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Medicinal product regulation and product liability in Thailand: overview

Alan Adcock, Areeya Pornwiriyangkura and Siraprapha Rungpry
Tilleke & Gibbins

global.practicallaw.com/6-500-8489

REGULATORY OVERVIEW

1. What are the main legislation and regulatory authorities for pharmaceuticals in your jurisdiction?

Legislation

The key piece of legislation regulating drugs in Thailand is the Drug Act 1967, as amended (Drug Act), together with ministerial regulations and notifications.

Regulatory authorities

The regulation of medicinal drugs in Thailand is overseen by the Ministry of Public Health (MOPH). The Drug Control Division of the Food and Drug Administration (FDA) (*www.fda.moph.go.th/eng/drug/index.stm*), a department of the MOPH, handles the four main aspects of drug regulation:

- Pre-marketing control (including licensing and registration).
- Post-marketing monitoring and surveillance.
- Consumer education and dissemination of information.
- Promotion of technological development and research for export.

2. Briefly outline how biologicals and combination products are regulated in your jurisdiction.

All pharmaceutical products, including chemical, biological, and combination products, are regulated by the FDA in accordance with the Drug Act. Before launching any pharmaceutical products in Thailand, companies must first obtain a licence from the FDA to produce, sell, or import the products into the country. In addition, companies must also obtain marketing approval, that is, by registering their product for actual sales.

The marketing approval procedure and post-approval regulations of chemical, biological, and combination products are largely the same. The FDA requires an applicant to follow the Association of Southeast Asian Nations (ASEAN) Common Technical Dossier, as the technical document template for submission of both biological and chemical drugs.

In particular, the approval process and requirements for new biological products are similar to those of new chemical (low-molecular-weight) drugs. However, the approval process for generic biological products (that is, biosimilars) is more stringent than the approval process for generic chemical drugs. For a biosimilar product, the application dossier must include:

- Administrative and product information.
- Information regarding drug quality (drug substance and manufacturing process).
- Clinical trial data.
- A risk management plan.

For a combination product, if the combination is new, the FDA classifies it as a new drug. An application dossier must contain documentation similar to that of a new chemical or a new biological product.

3. Briefly outline how medical devices and diagnostics are regulated in your jurisdiction. Is there any specific regulation of health IT issues and mobile medical applications?

The key legislation that regulates medical devices and diagnostics is the Medical Instrument Act B.E. 2551 (also known as the Medical Device Act 2008), together with ministerial regulations and notifications of the Ministry of Public Health (MOPH).

A place of business registration (an establishment licence) by a local company is required, for both importers and manufacturers of medical devices/diagnostics.

Currently, medical devices are divided into three classes, depending on the level of control by the FDA.

Class 1 licensed medical devices

This is the most rigorously controlled class, comprised mainly of condoms, HIV diagnostic kits, contact lenses, and so on. The following details for these medical devices, among other things, must be submitted to the FDA:

- Certificate of free sales.
- Certificate of quality system of manufacture, for example, the relevant International Organisation for Standardisation (ISO) certificate.
- Clinical evaluation.
- Sterility.
- Stability.
- Raw material and finished product specifications.
- Thai label and leaflet.
- Product photo.
- Manufacturing process.

The FDA requires an applicant to use the ASEAN Common Submission Dossier Template (CSDT) for the technical document requirements for submission of licensed medical devices.

Class 2 notification medical devices

The level of control in this class is less stringent than class 1. Examples of medical devices in this class include physical therapy products, silicone breast implants, and alcohol detectors. The documents required for submission to the FDA are similar to those of class 1. An applicant must prepare the dossier according to the CSDT.

Class 3 general medical devices

This class is subject to the least stringent control by the FDA. All medical devices which are not classified as class 1 or class 2 fall in this class. The required documents are:

- Certificate of free sales.
- Catalogue/product photo.
- Specifications.
- ISO 13485 (in some human use product categories, for example implant products and sterile products).

There are no specific regulations regarding health IT issues and mobile medical applications. According to the Medical Instrument Act, software and IT systems are also classified as medical devices. Normally, an importer will register it together with the main medical device.

PRICING, STATE FUNDING AND REIMBURSEMENT

4. What is the structure of the national healthcare system, and how is it funded?

There are three main schemes relating to the healthcare system in Thailand.

Social Security Scheme. This is administered by the Social Security Office and covers employers with one or more employees. However, this scheme is not applicable to:

- Government employees in the central, provincial and local administrations.
- Employees of foreign governments or international organisations.
- Employees stationed abroad, despite their employers' office being in Thailand.
- Private school teachers and headmasters.
- Students, including undergraduate students, nursing students and apprentice doctors who are employees of schools, universities or hospitals.
- Employees of other undertakings as prescribed by royal decree.

Civil Servant Medical Benefit Scheme (CSMBS). This is administered by the Social Security Office and covers government officials and their dependants (parents and up to three children).

National Health Insurance (THB30 Scheme). This is administered by the MOPH and covers the remaining population not covered under either the Social Security Scheme or the CSMBS.

5. How are the prices of medicinal products regulated?

Prices of medicinal products are regulated when they are listed on the National List of Essential Drugs (NLED), a "maximum list" from which government hospitals are expected to select their individual hospital formulary. The prices of the drugs on this list are subject to a median price policy.

In addition, the Ministry of Finance has implemented a notification which sets prices for government hospitals. However, these prices only apply to persons under the CSMBS. The MOPH has implemented a notification on how much government hospitals are allowed to charge patients. The Drug Act is currently being revised, and these revisions may include cost-effectiveness as a required element for drug registration.

6. When is the cost of a medicinal product funded by the state or reimbursed? How is the pharmacist compensated for his dispensing services?

Medicines are reimbursed by the state when the drugs are listed in the NLED (*see Question 5*). However, this list is only available to government hospitals.

Government hospitals generally provide drugs from the NLED to civil servants under the CSMBS and to all other persons under the THB30 Scheme. In this case, the patient either pays nothing to the hospital or, for people under the THB30 Scheme, a maximum of THB30 in certain circumstances. The hospital is reimbursed completely by the government. Medical devices are not listed on the NLED. However, in 2005 the Ministry of Finance began allowing the reimbursement of some medical therapy equipment and artificial organs for civil servants.

For persons under the Social Security Scheme, reimbursement is partially covered if the medicinal product was administered by a doctor in a government hospital. Persons under the Social Security Scheme can also acquire private health insurance to cover the remainder of the cost.

CLINICAL TRIALS

7. Outline the regulation of clinical trials.

Legislation and regulatory authorities

There is no centralised regulation for clinical trials. However, a draft bill covering human research is currently under public hearing and will probably progress to the Cabinet, then to the Council of State and then parliament for promulgation. At least six regulatory authorities have jurisdiction over various aspects of clinical trials:

- FDA of the MOPH.
- Department of Medical Sciences of the MOPH.
- Department of Communicable Diseases Control of the MOPH.
- Ethical Review Committee for Research in Human Subjects of the MOPH.
- National Sub-Committee of HIV Vaccine of the MOPH.
- Medical schools and hospitals with specific regulations and/or ethics committee.

