Practical Law™
GLOBAL GUIDE 2018
LIFE SCIENCES

Pharmaceutical IP and competition law in Thailand: overview

Alan Adcock, Dr Atthachai Homhuan, and Siraprapha Rungpry
Tilleke & Gibbins

global.practicallaw.com/3-560-1306

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/en*). 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 (invention patent, petty patent or design patent). 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

To apply for an invention patent, the 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. Subsequently, a substantive review of the invention is 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.

4. How can a patent be revoked?

The validity of patents can be challenged by filing an invalidation claim with 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 (that is, it is obvious) 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 exclusive rights 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?

Non-patent barriers are not available in Thailand.

Previously, new drugs under the Safety Monitoring Programme (SMP) (two to four years) effectively received market exclusivity during that period, as no generic drugs could be launched while the SMP was ongoing. This is no longer the case. Due to the Thai government's healthcare policy which seeks to improve access to medicines, the FDA currently grants approval of generic drugs during the SMP period.

In relation to data submitted to the 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), is the key legislation governing registered trade marks.

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.

Further, the Thai Trade Mark Act was recently amended. According to the Trade Mark Act 2016, the registration of trade marks through the Madrid system is now applicable in Thailand. In addition, the Act has changed the trade mark regime as follows:

- Trade marks for sounds are acceptable for registration.
- The definition of a distinctive trade mark has been broadened to include shapes or three-dimensional objects that are not the natural shapes of the applied goods.
- Multiple-class applications are allowed.
- 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 transactions have also been revised.

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/en*). Guidance on the application procedure is available on this website (in Thai only).

Multiple class applications are allowed.

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. Registered trade marks are also subject to cancellation after three years of non-use.

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

Conditions

The registered trade mark owner has the exclusive right to use the trade mark for the goods for which registration has been granted (*section 44, Trade Mark Act*). Any person who violates the trade mark owner's exclusive right is subject to infringement liability, including civil liability and criminal penalties.

Claim and remedies

A trade mark owner can enforce their trade mark rights through criminal and/or civil actions against an infringer by submitting a complaint directly to the IP & IT Court or, more commonly, lodging a complaint with the police authorities.

The owner of a registered trade mark that has been infringed can file a civil 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. Furthermore, infringement of a registered trade mark is a criminal offence leading to penal remedies. 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 a drug is subject to patent protection in Thailand, both civil and criminal actions can be taken against an alleged infringer. 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 civil action can be initiated by filing a complaint directly with the IP & IT Court. Civil actions are more common than criminal actions for enforcement of pharmaceutical patents.

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

Trade mark enforcement

If a trade mark is used on a pharmaceutical product without authorisation of the trade mark owner, the trade mark owner can initiate a criminal and/or civil action against an infringer (*see above, Patent enforcement*).

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 production, import, marketing and distribution of pharmaceutical products in Thailand are regulated by the Drug Act B.E. 2510, which is administered by the Thai FDA. In particular, section 72 of the Drug Act provides that 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.

For information on pharmaceutical pricing and state funding, manufacturing, marketing, clinical trials, advertising, labelling, and product recall and liability, see *Medicinal product regulation and product liability in Thailand: overview.*

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. 2560 (the 2017 Act), which has repealed and replaced the first competition law in Thailand, the Trade Competition Act B.E. 2542 (the 1999 Act).

Overall, the Trade Competition Act prohibits or otherwise limits practices that potentially restrict competition. The 2017 Act came into effect on 5 October 2017. Under the 2017 Act, the following are prohibited:

- Abuse of market dominance.
- Anti-competitive agreements, for example:
- price fixing;
- output restrictions;
- market allocation;
- exclusive dealing;
- reducing quality;
- setting conditions/practices for selling goods/services;
- Overseas agreements which may lead to a monopoly or an unreasonable restraint of competition.
- Various unfair trade practices, for example:
- unfair obstruction of the business operation of others;
- unfair use of a superior bargaining position;
- unfair determination of trade conditions in order to restrict or impede the business operation of others.

