

Protection of Patents in the pharmaceutical industry under Egyptian Laws

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The noticeable growth in technological innovation during the past two decades has caused intellectual property (IP) rights to become one of the most economically resourceful tools for companies to protect their products. The introduction of the Trade-Related Aspects of Intellectual Property Rights ("TRIPS") agreement by the World Trade Organization ("WTO") has further strengthened this tool holding the growth of free trade contingent upon the recognition of IP rights. In this context, after its accession to the WTO on June 30, 1995, and with a view to implementing a policy that promotes innovation, Egypt promulgated new IP laws in accordance with TRIPS.

On the patent front and prior to the introduction of TRIPS, the abrogated Law no. (133) of 1949 regulated patents in Egypt. This law was very restrictive, as it did not allow for the patenting of pharmaceutical products and their chemical combinations. Instead, the abrogated law allowed for the granting of patents to the methods of manufacturing such products. Thus, so long as a third party's method of manufacturing was different from that of the patent proprietor, the same products could be manufactured and sold by a third party.

Recognizing the need to remove such restrictions on the patenting of pharmaceutical products and the need to promote foreign direct investment, research and development ("R&D"), the Egyptian Legislature enacted Law no. (82) of 2002 regarding the Protection of Intellectual Property Rights ("2002 IP Law"). This law complies with the general rules and principals set forth by TRIPS. The policy behind Egypt's introduction of this 2002 IP law aimed to strike a balance between creating a free trade market economy and recognizing legitimate IP based interests in monopolizing patentable inventions and discoveries. To this end, the 2002 IP Law upholds the principles of fair competition and the encouragement of innovation in all sectors. Pursuant to this policy and these principles, under the 2002 IP Law, pharmaceutical products, chemical combinations of active ingredients, as well as newly discovered fungi and bacteria are patentable.

The Egyptian legislature appreciated that, for instance in the field of developing patentable pharmaceutical products, R&D projects can only prosper if stakeholders are entitled to claim exclusivity over the benefits of the results of the of funding of such projects. As a result, the relevant patent rights are not only recognized and protected under the 2002 IP Law in Egypt, but are also protected under the Egyptian Constitution and Egyptian Trade Law.

In this article, we will very briefly examine the 2002 IP Law and then explore the other legal mechanisms available to contest a patent infringement in absence of an Egyptian granted patent.

Protection of Patentable Rights against Infringements in the presence of an Egyptian Granted Patent

The Egyptian 2002 IP Law now follows a strict no tolerance policy towards patent infringements. It imposes severe penalties for such infringements, which include a fine on the infringer of not less than EGP 20,000 and not exceeding EGP 100,000 and the imprisonment of the perpetrator in case of a repeat offence. Actions such as imitation of the patented subject matter for commercial purposes constitute infringement under Egyptian IP Law. Specifically, the sale, offer for sale, circulation, importation or possession with the

intention to trade, of products known to that party to be imitations are subject to these penalties under Egyptian IP Law.

The 2002 IP Law also grants the patent owner the right to request the courts to issue an order, as a precautionary measure, against products or goods that are suspected to infringe a patent, similar to an *ex parte*, in order to preserve the patent owner's rights vis-à-vis such products. In such a case, the court may issue a preliminary injunction before initiation of the proceedings that would expire if the proceedings were not instituted within (8) days from the date of the injunction.

Protection of Patentable Rights against Infringements in the absence of a Patent

Egyptian law still recognizes a patent holder's right in respect of chemical combinations, the methods of manufacture and/or the ingredients of a pharmaceutical product even where the Egyptian authority has yet to grant the relevant patent in Egypt. If a person other than their proprietor imitates the products in question, and in absence of the patent, the proprietor can legally pursue the infringer by filing an unfair competition action before the Economic Court. This action is undertaken in accordance with Article (66) of Egyptian Trade Law no. (17) of 1999 (the "Trade Law"), through which the plaintiff has the right to request the immediate ceasing of the infringement, and also claim compensation for profits gained and losses sustained.

In reliance on the Trade Law, a major international pharmaceutical company ("Claimant") filed an often cited and important action against a local Egyptian company ("Defendant"). The Claimant requested the revocation of a preliminary acceptance notice obtained by the Defendant from the Central Administration for Pharmaceutical Affairs ("CAPA"). The notice related to a pharmaceutical product that was identical in its chemical combination and concentration of the active ingredients to a foreign granted patent owned by the Claimant. The Claimant based their action on unfair competition.

Apart from the Claimant's legitimate reliance on the Trade Law to contest the infringement in absence of holding an Egyptian patent, the case raised questions about the relationship between patenting a pharmaceutical product and the registration of the same product at CAPA, i.e. obtaining a license to market and sell the product in Egypt. The Egyptian courts have yet to resolve this case in a final and reasoned decision. However, the case raises the necessity of synchronizing CAPA's system with that of the Egyptian patenting system in the first instance (where an Egyptian patent exists) and that of major foreign patenting jurisdictions such as those of the EU and the US in the second instance (where an Egyptian patent does not exist). To address registration issues with CAPA, the Minister of Health's Decision no. (296) of 2009, confirmed that the party seeking the registration of their product must submit a sworn affidavit stating that the registration of this product would not infringe any third party's IP rights. In principle, if it later appears that this sworn affidavit is untrue, the party that submitted it ought to be civilly liable under Egyptian laws for falsely representing information to CAPA. As such, with the requirement of the sworn affidavit, the Minister's decision appears to support the protection of patent rights against third party infringements such as those claimed in the cited case based on the Trade Law.

Conclusion

With the ongoing attention given to the protection of IP rights nowadays, the general policy in Egypt is to create a safer and more secure environment for the growth of investment and trade. Under the present law governing the protection of IP rights, pharmaceutical companies are reassured. These laws have increased investors' confidence in that the returns on their capital investments in the R&D of new drugs and products will enjoy legal protection in Egypt.