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Report Q202

in the name of the Philippine Group
by Rogelio NICANDRO

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. Section 72.3) of the Philippine IP Code (Republic Act No. 8293) provides that the owner of a patent has no right to prevent third parties from making or using a patented product or process where the making or using is done exclusively for the purpose of experiments that relate to the subject matter of the patented invention.

Section 72.3), however, does not specify the conditions under which the provision applies.

Neither is the scope of the research exception defined.

We believe that research or experimental use for commercial purposes is not covered because of the employment of the phrase "exclusively for the purpose of experiments."

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?*

There is no specific provision under our Intellectual Property Code covering a Bolar-type exception.

We believe that the use of an invention without the patentee's consent for the purpose of obtaining approval of a generic product before the expiry date of the patent is not covered by the research exception. The Bolar type exception appears to be not for purely experimental purposes but is undertaken with a view to the marketing of a generic product.

However, a proposed law, House Bill No. 2844, entitled "Cheaper Medicine Act" provides for a Bolar type exception, subject to certain rules and regulations to be issued by the IPO in consultation with appropriate government agencies.

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?*

There is no specific provision under the Intellectual Property Code allowing parallel imports of patented medicines, medical devices or similar goods. Article 6 of the TRIPS Agreement, to which the Philippines is a signatory, has given member countries the freedom to incorporate the principle of exhaustion of rights into their domestic law with a national, regional or international reach. Internationally applied, the exhaustion principle will allow parallel imports from any country. For now, however there is yet no law on this matter although there is a pending bill (House Bill No. 2844, supra) intended to cover this matter.

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

Section 72.4) of our IP Code provides that the owner of a patent has no right to prevent third parties from the preparation for individual cases, in a pharmacy or by a medical professional, of a medicine in accordance with a medical prescription or acts concerning the medicine so prepared;

For the exception to apply, therefore, the preparation of the patented drug for an individual case must be done in a pharmacy or by a medical professional pursuant to a medical prescription.

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?*

Our IP Code in Section 22.3) specifically excludes from patent protection methods of treatment for both human or animal body. We quote the said provision.

Sec. 22) Non Patentable Inventions – The following shall be excluded from patent protection:

22.3) Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body. This provision shall not apply to products and composition for use in any of these methods;

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, Sections 93-102 of our IP Code cover compulsory licenses. Sec. 93) specifically provides the circumstances or grounds under which a compulsory license may be granted, namely:

1) National emergency or other circumstances of extreme urgency;
2) 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 appropriate agency of the Government, so requires; or
3) Where a judicial or administrative body has determined that the manner of exploitation by the owner of the patent or his licensee is anti-competitive; or
4) In case of public non-commercial use of the patent by the patentee, without satisfactory reason;
5) If the patented invention is not being worked in the Philippines on a commercial scale, although capable of being worked, without satisfactory reason: Provided, That the importation of the patented article shall constitute working or using the patent.

It may be instructive to likewise state the conditions under which the requirements for the grant of a compulsory license need not be observed; in other words, the situations where compulsory license may be issued even though no efforts have been exerted by the petitioner to obtain a voluntary license before filing a petition for compulsory license. Section 95 provides:

Sec. 95) Requirement to obtain a License on Reasonable Commercial Terms.

95.1) The license will only be granted after the petitioner has made efforts to obtain authorization from the patent owner on reasonable commercial terms and conditions but such efforts have not been successful within a reasonable period of time.

95.2) The requirement under Subsection 95.1 shall not apply in the following cases:

a) where the petition for compulsory license seeks to remedy a practice determined after judicial or administrative process to be anti-competitive;

b) in situations of national emergency or other circumstances of extreme urgency;

c) in cases of public non-commercial use.

95.3) In situations of national emergency or other circumstances of exreme urgency, the right holder shall be notified as soon as reasonably practicable.

95.4) In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly.

Yes, we are aware of a few compulsory licenses for the manufacture and supply of pharmaceutical products granted in our country. The said compulsory licenses together with their respective status are as follows:

1. IPC No. 1907 – 1-(1,3-DIOXOLAN-2-YLMETHYL)-1H-IMIDAZOLES AND 1H-1,2,4-TRIAZOLES

PETITIONER UNITED LABORATORIES, INC., LOCAL (MANDALUYONG CITY RESPONDENT-PATENTEE-JAN HEERES, LEO J.J. BACKX AND JOSEPH H. MOSTMANS, FOREIGN (BELGIUM)

– Date Filed: February 18, 1985
– Decided under ORDER NO. 2002-16 (D) dated 04/11/2002
– Lapse/expired

2. IPC NO. 2058 – MAINTENANCE TREATMENT FOR THE PROPHYLAXIS.....

PETITIONER – DOCTORS PHARMACEUTICAL, INC., LOCAL (CALOOCAN) RESPONDENT-PATENTEE-SMITHKLINE & FRENCH LAB., FOREIGN (ENGLAND)

