

BOLAR-LIKE HURDLE FOR GENERICS

Precis: The judgment of the Ankara IP court in a case involving a marketing authorisation application demonstrates that an exemption similar to the so-called Bolar exemption can apply to Gx pharmaceutical companies.

Background

The so-called Bolar exemption was introduced into Turkish law on 22 June 2004 with an amendment to Patent Decree Law No 551 and was maintained in the IP Code that entered into force on 10 January 2017.

Article 85/3(c) of the IP Code rules that "experimental acts comprising the invention which is subject to a patent, including the registration of medicines and the relevant tests and experiments" are exempted from patent protection.

On the other hand, existing case law interprets the limits of the so-called Bolar exemption broadly and accepts that, in addition to all kinds of regulatory acts such as price approval and sales permission, applying to the Social Security Institute to be included in their reimbursement list should also be interpreted within the scope of the so-called Bolar exemption rules.

Until recently, the Bolar exemption was evaluated as a hurdle that only the patent holder needed to tackle. Indeed, on the one hand, an 'early' enforcement of a patent right before the acts of the generic firm fall out of the exemption was strictly barred. On the other hand, the generic firm was welcomed to file any action without considering if its generic product was granted with MA, had price approval and so on.

In the concrete case, a determination of non-infringement action was filed by the plaintiff (a Gx pharmaceutical company) against the patent holder. The plaintiff requested the court to determine that its generic products, for which it filed a marketing authorisation application, do not infringe the defendant's patent rights.

The Ankara IP Court determined the status of the marketing authorisation application of the plaintiff before initiating the examination phase of the action, and ruled that the marketing authorisation application of the generic pharmaceutical had not been finalised as of the filing date of the action, and dismissed the case due to lack of legal benefit.

The impact of the decision

The judgment of the IP Court reveals that an exemption similar to the so-called Bolar exemption is now not only an instrument that can be applied against patent rights holders, but also to Gx pharmaceutical companies. It is fair to question the legal benefit of the generic company, while all legitimate acts and enforcement attempts of the patent holder are prevented.

The decision shows that the approach of the IP courts has started to shift and the legal interest of a generic firm is now being questioned, depending on the status of its generic marketing authorisation application. The approach of the IP courts is not confirmed yet. However, once it becomes case law, it will be an important aspect that should be considered by the generic companies while developing their strategies.