Thailand
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Report Q202

in the name of the Thai Group
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The impact of public health issues on exclusive patent rights

Questions

I) Analysis of current law and case law

1) *Is a research or experimental use exception recognised under your patent law? If so, under which conditions? What is the scope of the research exception? Specifically, is research or experimental use permitted for commercial purposes?*

A research or experimental use exception is recognised under the Thai Patent Act B.E. 2522 (A.D. 1979) as amended.

Any act for the purpose of study, research, experimentation or analysis of the valid patent, without the patent holder's permission, shall not constitute an infringement, provided that it does not unreasonably conflict with a normal exploitation of the patent and does not unreasonably prejudice the legitimate interests of the patent holder. (Section 36, paragraph two, (1)).

This statutory provision is not clearly limited to non-commercial purposes only. Therefore, the research or experimental use for a commercial purpose is permitted, provided that it does not unreasonably conflict with a normal exploitation of the patent and does not unreasonably prejudice the legitimate interests of the patent holder.

2) *Is a Bolar-type exception recognised under your patent law? If so, under which conditions? What is the scope of the Bolar exception? Specifically, is it limited to drugs or does it also apply to other products, including biological products, research tools, etc.? If your patent law does not provide for a Bolar exception, will using an invention without the patentee's consent for the purpose of obtaining approval of a generic product be covered by the research exception?*

The Bolar-type exception was first recognised by Patent Act (No. 2) B.E. 2535 (A.D. 1992).

Any act concerning an application for drug registration, the applicant intending to produce, distribute or import the patented pharmaceutical product after the expiration of the patent term, shall not constitute a patent infringement. (Section 36, paragraph two, (4)).

A definition of drug is not explicitly prescribed under the current Patent Act (as amended). Therefore, the provision of Section 4 of the Drug Act B.E. 2510 (A.D. 1967) as amended concerning the definition of drug shall be applied mutatis mutandis.

Section 4 of the Drug Act B.E. 2510 as amended provides that "Drugs" means:

1) substances recognized by pharmacopoeias notified by the Minister;

2) substances intended for use in the diagnosis, treatment, relief, cure or prevention of human or animal disease or illness;

3) substances which are pharma chemicals or semi-processed pharma chemicals; and

4) substances intended to affect the health, structure or function of the human or animal body.

The Bolar-type exception is limited to drugs only. Therefore, other products, such as biological products, research tools, etc., are excluded from the Bolar-type exception.

3) Are parallel imports of patented medicines, medical devices or similar permitted? If so, under which conditions? Do the same principles apply if the products originate from markets where they were made available under a compulsory license?

The principle of parallel import of patented products was first introduced by Patent Act (No. 3) B.E. 2542 (A.D. 1999).

The use, sale, having in possession for sale, offering for sale or importation of a patented product shall not constitute a patent infringement when the product has been produced or sold with the authorization or consent of the patent holder. (Section 36, paragraph two, (7)).

The parallel import exception does not apply to the patented products originating from markets where they are made available under the compulsory license because the compulsory licensing forces the patent holder to allow others to use the patent at a fee set by the government. The patent holder is not allowed to refuse to license or to negotiate voluntary license fee.

4) Is an individual prescriptions exception recognised under your patent law? If so, under which conditions?

An individual prescription exception was first prescribed by the Patent Act (No. 2) B.E. 2535 (A.D. 1992).

The preparation of drugs for an individual case according to a doctor's prescription by a professional pharmacist or medical professional, including any act done to such pharmaceutical product shall not constitute a patent infringement. (Section 36, paragraph two, (3)).

5) Please answer this question only if in your country methods of medical treatment are patentable subject matter: Does your patent law provide for a medical treatment defence or similar exception to the patentee's exclusive rights?

Methods of medical treatment are not patentable subject matter under the Thai Patent Act B.E. 2522 (A.D. 1979) as amended.

6) Are compulsory licenses available under your patent law? If so, under which conditions and on which grounds (e.g. to remedy anticompetitive conduct, for cases of emergency, other public interest grounds, etc.)? Are you aware of any compulsory licenses granted in your country for the domestic manufacture and supply of pharmaceutical products? If so, please provide details, including the name of the licensor, the licensee and the product covered.

