Thailand

Contributing firm
Rouse

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According to healthcare information group IMS Health, the value of the Asia-Pacific pharmaceutical market amounts to $50 billion, while the total value of the Association of Southeast Asian Nations (ASEAN) pharmaceutical market is $9.66 billion. Thailand's pharmaceutical market is the largest in the ASEAN region with a 26% share.

Selection, clearance and registration

Trademark selection

The pharmaceutical industry is slightly different from other industries when it comes to selecting trademarks for new products. Companies generally choose a trademark that is as distinctive as possible – namely, either an invented or fanciful word (eg, LYCRA), or an arbitrary term (eg, ORANGE for telecommunications). However, with regard to pharmaceuticals, there is an advantage to be gained by selecting a trademark that is similar to the World Health Organization's (WHO) international non-proprietary name (INN), so that the mark can be identified by consumers as referring to a certain type of goods, while still functioning as an indicator of origin. Nevertheless, the WHO encourages pharmaceutical companies to select trademarks that do not use the entire INN, but only part of it.

Registration

In Thailand, a pharmaceutical trademark will be accepted for registration as long as:

- there is no likelihood of confusion with the corresponding INN;
- registration of the mark does not infringe prior third-party rights; and
- the mark is sufficiently distinctive.

With regard to goods in Class 5 of the Nice Classification (including pharmaceuticals), the Thai Department of Intellectual Property applies slightly less stringent criteria than for other types of goods. However, the department takes a strict approach to the itemization of the goods covered by a mark. For example, it is insufficient to apply for "vaccines" in Class 5 – the applicant must specify the intended use of the vaccines (eg, "vaccines for human use in the treatment of influenza").

Non-traditional trademarks

The department considers that non-traditional trademarks are not inherently distinctive. Single colour marks are usually found to lack distinctive character, but marks consisting of a combination of colours have been allowed. Obtaining registration of a three-dimensional mark remains extremely difficult, but may be achieved where:

- there is strong evidence of acquired distinctiveness; and
- the features of the mark are not determined solely by the function of the goods (eg, the mark consists of the shape of a tablet).

However, a judicial committee has been considering a number of amendments to the

Trademark Act (BE 2534), as amended by the Trademark Act (BE 2543), which would make the registration of non-traditional trademarks even more difficult. The proposed revisions include the rewording of Section 7(3) of the act, which states that "a combination of colours represented in a special manner, stylized letters, numerals or invented words" will usually be considered to be distinctive. The amended provision would read as follows: "a combination of colours, numerals or letters represented in a specific or particular manner." Moreover, Section 7(7) would be amended to read as follows: "a shape or three-dimensional object to be used in trade to cause the public or users of such goods to know and recognize that goods using such a shape or three-dimensional object are different from other goods."

Importantly, the Thai Food and Drug Administration (FDA) requires that companies obtain approval of any proposed trademark and product before the drug is allowed to be imported, marketed and sold in Thailand. In order to do so, applicants must obtain a licence from the Drug Control Division of the FDA.

Parallel imports and repackaging

Parallel imports

Thailand is at the forefront in providing affordable drugs to fight HIV/AIDS. For a number of years, the courts and the legislature have been encouraging the parallel importation of drugs.

The Trademark Act contains no express provision on parallel imports. Under Section 44, a trademark owner has the "exclusive right to use its mark for the goods for which it is registered". In 2000 the Supreme Court of Thailand interpreted this provision by applying the principle of international exhaustion of rights (Decision 2817/2543). The court allowed the importation and resale in Thailand, without the consent of the trademark owner, of a branded product that had been legally marketed in the exporting country. However, the opinion of the presiding judge, Nandana Indananda, gave an indication of the type of restrictions that could apply to parallel imports in Thailand: "In some cases, the court might prohibit parallel imports even where the products are genuine – for example, where the products have been made pursuant to a compulsory licence in a foreign country, where the quality of the goods is lower than that in the country of origin, where the products have been sold by an unrelated company, or where the repackaging of the goods might create confusion among consumers."

The principle of international exhaustion of rights may also be found in Section 36(7) of the Patent Act (BE 2522), as amended by the Patent Act (No 2) (BE 2535) and the Patent Act (No 3) (BE 2542). Under this provision, the use, sale, possession for sale, offering for sale or importation of a patented product which has been produced or sold with the authorization or consent of the patentee shall not be considered as an infringement of the patent.