The FDA does not have a direct mandate to regulate clinical trials in humans. Instead, the FDA's authority to control the import of drugs for research purposes is frequently used to indirectly allow the FDA to regulate clinical trials of drugs in humans.

Although Thailand has not yet ratified the following treaties on the conduct of clinical trials, it follows them:

- World Medical Association Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects 1964.

- International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use, Guidelines on Good Clinical Practice 1996 (ICH GCP). This sets out a standard for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of clinical trials. It ensures consistency in relation to the quality of data and ethics.

Authorisations

To obtain approval for clinical trials in Thailand, the drug developer/sponsor must first select a research facility and a team of physicians to conduct the study. The facility is usually a hospital or university medical centre. The sponsor must then obtain approval to conduct a study in humans from the Ethical Review Committee for Research in Human Subjects of the MOPH (ERC) and/or the ethics committee of the research institute or university that will conduct the trial. This can take two to three months. If an approval is obtained from the ethics committee of the research institute or university conducting the trial, an approval from the ERC is usually optional (unless it is further required by the internal rules and regulations of that research facility).

Once the drug developer/sponsor receives approval from the relevant ethics committee, it can apply to the FDA for a licence to import investigational drugs into Thailand for research purposes. To obtain this licence, the drug developer/sponsor must submit approval from an authorised (or FDA approved) ethics committee, together with documentation, including:

- Details of the drugs to be imported.
- Pre-clinical trial reports.
- A complete clinical trial protocol.
- The estimated amount of drugs required.
- A power of attorney.

The licence is only valid for one year. If the clinical trial is not complete within a year, a new import licence must be obtained.

Consent

There is no specific legislation governing clinical trials in Thailand. This area, including issues relating to consent, is regulated by the Civil Code. Trial subjects are required to sign an informed consent form before commencement of clinical trials (*Civil Code*). The consent forms must emphasise that participation is voluntary and, therefore, subjects have the right to withdraw from the trial at any time.

To be valid, the consent form must be signed and dated by the volunteers. However, if they are unconscious, an authorised legal representative can sign the form on their behalf. Participants in the study cannot act as witnesses to the signature. The consent of volunteers or patients who are not capable/authorised to give consent can be provided by their legal representatives.

Trial pre-conditions

The trial pre-conditions and recruitment of the participants are in the protocol submitted to IRB/EC. A sponsor must have a local representative (that is, an investigator or co-investigator) to fulfil the appropriate local responsibilities. A sponsor is also responsible for the appropriate selection of investigators.

An import licence must be obtained for samples to be used in the trial.

Insurance is not always a mandatory requirement. The Ethics Committee determines whether insurance is required on a case by case basis, depending on the level of risk involved in the trial.

Procedural requirements

The following procedure must be complied with during the conduct of a clinical trial (*ICH GCP*):

- **Investigator brochure.** This brochure will gather the clinical and non-clinical information of the drug intended to be studied. The aim is to provide information to the investigator and the relevant persons in order to understand the Research Protocol (such as frequency/interval of drug administration, route of administration and safety monitoring). Only the sponsor and the investigator have access to the entire brochure and it is not made available online. This brochure must:
  - be regularly updated and contain all the essential information in relation to the product;
  - be prepared by the investigator (from the literatures/product leaflet/FDA registered number or from the reports of Investigational New Drug).
- The brochure should be attached with the project proposal and submitted to IRB/EC. There is no formal time limit for submission.
- **Source data.** Original documents must be archived for at least 15 years and include:
  - signed and dated consent forms;
  - patient OPD cards;
  - doctor's notes (or any other medical professional's note);
  - lab tests;
  - study evaluation tests; and
  - any other documents related to the research.
- **Monitoring by the sponsor and ethics committee.** To ensure the study does not raise any ethical or other issues, the sponsor and ethics committee must:
  - check all source data;
  - verify the quantity of medication delivered; and
  - prepare a report on any adverse effects.
- **Safety report.** This report must list any adverse events, serious adverse events, adverse drug reactions, or suspected or unexpected serious adverse reactions, and should be submitted to the ethics committee. According to the ICH guidelines, the sponsor should report the serious/unexpected adverse drug reactions (ADRs) to the investigator/medical centre and IRB/ECs as early as possible. The report should conform with the ICH *Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting*.
- **Auditing.** This step ensures that the trial is conducted in accordance with the GCP guidelines.

MANUFACTURING

8. What is the authorisation process for manufacturing medicinal products?

Application

Applications are made to the FDA for Bangkok and its territories. Applications are made to the appropriate provincial public health offices for other provinces.

Conditions

A licence from the FDA is required for the manufacture of "modern medicines". The FDA issues a licence to manufacture, sell or import modern medicines, or order them into Thailand, if the applicant:

- Is the owner of the business and has sufficient property or status to be able to establish and operate the business.
- Is at least 20 years of age.
- Is resident in Thailand.
- Has not been convicted for an offence against certain laws, such as laws concerning narcotics and psychotropic substances.
- Has premises to produce, sell, import or store drugs and equipment for use in the production, sale or storage of drugs, and the control or maintenance of drug quality and quantity as prescribed in ministerial regulations.
- Uses a trade name that is not a repetition of, or similar to, the trade name used by a licensee whose licence is suspended or has been revoked for less than a full year.

All of the above conditions must be met to obtain a licence to manufacture in Thailand.

Restrictions on foreign applicants

A foreign applicant must be a resident of Thailand to obtain a licence to manufacture, sell or import drugs.

Key stages and timing

An application for a licence to manufacture is submitted to the Drug Control Division of the FDA. The applicant's buildings and facilities are then inspected by the MOPH to assess compliance with Pharmaceutical Inspection Cooperation Scheme (PIC/S) Good Manufacturing Practices (GMP). The MOPH then determines whether the applicant has adequate facilities and the appropriate personnel to manufacture these medicines.

Fee

The fees are listed on the Drug Control Division's website, but are only available in Thai. They are as follows:

- Licence to manufacture modern medicines: THB8,000.
- Licence to manufacture traditional medicines: THB5,000.

Period of authorisation and renewals

Licences for modern medicines are valid up until 31 December of the year in which they are issued. An application for renewal must be submitted before expiration of the current licence.

Monitoring compliance and imposing penalties

Regulators can inspect manufacturing sites for GMP compliance, and monitor manufacturing process changes to ensure that there are no adverse effects on the safety or efficacy of the medicines being produced.

The regulator can suspend or revoke the manufacturing licence if the licensee violates any provision of the Drug Act. Licensees can appeal to the Minister of Public Health within 30 days of notification of an order to suspend or revoke a licence.

