

## **Report Q202**

in the name of the Egyptian Group  
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### **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? If so, under which conditions? What is the scope of the research exception? Specifically, is research or experimental use permitted for commercial purposes?*
  - 1.1) From our reading to Egyptian IP Law No. 82 of 2002, as amended (the "IP Law"), we conclude that the IP Law in its Article 10 provides that for an exception for scientific research or experimental use from the right to prevent third parties from exploiting a patented invention by any way (i.e. exclusivity rights).
  - 1.2) Please note that the scope and conditions of this exception are confined to scientific purposes. However, we note that Article 10 of the IP Law provides for certain cases, where the exception is somehow indirectly connected to commercial purposes. These cases can be summarized as follows:
    - a) Manufacturing a product, using the method of manufacturing a specific product, or taking serious arrangements relating thereto by a third party acting in good faith, in the Arab Republic of Egypt, before the date the patent application is filed by another person for the same product, or for the method of its manufacture. Despite the issue of the patent, that third party, shall have the right of continuing the same said works in the interest of his establishment solely and without expanding them. The right of carrying out these works may not be assigned or alienated except with the rest elements of the establishment.
    - b) Manufacturing, assembling, using, or selling the product by a third party during the period of its protection, with the aim of extracting or obtaining a license for marketing thereof, provided that such marketing shall not take place except following the lapse of that period.
    - c) Works other than the foregoing, as carried out by third parties, provided that they shall not unreasonably contradict the normal use of the patent or irrationally prejudice the legitimate interests of the patentee, subject to the legitimate interests of third parties.
- 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?*

- 2.1) We see that the IP Law does not regulate the Bolar-type exception explicitly. However, due to the generality of Article 10 of the IP Law listing the exemptions from patent infringement, we see that the Bolar-type exception is implicitly recognized under the IP Law.
- 2.2) Of course, the scope and conditions of a Bolar exception will not differ from what we have prescribed above (mainly using a Bolar exception in a good faith and provided that this shall not unreasonably contradict the normal use of the patent or irrationally prejudice the legitimate interests of the patentee).
- 2.3) We see that this applies to all 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?*
- 3.1) Egypt adopts the concept of International Exhaustion. Hence, parallel imports are permitted without restrictions.
- 3.2) Egyptian Law did not address the case where the products are originated from markets where they were made available under a compulsory license, but we see that pursuant to article 31 (bis) of Trips parallel imports should not be permitted in this case.
- 4) *Is an individual prescriptions exception recognised under your patent law? If so, under which conditions?*
- No.
- 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?*
- According to Egyptian IP Law methods of medical treatment 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.*
- 6.1) Yes, compulsory licenses are recognized under Egyptian IP Law. Please find below the relevant articles on compulsory license under the IP Law: (Articles 23 and 24 of the law).

### **1) Grounds**

The Patents Office, following approval of a Ministerial Committee to be formed by virtue of a Prime Minister's decree, shall grant compulsory licenses for exploitation of the invention, and the committee shall determine the financial rights of the patentee upon issuing these licenses, in the following cases:

#### **First:**

If the concerned Minister decides, as the case may be, that the exploitation of the invention shall realize the following:

- 1) Non-commercial public interest. National security, health, environment and food safety are considered non-commercial public interest to this effect.
- 2) Confronting emergency cases or conditions of paramount necessity.

The compulsory license shall be issued in order to confront the cases prescribed in items (1) and (2) above without need for a prior negotiation with the patentee, or due to the lapse of a period of time following negotiation with him, or because of offering reasonable conditions to obtain his approval of exploiting the patent.

- 3) Support national efforts in sectors of importance for economic, social and technological development, without unreasonable prejudice to the patent owner's rights, and subject to the legitimate interests of third parties.

The patent owner shall be notified of the compulsory licensing decision, immediately in the cases prescribed in items (1) and (3) above, and within as soon as practicable in the cases prescribed in item (2) above.

**Second:**

If the Minister of Health demands issuing the compulsory license in any of the cases where the quantity of patent protected medicines fails to cope with the needs of the State, or due to their low quality, or the unusual hike in their prices, or if the invention is connected with medicines for critical cases, or chronic, incurable, or endemic diseases, or with products used in protection from these diseases, whether the invention is connected with the medicines, the method of their production, the fundamental raw materials used in their production, or the method of preparing the raw materials necessary for their production.

In all these cases, the patentee shall be notified immediately of the compulsory license decision.

**Third:**

If the patentee refuses to license a third party to exploit the invention, regardless of the purpose of exploitation, despite offering him reasonable conditions and the lapse of a reasonable negotiations period.