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.

Short-form recordable patent licence agreements based on a main technology licence agreement are acceptable. Generally, the Patent Registrar will take around three months to complete a patent license agreement recordal review.

The Ministerial Regulations No. 25 expands 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?

Thailand's new Trade Competition Act B.E. 2560 (2017) maintains the longstanding principle that being a market dominant player does not automatically raise a competition law issue. To date, there have been no abuse of market dominance 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 and a trade mark licence agreement must be registered with the Department of Intellectual Property to be enforceable under Thai law.

For information on pharmaceutical pricing and state funding, manufacturing, marketing, clinical trials, advertising, labelling, and product recall and liability, see *Medicinal product regulation and product liability in Thailand: overview.*

Practical Law **Contributor profiles**

Alan Adcock

Tilleke & Gibbins

T +66 2056 5871
F +66 2056 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, agrichemical and biotechnology regulatory matters.
- Advising innovator pharmaceutical companies in patent infringement litigation against local generic companies.
- Advising companies on plant variety protection, enforcement and commercialisation in Thailand.
- Registering products with the Food and Drug Administration and Ministry of Agriculture in Thailand and throughout Southeast Asia.

Languages. English, Mandarin

Professional associations/memberships. Member INTA Emerging Issues Committee; Member INTA Global Advisory Council Asia Pacific; AIPPI Thailand National Group Reporter; President of LES Thailand

Publications

- *Distribution and Marketing of Drugs Global Guide - Thailand Chapter, Practical Law, 2015 (with Siraprapha Rungpry).*
- *Life Sciences Global Guide – Thailand Chapter, Practical Law, 2015 (with Dr Atthachai Homhuan and Siraprapha Rungpry).*

Dr Atthachai Homhuan

Tilleke & Gibbins

T +66 2056 5610
F +66 2056 5678
E atthachai.h@tilleke.com
W www.tilleke.com

Areas of practice. Intellectual property; regulatory affairs.

Recent transactions

- Implemented a quality system and GMP-related topics for the manufacturing of vaccines. This involved working closely with the Department of Medical Sciences of the Thai FDA in regard to biohazard manufacturing, ex-plan audit, in order to obtain approval.
- Participated in conducting clinical trials and bioequivalence studies for new drugs and conventional products, and ensured the trials/studies and protocols were in accordance with the Good Regulatory Practices and Good Clinical Practices.
- Co-invented several pharmaceutical products regarding liposomal vaccines and stem cell therapy, each of which is patented in Japan.

Languages. Thai, English

Professional associations/memberships. Regulatory Affairs Pharmacy Association (Thailand); European Association for Business and Commerce; International Association for the Protection of Intellectual Property.

Publications

- *Life Sciences Global Guide – Thailand Chapter, Practical Law, 2015 (with Alan Adcock and Siraprapha Rungpry).*
- *Allow Case-by-Case Patent "Evergreening" of Pharmaceuticals, Bangkok Post, 3 October 2014.*
- *Expediting the Patent Examination System in Thailand: Recent Developments, Informed Counsel, 3 March 2014.*
- *Electronic Data Linkage Between Thai FDA and Customs, Informed Counsel, 26 August 2013.*

Siraprapha Rungpry

Tilleke & Gibbins

T +66 2056 5874
F +66 2056 5678
E siraprapha.r@tilleke.com
W www.tilleke.com

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

Recent transactions

- Advised pharmaceutical clients on various IP and regulatory issues, product liability, government advocacy on new regulations, and compulsory licences.
- Advised multinational pharmaceutical companies in patent infringement litigation against local generic companies.

Languages. Thai, English

Publications

- *Distribution and Marketing of Drugs Global Guide - Thailand Chapter, Practical Law, 2015 (with Alan Adcock).*
- *Life Sciences Global Guide – Thailand Chapter, Practical Law, 2015 (with Alan Adcock and Dr Atthachai Homhuan).*
- *Patent Litigation in Thailand: Know Your Rights and Duties, Bangkok Post, 7 February 2014.*