

TURKEY

Ex-parte preliminary injunction granted against a generic product on market

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The Istanbul Civil Court for Intellectual and Industrial Rights (IP court) has granted an *ex-parte* preliminary injunction (PI) against a marketed generic product. As per the PI decision, the price of the original product has been reinstated and the generic product has been removed from the reimbursement list of the Social Security Institution (SSI).

Background

Although the IP court issued the PI decision in a fairly short period of time, the patent holder's fight to protect its patent rights took several years. Back in 2017, the patent owner had three patents covering different indications of an active ingredient, and found out that a generic product had obtained marketing authorisation covering all of the patented indications.

Despite the obvious patent infringement, all enforcement attempts (PI applications) of the patent owner met with obstacles due to so-called Bolar exemption. However in one of these PI applications, the IP court understood the need to collect the evidence and decided to conduct an expert examination on infringement allegations. Although the expert report confirmed that the generic products infringed the patent; the PI demand was rejected on the ground that infringing products were not listed in the reimbursement list of Social Security Institution (SSI).

Finally, the Gx product has been launched with a skinny label which still covers one of the patented indication and the patent owner suffered from 40% decrease of original

price.

The patent owner immediately filed an infringement action on merits with a PI request in order to prevent further damages. As evidence, the patent owner submitted the court appointed expert panel's report obtained from the previous PI application, along with the documents showing that the generic product was launched and original products price was decreased.

Considering the urgent nature of the case and existing clear patent infringement, the Istanbul IP court issued an *ex-parte* PI decision in couple of days without conducting another expert examination.

Impact of the decision

The PI decision aimed to prevent the patent owner from further damages. For this purpose, the IP court decided to suspend the price decrease decision set for patented products upon launch of Gx by reinstating the original price and by excluding the Gx products from the reimbursement. For execution of the PI, the court sent writs to the SSI and Turkish Medicines and Medical Devices Agency.

The court also ordered the generic company not to file another application before the SSI for reimbursement of generic products and if it has already filed such an application, to make necessary applications for withdrawal of the relevant application and removal of the generic product from the SSI's reimbursement list.

This PI decision is a very important development for Turkish patent law as it is quite difficult to obtain an *ex-parte* PI decision from Turkish IP courts since the judges do not have any technical backgrounds and tend to conduct expert examinations which may take at least two to four months.

In this case, the expert report obtained from the discovery of evidence (DoE) application played a significant role and proved the importance of such applications once

again even they are rejected. Although the Turkish IP courts interpret the Bolar exception broadly, DoE applications help the patent owners to navigate their long-term enforcement strategies and in cases such as this case, may provide an important evidence for the main patent infringement actions and accelerate legal proceedings.