Indonesia
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Report Q202

in the name of the Indonesian Group

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?*

Yes, exception for research, experimental use, education or analysis is recognized under our patent law. The above exception is applicable under the condition that it does not violate normal interest of the patent holder *[Article 16]*. The Elucidation of Article 16 explains that the scope of the research exception merely covers research and education including bioequivalent experiments or other forms of experiments. The exception does not cover commercial exploitation of a patent.

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?*

Yes, we do have Bolar-type exception under our patent law. Article 135 (b) stipulates that it is exempted from criminal provisions to produce patented pharmaceutical product within two years prior to the expiry of the patent with the purpose to process market permit. It is clear from this provision that the Bolar exception only covers pharmaceutical products.

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?*

Yes, Article 135 (a) stipulates that it is exempted from criminal provisions to import a patented pharmaceutical product if the product has been marketed in a country by the patent holder and the importation is conducted in accordance with the prevailing laws.

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

No, there is no provision under our patent law which regulates this matter.

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 under our patent law.

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.*

Yes, compulsory licenses are available under our patent law. Compulsory licenses can be granted under any of the following conditions:

a) if the patent has not been used within 36 months from the grant date of the patent *(non use);*

b) if the patent has been implemented in a manner that contravenes the public interests;

c) if a patent holder can not implement his patent without violating another existing patent *(cross-license)*; and

d) if the Government considers that a patent is very important for the conduct of defense and security and for an urgent need of public interest.

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.*

– Yes.

– Not yet.

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?*

Not allowed.

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

There is no provision under our patent law which allows the Government to expropriate a patent. The Government can only exploit the patent by giving royalty to the patent holder. The conditions for such exploitation can be seen in the above answer of point 6.d.

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.*

Not yet.

II) Proposals for adoption of uniform rules

1) *Should patent law provide for*

– *research and experimental use exception;*
(Article 16 (3)).

– *Bolar exception;*
(Article 135 (b)).

– *parallel import of patented medicines;*
(Article 135 (a)).

– *individual prescriptions exception;*
(Not yet).

– *medical treatment defence;*
(Not applicable as medical treatment is unpatentable under our patent law).

– *compulsory licensing;*
(See point I.6).

– *expropriation;*
(Not yet).

– *any other limitations of the exclusive patent rights to facilitate access to medicines, diagnostics, medical devices and the like?*
(Not yet).

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

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?

Not available.

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?

Yes, by balancing the cost if R & D and the profit of selling the patentee's medicine.