Further, the authorities can impose fines and terms of imprisonment for manufacturing without a licence. Manufacturing modern medicines without a licence can lead to up to five years' imprisonment and a fine of up to THB10,000. Manufacturing traditional medicines without a licence can lead to up to three years' imprisonment and a fine of up to THB5,000.

MARKETING

Authorisation and abridged procedure

9. What is the authorisation process for marketing medicinal products?

Application

Applications are made to the FDA.

Authorisation conditions

Companies and individuals wishing to place a drug on the market must:

- Obtain a licence from the FDA to manufacture, sell or import drugs in Thailand.
- Then obtain FDA registration for the medicine to market and sell the drug in Thailand. Registration requirements differ for general drugs (which include generics, new medicines and new generics) and traditional drugs. Registration of a new modern drug requires an application to the Drug Control Division of the FDA for permission to import a drug sample into Thailand or, less frequently, permission to manufacture a sample.
- Then submit a full marketing approval application, together with samples, to the FDA for review and registration (*see below, Key stages and timing*).

Key stages and timing

The FDA review of a marketing approval application can take at least nine months, depending on the type of drug, with different timelines for new drugs and generic drugs. The review can take up to two years for a new drug that has never applied for a marketing licence in Thailand. The timeline also depends on the credibility and comprehensiveness of the information submitted along with the application.

Once the review has been passed, the new drugs must undergo a two-year safety monitoring period, during which the product can only be prescribed in hospitals and clinics. Safety reports must then be submitted to the authorities for consideration as to whether general marketing will be permitted.

For generics, see *Question 11*.

Fee

The fees are not listed on the FDA's website. The fee for a licence to market a drug is THB2,000.

Period of authorisation and renewals

Once approved, the certificate of product registration is valid as long as the product marketing remains active. If the product is not on the market for longer than two years, the FDA will automatically cancel the registration.

Monitoring compliance and imposing penalties

The Medical Sciences Department under the MOPH is the main authority responsible for ensuring the quality and safety of drugs on the market in Thailand. Samples are regularly tested at its laboratories to monitor the safety of new drugs.

The Medical Sciences Department can, if necessary, remove drugs from the market. The authorities can also suspend or revoke a licence. A breach of a marketing authorisation is considered a criminal offence and is subject to both imprisonment and a fine. Licensees can appeal to the MOPH within 30 days from the date of notification of an order to suspend or revoke a licence.

10. What commitments and pharmacovigilance obligations apply after a company has obtained marketing authorisation? Are there further conditions concerning how the drug is distributed and accessible to patients?

After the registration number for a new drug is issued, the licence holder must submit a protocol of Safety Monitoring Programme (SMP) to the FDA, and the pharmaceutical product must follow the safety monitoring protocol of the FDA for at least two years. During the monitoring process, the new drug can only be used and sold in clinics and hospitals.

Some drugs can only be dispensed by hospitals during the SMP. In 2012, the FDA issued an announcement to set out guidelines for the SMP. The announcement provides a specific time frame for a licensee to submit the monitoring report. For instance, a report of a death that relates to use of the new drug must be reported verbally within 24 hours, and the completed written report must be submitted within seven days after first knowledge of the death.

If there is no report of serious events or side effects, the committee will consider the regularly submitted report, and release the drug from the SMP, so that the drug can be sold in any clinics, hospitals, and pharmacies throughout Thailand.

11. Which medicinal products can benefit from the abridged procedure for marketing authorisation and what conditions and procedure apply? What information can the applicant rely on?

Generics enjoy an abridged registration process. To benefit from the streamlined procedures, the product must meet the criteria for a generic. Generics are pharmaceutical products with the same active ingredients and the same dosage forms as those of the original products, but they are made by different manufacturers.

To register generics, an applicant must submit an application for permission to import or manufacture drug samples. The requirement is similar to that for registration of new drugs (*see Question 9, Key stages and timing*).

The applicant then submits various details about the drug production process to be used, including:

- Manufacturing methods.
- In-process controls.
- Specifications of the active ingredients.
- Excipients used in the production process.

Information about the drug storage conditions and details about the stability of the drug are also required.

The applicant then submits a formal application for a drug registration certificate. The entire process can take six to 12 months.

There are also "new generics", or medicines with the same active ingredients, doses and dosage forms as those of new compounds registered after 1992. To register new generics, the FDA only requires dossiers of bioequivalence studies, in addition to the required documentation for a generics submission (*see above*).

12. Are foreign marketing authorisations recognised in your jurisdiction?

An existing market authorisation issued in a foreign jurisdiction does not provide fast-track approval for an application filed with the FDA. However, the application requires the applicant to inform the FDA of any approved and pending marketing authorisation for the product in other countries.

If the foreign authorisation belongs to a country where regulatory practice is credible and globally accepted, this adds credibility to the authorisation application and the evidence submitted to the FDA with the application for marketing approval.

Parallel imports

13. Are parallel imports of medicinal products into your jurisdiction allowed?

Generally, most intellectual property laws in Thailand recognise the exhaustion of rights principle. Therefore, parallel imports are not generally regulated in Thailand.

However, parallel imports are not permitted in the pharmaceutical sector. To import a drug into Thailand, a company needs a licence from the FDA. When applying for product registration, the FDA will not accept an application for a product that has a trade mark identical to other products in the Thai market.

Restrictions on dealings with healthcare professionals

14. What are the restrictions on marketing practices such as gifts, sponsoring, consultancy agreements or incentive schemes for healthcare establishments or individual medical practitioners?

The Drug Act does not restrict marketing practices. However, a state official can only receive property or any other benefit from any person (other than a relative) if the value of the benefit received from each person, and on each occasion, does not exceed THB3,000 (*section 103, Organic Act 1999 (as amended) and Notification of the National Counter Corruption Commission Concerning the Provisions on the Acceptance of Property or Any Other Benefit on an Ethical Basis by State Officials B.E. 2543 (2000)*). This applies to gifts, entertainment, services, training and so on.

For pharmacists or officers who are not employed by the government, marketing practice is restricted by the Code of Sales and Marketing Practices issued by the Pharmaceutical Research and Manufacturers Association (PReMA) (PReMA Code). The PReMA Code provides detailed marketing restrictions in different situations.

Generally, gifts to healthcare professionals and institutions for customary courtesy and traditional occasions are allowed. The gift must not be distributed frequently and the value of any gift must not exceed THB3,000 per healthcare facility or professional on each occasion.

Special requirements and guidelines apply to government purchases of pharmaceuticals, particularly during the procurement process and tender bidding. Pharmaceutical product procurement must generally be conducted with a higher than normal degree of transparency (all quantities and pricings of products must be disclosed).

SALES AND MARKETING

15. What are the restrictions on selling medicinal products? Are there specific regulations for the sale of medicinal products on the internet, by e-mail and by mail order?

