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IP court issues preliminary injunction against drug in Turkey's named patient programme

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The Istanbul Civil Court for Intellectual and Industrial Rights has granted a preliminary injunction to remove a pharmaceutical product from the foreign drug list of the Turkish Medicines and Medical Devices Agency (TMMDA). The drug was supposed to be supplied via the named patient programme (NPP) and was removed on the grounds of patent infringement. Further, the supplier company has been prevented from directly or indirectly commercialising the product, which includes its import, storage, sale and promotion, as well as possessing it for commercial purposes.

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The NPP enables a pharmaceutical product to be supplied on request of a physician, in the case that it has no marketing authorisation in Turkey or the valid marketing authorisation has not yet been launched there. If approved, it is added to the foreign drug list and is generally imported by the Turkish Pharmacists' Association's Economic Enterprise (TEB) and the Social Security Institution (SSI) on a named-patient basis. The foreign drug list provides the product's name, active ingredient and purpose of use, but nothing about the supplier or manufacturer.

In the case at hand, the company making the infringement claim owns a patent, which covers the use of an active ingredient to treat a specific disease and supplies the pharmaceutical product covered by the patent to Turkey via the NPP. It claimed that another product containing the same active ingredient was being used to treat the same disease and was included in the foreign drug list. The patent owner requested that the IP court grant a preliminary injunction based on the information provided in the list (ie, the name of the infringing drug and the manufacturing company) and information on the manufacturing company's website. As the supplier company was neither known nor declared, the patent owner requested that the court find the supplier by sending writ to the SSI, TMMDA and TEB. Here, it aimed to avoid the handicaps caused by the NPP and reimbursement processes not being publicly shared, and to file a patent infringement case against the supplier domiciled in Turkey.

The IP Court referred to an expert panel to evaluate the patent infringement, which stated that the infringing product contained the active ingredient covered by the company's patent and was put on the market for the purpose indicated in the patent. The court sent a writ to the SSI to identify the supplier company and – once the petitioner had paid a deposit – granted a preliminary injunction to remove the product from the foreign drug list. The court also handed down its decision to prevent the supplier company (which had been confirmed by the SSI) from commercialising the product, directly or indirectly, including import, storage, sale and promotion of this product and possessing it for commercial purposes.

NPP and Bolar exemption

When enforcing pharmaceutical patents, patent owners are usually prevented from enforcing their rights due to Article 85/3(c) of the IP Code, (ie, the Bolar exemption), which states that experimental activities – including experiments involving an invention subject to a patent, licensing of pharmaceuticals and all necessary tests and experiments – are outside the scope of the rights conferred by a patent. The exemption is often misinterpreted by IP courts, which illegitimately expands the scope. Fortunately, the exemption does not apply to products supplied through the NPP, since these are provided directly from abroad and are not subject to experimental activities as they are not required to be licensed in Turkey. In this respect, NPP products are particularly important in terms of demonstrating that the patent owner can use its rights properly in an area where the Bolar exemption is not misinterpreted.

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