– Date Filed: 3/30/1987
– Decided under DECISION NO. 94-20 DATED 02/14/1994
– Granted Petitioner

3. IPC NO. 2065 – NOVEL N-HETEROCYCLYL-4-PIPERIDINAMINES, PHARMACEUTICAL COMPOSITION CONTAINING SAME & METHOD OF USE.

PETITIONER-UNITED LABORATORIES, INC., LOCAL
RESPONDENT-PATENTEE-JANSSEN PHARMACEUTICA, N.V., FOREIGN

– Date Filed: 6/30/1987
– Decided under ORDER NO. 2002-44 (D) dated 08/21/2002
– Lapse/expired

4. IPC NO. 2085-1-CYCLOPROPYL-6 FLUORO-1.....

PETITIONER – UNITED LABORATORIES INC., LOCAL – (MANDALUYONG) RESPONDENT-PATENTEE – BAYER AKTIENGESELLSCHAFT, FOREIGN (GERMANY)

- Date Filed: 10/02/1987
- Decided under DECISION NO. 2002-15 dated 08/23/2002
- Granted/Petitioner

5. IPC NO. 3098 –CARBOSTYRIL DERIVATIVES AND PROCESS FOR PREPARING THE SAME.

PETITIONER-UNITED LABORATORIES, INC., LOCAL (MANDALUYONG)
RESPONDENT-PATENTEE – KAZAYUKI NAKAGAWA, ET. AL., FOREIGN (JAPAN)

- Date Filed: 06/30/1988
- Decided under DECISION NO. 94-21 dated 02/15/1994
- Granted/Petitioner

6. IPC NO. 3252 –BUSPIRONE ANTI-ANXIETY METHOD

PETITIONER-UNITED LABORATORIES INC., LOCAL (MANDALUYONG)
RESPONDENT-PATENTEE-BRISTOL-MYERS COMPANY LTD., FOREIGN (U.S.A.)

- Date Filed: 10/04/1988
- Decided under ORDER NO. 2002-15 (D) dated 03/26/2002
- Lapse /expired

7. IPC NO. 3851 –AMINOALKYL-FURAN DERIVATIVES

PETITIONER – UNITED LABORATORIES INC., LOCAL (MANDALUYONG)
RESPONDENT-PATENTEE-GLAXO GROUP LIMITED, FOREIGN (ENGLAND)

- Date Filed: 12/08/1992
- Decided under DECISION NO. 2001-32 dated 12/19/2001
- Granted/Petitioner

8. IPC NO. 3852 – PHARMACEUTICAL COMPOSITION CONTAINING FORM 2 RANITIDINE HYDROCHLORIDE & PROCESS

PETITIONER – UNITED LABORATORIES INC., LOCAL (MANDALUYONG)
RESPONDENT-PATENTEE – GLAXO GROUP LIMITED, FOREIGN (ENGLAND)

- Date Filed: 12/08/1992
- Decided under DECISION NO. 2001-32 dated 12/19/2001
- Granted/Petitioner

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.*

Article 31 bis TRIPS has not been ratified in the Philippines.

The aforementioned House Bill 2844 provides specifically in the proposed new Section 93-A of the IP Code for the grant of a compulsory license to import patented drugs or medicines pursuant to the WTO decision of August 30, 2003.

No compulsory licenses have been granted in the Philippines for the importation or exportation of pharmaceutical products.

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?

Our IP Code specifically provides the conditions under which the government may make use of a patented invention without previous license. Sec. 74) provides as follows:

Sec. 74) Use of invention by Government – 74.1) A Government agency or third person authorized by the Government may exploit the invention even without agreement of the patent owner where:

a) the public interest, in particular, national security, nutrition, health or the development of other sectors, as determined by the appropriate agency of the government, so requires; or

b) a judicial or administrative body has determined that the manner of exploitation, by the owner of the patent or his licensee, is anti-competitive.

74.2) The use by the Government, or third person authorized by the Government shall be subject, mutatis mutandis, to the conditions set forth in Sections 95 to 97 and 100 to 102.

For a better grasp and understanding of these conditions and for easy reference, we quote verbatim Sections 95-97 and 100-102:

Sec. 95) Requirement to obtain a License on Reasonable Commercial Terms.

95.1) The license will only be granted after the petitioner has made efforts to obtain authorization from the patent owner on reasonable commercial terms and conditions but such efforts have not been successful within a reasonable period of time.

95.2) The requirement under Subsection 95.1 shall not apply in the following cases:

d) where the petition for compulsory license seeks to remedy a practice determined after judicial or administrative process to be anti-competitive;

e) in situations of national emergency or other circumstances of extreme urgency;

f) in cases of public non-commercial use.

95.3) In situations of national emergency or other circumstances of exreme urgency, the right holder shall be notified as soon as reasonably practicable.

95.4) In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly.

