Turkey: Generic vs. Innovator, Damages Action, Second Civil Court of Intellectual and Industrial Property Rights in Istanbul, 1111/222 E. (2222/333 E.), 20 September 2013

Kluwer Patent Cases

Court structure (/court-structures/patents/Turkey.pdf) (PDF)

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Headnote

The Turkish Court of first instance held that the liability for damages arising from an unfair preliminary injunction (where no infringement was found in the action on the merits) is a type of strict liability and therefore did not investigate whether the defendant was at fault when ruling that the conditions for compensation were deemed to be fulfilled. The decision given in this case is the first known decision in Turkey for the compensation of damages arising from an unfair preliminary injunction decision in the pharmaceutical industry, and may therefore establish an important precedent.

See the full text of this case on KluwerIPLaw.com at KLI-KPL-ONS-19-23-005.pdf (http://www.kluweriplaw.com/CommonUI/document.aspx?id=KLI-KPL-ONS-19-23-005.pdf)

Summary

Facts of the case

The defendant companies requested a preliminary injunction be granted due to the imminent danger of infringement of the patent by the Claimant (a local pharmaceutical company)'s generic product. The court granted the PI and decided to suspend the manufacture of the Gx products, pending the outcome of a court-appointed expert panel's report.

The defendant then filed an infringement action on the merits and the PI was maintained throughout the proceedings. Within the scope of the action on the merits, a new expert examination was conducted which found no patent infringement. Due to the conflicting expert reports, the Court lifted the PI. Ultimately, the infringement action on the merits was rejected and the decision became final following the Appeal process.

The claimant then filed an action claiming compensation for damages, alleging that it had incurred a loss of profits due to not being able to manufacture the Gx products due to the unfair PI.

Question in Dispute

Was the rejection of the action on the merits sufficient to claim compensation for damages due to the preliminary injunction? If a pharmaceutical company did not put the Gx product on the market even after the preliminary injunction decision had been lifted, can it still demand compensation on the ground that it was unfairly prevented from manufacture and marketing of the Gx products; if yes, on what basis should the loss of profit/damages be calculated for a pharmaceutical product that was never put on the market?

Arguments of the Parties

The plaintiff mainly argued that it was prevented from manufacturing and marketing its Gx products due to the unfair PI and that had it not been prevented as such, it would have been the first Gx on the market and 85% of the market share of the patented pharmaceutical would have automatically shifted to the plaintiff company. It also argued that liability to compensate for damage caused by the preliminary injunction was subject to strict liability provisions, so the defendant did not need to be at fault in order to pay the compensation. For this reason, it claimed 85% of the sales of the defendant during the entire period of the preliminary injunction as compensation. Based on these arguments, the plaintiff asked the Court to order the defendant to pay the amount of TL 4,500,000 (approximately EUR 750,000) as compensation for its damages due to the unfair PI.

The defendant firstly stated that the casual link between the damage alleged by the plaintiff and the fault could not be proven, and more importantly the Gx product was never put on the market even after the PI was lifted. Therefore the damages demand should be rejected. In relation to the alleged damages, the defendant pointed out that at the date of the PI the Gx product only had a marketing authorization, which is not sufficient to launch the product. The regulatory steps that need to be completed (price approval, sales permission etc) had been taken by the plaintiff at a later stage and it took 125 days for the plaintiff to complete these steps and become ready for launch. Therefore, the aforementioned 125 days had to be deducted from the term of the PI when calculating the damages. The defendant further emphasized that the Gx product had only been approved for a single indication while the original product had two different indications. Consequently, the market share of the original product with

two indications would naturally be higher than the market share of the Gx. The Court should take the approved indication's market share only. The defendant further stated that in any case it could not be assumed that the Gx would automatically take over the whole market share of the originator. Especially in the area of oncology drugs, the trust in the original product and the originator company makes physicians and patients less inclined to switch to the Gx. This is especially true when it is considered that the plaintiff has changed the formulation of its drug in question five times. Finally, the defendant provided the Court with the official data which indicated the market share of the first Gx to enter the market with a very similar oncology drug. The market share of the Gx was between 6% to 16% and the Gx company in that case was a very well-known and reputable one, unlike the Gx company in the current action. Finally, in relation to the calculation of loss of profit of the plaintiff, the defendant emphasized that the first price approved by the Ministry of Health could not be taken into consideration because there has to be mandatory and arbitrary discounts on the pharmaceutical prices until they reach an end price. Besides, the court should also calculate the expenses of the Gx company as well in order to ascertain the profit it could have had if there was no PI.

Judgment of the Court

The court of first instance (Istanbul 2nd Court of Intellectual and Industrial Property Rights) ruled that in order to be held liable for compensation for damages incurred due to the preliminary injunction decision, it was sufficient that the main case (here the infringement case) was rejected and that there was no need to investigate whether the defendant was at fault.

For the calculation of the damages, the Court deducted 17 days from the term of the PI as being the period necessary to have the sales permission granted. Then, the Court took the example provided by the defendant (indicating that the market share of a similar oncology Gx product as the first Gx on the market was between 6-16%) and decided that the market share of the plaintiff would have been 16% if the PI had not been granted, without considering the fact that the Gx was approved only for one indication whereas the original product had two indications. Finally, the Court took the first price (the highest price) approved by the Ministry of Health, which would certainly not be the sales price of the Gx product, due at the least to legal mandatory discounts applied to pharmaceuticals in Turkey.

Finally, the Court ordered the amount of TL 2,000,000 (approximately EUR 330,000) to be paid to plaintiff company as compensation for its damages due to the unfair PI.

Both parties appealed the decision. At the time of writing, the file was still pending before the District Court.

Annotation

The essential issue in this case was the calculation of loss of profit of a Gx company which had never launched its product on the market. The market share, the price and the possible expenses of the Gx company had to be calculated in order to ascertain what would have been the profit of the Gx company if it could have launched during the term of the PI. In order to visualize this scenario in as concrete a way as possible, both parties came up with suggested solutions serving their own interest. However it is important to note that the plaintiff did not bring any evidence indicating that it would have been able to sell its Gx product at the highest price granted by the

Ministry of Health and that it would have possessed 85% of the market. The only ground relied on by the Gx company was the argumentation of the patentee brought during the PI proceedings that there was a risk of the patented product losing 85% of its market share if the Gx launched. This was the only argumentation of the plaintiff Gx company that it would "objectively" possess 85% of the market. As the plaintiff never launched its Gx products, it also relied on the sales figures and market shares of the actual first Gx entered onto the market; as if whatever the figures say for the actual first Gx would be identical for the plaintiff's product. The IP Court rejected all these arguments on the counter arguments brought by the defendant, stating that 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 sector where the product will enter the market for the first time are of great importance in the calculation of the market share.

In addition, the court ignored a very important issue: the mandatory discount rates to be made on the first price of the Gx product. Accordingly, the alleged loss of profit cannot be calculated as if the Gx company would be able to sell its products at the highest price approved by the Ministry of Health.

It is also noteworthy that the Court considered liability to compensate the damage caused by the preliminary injunction to be one of the strict liability cases, despite the fact that the strict liability cases are counted as numerous clauses within the Turkish law and the liability to compensate damage caused by the preliminary injunction is not among them.

With all these factors, the decision to be issued by the District Court on the reasoning and evaluation of the 2nd Court of Intellectual and Industrial Property Rights is significant, since this decision will constitute the first court precedent in the pharmaceutical industry for the compensation of damages arising from an unfair preliminary injunction decision.

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