The compulsory license applicant shall in this case provide evidence of having exerted serious attempts and efforts to obtain the voluntary license from the patentee.

**Fourth:**

If the patentee has failed to exploit it in the Arab Republic of Egypt by himself or with his approval, or if its exploitation has been inadequate, despite the lapse of four (4) years from the date of submitting the application of the patent's registration, or three (3) years from the date of granting it, whichever is longer, and also if the patentee discontinues exploiting the invention without a reasonable excuse for a period of more than one (1) year.

The patent shall in this case be exploited by processing the product subject of protection in the Arab Republic of Egypt, or by using the method of manufacture which is protected by the patent in the Arab Republic of Egypt.

However, if the Patents Office judges, despite the lapse of any of the aforementioned two periods – that non-exploiting the invention is due to legal, technical, or economic reasons beyond the power of the patent owner, it may grant him another adequate period of exploiting the invention.

**Fifth:**

If proven that the patentee is abusively using his rights derived from the patent or he has exercised his rights in an anti-competitive manner. The following are considered instances of this sort:

- 1) Exaggeration in the sale prices of protected products, or discrimination between clients in terms of the sale prices and conditions of these products.

- 2) Failure to provide the protected product in the market, or launching it with unfair conditions.
- 3) Discontinuing the production of the protected commodity, or producing it in quantities inadequate to realize congruence between the productive energy and market needs.
- 4) Undertaking works or acts negatively affecting the freedom of competition, according to the prescribed legal controls.
- 5) Using the rights granted by the law in a way negatively affecting the transfer of technology.

In all the previous cases, the compulsory license shall be issued without need for negotiation, or upon the lapse of the period prescribed for obtaining it, even if the compulsory license does not target the fulfillment of local market needs.

The Patent Office shall have the authority to refuse terminating the compulsory license if the conditions that called for issuing it indicate their continuity, or predict their recurrence.

In estimating the compensation due to the patent owner, the damages caused by his abusive or anti-competitive practices shall be taken into account.

The Patent Office may cancel the patent if after the lapse of two (2) years from granting the compulsory license it transpires that such license was inadequate to repair the negative effects caused to national economy on account of the patent owner's arbitrariness in using his rights or due to his anti-competitive practices.

#### **Sixth:**

If exploiting the invention by the holder of the right to use the patent cannot be realized except through exploiting another invention necessary for it, which comprises a concrete technological advancement and a technical and economic importance, compared to that invention, the patent user shall then have the right to obtain an compulsory license vis-à-vis that other patent holder, and the latter shall have the same right in this case.

Assigning the licensed exploitation of either patent shall not be allowed except by assigning the exploitation of the other patent.

#### **Seventh:**

In the cases of inventions connected with semi-conductors technology, the compulsory license shall not be granted except for non-commercial public utility purposes, or for remedying the effects proven to be anti-competitive.

### **II) Conditions**

On issuing the compulsory license the following shall be observed:

- 1) The application for issuing the compulsory license shall be decided according to each case separately, and the license shall basically aim to provide the local market needs.
- 2) The license applicant shall establish having exerted serious attempts, within a reasonable period, to obtain a voluntary license from the patent holder against a fair consideration, but failed to obtain such license.
- 3) The patentee shall have the right of to challenge the decision of granting the compulsory license to a third party, before a committee formed according to the IP Law, within thirty (30) days from the date he is notified of the grant of that license.
- 4) The applicant for the compulsory license, or the person in whose favour the license is issued shall have the ability to exploit the invention in a serious manner in the Arab Republic of Egypt.

- 5) The party to whom the compulsory license is granted shall be committed to use the invention within the scope, according to the conditions and throughout the period to be determined in the decision granting that compulsory license.

If the period of the compulsory license expires without realizing the purpose of using the invention, the Patent Office may renew such period.

- 6) Using the compulsory license shall be confined to its applicant. However, the Patent Office may grant it to a third party.
- 7) The party granted the compulsory license shall have no right to alienate it to a third party except with the enterprise, or with the portion connected with using the invention.
- 8) The patent holder shall have the right of obtaining a fair consideration in return for exploiting his invention. The economic value of the invention shall be taken into account in estimating that consideration.
- 9) The compulsory license shall terminate with the expiry of its period. However, the Patent Office shall be powered to decide canceling the compulsory license before the lapse of its period, if the reasons that led to granting it cease to exist, and that there is no probability that these reasons will recur.
- 10) The owner of the invention shall have the right to request canceling the compulsory license before expiry of the period determined therefor, if the reasons that led to obtaining it cease to exist and there is no probability that they will exist once more.
- 11) The legitimate interests of the licensee shall be observed on terminating the compulsory license before expiry of its period.
- 12) The Patent Office shall have the authority to amend the conditions of the compulsory license or revoke the license of its own initiative, or upon the request of all concerned party, if the licensee who is authorized to exploit the license fails to use it within two (2) years from the date of granting it or if he violates the obligations stipulated upon in the license.