Sec. 96) Compulsory Licensing of Patents Involving Semi-Conductor Technology- In the case of compulsory licensing of patents involving semi-conductor technology, the license may only be granted in case of public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competetive.

Sec. 97) Compulsory License Based on Interdependence of Patents. – If the invention protected by a patent, hereafter referred to as the "second patent," within the country cannot be worked without infringing another patent, hereafter referred to as the "first patent," granted on a prior application or benefiting from an earlier priority, a compulsory license may be granted to the owner of the second patent to the extent necessary for the working of his invention, subject to the following conditions:

97.1) The invention claimed in the second patent involves an important technical advance of considerable economic significance in relation to the first patent;

97.2) The owner of the first patent shall be entitled to a cross-license on reasonable terms to use the invention claimed in the second patent;

97.3) The use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent; and

97.4) The terms and conditions of Sections 95, 96 and 98 to 100 of this Act. (Sec. 34-C, R.A. No. 165a)

Sec. 100) Terms and Conditions of Compulsory License – The basic terms and conditions including the rate of royalties of a compulsory license shall be fixed by the Director of Legal Affairs subject to the following conditions:

100.1) The scope and duration of such license shall be limited to the purpose for which it was authorized;

100.2) The license shall be non-exclusive;

100.3) The license shall be non-assignable, except with that part of the enterprise or business with which the invention is being exploited;

100.4) Use of the subject matter of the license shall be devoted predominantly for the supply of the Philippine market: Provided, That this limitation shall not apply where the grant of the license is based on the ground that the patentee's manner of exploiting the patent is determined by judicial or administrative process, to be anti-competitive;

100.5) The license may be terminated upon proper showing that circumstances which led to its grant have ceased to exist and are unlikely to recur: Provided, That adequate protection shall be afforded to the legitimate interest of the licensee; and

100.6) The patentee shall be paid adequate remuneration taking into account the economic value of the grant or authorization, except that in cases where the license was granted to remedy a practice which was determined after judicial or administrative process, to be anti-competitive, the need to correct the anti-competitive practice may be taken into account in fixing the amount of remuneration.

Sec. 101) Amendment, Cancellation, Surrender of Compulsory License. – 101.1. Upon the request of the patentee or the licensee, the Director of Legal Affairs may amend the decision granting the compulsory license, upon proper showing of new facts or circumstances justifying such amendment.

101.2) Upon the request of the patentee, the said Director may cancel the compulsory license:

a) If the ground for the grant of the compulsory license no longer exists and is unlikely to recur;

b) If the licensee has neither begun to supply the domestic market nor made serious preparation threfor;

c) If the licensee has not complied with the prescribed terms of the license;

101.3) The licensee may surrender the license by a written declaration submitted to the Office.

101.4) The said Director shall cause the amendment, surrender, or cancellation in the Register, notify the patentee, and/or the licensee, and cause notice thereof to be published in the IPO Gazette.

Sec. 102) Licensees Exemption from Liability – Any person who works a patented product, substance and/or process under a license granted under this Chapter, shall be free from any liability for infringement: Provided, however, That in the case of voluntary licensing, no collusion with the licensor is proven. This is without prejudice to the right of the rightful owner of the patent to recover from the licensor whatever he may have received as royalties under the license.

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

There is no specific provision in the IP Code allowing outright expropriation by the government of 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 IP Code does not specifically provide for means to facilitate access to medicines, medical devices, etc. in the context of public health crisis.

However, the Philippines is a signatory to the Doha Convention which recognizes the need to make provisions to allow access by the poorer sector of the society to medicines, medical devices, etc. Presently, the pending bill (House Bill No. 2844, supra) in the Philippine Congress is intended to address this situation.

II) Proposals for adoption of uniform rules

1) *Should patent law provide for*

- *research and experimental use exception;*
  Since our IP Code already provides for use of experimental exception this item need not be answered here.
- *Bolar exception;*
  Under certain circumstances, a Bolar exception may be likewise provided in the IP Code with sufficient safeguard to protect investment of patentees for their patented medical product.
- *parallel import of patented medicines;*
  The authorization of parallel imports of patented medicine may likewise be provided but the conditions under which such import may be made to protect drug companies and or distributor from losing their investments should be provided.
- *individual prescriptions exception;*
  Since the Philippine IP Code already provides an individual prescription exception, this question does not apply to the Philippines.
- *medical treatment defence;*
  This exception is already provided in our IP Code (Sec. 72.4, supra).
- *compulsory licensing;*
  Our IP Code already provides an entire chapter to this subject.
- *expropriation;*
  This may be only provided in extreme situations because it is a harsh measure even if just compensation is required.
- *any other limitations of the exclusive patent rights to facilitate access to medicines, diagnostics, medical devices and the like?*

  None. Regard should also be made for the time, research and promotion efforts and expense of the patentee to create and develop the patented medicine. Additional limitations to the patentee's rights may affect adversely new research and development efforts.

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?*
At the present time, No.

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, through the WTO.