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Report Q202

in the name of the Singapore 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?*

An experimental use exception is recognised under Singapore patent law. Research use, while not specifically recognised under Singapore patent law, may fall into the exception of acts which are done privately for non-commercial purposes which is permitted under Singapore law.

The scope of the experimental use exception is limited to experimental purposes "relating to the subject-matter of the invention", however, while there is no established body of case law on this provision, there appears to be no limitation of this exception to non-commercial purposes.

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, a Bolar-type exception is recognised under Singapore patent law. The Bolar exception is limited in scope and applies only to acts performed in relation to the subject matter of the patent to support an application for marketing approval for a pharmaceutical product provided that anything produced to support the application is not

i) made, used or sold in Singapore; or

ii) exported outside Singapore.

For purposes other than for purposes relating to meeting the requirements for marketing approval for that pharmaceutical product.

Use of an invention without the patentee's consent for the purpose of obtaining approval of a generic product would unlikely be covered under the exception of acts done privately for non-commercial purposes. The phrase "non-commercial purposes" is unlikely to exclude all acts which *may* have a commercial end, however, as the approval of the generic drug has an immediate commercial purpose and is not used for an individual's own use and benefit, this exception is unlikely to apply.

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?*

Parallel imports of patented products or products obtained by means of a patented process produced with the consent of the patentee is an exception to infringement. However, if following conditions are met, the exception does not apply

i) the product has not previously been sold or distributed in Singapore by or with the written consent of the patentee or his licensee; and

ii) the import of the product by the importer would result in the product being distributed in breach of contract between the patentee and his licensee; and

iii) the importer has actual or constructive knowledge of the breach of contract indicated in (ii).

This, in effect, gives the patentee the "first mover advantage" that allows him to be the first one to bring in the patented pharmaceutical product. However, once the patentee brings the pharmaceutical product into Singapore, the parallel importer will then be allowed to similarly import, use or dispose of a generic drug in Singapore.

Furthermore, under Singapore law, a parallel importer is also entitled to import and use a drug for use by or on a specific patient. The use of the pharmaceutical product for that specific patient must meet the following conditions

i) the use of the pharmaceutical product shall be by or on that patient;

ii) the authorities must have granted approval specifically for the import of that product for use by or on that patient; and

iii) that product was produced by or with the consent of the patentee or his licensee.

It is unclear whether the same principles would apply if the products originated from markets where they were made available under a compulsory licence.

However, it is suggested that the importation of products made under a compulsory licensing scheme would not fall under the exception as Singapore is a party to the TRIPS Agreement, and particularly Article 31(f). Article 31(f) enables grant of compulsory licences for "predominately the supply of the domestic market". For countries that are unable to domestically manufacture pharmaceuticals this is problematic. Accordingly, under the 6 December 2005 amendment (or Article 31bis), parties have agreed to waive the restriction under Article 31(f) thereby allowing countries to export pharmaceutical products made under a compulsory licence.

In this regard, Singapore has indicated that such system would only be used in emergencies or extremely urgent situations. Accordingly, it is unlikely that Singapore would take the general position to allow parallel importation of pharmaceutical products made under compulsory licence

In addition to any restrictions under the Patents Act in Singapore, all medicines are subject to the Medicines Act and, except in accordance with a licence granted, no person shall deal with, procure the dealing with or exportation of, or procure the manufacture or assembly of a medical product. However, in order for an applicant to obtain a licence, the applicant is required to make a declaration, such declaration including the following information:

i) whether a patent under the Patents Act is in force;

ii) if there is such a patent in force, whether he is the proprietor of the patent;

iii) if there is a patent in force, and he is not the proprietor of the patent, a declaration stating:

- the name and particulars of the proprietor;
- whether the proprietor has consented or has acquiesced in the grant of the licence to the applicant; or, in his opinion and to the best of his believe, that the patent is invalid or would not be infringed by the doing of the act for which the licence is sought.

In the event that the applicant declares that he is not the proprietor under (iii) (listed above) the licensing authority may require the applicant to serve on the proprietor of the patent, a copy of his application and to furnish the Health Science Authority, such evidence of the service of the application form as the licensing authority may require. The added step of alerting the patent owner of the applicant's interest in a licence assists the patent owner with the enforcement of his rights.

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

An individual prescriptions exception is recognised under Singapore patent law provided that it meets the following conditions

i) the act must consist of extemporaneous preparation of a medicine (or consist of dealing with a medicine so prepared);

ii) the act must be performed by an individual; and

iii) the act must be performed in accordance with a prescription given by a registered medical or dental practitioner.

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?*

Under Singapore Law, a method of medical treatment is not regarded as being capable of industrial application and not patentable.

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.*

Under the Singapore Patents Act any person may apply to the court for the grant of a patent licence on the grounds that the grant of the licence is necessary to remedy an anti-competitive practice if:

i) there is a market for the patented invention in Singapore; and

ii) that market is not being supplied or not being supplied on reasonable terms; and

iii) the court is of the view that the proprietor of the patent has no valid reason for failing to supply the market with the patented invention.

The licence granted under the compulsory licensing scheme is non-exclusive and is not assignable otherwise than with the goodwill of the business in which the invention was used.

We are unaware of any compulsory licences granted in Singapore.

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.

Singapore has ratified Article 31bis however, no legislative amendments have yet been made. We are unaware of any compulsory licences granted in Singapore.

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, or any party authorised in writing by the government, is entitled to make use of a patented invention without a previous licence for a public non-commercial use or in the event of a national emergency or other circumstances of extreme urgency.

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

The government has no right of expropriating a patent under Singapore law.

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.*

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?

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?*

No further comment, save that Singapore is quite current with developments in this area, and has been moving towards the harmonisation initiatives.