6.2) We are not aware of any compulsory licenses granted in Egypt for the domestic manufacture and supply of pharmaceutical products.

- 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.*

7.1) To the best of our knowledge, Egypt has not yet ratified Article 31bis. Also, there is no amendment introduced to amend the IP Law with the view to implement the WTO decision of August 30, 2003.

7.2) We are not aware of any compulsory licenses granted in Egypt for the domestic manufacture and supply 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?*

Please see our response on compulsory license.

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

Article 25 of the IP Law provides for the following:

- 9.1) The concerned Minister may, upon the approval of a Ministerial Committee to be formed by virtue of a Prime Minister's decree, expropriate the ownership of an invention patent for national defence and in conditions of extreme emergency purposes, where a compulsory license is not sufficient for confronting said conditions.
  - 9.2) Expropriation of ownership should be limited to exploitation of the invention for the purpose of meeting the State's need. In all cases, expropriation should be made against fair compensation.
  - 9.3) The expropriation decree is to be published in the Patent Journal, and appealing said decree and the committee decree before the Administrative Court, within sixty (60) days from the date on which the concerned party was notified with said decree by registered mail, as the Court will hold its judgment on an urgency basis.
- 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.*

We do not see other means other than those prescribed above.

### **Summary**

The IP Law in its Article 10 provides that for an exception for scientific research or experimental use. The scope and conditions of this exception are confined to scientific purposes. However, we note that Article 10 of the IP Law provides for certain cases, where the exception is somehow indirectly connected to commercial purposes.

- Manufacturing a product, by a third party acting in good faith, before the date the patent application is filed by another person.
- Manufacturing, assembling, using, or selling the product by a third party during the period of its protection, with the aim of extracting or obtaining a license, provided that such marketing shall not take place except following the lapse of that period.
- Works other than the foregoing, provided that they shall not prejudice the legitimate interests of the patentee.

#### **Bolar-type**

The IP Law does not regulate the Bolar-type exception explicitly. However, due to the generality of Article 10 of the IP Law, we see that the Bolar-type exception is implicitly recognized under the IP Law.

#### **International Exhaustion**

Egypt adopts the concept of International Exhaustion. Hence, parallel imports are permitted without restrictions. The Egyptian Group believes that pursuant to article 31 (bis) of Trips parallel imports should not be permitted in this case when the products are originated from markets where they were made available under a compulsory license. According to Egyptian IP Law methods of medical treatment are not patentable.

#### **Compulsory licenses**

The Patent Office, following approval of a Ministerial Committee shall grant compulsory licenses for exploitation of the invention and the Committee shall determine the financial rights of the patentee. The grounds for Compulsory Licensee are:

- National security, health, environment and food safety are considered non-commercial public interest to this effect.
- Confronting emergency cases or conditions of paramount necessity.
- Support national efforts in sectors of importance for economic, social and technological development, without unreasonable prejudice to the patent owner's rights, and subject to the legitimate interests of third parties.
- If the patentee has failed to exploit it in the Arab Republic of Egypt by himself, despite the lapse of (3) years from the date of granting it.
- If proven that the patentee is abusively using his rights derived from the patent or he has exercised his rights in an anti-competitive manner.

In estimating the compensation due to the patent owner, the damages caused by his abusive or anti-competitive practices shall be taken into account.

- If exploiting the invention by the holder of the right to use the patent cannot be realized except through exploiting another invention necessary for it.

In the cases of inventions connected with semi-conductors technology, the compulsory license shall not be granted except for non-commercial public utility purposes, or for remedying the effects proven to be anti-competitive.

The Ministry of Health or the Ministry of Defence are allowed to stop the registration of a patent application (Art. 17) or to expropriate a patent (Art. 25) for the following:

- For national defence and in conditions of extreme emergency purposes, where a compulsory license is not sufficient for confronting said conditions (Art. 17).
- Expropriation of ownership should be limited to exploitation of the invention for the purpose of meeting the State's need. In all cases, expropriation should be made against fair compensation.