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Are Clinical Trials Excluded From Patent Protection in Turkey?

The Turkish IP Law (6769) rules on acts that constitute patent infringement and acts that are excluded from patent protection. However, when it comes to evaluating whether clinical trials in Turkey should be excluded from patent rights, it is important to take the experimental use exemption under Article 85/3(b) and the Bolar exemption under Article 85/3(c) into consideration.

Unfortunately, this is easier said than done. There is no case law in Turkey that claries which acts are included in the experimental use exemption. With regard to the Bolar exemption, existing case law focuses on marketing authorisation acts and rules that all kinds of regulatory act, such as price approval, sales permission and applying to the Social Security Institute (SSI) to be included in their reimbursement list should be interpreted within the scope of these rules.

Although there is no case law in Turkey that analyses the differences between the experimental use exemption and the Bolar exemption, Turkish legal scholars generally hold that experimental acts regulated under the Bolar exemption have a commercial purpose, whereas those under the experimental use exemption do not.

So, when it comes to a clinical trial conducted for the purpose of ling a marketing authorisation application, it is important to evaluate whether the marketing authorisation application should be led in Turkey or whether the clinical trial is still exempt from patent rights even if the marketing authorisation application has not been led in Turkey.

To answer this, it is useful to examine the purpose of the Turkish IP Law. The reason behind the experimental use exemption under Article 85/3(b) reads as follows: “Experimental acts comprising the invention which is subject for a patent are excluded from the scope of patent protection on the ground that such acts may improve technological progress.”

With regard to the legal purpose for bringing experimental use exemption in Turkey; the legislator focused on “improving technological process” and does not mention the need for a marketing authorisation application. This therefore

suggests that clinical trials carried out in Turkey serve to improve technological progress and their goal is less associated with commercial purposes.

The legal reasoning behind the Bolar exemption under Article 85/3(c) reads as follows:

"it is regulated that patented medicines can be used for the tests and experiments for registration of generics provided that mass production other than those required for registration is not carried out, stored and offered for sale. Thus, period for generics to enter into market will be shortened at the expiry date of the patent production. In further, experimental acts comprising the invention within the scope of this subparagraph are excluded from the scope of patent protection since such acts may improve technological progress".

The legal purpose for bringing the Bolar exemption in Turkey is not only to provide the market with cheaper, generic pharmaceuticals but also to improve R&D and technology in the country and take advantage of the know-how and the prot gained via clinical trials. Having said that, the connection between marketing authorisation applications and clinical trials is quite strong for the Bolar exemption, since the wording of Article 85/3(c) explicitly mentions the registration of medicines. In this respect, where a clinical trial is carried out in order to obtain marketing authorisation in Turkey, it should benet from both experimental use exemption and the so-called Bolar exemption.

Although a case-by-case evaluation should be made, clinical trials should be exempt from patent rights in Turkey under the experimental use exemption in Article 85/3(b) and under the Bolar exemption.