

Report Q202

in the name of the Chinese Group
by Wei CHENG

The impact of public health issues on exclusive patent rights

Questions

1) 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?*

In accordance with the provision under Article 63(4) of the Patent Law of P. R. China, the following action shall be deemed as an infringement of the patent right: "Where any person uses the patent concerned solely for the purposes of scientific research and experimentation". The expression "scientific research and experimentation" refers to such scientific research and experimentation which is solely made for the patented technique itself, the purposes of which consists in reviewing technical characters or technical effects of the patented technique itself, or further improving the patented technique itself, and not generally refers to generic scientific research and experimentation. The expression "uses the patent concerned" refers to, for the above-mentioned purposes, the manufacture of the patented product or the implementation of the patented method, or the analysis and the review for the patented technique according to the published application documents, and not refers to the implementation of other scientific research and experimentation projects by using the means of the patented technique.

The scientific research and experimentation for the commercial purposes is prohibited under the Patent Law of P. R. China.

- 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 present Patent Law of P. R. China does not have any explicit provision concerning for Bolar-type exception. However, the provision for Bolar-type exception would probably be added into the Patent Law of P. R. China on its third amendment. The term of the Bolar-type exception in the draft of the third amendment of the Patent Law involves medicines and medical devices.

- 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 present Law of P. R. China does not have any explicit provision concerning for parallel imports. Currently, the principle dealing with "parallel import" is, when the patented products legally sold in the output country are "parallel imported", an explicit or implicit permission from the Chinese patentee is required. The implicit permission means that the patentee or the licensee does not add explicit limitation when he sells his patented products in the output country. As for the products manufactured under compulsory license, an explicit permission or implicit permission from the Chinese patentee is required as well when they are "parallel imported".

The parallel import for some medicine for treating certain epidemic disease is exceptional case. In case a patent right is granted to any medicine for treating certain epidemic disease in China, the medicines purchased by any entity or natural person from the other countries or areas where the medicines are manufactured and sold by the patentee or manufactured and sold with the permission of the patentee, can be imported into China without the compulsory license granted from the State Intellectual Property Office of P. R. China.

In addition, the term of permission for parallel import would probably be added into the third amendment of the Patent Law of P. R. China.

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

In accordance with the requirement of Article 25(1.3) of Patent Law of P.R. China, as to methods for the diagnosis or for the treatment of diseases, no patent right shall be granted. For humanity and ethical reasons, it is acknowledged that a doctor shall be given the freedom to choose any means in the course of diagnosis or treatment of diseases. Moreover, this kind of methods are not susceptible of industrial application because they are practiced directly on living human or animal bodies, and are not inventions-creations in the context of the patent law. Therefore, methods for diagnosis or for treatment of diseases shall not be granted patent rights.

Generally, the prescriptions for individual cases are regarded as methods of treatment for diseases by using medicines which are not patentable, should not be granted patent rights.

- 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?*

In accordance with the requirement of Article 25(1.3) of Patent Law of P.R. China, as to methods for the diagnosis or for the treatment of diseases, no patent right shall be granted. Methods for diagnosis or for treatment of diseases refer to the processes of identifying, determining, or eliminating the cause or focus of diseases which are practiced directly on living human or animal bodies.

However, instruments or apparatus for implementing these methods of diagnosis or treatment, or substances or materials for use in such methods are subject matters for which patent right may be granted.

- 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.*

Compulsory license is available under Patent Law of P.R. China. The grounds on which compulsory License for exploitation of patent may be granted are provided as follows (the Article 48, 49 and 50 of Patent Law of P.R. China may be referred to):

- 1) Where any entity which is qualified to exploit the invention or utility model has made requests for authorization from the patentee of an invention or utility model to exploit its or his patent on reasonable terms and conditions and such efforts have not been successful within a reasonable period of time;
- 2) Where a national emergency or any extraordinary state of affairs occurs, or where the public interest so requires; or
- 3) Where the invention or utility model for which the patent right has been granted involves important technical advance of considerable economic significance in relation to another invention or utility model for which a patent right has been granted earlier and the exploitation of the later invention or utility model depends on the exploitation of the earlier invention or utility model.

