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## A New Slant on the Implementation of the Bolar Exemption in Turkish Patent Law

The Bolar Exemption falls under the provision of Article 85(3)/(c) of the Industrial Property Code No. 6769 (IP Code) and regulates the marketing authorisation of pharmaceuticals, the testing and experiments required for this purpose and the exemption of experimental acts involving the patent subject to the invention from the scope of rights protected by the patent. The aim of the Bolar Exemption is to ensure that Gx pharmaceutical products can be put on the market without delay when the patent protection period expires, thus preventing the de facto extension of the period of patent protection.

While the wording of the provision in question clearly sets the boundary of the scope of the Bolar Exemption, limiting it to marketing authorisation and the testing and experiments required for this purpose, the provision has been interpreted in a way extending the scope of the provision by the Istanbul, Ankara and Izmir Civil Courts for Intellectual and Industrial Property Rights, as well as before District Courts and Courts of Appeal.

The Civil Courts for Intellectual and Industrial Property Rights interpret the Bolar Exemption too broadly and refuse requests for discovery of evidence on the grounds of the Bolar Exemption, even in cases where the Gx pharmaceutical product has received marketing authorisation, price approval and the product is placed on the reimbursement list of the Social Security Institution ("SSI").

If the Bolar Exemption is applied according to this broad interpretation, there is an extremely limited window of time for patent owners to determine whether there has been an infringement of their patent rights and to exercise their legal rights before the 40% price decrease of the original pharmaceutical as a result of the introduction of the Gx product to the market and the Bolar threshold is deemed to have been exceeded.

Although a case can be filed even after the Gx product has entered the market, it is often not possible to reverse the price decrease and market loss, and even when it is possible, this is quite a time consuming process which results in significant financial loss to the patent owner.

Therefore, the Bolar Exemption should be applied in accordance with the wording and purpose of the relevant article, and to allow for the pharmaceutical patent owner to use the only legal remedy available (i.e. discovery of evidence) for determining whether their patent rights have been infringed. By doing so, patent owners may not be forced to file lawsuits on merits due to not being able to request discovery of evidence (which cannot

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be applied due to the broad interpretation of the Bolar Exemption) as a means of determining whether their patent rights have been infringed upon, and the number of lawsuits on merits can be reduced and settlements may instead be reached.

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A recent discovery of evidence ruling has raised hopes that the Bolar Exemption will be interpreted in accordance with the clear wording of the legislation, in line with the purpose intended by legislators, and that sound rulings will be rendered.

In the relevant case, the patent owner requested discovery of evidence based on a strong indication of patent infringement upon becoming aware that a Gx pharmaceutical product obtained price approval in addition to marketing authorization, and requested discovery of evidence by an examination of the marketing authorisation file of the product, which cannot be done without a court order.

Upon the examination of the request, the Ankara Civil Court of Intellectual and Industrial Rights concluded that the patent owner had a legal interest in accordance with Articles 400 (et seq.) of the Code of Civil Procedure No. 6100 and deemed it obligatory to for the immediate protection of its rights and ruled to accept the request for discovery of evidence in accordance with the law. Subsequently, an examination was carried out with the participation of the party attorneys and experts regarding the relevant sections of the marketing authorisation files of the Gx pharmaceutical product before the Turkish Medicines and Medical Devices Agency. As a result of this examination, the patent owner was able to assess whether there was an infringement and determined that the counterparty's products did not infringe their patent rights, preventing unnecessary disputes.

This ruling, which was rendered in accordance with the law and the balance of interests of the parties, has strengthened the opinion that a fairer system can be adopted regarding the discovery of evidence. No doubt, applying of the wording of the law and foreseen purpose will ensure that justice is rendered in accordance with the law and will thus be to the advantage of all parties.