Drugs classified as dangerous drugs must be dispensed by a pharmacist or doctor and most drugs are classified as dangerous drugs under Thai law. Drugs that are not classified as dangerous

drugs (for example, traditional drugs or household remedies) are specifically listed by the MOPH. Patients can buy these drugs without the need for a pharmacist to dispense the drug.

Marketing pharmaceutical products online, by e-mail, and/or by mail order is not permitted (*see Question 16*). According to the FDA, most advertisements (more than 85%) on the internet are being run without FDA permission. The FDA has prioritised the solving of this problem.

ADVERTISING

16. What are the restrictions on advertising medicinal products?

Legislation and regulatory authority

Sections 88 to 90 of the Drug Act regulate the advertising of medicinal products and are enforced by the FDA. The authorities also take the Consumer Protection Act 1979 into consideration when regulating advertising practice. Further, pharmaceutical companies that are members of PReMA must comply with the PReMA Code. Although the PReMA Code is not considered to be law, and the FDA does not have the authority to enforce it, a violation of the PReMA Code can be reviewed by the PReMA Committee, which can sanction its members.

Restrictions

Advertisements for prescription or pharmacy dispensed medicines can only be targeted to professionals. Drugs in the household remedy category can be advertised directly to consumers and the general public, but that advertising is subject to FDA review and approval before dissemination.

Dangerous drugs cannot be advertised directly to consumers and the general public. Most drugs are classified as dangerous drugs under Thai law (*see Question 15*).

Advertising must be approved by the FDA before dissemination (*section 88 bis, Drug Act*). Advertisements must not (*section 88, Drug Act*):

- Boast that a medicine can miraculously or absolutely treat, cure or prevent disease or illness.
- Exaggerate or falsely declare properties of the medicine.
- Give the impression that the drug has a substance as its chief or component ingredient that it either:
  - does not have; or
  - has in a lower quantity than believed to be present.
- Give the impression that it is an abortifacient or a strong emmenagogue.
- Give the impression that it is an aphrodisiac or a birth control drug.
- Advertise specially controlled drugs or dangerous drugs.
- Contain certification or endorsement of its therapeutic properties by any other person.
- Show its therapeutic properties as being capable of curing, mitigating, treating or preventing diseases (or symptoms of them) as notified by the MOPH under section 77 of the Drug Act.

Further, advertisements must not (*FDA Internal Rules 2002*):

- Be contrary to traditions, for example, local beliefs, norms and morals.
- Persuade patients to consume the product more than necessary or create a misunderstanding that the product should be used regularly.
- Make a comparison that would defame other products.
- Cause consumers to misunderstand that the drug is equivalent to other products, such as food or cosmetics.
- Encourage acts or activities contrary to law.

Advertisements must meet the FDA information requirements (for example, contain the drug name, ingredients and manufacturing source).

Internet advertising

Information distributed on the internet which is intended for customers or patients in Thailand must meet the same requirements (*see above, Restrictions*).

DATA PROTECTION

17. Do data protection laws impact on pharmaceutical regulation in your jurisdiction?

In relation to sensitive personal data, even though the right of privacy is firmly protected by the Constitution, at present Thailand does not have a unified and dedicated statute which confers a clear right of data privacy. There is no specific body of law that offers direct protection or mandates specific compliance with regard to data privacy. However, there are other laws that would allow for relief if the use of data or information causes damage to reputation, health, or property of the information owner/subject.

PACKAGING AND LABELLING

18. Outline the regulation of the packaging and labelling of medicinal products.

Legislation and regulatory authority

The Drug Act deals with packaging and labelling. The regulations relating to the packaging and labelling of medicinal products are overseen by MOPH. The Drug Control Division of the FDA handles enforcement. The label and the current size of the packaging are mandatory documents that must be submitted to the FDA to obtain FDA marketing approval.

Information requirements

For labelling, the Drug Act requires that either a package insert, a Summary of Product's Characteristics or a Patient Information Leaflet are submitted. Required information is listed in the FDA Guidelines. If an applicant submits a Patient Information Leaflet, he must also submit the package insert.

Package inserts must contain the following:

- Product name.
- Name and strength of the active ingredients.
- Product description.
- Pharmacodynamics/pharmacokinetics.
- Indications.
- Recommended dose.
- Instructions for use, including modes of administration, contra-indications, general warnings and precautions, interactions with other medical products, warnings and precautions for pregnant and lactating women, undesirable effects, and possible overdose and treatment.
- Dosage forms and packaging available.
- Name and address of manufacturing/marketing authorisation holder.

- Date of revision of package insert.

A package label must include the following mandatory information:

- Product name.
- Registration certificate number.
- Content.
- Composition or active ingredient with the quantity/potency.
- Lot/batch number.
- Manufacturer's name and country of origin.
- Date of manufacture.
- If applicable, and on a red label, a statement that the drug is classified as a specially controlled drug, dangerous drug, or common household drug in Thailand.
- Expiration date and the word "expiry" in Thai.

Other conditions

All of the above information can be in Thai or English, except for the information noted above that must be expressly stated in Thai (*see above, Information requirements*). Further, periodically the FDA will issue ministerial notifications to set out specific required information to be included on the label of specific drugs such as antibiotics, antihistamines, sedatives and hypnotics.

PRODUCT LIABILITY

19. Outline the key regulators and their powers in relation to medicinal product liability.

The key regulator is the Drug Control Division of the Food and Drug Administration (FDA), Ministry of Public Health (MOPH). It directly regulates and monitors all pharmaceutical products in Thailand, including the authority to recall products and impose penalties for non-compliance.

20. Are there any mandatory requirements relating to medicinal product safety?

Product labels must be approved by the FDA (*see Question 18*).

After a new drug is approved by the FDA, the licence holder must submit a protocol of Safety Monitoring Programme (SMP) to the FDA, and the pharmaceutical product must follow the safety monitoring protocol of the FDA for at least two years (*see Question 10*).

Product recall and/or rapid alert notification of a defective medicinal product can be ordered by the FDA, if it is deemed necessary. Public notifications and information regarding product recalls and safety alerts are provided online by the Drug Control Division of the FDA. See *http://newsser.fda.moph.go.th/safetyalert*.

21. Outline the key areas of law applicable to medicinal product liability, including key legislation and recent case law.

Legal provisions

Thailand has adopted the following laws to specifically address product liability.

Unsafe Goods Liability Act 2008. This is a substantive law, also known as the Product Liability Act, which came into force in February 2009. It is designed to protect consumers who incur damage from defective or dangerous products, by imposing strict liability on business operators involved in the manufacture and/or sale of the product. It addresses manufacturing defects, design defects and warning defects (or failure to warn).

