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Report Q202

in the name of the Malaysian 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?*

YES, research and experimental use of inventions is an exception under the Malaysian Patent Law pursuant to **Section 37(1) of the Patents Act, 1983 (the Act)** which provides as follows:

The rights under the patent shall extend only to acts done for industrial or commercial purposes and in particular not to acts done only for scientific research.

The Act limits such exception to scientific research only. Research and experimental use for commercial purposes is not permitted.

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 recognized under the Malaysian Patent Law as provided in **Section 37(1A) of the Patents Act 1983** which provides as follows:

The rights under the patent shall not extend to acts done to make, use, offer to sell a patented invention solely for use reasonably related to the development and submission of information to the relevant authority which regulates the manufacture, use or sale of drugs.

As provided above the exception is limited solely to use of the patented invention in connection with information to be given to the relevant authority which regulates the manufacture, use of drugs (ie the Ministry of Heatth).

The term used in the above exception is "patented invention" and is therefore not limited to drugs and can include biological products, research tools etc.

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, parallel imports of patented medicines, medical devices or similar are permitted in Malaysia pursuant to **Section 37(2)(i) of the Patents Act 1983** and **Section 58A of the Patents Act 1983** which provide as follows:

Section 37(2)(i) of the Patents Act 1983
Without prejudice to Section 58A the rights under the patent shall not extend to acts in respect of products which have been put on the market ... by the owner of the patent.

Section 58A(1) of the Patents Act 1983
It shall not be an act of infringement to import, offer for sale, sell or use:

a) any patented product;

b) any product obtained directly by means of the patented process or to which the patented process has been applied;

which is produced by, or with consent, conditional or otherwise, of the owner of the patent or his licensee.

Based on the above provisions parallel import does not seem to be permitted where the products originate from markets where they are made available under a compulsory licence since such products would not have been put on the market by the patent owner (under Section 37(2)(i)) and further would not have been produced with the consent of the patent owner (under Section 58A(1)).

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

NO, there is no express exception for individual prescriptions under the Act.

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?

Pursuant to the provisions of **Section 13(d) of the Patents Act 1983** methods for the treatment of human or animal body by surgery or therapy, and diagnostic methods practiced on the human or animal body are inventions that are 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.

YES, compulsory license is available in Malaysia pursuant to the provisions of Part X of the Patents Act 1983 which includes **Sections 48** to **Section 54** of the **Patents Act 1983**.

Section 48 of the Patents Act 1983 defines "compulsory license" to mean the authorization to perform in Malaysia without the agreement of the owner of the patent in respect of the patented invention including any acts to exploit the patented invention:

The acts which consist of exploitation is limited to the following acts namely;

a) where the patent is granted in respect of a product: making, importing, offering for sale, selling or using the product; stocking such product for the purpose of offering for sale, selling or using.

b) where the patent is granted in respect of a process: using the process, doing any of the acts referred to in paragraph (a), in respect of a product obtained directly by means of the process.

Pursuant to **Section 49 of the Patents Act 1983** a compulsory license can be applied by a person anytime after the expiration of three years from the grant of the patent or four years from the filing date of the patent application, whichever is later on the following *conditions:*

a) Where there is no production of the patented product or application of the patented process in Malaysia without any legitimate reason;

b) Where there is no product produced in Malaysia under the patent for sale in any domestic market, or there are some but they are sold at unreasonably high prices or do not meet the public demand without any legitimate reason;

c) Where the invention claimed in a patent cannot be worked in Malaysia without infringing a patent granted earlier. Such ground is known as the interdependent patents.

The application for compulsory licence is made to the Registrar of Patents and the compulsory licence is granted by the Intellectual Property Corporation of Malaysia which operates under the name of the Malaysian Intellectual Property Office (MyIPO).

Under **Section 53 of the Patents Act 1983** of the Act a compulsory licence cannot be assigned otherwise than in conection with the goodwill or business or that part of the goodwill or business ion which the patented invention is used. Furthermore the compulsory licence is limited to the supply of the patented invention predominantly in Malaysia and the beneficiary of the compulsory licence is not allowed to conclude licence contracts with third persons under the patent in respect of which the compulsory licence was granted.

No compulsory licences have yet been granted in Malaysia under the above provisions. However the Government has in 2003 used its power under Section 84 of the Act to authorise a third party to exploit a patented invention (which is a different form of compulsory licensing) but this is discussed under Question 8 below.

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.

NO, the new Article 31bis TRIPS has not yet been ratified by Malaysia but we understand that the Government is currently studying the issue with a view towards considering ratification of the provision. We are not aware of any legislative amendment in Malaysia made with a view to implementing the WTO decision of August 30, 2003.

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?

YES, the Government has the right to use a patented invention without previous license based on the conditions set out under **Section 84(1)(a) and (b) of the Patents Act 1983**.

Pursuant to **Section 84(1) of the Patents Act 1983** the Government may authorize a Government Agency or a third party designated by the Government to exploit a patented invention on the following *grounds and conditions:*

i) Where there is national emergency or where the public interest, in particular, national security, nutrition, health or the development of other vital sectors of the national economy as determined by the Government;

ii) Where a judicial or relevant authority has determined that the manner of exploitation by this owner of the patent or his licensee is anti-competitive.

This right of the Government has been exercised once before in October 2003 whereby a Malaysian company was given the authorisation for a period of 2 years (1 November 2003 to 31 October 2005) to exploit patented inventions for certain anti-retroviral medicines used in the treatment of Acquired Immuno Deficiency Syndrome (AIDS) including Didnosine, Zidovudine and Lamivudine with a correspondiong limited right to import the said drugs from Mumbai-based pharma manufacturer CIPLA.

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

Currently there is no law which allows the Government 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.*

Our patent law does not seem to recognise other means of facilitating access to medicines, medical devices, diagnostics and the like.

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?

We are unable to comment on the above except to say that the above appear to be policy decisions which the Government need to consider in seeking to balance the interests of patent owners and public health.

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?*

We are unable to comment on the above.

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 unable to comment on the above.