



Istanbul IP Court reaches landmark decision on precautionary injunction

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The trigger point and the timing of a request for a precautionary injunction (PI) is crucial. However, in pharmaceutical patent enforcement, most damage occurs from the launch of the Gx product, which can account for a price cut of as much as 40% from the originator's drug. Therefore, the PI must be filed and granted before the Gx launches, yet while there is sufficient proof available to overcome the so-called Bolar exemption hurdle. The PI filing date serves this aim, because most cases are referred to a court-appointed expert panel for evaluation, which takes at least three months. Consequently, the date of the PI grant decision may come after the launch of the Gx.

The main concern for patent holders lies in the fact that IP courts do not wish to interfere with administrative decisions and applications (including for the pricing of original drugs) and limit the PI decision in terms of prevention of the marketing, trading or import of the Gx product. Therefore, even when a PI is granted, the price cut cannot usually be remedied. Where a patent holder suffers a loss, they may only be subject to a compensation action for the next couple of years.

The Istanbul IP Court recently reached a groundbreaking PI decision, in which it suspended the price cut decision issued by the Ministry of Health (MOH), reinstated the original drugs price and prevented the Gx from being listed in the reimbursement list of the Social Security Institute (SSI).

A worldwide operating Gx company was granted an abridged marketing authorisation referring to the originator's drug dossier. Shortly after this, the Gx was awarded price and sales permission and was listed in the reimbursement list. The originator's price was cut by 40%. The originator (ie, the patent holder) faced not only serious damage in Turkey, but also in other countries due to the reference pricing system.

The patent in question disclosed use of a certain active pharmaceutical ingredient for the treatment of a particular disease. The summary of product characteristics of the Gx drug clearly indicated infringement of the patent.

In these circumstances, the patent holder asked the IP Court to grant a PI that not only prevented further damages but also reduced the current damages.

The Istanbul IP Court referred the case to an expert panel as expected. However, the extra time that this involved was balanced by the satisfying decision. The court ordered the suspension of the MOH's price decrease decision with regard to the original drugs; thus preventing the Gx company from filing a reimbursement application before the SSI and, if such an application was already filed, then the court ordered it to be withdrawn by the Gx company. The court also addressed the SSI in its PI decision and requested that the Gx products be prevented from being included in the SSI's foreign drug and reimbursement lists, and if the products had already been included in these lists, to be removed from the SSI's provision system.

This not only provided a timely remedy for the patent holder in question, but also supports patent rights more generally. It is a promising precedent that prevents patent holders from being exposed to the current consequences of infringing acts, with the hope of future compensation.

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