Compulsory licences

In addition to parallel imports, the Thai government relies on compulsory licensing, the Bolar exemption and patent linking in order to facilitate access to cheaper drugs. The grant of compulsory licences for the heart disease drug clopidogrel (patent holder: Sanofi-Aventis), the HIV/AIDS antiretroviral drugs lopinavir and ritonavir (patent holder: Abbott Laboratories) and the anti-HIV/AIDS drug efavirenz (patent holder: Merck Sharp & Dohme) drew harsh criticism from pharmaceutical firms and various foreign governments. In particular, they argued that the conditions of the compulsory licences should have been negotiated with the patent holders before the issuance of the licences; in addition, they questioned whether the Department of Disease Control of the Ministry of Public Health had the authority to issue compulsory licences for non-commercial use.

In light of the foregoing, it is not surprising that Thailand was elevated to the Priority Watch List in the 2007 Special 301 Report from the Office of the US Trade Representative: "While the United States acknowledges a country's ability to issue such licences in accordance with [World Trade Organization] rules, the lack of transparency and due process exhibited in Thailand represents a serious concern. These actions have compounded previously expressed concerns, such as delay in the granting of patents and weak protection against unfair commercial use for data generated to obtain marketing approval."

Anti-counterfeiting and enforcement

Prompted by such criticism, Thailand has recently introduced various initiatives aiming to strengthen the cooperation between the various enforcement authorities in order to prevent and curb the distribution of counterfeit drugs.

On February 14 2008 the Department of Intellectual Property, the Thai Customs Department, the Royal Thai Police, the Department of Special Investigation and the Pharmaceutical Research and Manufacturers Association of Thailand signed a memorandum of understanding on the prevention and suppression of counterfeit drugs. Unfortunately, the FDA — which has the authority to investigate and take measures against drug counterfeiters — did not sign the memorandum of understanding.

The objectives of the memorandum are to:

- encourage the public and private sectors to cooperate in order to prevent and curb the production, sale, importation and exportation of counterfeit and illegal drugs through the use of all relevant laws;
- facilitate the enforcement of the laws relating to the protection of IP rights, including the Trademark Act and the Patent Act;
- promote morality and trade discipline, and protect the life and health of the public; and
- review and implement various measures in order to create a systematic and effective enforcement framework.

Other memoranda of understanding on piracy and counterfeiting have been entered into since 2004. These memoranda resulted in practical benefits for IP rights holders, as the number of customs raids increased.

However, the Thai enforcement authorities and the pharmaceutical industry must now act together in order to remove counterfeit drugs from the market. Although the enforcement authorities have initiated actions of their own accord (eg, the Royal Thai Police investigated the sale of counterfeit drugs on the Internet), their success in this regard has been limited. Therefore, the burden to detect the presence of counterfeit drugs and coordinate enforcement actions still lies on the pharmaceutical firms.

Advertising

Regulation

The advertising and promotion of drugs must be truthful and non-misleading. Advertisements through any type of media (including audio-visual transmission) must be approved in advance by the authorities. Advertising of prescription-only or pharmacy medicines to the general public is prohibited. Advertising of such drugs to professionals is permitted. Drugs belonging to the category of household remedies may be advertised directly to the general public.

Specifically, under the Drug Act (BE 2510), advertisements for drugs must not:

- claim that the drug is capable of miraculously curing the disease or illness, or prevent the disease or illness;
- make exaggerated or false claims about the drug; and
- mislead consumers into believing that the drug contains medicinal substances or ingredients which it does not actually contain.

Violations of the Drug Act carry a prison term not exceeding six months and a fine not exceeding Bt10,000 (approximately $285).

Planned product liability legislation

The government is planning to introduce new legislation imposing strict liability on those involved in the production and sale of unsafe products causing loss or damage to consumers. The Unsafe Product Liability Act is due to come into force on February 20 2009 and will impose strict liability on manufacturers, sellers, importers and others in the distribution chain in respect of all products manufactured or imported for sale.

An 'unsafe' product is one that causes or may cause injury due to:

- manufacturing or design defects;
- the manufacturer's failure to provide adequate warnings;
- inadequate or unclear information in relation to the product; or
- its use and storage in normal conditions and circumstances.

