Thailand

Contributing firm
Rouse

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A brand name is to medical tourism what a geographical indication is to agro-tourism. The Medical Tourism Association defines 'medical tourism' as when people who live in one country travel to another country to receive medical, dental or surgical care which is equal to or better than the care they would receive in their own country, more affordable and/or more readily available.

Thailand is counting on medical tourism to help drive economic growth. This provides an additional incentive to respect intellectual property, as well as consumer and patient protection norms, in order to boost the country's image in the eyes of the pharmaceutical industry and prospective medical tourists.

Selection, clearance and registration

Pharmaceutical trademarks are treated no differently from trademarks in other industries. A medicinal product brand can be registered as a trademark under the Trademark Act 1991, as amended by the Trademark Act 2000. In addition to conventional trademarks, protection extends to combinations of colours and shapes of goods. To be registrable, a trademark must be distinctive and permitted by the act; in addition, it must not be identical or confusingly similar to other prior registered trademarks.

There are limitations to trademarks that can be registered in Thailand. In particular:

- the registrar tends to treat all products in Class 5, which includes pharmaceuticals, as similar. Thus, veterinary and a wide range of other substances will continue to be treated as similar to human preparations;
- the Trademark Office has a strict approach to itemising the classification of trademarks. For example, it is not sufficient to apply for vaccines in Class 5 – one must specify the use of those vaccines (eg, "vaccines for human use in the treatment of influenza"); and
- the registrar is inconsistent when considering the similarity between conflicting marks and the registrability of slogans.

Examples of confusingly similar marks include the following:

- DUPHACYCLINE v DUMOCYCLINE (Decision 48/2542);
- RABIKA v ROBICA (Decision 4/2546); and
- FLUCOZOLE v FUCOZONE (Decision 775/2545).

Examples of marks that were found not to be confusingly similar include the following:

- CITROLE v SECTROL (Decision 24/42);
- REGINOX v UGINOX (Decision 679/2542); and
- ANTAROX v INTEROX (Decision 58/2542).

The following marks have been found to be common general descriptions and therefore non-distinctive:

- BREAK THE BREAKOUT CYCLE, Class 5 (Decision 670/2545); and
- BETTER FOOD, BETTER WORLD, Classes 1, 5, 31 and 42 (Decision 336-902545) – this

mark was found to be both descriptive and non-distinctive.

However, the mark WE KEEP OUR PROMISES (Application 448803, Class 5) was accepted for registration.

The registrar requires trademark applicants to disclaim exclusive rights to use any non-distinctive parts in an inconsistent manner.

Names of colours that have been accepted without disclaimer/objection include the following:

- Application 449650 – GOLDER CORN;
- Application 412913 – GOLD LINE; and
- Application 488342 – GREEN CAST.

However, although the following were accepted, it was only with a disclaimer:

- Application 364461 – GREENJOY;
- Application 506237 – GOLDEN BEAR;
- Application 496869 – GOLDEN ELEPHANT; and
- Application 498480 – BLACK TURTLE.

With regard to the assignment of registered associated marks, some associated marks cannot be selected for separate transfer. In the latest draft amendments to the Trademark Act, separate transfers are possible with a restriction as to the method or scope of use of such marks, or other conditions that the registrar deems appropriate.

Provided that it meets the requirement of distinctiveness and there is no likelihood of confusion with an international non-proprietary name, a trademark should be acceptable for registration, subject to other prior third-party rights.

Although single colour marks are not allowed, combinations are. Shapes of goods or marks depicting containers remain difficult, but not impossible, to register, provided that there is strong evidence of acquired distinctiveness and the mark is not descriptive of the goods (eg, if the three-dimensional mark is packaging in the shape of the tablet). Examples of trademarks rejected due to lack of distinctiveness, include:

- a product container for goods in Class 3, such as cosmetics, lotions and bathing preparations (Decision 149/2545, Application 430996 TM); and
- a product container for chemical preparations Class 5 (Decision 151/2545, Application 428539 TM).

An example of a trademark rejected because it was descriptive of the goods applied for includes a toothbrush device for toothbrushes in Class 21 (Decision 157/2545, Application 430592 TM).

The Thai Food and Drug Administration (FDA) requires that companies obtain approval for their proposed trademarks and products before the drug can be imported, marketed and sold in Thailand. Rights holders must obtain a licence from the FDA's Drug Control Division. The pharmaceutical industry must guard against revocation for non-use with particular care, given the delay between registration and use of a pharmaceutical trademark.

