

Assessing the difficulties of enforcing patent rights over NPP products

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The supply of pharmaceutical products to Turkey via the named patient programme (NPP) is one of the exceptional importation regimes for pharmaceutical products. Where a pharmaceutical product is not granted marketing authorisation in Turkey but patients are in need of it, it can be supplied via this special route. The entities that are authorised to import pharmaceuticals from abroad within the scope of the NPP are the Turkish Pharmacists' Association (TEB) and the Ibn-i Sina Health Social Security Center Warehouse established under the Social Security Institution (SSI Warehouses).

If the product is approved for the NPP, then it is added to the Foreign Drug List of the Ministry of Health (MOH) and the TEB and SSI import the products on a named patient basis.

In most cases, there is a Turkish entity which plays a role in the supply of the pharmaceutical product via the NPP route. The role of these companies is either to find and offer for sale the pharmaceutical products to the TEB or SSI Warehouse or to bid for such supply.

Infringement

Quite frequently, the supply method causes some problems for the protection and enforcement of patent rights in circumstances of potential patent infringement in Turkey. The patent owner, who also supplies the patented product via the NPP in Turkey, becomes aware of the competitor product by its inclusion on the foreign drug list. In some cases, the patent in question is a compound patent and therefore the infringement by



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Selin has been involved in a number of advisory and litigious matters in all fields of IP and has handled hundreds of contentious and non-contentious administrative oppositions and court actions involving intellectual property rights, particularly in relation to the protection of patent rights. She regularly advises on patent infringement actions, declarations of non-infringement and nullity actions.

She represents multinational pharmaceutical companies before the Ministry of Health on regulatory issues and examinations.

Selin is the spokesperson for some NGOs in Turkey and in Europe (EFPIA, Research Based Pharmaceutical Companies Association [AIFD], Foreign Investors Association, Turkey Industry and Business Association) and represents these NGOs before the Turkish parliament and Turkish ministries. The Delegation of the European Union to Turkey contacts Selin every year before drafting the IP section of the EU Progress Report of Turkey. By the invitation of the Ministry of Development, Selin contributes to the IP team of the ministry in preparation for the Progress Report of Turkey. Selin also advises commercial counsellors of the Embassy of the USA, British Embassy, and the Embassy of Switzerland in relation to IP law and developments in Turkey.

the newly-added NPP product is inevitable. On the other hand, it may also be the case that the patent holder knew about the newly-added product from other markets and already tested it and approved the patent infringement.

In these scenarios, the patent owner is almost certain about the patent infringement and ready to take legal action in order to prevent the infringement. However, the only known party to the patent owner, taking the steps causing infringement, is either the TEB or SSI Warehouses, as the importer of the infringing products. Indeed, there is case law from the Courts of Appeal ruling that in cases of supply of an infringing product via the NPP, the TEB should be the addressee of the patent infringement action as the importer of the infringing products.

However, the TEB or the SSI Warehouses are the business partners of the patent owner for supply of its patented product via the NPP in Turkey. Consequently, the patent owner prefers taking action against the company that offers the infringing product for sale to the TEB or SSI Warehouses, if such company can



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With a combination of advisory and litigation expertise as well as in-depth knowledge of the life sciences sector, Özge advises clients across all phases of the business cycle of life sciences products, such as registration/authorisation procedures, promotion practices, pricing and reimbursement regulations, distribution relationships and co-marketing deals, as well as issues relating to merger control, vertical restraints and abusive conduct.

Özge has acted on behalf of originators in numerous complex patent infringement and validity actions in the pharmaceutical industry and was involved in the first ever pharmaceutical data exclusivity actions in Turkey.

In addition to her corporate work, Özge serves as a counsel to the Association of Research-Based Pharmaceutical Companies (AIFD) and the Association of Research-Based Medical Technologies Manufacturers (ARTED) in Turkey and advises on numerous regulatory policy papers and drafting regulations for the Turkish government authorities.

be located at all. Even though this information is available to the TEB and SSI warehouses they strongly resist giving information about the identity of the company offering the infringing products for sale to the TEB or SSI warehouses. In some cases finding the identity of the Turkish company taking part in the NPP supply of an infringing product may also not be sufficient to prevent the infringement. In a precedential case, the IP Court

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rejected a precautionary injunction demand, stating that the real person who offered the supply of the infringing product to SSI was an employee of a foreign company located abroad and ruling that the PI demand should be directed to the foreign company located abroad. It is also debatable whether the foreign company’s act of supplying products to a real person resident in Turkey or a Turkish company abroad would constitute patent infringement according to Turkish IP Law.

Compulsory licences

Another problem that patent owners face regarding NPP products is the threat of a compulsory licence due to insufficient use of the patented product. It is clear that administrative bodies would like to supply patients with the cheapest product. With this primary aim, they ignore the patent infringement committed against the original NPP product. Therefore if the patent owner pushes hard to prevent supply of a cheaper infringing product via the NPP, the administrative authorities may decide to consider if there is room for a compulsory licence due to insufficient use of the patent disclosing the NPP product in Turkey or for public interest reasons.

In terms of a compulsory licence due to insufficient use of a patent, the third party demanding a compulsory licence should

apply to the patent holder first to ask for a contractual licence and if this demand is rejected or not responded to within a reasonable time limit then an application before the Turkish IP Court should be filed. Consequently, the IP Court should evaluate and decide if the conditions for a compulsory licence due to insufficient use of a patent are fulfilled.

The provision on compulsory licences due to public interest also stipulates non-use or insufficient use of the patent, which causes serious damage to the technological or economic development of Turkey. However, in this case it is not necessary to apply to the patent owner for a contractual licence first or to apply to the IP Court. Compulsory licences due to public interest reasons may be granted by the decision of the president. Consequently it is a much more straightforward way of grant of a compulsory licence over a patent, especially for a patent protecting an NPP product which is a burden for the public budget.

There is no precedent case yet in which the administrative body has granted a compulsory licence for a patent protecting an NPP product, on the ground that the patent is being used insufficiently and the insufficient use of the patent causes serious damage to technological or economic development in Turkey. However, in a very recent case, the Ministry of Health used this option as a tool to negotiate the price of the patented NPP product and managed to convince the patent owner to supply the government with the patented NPP product in return for a drastically discounted price.

Our feeling is that the MOH as well as other governmental bodies may frequently use the compulsory licence due to public interest provision as a tool in price negotiations, especially for NPP products.

There are legal steps that may be taken against arbitrary interpretation of the provision on compulsory licences due to public interest reasons. However, the foreign companies supplying NPP products to Turkey will most probably refrain from taking legal action against the government until it becomes a must for them.