Consumer Case Procedure Act 2008. This is a procedural law governing court proceedings for disputes between consumers and business operators, which came into force in August 2008. It was adopted to make it easier for consumers to pursue product liability claims against business operators. It simplifies and expedites the legal process for an injured party to seek redress. For example, consumers can orally file complaints and court fees are waived for consumers who file an action. Further, the court is given considerable discretion to conduct the proceedings and ensure that consumers receive fair treatment.

Substantive test

The Unsafe Goods Liability Act imposes a strict liability standard. A business operator can be liable regardless of whether it was negligent in making or selling the product. An injured party must only prove that he was injured or suffered damage from the defective product while using the product in the way it was intended to be used. There is no need to prove fault or negligence.

22. Who is potentially liable for defective medicinal products?

A potentially liable "operator" includes a:

- Producer, outsourcer or importer of the defective product.
- Seller who cannot identify the manufacturer, outsourcer or importer of the product.
- Person using a trade name, trade mark, logo, wording, or showing by any means, in a manner that would cause people to understand that he is a producer, an outsourcer or an importer.

In the pharmaceutical context, the following persons can be liable if the product is found defective and/or has resulted in damage to a consumer:

- Drug manufacturers, including contract manufacturers and ingredient producers.
- Local importers and distributors.
- Hospitals, clinics and drug stores that sell the drugs.

Product liability cannot be waived or limited by way of contract, or by any waiver or limitation of liability statement given by a business operator.

23. What defences are available to product liability claims? Is it possible to limit liability for defective medicinal products?

The Unsafe Goods Liability Act provides several defences for a defendant operator. For instance, an operator is not liable if it can prove one of the following:

- The product was not defective.
- The injured party was aware that it was defective but used it anyway.
- The damage was due to improper use or storage of the product.

The Unsafe Goods Liability Act also provides defences for producers of custom-made products and component producers, who are generally not liable if they can show that the defect was

due to the specifications or design of the final product provided to them by the outsourcer or producer.

24. How can a product liability claim be brought?

Limitation periods

The right to claim damages expires after three years from the date that the injured person knew of both the injury and the identity of the business operator liable for loss or damage, or ten years after the date of sale of the product.

If the injury occurred to life, body or health as a result of substances accumulated in the body of the injured person, or if it takes time to show symptoms, the injured party (or the person with a right to file a legal action on behalf of the injured party) must bring the claim within three years from the day that he knows of the injury, and can identify the responsible business operator. However, this must not exceed ten years from the date on which the injury was discovered.

Class actions

At present, it remains unclear whether a product liability claim can be brought as a class action lawsuit. Class actions are not common in Thailand.

A foreign claimant can file a product liability action in Thailand, only if the damage arising from a defect occurred in Thailand (*sections 3 to 10, Civil Procedure Code* and *section 17, Consumer Case Procedure Act*).

25. What remedies are available to the claimant? Are punitive damages allowed for product liability claims?

Damages under the Unsafe Goods Liability Act consist of two components:

- Damages for a wrongful act as provided for in the Civil and Commercial Code.
- Additional categories of damages specially provided under the Unsafe Goods Liability Act, including:
  - compensation for mental damage as a result of damage to the body, health or sanitation of the injured party;
  - punitive damages.

A court can award punitive damages on top of actual damages if it can be shown that the defendant either:

- Produced, imported or sold the product, despite being aware that it was defective, or was unaware that the product was defective due to gross negligence.
- Became aware of its defect after production, importation or sale, but failed to take proper action to prevent any damage, for example by failing to recall a defective product.

In these cases, the court can award punitive damages in an amount that the court deems appropriate (with a maximum limit of no more than twice the amount of the actual damages).

REFORM

26. Are there proposals for reform and when are they likely to come into force?

There are currently three bills under review that concern the pharmaceutical industry.

The Trade Mark Bill has passed three readings at the House of Representatives, and it was sent to the Senate for consideration on 1 January 2013. It will become law after it passes three readings before the Senate.

This bill will change the trade mark regime as follows:

- Smells and sounds trade marks should be acceptable.
- The definition of a distinctive trade mark will be broadened.
- Multiple-class applications should be acceptable.
- A licence agreement will not be terminated as a result of the transfer or inheritance of rights to the underlying mark.
- Government fees for certain translations may be increased.

The Patent Bill is currently under the consideration of the Legal Affairs Office of the Department of Intellectual Property for review and study. Issues under discussion and consideration include novelty criteria and the process for compulsory licensing.

A Drug Bill has been drafted and revised many times in recent years, but it is not currently high on the government's legislative agenda. The contentious issues, among others, are civil liability and price controls. The Bill is currently under consideration of the Office of the Council of State. Later, it will be sent to the Cabinet, and then to Parliament.

ONLINE RESOURCES

Thai Food and Drug Administration, Ministry of Public Health

W www.fda.moph.go.th/eng/drug/index.stm

Description. The Food and Drug Administration website, Ministry of Public Health, contains official versions of the Drug Act, in Thai only.

W www.ipthailand.go.th/ipthailand

Thai Department of Intellectual Property

Description. The Department of Intellectual Property website. It contains unofficial English translations of the Patent Act and the Trade mark Act.

W www.ipthailand.go.th/ipthailand/index.php

Thailand Office of Consumer Protection Board

Description. The website of the Office of Consumer Protection Board. It contains unofficial translations of product liability legislation, including the Unsafe Goods Liability Act 2008.

W www.ocpb.go.th/

Practical Law Contributor profiles

Alan Adcock

Tilleke & Gibbins
T +66 2653 5555
F +66 2653 5678
E alan.a@tilleke.com
W www.tilleke.com

Professional qualifications. New York and New Jersey, 1999

Areas of practice. IP and regulatory affairs; IP commercialisation

Recent transactions

- Advising leading life sciences companies on pharmaceutical, food and beverage, medical device, veterinary, cosmetic and biotechnology regulatory matters.
- Registering products with the Food and Drug Administration and Ministry of Agriculture in Thailand and throughout Southeast Asia.

Languages. English, Mandarin

Areeya Pornwiriyangkura

Tilleke & Gibbins
T +66 2653 5882
F +66 2653 5678
E areeya.p@tilleke.com
W www.tilleke.com

Professional qualifications. Thailand, 2010

Areas of practice. Intellectual property; pharmaceutical law; commercial IP transactions.

Recent transactions

- Advising clients in the pharmaceutical industry, with a focus on regulatory review.
- Carrying out patent litigation matters, including infringement of pharmaceutical patents.
- Advising on general intellectual property matters.

Languages. Thai, English

Professional associations/memberships. ASEAN Patent Attorneys Association, serving on Thailand's committee of the Intellectual Property Emerging Rights group.

