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"Bolar provision" in Ukraine: fiction or reality?

Anton Polikarpov (Head of IP Arzinger Law Office) · Thursday, February 19th, 2015

Ukraine has always been the subject of interest of innovators and generic manufacturers trying to maximize profits from selling their medicines, and ordinary consumers who just want to recover from any diseases.

Being a developing country ^[1] Ukraine should make every effort just to provide people with quality drugs at reasonable prices. In such a situation generic medicines could help to reach this aim. In order to achieve a balance between the interests of patent holders and public interests a lot of states inserted patent exemptions into national pharmaceutical legislation.

Among the prevailing patent exemptions is the “Bolar provision”. Its context may vary in different states. The key feature is that conducting studies and trials and the submission of testing data to a regulatory agency for the purposes of obtaining market approval is not considered an infringing act if a generic manufacturer abstains from entering the market until the patent expires. Therefore, the main benefit of the “Bolar provision” is gaining time for all formalities.

While patent exemptions are envisaged under TRIPS, and Ukraine is a WTO member state, the current Ukrainian legislation does not provide a “Bolar provision”. Exemptions provided by Ukrainian legislation are the following:

- use of a patented invention (or utility model) for scientific purposes or for carrying out an experiment ^[2];
- use of a patented invention (or utility model) without commercial purposes.

As a “Bolar provision” has not been included into Ukrainian legislation, a lot of complicated issues arise. The principal one is that generic manufacturers often understand “non-commercial use” too broadly. For example, they try to prove that preparation and obtaining market approval for generic before a patent expires is just non-commercial use of a patented invention, but not a patent infringement. Let’s turn to Ukrainian court practice in order to understand that “Bolar provision” is currently out of the question under Ukrainian case law too.

Ukrainian courts have declared the start of any preparation for market entry by a generic manufacturer to be a patent infringement. This opinion will likely not change for a considerable period because of the following reasons.

First of all, any actions taken to start the process to obtain a marketing authorization before the

patent term expires are considered a patent infringement. This was set out in the significant *H. Lundbeck A/S v Farmak JSC* case ^[3]. In this case the patent holder, Lundbeck, brought a claim because Farmak started the procedure to prepare the launch of a generic medicine while the patent was still in force. The court issued an injunction against, inter alia, the production, sale and offering for sale and the launch of the marketing authorization process.

Second, Ukrainian law prescribes that the applicant for a marketing authorization has to submit a sample of medicine to state regulatory bodies as part of the marketing authorization procedure. Production of such sample of medicine itself will be also considered as patent infringement without any difference whether it was just a non-commercial medicine production or not. This follows from the *H. Lundbeck A/S v Chemo Iberica, S.A.* case ^[4]. Initially, Chemo Iberica submitted a marketing authorization application. Then Lundbeck claimed that obtaining recommendation for state registration of such generic medicine was a precondition for market launch, and therefore would lead to patent infringement. Moreover, Lundbeck stated that Chemo Iberica submitted samples of generic medicines for further state registration, which should be considered as an evidence of manufacturing of this medicine and patent infringement as well. Therefore, Lundbeck's claim was satisfied.

Even if a marketing authorization for generic medicine is obtained when the patent is still in force, a patent holder will challenge its legitimacy. Under current case law, the court will issue a judgment concerning cancellation of a certificate on state registration of medicines.

Furthermore, the patent holder may file an application for an injunction. Recently; the Ukrainian court issued a ruling in the *AbbVie Inc. v NV Remedies Pvt. Ltd. and Hetero Labs Ltd.* case ^[5]. AbbVie sought an injunction against any actions to complete the marketing authorization process for a generic medicine. In particular, AbbVie argued that if the court failed to provide such provisional injunction it would be impossible to execute the court decision. The main reason was that Remedies and Hetero Labs would complete the marketing authorization process before the effectiveness of respective court decision, even if such actions were declared illegitimate. Consequently, the court fairly ruled on provisional injunction and imposed such prohibition.

It is complicated to predict whether a "Bolar provision" will be included in Ukrainian legislation. At the moment the pharmaceutical legislation is amended in Ukraine. Until then, the present court practice is the key indicator for this matter.

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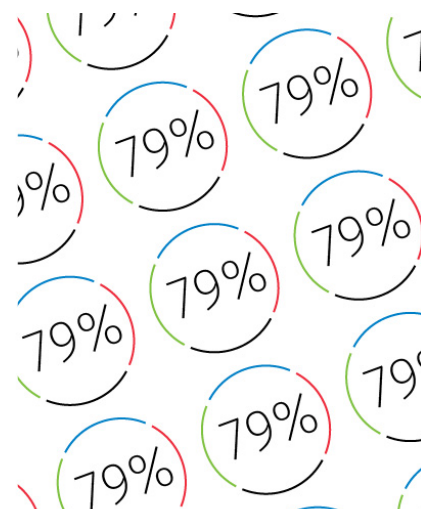
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