The principle of compulsory licensing was first introduced into the Thai Patent Act B.E. 2522 (A.D. 1979).

Under the current Patent Act (as amended), a compulsory licensing may be granted in the following circumstances.

1) Insufficient working of a patent
At any time after the expiration of three years from a grant of patent or four years from the date of application, whichever is later, any person may apply to the Director General for a license if it appears, at the time when such application is filed, that a patent holder unjustifiably fails to exercise his legitimate rights as follows:

– that the patented product has not been produced or the patented process has not been used in the country, without any legitimate reason; or

– that no product produced under the patent is sold in any domestic market, or that such a product is sold but at unreasonably high prices or does not meet the public demand, without any legitimate reason.

An applicant is required to show that he or she has attempted to obtain a license by offering sufficient conditions and royalties to the patent holder but an agreement could not be reached within a reasonable period. (Section 46).

2) Interdependent patents

If an exploitation of patented claims is likely to constitute an infringement of another person's patented claims, a patent holder, desiring to exploit his or her own patent, may apply to the Director General for a license under the patent of the other person under the following criteria:

– the applicant's patent involves an importation technical advance of considerable economic significance in relation to the invention for which the license is applied;

– the patent holder shall be entitled to a cross-license on reasonable term;

– the applicant shall not assign his or her right in the license to other persons except with the assignment of his or her patent.

An applicant is required to show that he or she is attempted to obtain a license by offering sufficient conditions and royalties to the patent holder but an agreement could not be reached within a reasonable period. (Section 47).

According to the above circumstances, the Director General shall fix the royalties, conditions and restrictions as he or she deems appropriate subject to the following requirements:

– the scope and duration of the license shall not exceed what is necessary under the circumstances;

– the patent holder shall be entitled to further license others;

– the licensee shall not be entitled to assign the license to others, except with that part of the enterprise or goodwill particularly of the part under the license;

– the license shall be aimed predominantly for the supply of the domestic market; and

– the royalties fixed shall be adequate for the circumstances of the case. (Section 50).

3) Public interest

The Patent Act authorises the government to utilize a patent for the benefit of the public in two circumstances:

– a Ministry, Bureau or Department may use any granted patent under Section 36 by itself or authorise another person to use it for the benefit of public utilities; national defence; the preservation or acquisition of natural resources or the environment; the prevention of severe shortages of food, medicine or other consumption items; or for other public interest. The authority is obliged to pay a royalty to the patent holder or the patent holder's licensee (Section 51); and

– the Prime Minister, with the approval of the Cabinet, shall have the power to issue an order to exercise any granted patent, during a state of war or emergency, necessary to defence and security of the country by paying a fair remuneration to the patent holder and shall notify the patent holder in writing without a delay. (Section 52).

By virtue of Section 51 of the Patent Act (as amended), the compulsory licenses have been granted by Ministry of Public Health to exercise the granted patents of the following pharmaceutical products.

1) Efavirenz (Stocrin®) for the treatment of HIV /AIDS owned by Merck & Co., Inc.;
2) Lopinavir and Ritonavir (Kaletra®) for the treatment of HIV /AIDS owned by Abbott Laboratories;
3) Clopidogrel (Plavix®) for the treatment of myocardial ischemia and cerebro-vascular accident owned by Sanofi-Aventis;
4) Docetaxel (Taxotere®) for the treatment of lung and breast cancers owned by Sanofi-Aventis.
5) Femara (Letrozole®) for the treatment of breast cancer owned by Novartis;
6) Erlotinib (Tarceva®) for the treatment of lung cancer owned by Roche; and
7) Imatinib (Glivec®) for the treatment of chronic myeloid leukemia and gastro-intestinal stromal tumours owned by Novartis.

The Ministry of Public Health has entrusted the Government Pharmaceutical Organization (GPO) in its name to exercise the patent rights under Section 36 paragraph one of the Patent Act (as amended), with a payment of royalties to the patent holders as prescribed by the Notifications of Ministry of Public Health.

7) Has new Article 31bis TRIPS been ratified in your country? Are you aware of any other legislative amendment in your country with a view to implementing the WTO decision of August 30, 2003? Are you aware of any compulsory licenses granted in your country for the importation or exportation of pharmaceutical products? If so, please provide details, including the name of the licensor, the licensee and the product, if they are publicly available.