Any individual who suffers damage or loss – whether to life, body, health, mind or property – due to the use of an unsafe product may bring a civil claim for loss or damage. In order to succeed on such claims, the plaintiff (or his or her representative) must prove that:

- he or she has suffered loss or damage;
- the loss or damage was caused by the product; and
- he or she had followed the instructions for use or storage of the product in normal circumstances.

The business operator will not be held liable if it can prove that:

- the product in question was not unsafe;
- if the product was unsafe, the injured party was aware of that fact before he or she started using it;
- the loss or damage was caused by incorrect use or storage of the product; or
- the injured party failed to take account of a warning or ignored relevant information which had been clearly and correctly provided.

Liability cannot be excluded or limited by contract.

The new legislation is likely to lead to an increased number of consumer claims. Apart from the immediate monetary implications for business operators, it may have a serious negative impact on any brand being used on or in relation to unsafe products.

Business operators should thus examine their manufacturing and other processes, and ensure that their products will not fall within the scope of the new legislation.

Generic substitution

When a physician prescribes a brand name drug, but authorizes the pharmacist to substitute a generically equivalent product, the potential exists for confusion in labelling. While the name of the drug product in the medical record and on the physician's prescription will be that of the brand name drug, the name of the product on the label affixed to the patient's container will be that of the generic drug.

Generic substitution is not in itself regarded as trademark infringement in Thailand, as there is no unlawful reproduction or use of a registered mark. However, it could be argued that the substitution of a generically equivalent drug amounts to passing off where such substitution is intended to deceive the patient as to the origin, nature and quality of the drug.

If the pharmacist sells a substandard drug, legal issues will also arise under the Drug Act – or, in the future, under the Unsafe Product Liability Act.

Online issues

In the report entitled "Thailand's Implementation of Intellectual Property Rights (May/October 2007)", the Thai Department of Intellectual Property acknowledged that "the problem of counterfeit pharmaceuticals has become a concern within the Thai society". The report also stated that "there is no evidence to suggest that the counterfeit drugs are produced in Thailand". In addition, the secretary general of the FDA, Dr Siriwat Tiptaradol, has warned that there are side effects and serious risks involved in taking counterfeit drugs, although he admitted that "[it is] hard for the authorities to arrest online drug sellers because goods are delivered by post".

Further to investigations carried out against an online trader advertising counterfeit Viagra on plaza.212cafe.com, a popular Thai website, 38,850 counterfeit Viagra pills were seized on September 30 2008. The counterfeiter, the director of a company incorporated in Thailand, admitted that all the counterfeit drugs had been imported from China. The Royal Thai Police estimated that the counterfeiter's losses amounted to Bt17 million (approximately $485,000).

This case illustrates the fact that the sale of counterfeit goods online is not necessarily carried out on a small scale. Sales of counterfeit drugs on the Internet are growing rapidly due to several factors, including:

- the increase in online drug sales in general;
- the technical skills of counterfeiters; and
- a false sense of security in countries where stringent regulatory measures are in place.

Conclusion

Medicines have become increasingly affordable in Thailand thanks to parallel imports, compulsory licensing, patent linking and generic substitution. However, the threats to IP rights have increased correspondingly. These threats will affect the ability of pharmaceutical companies to develop new medicines and make them available in Thailand. Due to the political instability in the country, it is unclear whether Thailand will pursue its moderate approach to protecting IP rights. Arguably, the current level of fines does not act as a deterrent. Tougher penalties are needed, especially in light of the lucrative profits to be made from the sale of counterfeit drugs. WTR

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Fabrice Mattei joined Rouse in 2000 to set up and manage the office in Bangkok. He initially trained in France with Gide Loyrette Nouel. He then moved to London where he worked for the law firms Middleton Potts and Donne Mileham & Haddock.

His experience includes managing IP protection and litigation programmes, patents and trademarks portfolio management, biotechnology, biopiracy and bioprospecting. Mr Mattei advises various pharmaceutical companies and life science firms on patent protection and enforcement. He also provides advice to several governmental organizations on biodiversity issues, including the Thai government on the protection and enforcement of Thai jasmine rice '*Hom Mali*'.

Mr Mattei has conducted research for a number of bodies on the protection of IP rights in Southeast Asia. From 2005 to 2007, he was retained by the European Patent Office and the Central Intellectual Property & International Trade Court of Thailand to train judges and public prosecutors.