In addition, the entity or individual that is granted a compulsory license for exploitation shall pay to the patentee a reasonable exploitation fee.

Up to now, China had not issued any compulsory licences for patent enforcement.

- 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.*

China has ratified new Article 31bis TRIPS. State Intellectual Property Office of the P.R.C. has promulgated "Measures for Compulsory License on Patent Implementation concerning Public Health Problems" (promulgated on November 29, 2005, and enter into force on January 1, 2006) with a view to implementing the WTO decision of August 30, 2003.

In addition, some interrelated term would probably be added into the third amendment of the Patent Law of P. R. China. In the current revised draft of Patent Law of the People's Republic of China (a draft for discussing), the content related to new Article 31bis TRIPS involves that: in case a patent right is granted to any medicine for treating certain epidemic disease in China, and developing countries or least-developed countries which do not have the capacity for the production of the medicine or have insufficient production capacity expect to import the medicine from China, the patent administration department under the State Council may, according to the provisions of international treaty, grant compulsory license for manufacturing the medicine and exporting the medicine to above-mentioned countries to the entity which is qualified to exploit the invention.

- 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 Patent Law of P. R. China allows the government to spread and apply a patent for invention without previous license. However, the patent for invention to be spread and applied must be of great significance to the interest of the State or to the public interest. Moreover, patentee of the patent for invention to be spread and applied only limit to State-owned enterprise or institution, a Chinese individual or an entity under collective ownership, and excluding a foreign individual, sino-foreign joint ventures, sino-foreign cooperative enterprise, foreign-funded enterprise, China private enterprise, and other entity under the mixed ownership. In addition, the exploiting entity shall, according to the regulations of the State, pay a fee for exploitation to the patentee.

Up to now, no patent for invention is spread and applied in China.

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

The government is not allowed to expropriate a patent.

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.*

There is no other means in our patent law.

II) Proposals for adoption of uniform rules

1) *Should patent law provide for*

- *research and experimental use exception;*
- *Bolar exception;*
- *parallel import of patented medicines;*
- *individual prescriptions exception;*
- *medical treatment defence;*
- *compulsory licensing;*
- *expropriation;*
- *any other limitations of the exclusive patent rights to facilitate access to medicines, diagnostics, medical devices and the like?*

If so, under what circumstances? If not, why not?

The Patent law should provide for the above-mentioned exceptions. The corresponding exceptions treatments should be made as long as belong to the legal cases.

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?*

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?*

National Groups are invited to comment on any additional issue concerning the impact of public health issues on the patentee's exclusive rights which they find relevant.

The Patent law should protect the benefit of the patentee. However, in the case where the patentee's exclusive rights come into conflict with public health, the public health right should be protected firstly. If the measure made for protecting the public health right damage patentee's benefit, the patentee would be paid adequate remuneration.

Summary

The present Patent Law of P. R. China recognizes the research or experimental use exception, and stipulates that methods for the diagnosis or for the treatment of diseases are not patentable subject matter. The Patent Law of P. R. China does not have explicit provision concerning for Bolar-type exception and parallel import, but would probably provide Bolar-type exception and allow parallel import on its third amendment. While the compulsory license is available under Patent Law of P.R. China, no compulsory licences for patent enforcement is issued in China Up to now. China has ratified new Article 31bis TRIPS, and promulgated "Measures for Compulsory License on Patent Implementation concerning Public Health Problems" (enter into force on January 1, 2006) with

a view to implementing the WTO decision of August 30, 2003, in addition, some interrelated term would probably be added into the third amendment of the Patent Law of P. R. China. The government is not allowed to expropriate a patent in China.