New Article 31 bis TRIPS is not yet ratified in Thailand. However, Ministry of Commerce has proposed to ratify the said Article in a draft of amendment to the current Patent Act which is in the process of reviewing the draft.

Thereafter, the Ministry of Commerce will forward the approved draft to the Office of the Council of State for review and approval before submitting the same to the Cabinet and the House of Representative, respectively.

8) Is the government allowed to make use of a patented invention without previous license and if so, on what basis (e.g. crown use) and under which conditions?

The government is allowed to make use of a patented invention without previous license in the following two circumstances.

1) A Ministry, Bureau or Department may exercise any granted patent by itself or authorise another person to exercise it for the benefit of public utilities; national defence; the preservation or acquisition of natural resources or the environment; the prevention of severe shortages of food, medicine or other consumption items; or other public interest; and
2) The Prime Minister, with the approval of the Cabinet, shall have the power to issue an order to exercise any granted patent necessary to defence and security of the country.

9) Is the government allowed to expropriate a patent and, if so, under which conditions?

The Director General may request the Board of Patents to revoke a valid patent when a compulsory license has been granted under Section 50 and a period of two years has lapsed

from the date of grant of license, the patent holder, the patent holder's licensee or the license's holder fails to produce the patented product or use the patented process in the country without any legitimate reason, or no patented product or product made by the patented process is sold or imported into the country or such a product is sold at unreasonably high price, and the director general is of the view that there is a good cause to revoke a patent. (Section 55 (1)).

10) *If your patent law recognises other means of facilitating access to medicines, medical devices, diagnostics and the like, notably in the context of public health crises (including, among others, information tools such as the Orange Book providing timely consumer information on generic drug approvals), which have not been discussed above, please explain.*

Other means of facilitating access to medicines, medical devices, diagnostics and the like are not explicitly prescribed by the Patent Act B.E. 2522 as amended.

II) Proposals for adoption of uniform rules

1) *Should patent law provide for*

- *research and experimental use exception;*
  Yes. The research and experimental use exception should not be limited to non-commercial purpose only in order to further develop and improve the technology of the patented invention, under the conditions that the said use does not unreasonably conflict with a normal exploitation of the patent and does not unreasonably prejudice the legitimate interests of the patent holder.
- *Bolar exception;*
  Yes. The Bolar exception should also extend to other products, including biological products, research tool, etc.
- *parallel import of patented medicines;*
  Yes. The parallel import exception should not be limited to patented medicines, but the exception should also extend to all patented products made under the authorization or consent of the patent holder.
- *individual prescriptions exception;*
  Yes. The individual prescription exception should be recognised under the developing countries' patent law to remedy the pharmaceutical access problem.
- *medical treatment defence;*
  We are of the view that the medical treatment should not be patentable subject matter. However, the country where the methods of medical treatment are patentable subject matter should stipulate the limitations to the exclusive rights in a patent law.
- *compulsory licensing;*
  Yes. The compulsory licensing is required in some circumstances, such as non-working of patent, national defence, or the needs of the national economy, or public health, etc. Each country should freely stipulate the grounds upon which compulsory licenses are granted.
- *expropriation;*
  Yes. The expropriation of patent should be recognised under the patent law under the condition that the patent has not been worked without any legitimate reason or within the reasonable period.
- *any other limitations of the exclusive patent rights to facilitate access to medicines, diagnostics, medical devices and the like?*

  None.

2) *Do you see other ways than by limitations of patent rights in which patent law might facilitate access to medicines, diagnostics, medical devices and the like?*

None.

3) *Should any of the limitations of patent rights, specifically the research and experimental use exception, Bolar exception, and individual prescriptions exception be harmonised? If so, how? If not, why not?*

We are of the view that the limitations of patent rights, specifically the research and experimental use exception, Bolar exception, and individual prescriptions exception should not be harmonised. This is because each country should have a freedom to stipulate the limitations of patent rights, taking into account the public interests of the country. Some limitations of patent rights may not be required in developed countries, but they may need in several developing countries.