

Preventing Price Decreases of Original Pharmaceutical Products with Partial Preliminary Injunctions

Timely and appropriately strategized action is key for owners of pharmaceutical patents wishing to maximise benefits of the rights granted to them. The Turkish Industrial Property Code regulates the exemption of patent rights concerning experimental acts regarding the product subject to the invention, as well as marketing authorisation, and the necessary testing and experiments within its scope. In practice, the Courts occasionally erroneously interpret the wording of the law concerned with the exemption (known as the Bolar Exemption), leading to the permission of applications to the the Social Security Institution (SSI) and even inclusion in the SSI reimbursement list. In such cases, the introduction of the generic pharmaceutical product to the market results in a decrease of 40% of the price of the original product and it is not always possible to reinstitute this decrease in price. Even if the price is reinstated, the time consuming process results in significant financial loss for the patent holder. Therefore, especially in cases of pharmaceutical patent disputes, applications for preliminary injunction and fair injunctions, is of great importance for the protection of the rights of patent holders.

In 2023, the Civil Court for Intellectual and Industrial Property Rights rendered a most striking decision. It determined that patent infringement was present, and issued a partial preliminary injunction to prevent the patent owner from suffering damages due to the price decrease until an expert report clarifying the situation related to the alleged infringement could be obtained. This is considered an extremely valuable precedent, especially for cases where highly complex legal, technical and procedural disputes exist simultaneously and several pieces of legislation come into play.

Within the scope of the patent infringement proceedings before the Ankara Civil Court for Intellectual and Industrial Property Rights ("Court"), a patent owner filed a request for discovery of evidence and preliminary injunction against the subject product which had completed all administrative processes necessary for its entry on to the market and which the patent owner argued had infringed their formulation patents.

One of the formulation patents had been approved by the European Patent Office but had yet to be validated by the Turkish Trademark and Patent Office. The patent owner informed the Gx pharmaceutical company of the invention and its scope by letter of notice sent via public notary in accordance with Articles 7 and 8 of the Regulation on Implementing the Convention on the Grant of European Patents in Türkiye and Articles 97(4, 5) of the Industrial Property Code and requested the cessation of the infringing acts. Although the company examined and interpreted the invention and its scope, it did not cease its acts of infringement.

The Court evaluated the request for discovery of evidence and preliminary injunction and deemed the request for discovery of evidence appropriate in the first stage, deciding upon an expert examination of the file. While the parties were waiting for the expert examination and preparation of the expert report, the infringing products were placed on the market. With the introduction of the Gx product to the market, pursuant to the Decision on Pricing of Medicinal Products for Human Use ("Decision"), the price of the reference product would have decreased by 40%. Taking this into consideration, the patent owner immediately purchased the infringing product with invoices and submitted this as evidence to the Court, proving that the infringing product was placed on the market. Subsequently, in the light of the available evidence, a request was submitted for a preliminary injunction to prevent the price decrease of the patented product to be accepted in the first instance by conducting an examination of the case file until the expert report is available, and that other requests for injunctions to prevent the commercialisation of the infringing product be evaluated after the preparation of the expert report.

The Court, taking into account the infringement on one of the patents (the basis of the request for injunction) confirmed by examination of the file and evidence of the presence of the infringing product being on the market, decided that the plausible proof condition was met and issued an interim injunction to prevent the price decrease of the patented product as a result of the request of the patent owner, in return for payment of a guarantee bond by the patent owner.

With this preliminary injunction, the patent owner was prevented from incurring damages due to the decrease in the price as a result of to the infringing product's entry into the market, but the infringing product was allowed to remain in the market until the infringement was established by an expert report. In this framework, a decision was made in accordance with the principle of justice and balance of convenience.

Following implementation of the preliminary injunction granted by the Court, the patent owner filed a case on merits in accordance with Article 397 of the Code of Civil Procedure, which regulates the procedures pursuant to the completion of the preliminary injunction. However, since the Code of Civil Procedure does not regulate partial preliminary injunction, there is no clear guidance in the law for the case at hand where the injunction issued by the court covers only one of the requests for preliminary injunction demanded and where the expert report is awaited for the decision to be rendered for the other requests for injunction. However, in accordance with the legislation, the case file on which a preliminary injunction is granted should be considered an annex to the case filed on merits. The Court applied this provision in line with this case and considered the case

