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The First of its Kind: Compensation for Damages Caused by Unfair Preliminary Injunction Decisions in the Pharmaceutical Industry

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One must have deep knowledge and experience in many different disciplines to play a role in the solution of complex and multi-layered patent law disputes. One of the most important examples of this situation are compensation actions filed following the abolition of preliminary injunctions in patent disputes related to the pharmaceutical industry. As a matter of fact, the decisions of the courts of first instance and the Court of Appeal in these types of cases give direction to deep debates both in sectoral, commercial and legal terms, and it is observed that these discussions gain more importance with each new decision.

In 2018, the first known decision of a court of first instance on a compensation action for the damages arising from unfair preliminary injunction in the pharmaceutical sector, and upon the appeal of this decision, the first district court decision was also given in 2022, establishing the first precedents of different degrees in this field.

The events giving rise to the action can be summarised as follows: The patent owner companies requested a preliminary injunction decision to be granted due to the imminent danger of infringement of the patent by a local pharmaceutical company's generic product (the Gx product). The court granted the preliminary injunction and decided to suspend the manufacture of the Gx products depending on the outcome of a court appointed expert panel's report. The patent owner then filed the infringement action on merits and the preliminary injunction was maintained throughout the proceedings. Finally, the infringement action on merits was rejected and the decision became final following the appeal process. The Gx Company then filed an action claiming compensation for damages, alleging that it incurred a loss of profit for not being able to manufacture the Gx products due to the unfair preliminary injunction.

The court of first instance, firstly, ruled that in order to be held liable for compensation of damages incurred due to the preliminary injunction decision, it is sufficient that the main action (infringement case in this example) is rejected and that there is no need to investigate whether the patent owner is faulty as per the related article of the Turkish Civil Procedural Law. Secondly, while calculating the loss of the Gx company, the court decided that the Gx product, which was the first Gx to enter into the market and was blocked by the preliminary injunction decision, would have had a market share of 16%, taking into account the market conditions at the date of the preliminary injunction decision, the legal regulations on the market at that time, the reputation and reliability of the Gx company and the pharmaceutical era in which the product would have entered the market for the first time.

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Nevertheless, the court ignored the very important issue that the mandatory discount rates were to be made on the initial price of the Gx product as per the relates regulation, despite all the objections of the patent owner. However, the alleged financial loss cannot be calculated assuming that generic products will be sold at the highest price approved by the Ministry of Health. Therefore, a higher-than-actual loss amount was calculated, as the mandatory discount rate was overlooked.

Both parties appealed the decision of the first-instance court. In 2022, and the District Court decision found all the above-mentioned inferences of the first-instance court correct.

Shortly after the District Court's decision, another first-instance decision was rendered on the compensation of damages due to unfair preliminary injunction. Although the new precedent estimating that the first Gx Company will achieve a maximum market share of 16% was shared with the court of first instance, it ignored the case-law and decided that the Gx firm would gain a 33.86% market share and made the compensation calculation accordingly. Thus, despite the availability of prior jurisprudence based on the sound assessment that a cancer drug Gx will gain 16% market share and the District Court's approval of this assessment, it was decided that a generic osteoporosis drug would reach a market share of 33.86%. However, considering that the average prices of an osteoporosis drug and a cancer drug are quite different, we are of the opinion that the second decision of the court of first instance, departing from the prior decision, was not correct.

It is worth noting that there are two points common in the decisions of the Courts: both courts considered the obligation to compensate for the damage caused by the preliminary injunction decision as a strict liability and both courts disregarded the mandatory discount rates that must be applied based on the initial price of Gx products.

Under these circumstances, it is clear that Türkiye needs many years to adopt uniform jurisprudence on this issue. Undoubtedly, the biggest role in the formation of this case-law fall to the guidance and evaluation of conscious lawyers who have a good command of different legal disciplines and the sectoral dynamics of their clients and competent experts.