Publications

- *Distribution & Marketing of Drugs – Thailand Chapter, European Lawyer Reference Series, 8 January 2013* (with Alan Adcock and Clemence Gautier).
- *Marks That Are Similar to INNs Cannot Be Registered, World Trademark Review, 13 December 2011.*
- *Advertising In The Face of Food and Drug Administration Registration, Informed Counsel, 30 November 2010.*

Siraprapha Rungpry

Tilleke & Gibbins
T +66 2653 5874
F +66 2653 5678
E siraprapha.r@tilleke.com
W www.tilleke.com

Areas of practice. Intellectual property; regulatory affairs; technology, media, and telecommunications.

Recent transactions

- Advised a pharmaceutical client on various IP issues, such as product liability, government advocacy on new regulations, compulsory licences, new laws (Patent Act, Drug Act), and trade mark registration.
- Acted as counsel to a major pharmaceutical company, which included liaising with the Thai FDA on marketing compliance issues, verifying that the client's marketing activities were in compliance with the complex regulations governing pharmaceutical practice in Thailand, and preventing and mitigating risk and loss.
- Represented a multinational pharmaceutical company in patent infringement litigation against a local generic company. Managed a major pharmaceutical-related patent during a trial on patent infringement.
- Prosecuted pharmaceutical patent litigation against various local producers of infringing generic drugs.

Languages. Thai, English

Publications

- *Patent Litigation in Thailand: Know Your Rights and Duties, Bangkok Post, 7 February 2014.*
- *Patents as a Tool for Business and Innovation, Bangkok Post, 12 July 2013.*

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LIFE SCIENCES

Pharmaceutical IP and competition law in Thailand: overview

Alan Adcock, Areeya Pornwiriyangkura and Siraprapha Rungpry
Tilleke & Gibbins

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PATENTS

1. What are the legal conditions to obtain a patent and which legislation applies? Which products, substances and processes can be protected by patents and what types cannot be patent protected?

Conditions and legislation

The usual criteria to obtain a patent are:

- Novelty.
- Non-obviousness.
- Industrial applicability.

The principal source of patent law is the Patent Act 1979, as amended by the Patent Act 1992 and the Patent Act 1999 (Patent Act). Ministerial regulations and various notifications published by the Department of Intellectual Property also form part of the patent regulatory scheme.

Scope of protection

Pharmaceutical patents are treated the same as inventions in other fields. A claim for a pharmaceutical innovation must meet the usual criteria of novelty, non-obviousness and industrial applicability.

The following subject matter is not patentable (*section 9, Patent Act*):

- Micro-organisms that naturally exist and their components, animals, plants or extracts from animals or plants.
- Scientific and mathematical rules and theories.
- Computer programs.
- Methods for diagnosing, treating or curing human or animal diseases.
- Inventions that are contrary to public order or morality, public health or welfare.

This exclusion from patent protection is absolute. The most problematic issues for the pharmaceutical sector relate to biologics, diagnostic methods and methods of treatment.

Generally, the following can be patented if it is novel, non-obvious and useful:

- Polymorphic forms (such as solvates or different crystalline forms of a known chemical compound).
- Formulations (that is, pharmaceutical compositions).
- New therapeutic use of a known chemical compound.
- Combination and dosage form.
- Methods for preparing medicinal products or related substances.

Until 30 September 2013, there were no specific examination guidelines for pharmaceuticals. To try to clear the longstanding backlog of patent applications for pharmaceutical and chemical inventions, the Department of Intellectual Property issued patent examination guidelines for these sectors.

One of the most debated issues is the acceptance of "use claims". There is now guidance that a claim indicating a process or method which results in an actual/concrete outcome is considered a patentable process under the Patent Act 1999, so long as use is not directed to a method of treatment of human or animal disease under section 9(4), which is not patentable.

Additionally, in the past, a "Swiss-type claim" would be readily acceptable. However, under the new examination guidelines this is not the case, and the Department of Intellectual Property will consider whether the specification sufficiently disclosed the claimed subject matter.

2. How is a patent obtained?

Application and guidance

Patent applications are made to the Patent Office of the Department of Intellectual Property, Ministry of Commerce (*www.ipthailand.go.th/ipthailand*). Guidance on the application procedure and fees are found on this website (in both Thai and English).

Thailand is a signatory to the Patent Cooperation Treaty (PCT). Since 24 December 2009, international patent applications can be submitted through the PCT system.

Government fees for filing a patent in Thailand depend on the type of patent (patent, petty patent or design patent) and the number of claims. In general, the government filing fees are minimal. Once the patent is granted, various maintenance fees apply from the fifth year onwards.

Process and timing

An applicant must first prepare a patent specification, including a detailed description of the invention, abstract, drawings and claims. Then the application must be filed with the Patent Office. The Patent Office then conducts a preliminary (formality) examination and publishes the patent application in the official *Patent Journal* in Thai. Substantive review is then undertaken. The entire process for issuance of an invention patent can take from three to five years. For pharmaceutical patents, the process can take six to eight years, and sometimes up to ten years. The problems caused by delayed processes are often raised by foreign pharmaceutical companies and foreign governments.

3. How long does patent protection typically last? Can monopoly rights be extended by other means?

Duration and renewal

A patent for an invention is valid for 20 years from the date of filing (*section 35, Patent Act*). No extensions or renewals are allowed.

Extending protection

Once the patent expires, the patentee's monopoly rights under the patent cannot be extended by other means, such as supplementary protection certificates or data exclusivity periods, which are not available in Thailand. However, new drugs must undergo a two-year safety monitoring period during which time no generic of the new drug can be launched, which is effectively a market exclusivity extension.

4. How can a patent be revoked?

The validity of patents can be challenged in the Intellectual Property and International Trade Court (IP & IT Court). The IP & IT Court can revoke a patent if one of the following applies:

- The invention is not new, lacks an inventive step or is not capable of industrial application.
- The subject matter of the invention is not patentable (*see Question 1*).
- The patent applicant did not have the right, or was not eligible, to apply for the patent.

5. How is a patent infringed? How is a claim for patent infringement made and what remedies are available?

Conditions for infringement

Specific rights of patentees are set out in section 36 of the Patent Act. They include the sole right relating to produce, use, sell, possess for sale, offer for sale or import into Thailand the patented products. The same protection is provided for processes.

Any person who violates the patentee's exclusive rights is subject to infringement liability, except where a statutory exemption applies.

Claim and remedies

Patentees can enforce their patent rights through criminal and/or civil actions in the IP & IT Court, which can issue injunctive remedies, search and seizure orders, damages and criminal penalties (fine and/or imprisonment).

6. Are there non-patent barriers to competition to protect medicinal products?

Apart from the two-year safety monitoring period during which no new generic drugs can be launched, non-patent barriers are not available in Thailand.

In relation to data submitted to the Thai Food and Drug Administration (FDA), a limited form of data protection is provided under the trade secrets law. Thailand does not offer data exclusivity protection.

