



## International report - Preliminary injunction granted in favour of second medical use patent

**05**  
OCT 16

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Large inventor companies that rightfully obtain patents for their inventions often face a number of invalidation actions. Alternatively, the threat of infringement may be such as to require the patent holder to file infringement actions against companies whose products may infringe its patent. The two occasionally come together, with the allegedly infringing generic company filing an invalidation action against the patent holder in response to an infringement action; commonly known in the patent litigation world as the 'torpedo strategy'.

The Court of Appeal has established precedent that registered rights must be fully protected until such time as they are invalidated. This rarely causes loss of a party's rights, since invalidation decisions are retrospective in effect and restitution is usually available. However, the first-instance courts generally refrain from ruling in favour of a patent, including the grant of injunctions, in an infringement action when invalidation actions are pending on the same patent. Due to the retrospective nature of invalidation decisions, courts do not wish to grant an injunction but then later declare that the same patent was invalid from the beginning. The nature of preliminary injunction requests, pressing as they are, requires that they be handled promptly.

### Recent decision

Recently the Second Istanbul IP Court was faced with a complicated case. When the present infringement action arrived before the court, along with a counterinvalidation action filed by the same generic, the court had four merged cases gathered under a single file: two invalidation actions by two different generics, and two infringement actions, one with a preliminary injunction request. Considering the reluctance of courts to grant injunctions while invalidation actions are pending, the Second Istanbul IP Court faced a complex task. The matter became even more difficult because the generic against which the injunction was sought had already entered the market with the allegedly infringing product, shifting the balance more in favour of the injunction request and towards equilibrium.

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The conditions for grant of a preliminary injunction were fulfilled, as there was imminent danger and irreparable loss because it was only a matter of days since the generic product had entered the market. In other words, the launch of the generic product was solid evidence. Further, the IP courts are the guardians of IP law, which favours the protection of registered IP rights and the interests of parties which invest in R&D to bring innovation to the market, which ultimately serves the general public. The rights of inventing parties are better protected since the protection period is already limited – any unfair denial of protection or court-mandated early (but wrongful) expiry of patent protection reduces time that cannot be brought back.

However, there were several pending invalidation actions for the same patents that formed the basis of the injunction. The patents were also not granted supplementary protection certificates by the European Patent Office or the Turkish Patent Institute, since this procedure is unavailable in Turkey, meaning that the patents were coming close to the end of their period of protection.

Judges have no technical backgrounds and must consult experts when ruling on highly technical matters, even if they are judges of the specialised IP courts. This is usually the case with the grant of preliminary injunctions as, being wary of granting preliminary injunctions where invalidation actions are pending, the courts wish to make sure that the balance of interests requires that the injunction be granted.

However, the Second Istanbul IP Court, when faced with the preliminary injunction request, granted it without consulting experts. The pressing nature of the situation due to the launch of the generic product on the market was supplemented by the fact that the patent in question was for second medical use, meaning that it was easy to see a likelihood of infringement by comparing the respective summaries of product characteristics of the generic product and the patent-protected original product. Since second medical use pharmaceutical patents claim rights on use of an active ingredient for a new indication, the judge compared the two summaries and, given the urgency of the matter, granted the preliminary injunction in exchange for a deposit payment. Since any loss incurred by the generic company was reparable, unlike any loss incurred by the inventor, the court was in favour of an injunction.

The grant of a preliminary injunction succeeded in protecting a patent that was registered following years of research and investment. Even though the injunction was granted amid pending invalidation actions, the pressing nature of the circumstances called for protection favouring the patent holder.

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