Parallel imports and repackaging

Patent products

The principle of parallel imports of patented products such as drugs was first introduced by the Patent Act ((No 3) BE 2542 (1999)). The use, sale, possession for sale, offer for sale or import of a patented product does not constitute infringement if the product has been produced or sold with the authorisation or consent of the rights holder anywhere in the world.

Unpatented products

There is no provision in the Trademark Act with regard to parallel imports. Under Section 44, the owner of a trademark has the "exclusive right to use its mark for the goods for which it is registered". In 2000 the Supreme Court of Thailand (*Dika* Court, Decision 2817/2543) interpreted this section by applying the principle of international exhaustion of rights and allowing the import and resale in Thailand, without the rights holder's consent, of a branded product that had been legally marketed by the rights holder in the exporting country.

Anti-counterfeiting and enforcement

According to the FDA, almost $30 million's worth of counterfeit drugs are sold in the country each year. The most common fake drugs are for treating AIDS, bird flu, malaria, tuberculosis, obesity and erectile dysfunction. It is difficult to confirm the accuracy of the FDA's figures, but the World Health Organisation estimates that counterfeit drugs make up over 25% of the medical market in developing countries.

Surveys conducted by private investigators in Thailand against pharmacies located in Bangkok, Pattaya and Phuket reveal a high rate of fakes, especially erectile dysfunction-related drugs. Further, Thai-based online traders of fake drugs have dramatically increased in number over the last three years.

The relevant legislation for tackling counterfeiting includes:

- the Trademark Act;
- the Patent Act;
- the Drug Act (BE 2530, 1987);
- the Medical Device Act 1988; and
- the Cosmetic Act (BE 2535, 1992).

In addition, on February 14 2009 Thailand introduced initiatives to strengthen the cooperation between various enforcement authorities to tackle 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 FDA plans to increase fines on importers, sellers and manufacturers of fake drugs as shown in the table below.

Advertising

The advertisement of medicinal products is regulated by several acts, including the Drug Act, the Medical Device Act and the Consumer Protection Act. The FDA and the Consumer Protection Board are responsible for enforcing these.

Advertisements through any medium, including audiovisual transmission, must be approved by the FDA before dissemination. The advertisement of prescription or pharmacy-dispensed medicines is permitted only by professionals. Drugs that fall within the category of household remedies may be advertised directly to the general public, but the advertisements are subject to FDA review and approval before dissemination.

The Drug Act requires that advertisements for a medicine must not:

- boast that it can miraculously or absolutely treat, cure or prevent disease or illness;
- exaggerate or falsely declare its properties;
- suggest that it has a substance as its chief or component ingredient which it

	Current law	Proposed amendment
Manufacturer of fake drug	Bt50,000 (approximately $1,500) and/or life imprisonment	Bt5 million (approximately $150,500) and/or life imprisonment
Importer/seller of fake drug	Bt10,000 (approximately $300) and/or 20 years' imprisonment	Bt2 million (approximately $60,000) and/or 20 years' imprisonment

does not have, or have less in it than the quantity suggested;
- suggest that it is an abortifacient or a strong emmenagogue;
- suggest that it is an aphrodisiac or a birth control drug;
- relate to specially controlled drugs or dangerous drugs;
- contain any certification or endorsement of its therapeutic properties by any other person; or
- show its therapeutic properties as capable of curing, mitigating, treating or preventing diseases or symptoms as notified by the minister of public health under Section 77 of the Drug Act.

Further, according to the FDA Internal Rules 2002, advertisements must:
- not be contrary to traditions;
- not persuade patients to consume more of a product than necessary or create a misunderstanding that the product should be used regularly;
- not make a comparison to defame other products;
- not cause a misunderstanding in consumers that the drug is equivalent to other products such as food or cosmetics;
- not encourage acts or activities contrary to law; and
- meet FDA information requirements (eg, drug name, ingredients and manufacturing source).

Drug manufacturers whose advertisements violate the act are liable for imprisonment for up to six months and a fine of up to Bt10,000 (approximately $300).

Mandatory requirements in relation to the labelling and the size of the packaging apply in order for the drug to obtain FDA marketing approval.

Product liability laws

The Thai legal system has weaker tort statutes than in the West, making malpractice suits by foreigners against doctors and hospitals in Thailand more difficult and defendants less likely to prevail. In February 2009 the Liability for Damages Arising from Unsafe Products Act came into effect. Drug and device manufacturers selling products in Thailand should be aware of the changes in the legal system.