Thailand enacted the Trade Secrets Act BE 2545 in 2002. The Trade Secrets Act creates a legal framework for the protection of trade secrets and other confidential information. It renders the unauthorised use and disclosure of such information to be an actionable offence, punishable by civil and criminal remedies.

In relation to data or information submitted to the FDA by a drug originator to obtain approval to market a new drug, the Trade Secrets Act recognises that such data or information, in whole or in part, may amount to a trade secret in the form of a testing result, or other information regarding its preparation, discovery, or creation. In this case, the owner has the right to request that the FDA maintain the confidentiality of the data submitted.

On such request, the FDA has "the duties to maintain the trade secrets from being disclosed, deprived of or used in unfair trading activities, in accordance with the regulations prescribed by the Minister". The Public Health Ministerial Regulation Regarding Trade Secrets (Data Protection) was subsequently issued in 2007. According to this Ministerial Regulation, after being notified that the data submitted is to be treated as a trade secret, the FDA will keep such data confidential for five years from the date of notification. However, the FDA takes the position that it only has a duty to keep the drug originator's data on file confidential, while it can still rely on such data to assess and approve a subsequent generic application.

TRADE MARKS

7. What are the legal conditions to obtain a trade mark and which legislation applies? What cannot be registered as a trade mark and can a medicinal brand be registered as a trade mark?

Conditions and legislation

The Trade Mark Act, B.E. 2534 (AD 1991), as amended by the Trade Mark Act, B.E. 2543 (AD 2000) (Trade Mark Act), applies.

A trade mark is registrable if the following requirements are met:

- It is distinctive.
- It is not forbidden under the Trade Mark Act.
- It is not identical or similar to trade marks registered by others.

Scope of protection

A medicinal product brand can be registered as a trade mark according to the Trade Mark Act.

There is no special register of pharmaceutical trade marks. Applicants for drug marketing approval are not required to obtain prior approval from the drug regulatory authorities for trade mark use. Notification No. 5 of the Ministry of Commerce prohibits the registration of a mark that is similar or identical to an international non-proprietary name (INN). This Notification has been in effect since 2000.

8. How is a trade mark registered?

Application and guidance

Applications are made to the Trade Mark Office of the Department of Intellectual Property, Ministry of Commerce (Trade Mark Office) (*www.ipthailand.go.th*). Guidance on the application procedure is available on this website (in Thai only).

One trade mark or service mark application can be filed per class. Multiple class applications are not available.

The registrar determines the filing fee and registration fee, based on the number of goods to be registered. The filing fee is THB500 and the registration fee is THB300 for one item of goods.

If a mark covers more than one item of goods, the cost of registering a mark in one class increases by THB800 for each additional item of goods.

Process and timing

After filing an application with the Trade Mark Office, it takes at least six to nine months for the registrar to examine an application. After the examination, if the application is accepted for registration, it is published in the *Trade Mark Gazette*. If no objections are filed within 90 days after publication, registration is granted, dated as at the application filing date. The registrar issues a notification requesting payment of the registration fee. The certificate of trade mark registration is issued within two months after the registration fee has been paid. Barring any problems, it normally takes about ten to 12 months for a trade mark to be registered.

9. How long does trade mark protection typically last?

Duration and renewal

A trade mark is protected for ten years from the filing date, and can be renewed every ten years. A renewal application can be filed within 90 days before its expiry, for an additional ten years from the date of expiry of the original registration, or from the date of the previous renewal. A trade mark can therefore be indefinitely renewed provided the formal procedure is completed.

Extending protection

There are no other ways to extend a trade mark.

10. How can a trade mark be revoked?

A trade mark can be revoked if it does not comply with the legal requirements, that is, it must be distinctive, not forbidden under the Trade Mark Act, and not identical or similar to trade marks registered by others.

11. How is a trade mark infringed? How is a claim for trade mark infringement made and what remedies are available?

Conditions

The person registered as the trade mark owner has the exclusive right to use the goods for which registration has been granted (*section 44, Trade Mark Act*). Infringement of the rights of a registered trade mark owner is a criminal offence leading to penal remedies.

Claim and remedies

A trade mark owner can bring criminal charges against an infringer by submitting a complaint directly to a court or, more commonly, lodging a complaint with the police authorities.

The owner of a registered trade mark that has been infringed can file an action claiming compensation from the infringer under sections 420 and 421 of the Civil and Commercial Code. The owner of a trade mark not yet registered in Thailand but registered elsewhere can receive protection under the passing off theory (*section 46, Trade Mark Act*). Proof of damage is required for economic recovery.

Penalties for forgery of a registered trade mark can include both:

- A fine of up to THB400,000.
- A prison sentence of up to four years (usually reduced or suspended for first-time offenders).

Penalties for imitation of a registered trade mark can include both:

- A fine of up to THB200,000.
- A prison sentence of up to two years (usually reduced or suspended for first-time offenders).

12. Outline the regulatory powers and enforcement action against counterfeiting in the pharmaceutical sector.

Patent enforcement

If drugs are subject to patent protection in Thailand, both civil and criminal actions can be taken against infringers of a Thai registered patent. Criminal action is initiated with the filing of a criminal complaint with the police, followed by a police raid (based on a lawful search warrant), arrest of the infringer, and seizure of the infringing goods.

A preliminary injunction is theoretically available, but rarely granted. The patent owner can apply to the court for an injunction if there is clear evidence that a person has committed to or is about to commit to an act in violation of a patent owner's patent. The court's issuance of such an injunction will not curtail the patent owner's right to claim for damages.

Trade mark enforcement

If fake drugs are contained in a package with an unauthorised trade mark, the legal framework for the protection of marks in Thailand is set out in the Trade Mark Act 1991, as amended by the Trade Mark Act 2000, the Penal Code, and the Civil and Commercial Code. Under this framework, there are essentially two alternatives to proceed to take legal action against an infringer, that is, a criminal action and/or a civil action.

Border enforcement: customs action

Under the Customs Act (No. 12) B.E. 2497, customs officers have the power to search without a warrant in the customs control zone. The exercise of this authority must be based on reasonable cause. Property and goods and also persons can be searched.

The Customs Laws B.E. 2496 grants customs officials the power to open and examine packages while the packages are passing through customs. It also allows officials to board and search vessels within Thailand's boundaries. Customs officials also have the authority to arrest persons on reasonable suspicion of an offence against the Customs Laws.

Enforcement by FDA

The sale of medicines in Thailand is regulated by the Drugs Act 1967 (as amended), which is administered by the Thai FDA. While the sale of a counterfeit drug can involve the infringement of various intellectual property rights, the sale of counterfeit medicines is also a criminal offence under the Drugs Act. Section 72 provides that the sale of fake or substandard drugs is a criminal offence.

Therefore, in addition to the actions that an aggrieved pharmaceutical producer can take under intellectual property laws against an infringer, complaints can be made directly to the FDA on the basis of counterfeiting. Such complaints will trigger an investigation which, if well-founded, can lead to criminal prosecution of the offender.

