

Report Q202

in the name of the Korean Group
by Seong-Ki KIM

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?*

Yes. Art. 96-1.

If so, under which conditions?

The patented invention is worked for the purpose of research on experiment.

What is the scope of the research exception?

Research or experiment conducted for the purpose of improvement or advancement of the subject technology is considered to be exempted from patent infringement.

Specifically, is research or experimental use permitted for commercial purposes?

Up to now, it is not clear whether experimental use is permitted for commercial purpose. Recently, a legislative bill is introduced to allow such use for commercial purpose in case of pharmaceutical or agrochemical inventions.

2) *Is a Bolar-type exception recognised under your patent law?*

No provision is provided in a statute including the Patent Act.

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.?

N/A.

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?

Though we do not have case law on the question, commentators believe such using would be covered by the research exception.

3) *Are parallel imports of patented medicines, medical devices or similar permitted?*

Yes, parallel imports of patented medicines are permitted, unless an agreement has been made to the contrary upon its first sale.

If so, under which conditions?

The same as the answer above.

Do the same principles apply if the products originate from markets where they were made available under a compulsory license?

Yes.

- 4) *Is an individual prescriptions exception recognised under your patent law?*

Yes.

If so, under which conditions?

The Patent Act provides that such an exception is applicable to individual prescription mixing two or more ingredients.

- 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?*

N/A.

- 6) *Are compulsory licenses available under your patent law?*

Yes, Art. 107 and Art. 138, Patent Act.

If so, under which conditions and on which grounds (e.g. to remedy anticompetitive conduct, for cases of emergency, other public interest grounds, etc.)?

One of the following grounds:

- i) insufficient working;
- ii) public interests;
- iii) to rectify anti-competitive activities;
- iv) to exploit a second, improved patent.

Are you aware of any compulsory licenses granted in your country for the domestic manufacture and supply of pharmaceutical products?

Six applications have made since 1966, but no grant of compulsory license has been made.

If so, please provide details, including the name of the licensor, the licensee and the product covered.

N/A.

- 7) *Has new Article 31bis TRIPS been ratified in your country?*

Yes.

Are you aware of any other legislative amendment in your country with a view to implementing the WTO decision of August 30, 2003?

Amendment to the Patent Act implementing Art. 31 bis TRIS has been made and is in force currently.

Are you aware of any compulsory licenses granted in your country for the importation or exportation of pharmaceutical products?

No.

If so, please provide details, including the name of the licensor, the licensee and the product, if they are publicly available.

N/A.

- 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?*

In case of emergency, the Government is allowed to make use of a patented invention related to national defense.

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

Yes, in case of national emergency of war or the like.

- 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.*

N/A.

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?

Yes.

- 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?*

Tools disseminating information on medical inventions/innovations such as the Orange Book should be adopted to facilitate access to medicines.

- 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?*

Should be harmonized by an international treaty as guidelines.