The Unsafe Products Act states that a consumer need only demonstrate that he or she was harmed by the normal use or storage of a product to be entitled to damages. Anyone involved in the sale or import of the product is jointly liable for damages, including the manufacturer and distributor. If found guilty of gross negligence or marketing unsafe products while aware of their danger, responsible parties may be ordered to pay punitive damages in addition to compensation for physical and mental damage. A contract or waiver signed before damage occurs does not limit the liability of the manufacturer or distributor.

In order to be found not guilty, the manufacturer and/or distributor must prove that:
- the product was not unsafe;
- the damaged party was aware that the product was unsafe, yet used it regardless; or
- the damage was caused by inappropriate product use or storage, clearly counter to the labelling or packaging instructions.

Contract manufacturers will not be liable for damages if they can prove that the flaw was in the design and they were unaware of its danger. Similarly, a manufacturer of product components will not be liable if it can prove that the flaw was in the design or assembly, not in the manufacture of the components themselves. In the pharmaceutical context, the following can be liable if the product is found to be defective and resulted in damage to a consumer:
- drug manufacturers, including contract manufacturers and ingredient producers;
- local importers and distributors; and
- hospitals, clinics and drug stores that sell the drugs.

Consumers have three years to sue after learning of the damage and the identity of the parties responsible, not exceeding 10 years after the product's date of manufacture.

In conjunction with the Consumer Case Procedure of August 2008, consumers need only demonstrate that they suffered damage from the unsafe product; they do not need to establish that the manufacturer or importer was at fault. The burden of proof thus lies with the manufacturer to demonstrate that its product was not unsafe.

Under the Medical Device Act, medical device manufacturers and importers must describe their manufacturing facilities and equipment, including details of quality control measures and storage facilities. These include medical device registration requirements for contact lenses and HIV test kits. The Ministry of Public Health is drafting additional laws. These include regulations on dental equipment, physical therapy equipment, *in-vitro* diagnostic kits, labels and inserts and advertising.

Generic substitution

When a physician prescribes a brand-name drug but authorises the pharmacist to substitute a generically equivalent product, the potential exists for labelling confusion.

The name of the drug in the medical record and on the physician's prescription will be that of the brand name prescribed, but the name of the drug on the label affixed to the patient's container will be the generic name.

Generic substitution is not in itself regarded as trademark infringement in Thailand, because there is no unlawful reproduction or use of a registered mark. However, the substitution of a generically equivalent drug could amount to passing off if it deceives a patient as to the drug's origin, nature or quality.

Legal issues will also arise under the Drug Act if the pharmacist sells a sub-standard drug or, in the future, under the Unsafe Product Liability Act.

Online issues

Further to investigations carried out against an online trader that advertised counterfeit Viagra on popular Thai website www.plaza.212cafe.com, 38,850 counterfeit Viagra pills were seized on September 30 2008. The counterfeiter confessed that all the counterfeit drugs had been imported from China. The loss to the counterfeiter was estimated by the Royal Thai Police as Bt17 million (approximately $485,000).

This clearly shows that online traders are not always small-scale counterfeiters. The growth of online drug sales, counterfeiters' increasing technological skill and a false sense of security in countries with stringent regulatory measures are among the factors that are facilitating the spread of this criminal activity.

Stronger consumer protection legislation, proposed amendments to the Drug Act conveying stronger penalties against counterfeiters of drugs and better controlled advertising, sale and storage of drugs and medical devices are all intended to improve the image of Thailand's pharmaceutical industry and to encourage medical tourism. However, the recent US government decision to keep Thailand on the Priority Watch List is a strong indication that further efforts are required from the Thai authorities to address IP concerns from various industries, including the pharmaceutical industry. WTR

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Fabrice Mattei's practice involves the management of IP protection and enforcement programmes for multinational companies and government organisations, dealing in particular with trademark, patent, biotechnology, bio-prospecting and litigation issues. He is also heavily involved in public policy and works closely with Thai and Association of Southeast Asian Nations enforcement agencies. Mr Mattei has worked with clients across a variety of sectors, including cosmetics, pharmaceuticals and biotech companies, medical device manufacturers, luxury and fashion, beverage and other consumer product producers, agricultural and milking equipment manufacturers, printing and publishing equipment manufacturers, software and IT companies, as well as producers of electronic equipment. Mr Mattei was recognised as one of the world's leading life sciences litigators by *IAM Life Sciences* 250 in 2010. He is listed in *Asialaw Leading Lawyers 2008* and is a recognised individual in the *PLC Intellectual Property Handbook 2007-8*.