IP and competition law issues

13. Briefly outline the competition law framework in your jurisdiction and how it impacts on the pharmaceutical sector. In particular, the competition authorities and their regulatory powers, key legislation, whether pharmaceutical investigations are common, key recent activity and case law.

General overview

The main body of competition law is in the Trade Competition Act B.E. 2542 1999. It seeks to establish a legal framework to curtail unfair trade practices and prohibited monopolies. The main provisions are as follows:

- Prohibition on businesses in a dominant position from abusing their market power by various specified acts (abuse of market dominance).
- Prohibition on mergers creating monopolistic power or reducing competition. Such mergers may be approved if it can be shown that the merger is necessary in the business and it is beneficial to the economy (merger control).
- Prohibition on business operators from colluding, agreeing between themselves, and conspiring to create monopolistic power or to restrict competition (restrictive activities). A number of restricted hardcore activities are, per se, anti-competitive. These include fixing the selling price of goods or services, or limiting quantities of goods/services for sale. In addition, there is a grey list of prohibited actions for which the business operator can apply for exemptions, to include them in the contractual relationship, if it can be shown that such restrictions are a "necessity in business" (collusion).
- Prohibitions on business operators in Thailand and overseas colluding in a manner which restricts the ability of residents in Thailand from purchasing goods directly from businesses overseas (agreements between domestic and overseas business).
- A catch-all clause prohibiting business operators from taking any action which is not free and fair competition and which causes destruction, damage, obstruction, impediment, or restriction to the business operation of other business operators, or which causes them to terminate their business operation (unfair trade practices).

The Trade Competition Committee oversees and administers the legislation. If a business violates any of the above provisions, the Trade Competition Committee has power to issue an order in writing instructing the business operator to suspend, stop, or rectify the actions. However, there are very few investigations for pharmaceutical products.

14. Briefly outline the competition issues that can arise on the licensing of technology and patents in a pharmaceutical context.

A patent licence (as well as assignments of patents) must be registered with the Department of Intellectual Property (*section 41, Patent Act*).

Under section 39 of the Patent Act and corresponding ministerial regulations, in particular Ministerial Regulations No. 25 1999 (B.E. 2542), a patent licence must not contain any provisions that unfairly restrict competition. On receipt of an application for registration, the Patent Registrar will examine the licence to ensure that it does not contain any anti-competitive provisions. Anti-competitive provisions will effectively bar the agreement from registration, meaning that the licence will be void by law.

The Ministerial Regulations No. 25 expand further on the various prohibited restrictions. There is no concept of a block/category exception under Thai law as there is, for example, under EU law. However, there are:

- Restrictive provisions under Clause 3 that may be prohibited (grey list).
- Hardcore actions under Clause 4 that are entirely prohibited, with no exception (black list).

Grey list

The Director General of the Department of Intellectual Property on analysis of the agreement can determine if there is an unauthorised unfair restriction. The Director General will consider "the object or intent of the parties" as to whether they intended to cause unfair practice, including the result which may occur. Therefore, there is scope for a type of "rule of reason" approach. The grey list generally includes the following prohibited activities:

- Tie-in restrictions requiring the sourcing of raw materials and other materials where these are not necessary to work the patent.
- Obligations on the licensee to hire specific persons for production of the invention, except where the person to be hired is required to work the patent.
- Obligations on the licensee to sell/distribute at least half of the products produced as a result of the licence back to the licensor or his designate.
- Restrictions that only permit sales/distribution to the licensor or his designate.
- Export prohibitions, or conditions requiring consent before export, except in instances where the licensor already has a pre-existing licence relationship in that export country.
- Limiting quantities of production, sale, or distribution.
- Restrictions on the licensee from conducting study, research, testing, or development of the patented invention or patented designs.
- Restrictions and prohibitions on the licensee using the patents of third parties.
- Limiting the autonomy of the licensee from determining resale prices.
- Defective product liability exemptions for the licensor where the defective nature of the product cannot be determined during the production by the licensee (that is, an inherent defect in the patented technology).
- Imposing higher royalty rates than usual or rates that are higher than those agreed with other licensees.
- Provisions that are against the "law relating to competition".

Black list

These clauses are, per se, anti-competitive and will automatically cause registration of a licence to be refused. The Director General cannot apply a rule of reason type analysis to these clauses:

- Requiring the licensee to use another patent/technology of the licensor on payment of a royalty, except where it can be shown that this additional patent is required so that the product to be produced by the licensee under the patent conforms to the invention in the main licensed patent (a form of tie-in).
- No challenge clauses.
- Requirements that licensees assign improvements without suitable remuneration.
- Requirements to pay royalties after expiration of the patent.

- Requiring the licensee to act in a manner that has been determined by the courts or other competent competition law officials to be anti-competitive.

15. Are there competition issues associated with the generic entry of pharmaceuticals in your jurisdiction?

There have been no competition cases brought to the Trade Competition Committee or before the courts relating to generic entry of pharmaceuticals.

16. Have abuse of dominance issues arisen in the pharmaceutical sector in your jurisdiction?

In January 2007, the Trade Competition Committee issued a guideline to define market dominance as either:

- Any business operator selling any product or rendering any service, whose market share in the past year was 50% or higher and whose sale proceeds in the previous year amounted to THB1 billion or above.
- The first three business operators of any product or service, whose market share during the previous year was a total of 75% or higher, and whose sales proceeds during the past year amounted to THB1 billion or above (except for a business operator whose market share in the past year was below 10% or a business operator whose sales proceeds of the past year were below THB1 billion).

However, there have been no cases relating to the pharmaceutical sector.

17. Have parallel imports of pharmaceuticals raised IP and competition law issues in your jurisdiction?

Parallel imports of pharmaceuticals have not raised IP and competition law issues in Thailand.

18. Does a patent or trade mark licence and payment of royalties under it to a foreign licensor have to be approved or accepted by a government or regulatory body? How is such a licence made enforceable?

There is no requirement for a patent or trade mark licence agreement and payment of royalties under it to a foreign licensor to be approved or accepted by a government or regulatory body. However, a patent or trade mark licence agreement must be recorded with the Department of Intellectual Property to be enforceable.

Practical Law Contributor profiles

Alan Adcock

Tilleke & Gibbins
T +66 2653 5555
F +66 2653 5678
E alan.a@tilleke.com
W www.tilleke.com

Professional qualifications. New York and New Jersey, 1999

Areas of practice. IP and regulatory affairs; IP commercialisation

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Areeya Pornwiriyangkura

Tilleke & Gibbins
T +66 2653 5882
F +66 2653 5678
E areeya.p@tilleke.com
W www.tilleke.com

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Siraprapha Rungpry

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E siraprapha.r@tilleke.com
W www.tilleke.com

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