutical products bear Meditag holograms with distinct registration numbers. However, recent reports show that counterfeiters have circumvented this by using fake holograms that mirror the original Meditag holograms.

Border measures
The Trademarks Act provides that the proprietor of a registered trademark in Malaysia may apply to the IPCM to restrict the importation of counterfeit goods into Malaysia. The IPCM then notifies the Royal Malaysian Customs, which will seize the counterfeit goods upon arrival. The proprietor of the registered trademark is expected to commence an action for trademark infringement against the importer within a specified period, failing which the seized goods will be returned to the importer.

Advertising

Governing legislation
The advertising of pharmaceuticals in Malaysia is governed by:

- Part 3 of the Malaysian Communications and Multimedia Content Code;
- the Medicines (Advertisement and Sale) Act 1956; and
- the Medicine Advertisement Board Regulations 1976.

The Medicines (Advertisement and Sale) Act provides that any person who wishes to publish any advertisement of a medicine must first seek approval from the Medicine Advertisements Board, a branch of the Pharmaceutical Services Division of the MOH.

Definition and general requirements
An 'advertisement' is defined as any notice, circular, report, commentary, pamphlet,

label, wrapper or other document, and any announcement made orally or by any means of producing or transmitting light or sound. Only pharmaceutical products registered with the MOH can apply for approval from the Medicine Advertisements Board. In general, the advertisement should contain information that is reliable, accurate, truthful, informative, balanced, up-to-date, capable of substantiation and in good taste. It should not contain any misleading or unverifiable information or omissions likely to induce medically unjustifiable use or to give rise to undue risks.

The board is also empowered by law to issue policies and guidelines on pharmaceutical advertisements that relate to medical and health claims. To date, the board has issued two guidelines to assist advertisers in creating advertisements which are deemed compliant and appropriate for publication. Advertisers are advised to adhere to these guidelines as the board uses them as the basis for its decisions.

Offences

The Medicines (Advertisement and Sale) Act specifies prohibitions relating to certain diseases, abortion and skills and services relating to treatment, prevention or diagnosis. Non-compliance with these provisions is an offence under the Medicines (Advertisement and Sale) Act, carrying a penalty of up to M$5,000 and/or imprisonment for a maximum of two years. Enforcement in this regard lies with the Medicine Advertisements Board; companies have been charged under these provisions and fined up to M$1,500. In 2004 the board reported a total of 70 cases investigated, out of which 10 cases were prosecuted in court.

Generic substitution

Regulation

Generic substitution is not prohibited in Malaysia. However, with the increasing availability of generic products, the MOH has issued bioequivalence studies requirements for certain categories of generic oral immediate-release products under the Malaysian Guidelines for the Conduct of Bioavailability and Bioequivalence Studies. Malaysia is also party to the Guidelines for the Conduct of Bioavailability and Bioequivalence Studies of the Association of Southeast Asian Nations.

All drugs, including generic products, must be registered with the Malaysian Drug Control Authority. The mechanism of bioequivalence ensures that pharmaceutical products are therapeutically equivalent to the innovator's products and are clinically interchangeable.

Definition and general requirements

Two medicinal products are deemed to be bioequivalent if:

- they are pharmaceutical equivalents or alternatives; and
- their bioavailabilities (ie, the rate and extent to which the active substance in the drug is delivered from a pharmaceutical form into the general circulation of the body) after administration in the same dose are similar to such degree that their effects, with respect to both efficacy and safety, will essentially be the same.

The Guidelines for the Conduct of Bioavailability and Bioequivalence Studies provide for applications of products containing new active substances and approved active substances. Products containing new active substances will need to show bioavailability and bioequivalence, while products containing approved active substances need show bioequivalence only if they are intended to be substituted for an approved medicinal product. A list of drugs requiring the submission of bioequivalence studies reports when formulated in oral solid dosage form are provided by the Drug Control Authority. In those cases, applicants will need to ensure that appropriate bioequivalence studies are conducted for the generic drug before applying for product registration.

Online issues

Trademark infringement

Use of a third party's registered trademark on a website (whether or not as a hypertext link) without consent may amount to trademark infringement. The Trademarks Act states that a registered mark is infringed by a person who, without the consent of the registered proprietor, uses an identical or similar mark "in an advertising circular or other advertisement issued to the public as importing a reference" to the person having the right to use the mark either as registered proprietor or as registered user. Arguably, a website may amount to "an advertisement to the public". Therefore, if all the other elements are present, a registered proprietor may file a claim for trademark infringement.

Domain names

The Malaysian Network Information Centre (MYNIC) is responsible for the registration of third-level domain names ('.com.my') in Malaysia. MYNIC is unable to accept registrations for second or first-level domain names. Domain names are registered on a first-come, first-served basis. MYNIC checks only that the domain name application does not conflict with an earlier registered domain name. There is no cross-checking against the Company Name Register or the Trademarks Register.

MYNIC's Domain Name Dispute Resolution Policy is an administrative process designed to provide simple, fast and affordable resolution of domain name disputes. Where the complainant successfully proves that the disputed domain name is identical or similar to a trademark in which it has rights and that the domain name was registered in bad faith, the disputed domain name will be transferred to the complainant or deleted. Examples of bad faith include registration or use of the domain name in a bid to sell it to the complainant for profit or to disrupt the complainant's business.

E-pharmacies

There are no specific legislative provisions on the sale of pharmaceuticals through e-pharmacies. In any event, any sale of pharmaceuticals, whether online or via retail pharmacies, requires licensing from the relevant authorities. WTR

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Chew Kherk Ying is an advocate and solicitor of the High Court of Malaya in Malaysia and Singapore. She heads the Intellectual Property Practice Group in Wong & Partners and has practised in the area of intellectual property since 1988.

She was voted by *Asia Law & Practice* as one of Asia's leading IP lawyers in 2004, 2005, 2006, 2007 and 2008 and is the principal author of the *Intellectual Property Laws of Malaysia* published by CCH. Ms Chew is also one of the panellists appointed by the Regional Centre for Arbitration Kuala Lumpur to handle disputes for the Malaysian Domain Name Dispute Resolution Service.

Ms Chew is a past president of the Licensing Executives Society Malaysia, a committee member of the Intellectual Property Committee of the Bar Council Malaysia and also the EXCO Member of the Malaysian Chapter of AIPPI (the International Association for the Protection of Intellectual Property).