International report - Originator challenges generic drug and ministry price reduction decision

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On October 12 2012 a global pharmaceutical company filed a patent infringement action and sought a precautionary injunction against a generic company on the grounds that the generic company had filed an abridged marketing authorisation application for the pharmaceutical which referred to the marketing authorisation dossier of the original product, one of the originator's most profitable drugs in Turkey. The generic company was an affiliate of a major Turkish group.

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The patent infringement action was delayed by the generic company through tactical moves such as merging the defendant generic company with another group company and transferring the marketing authorisation to a third party (which was in fact another group company). Once the originator company directed the action to the new marketing authorisation holder, the generic company transferred the marketing authorisation again.The generic company could have continued to transfer the marketing authorisation between the 12 group companies until the IP Court finally granted a precautionary injunction decision to prevent further transfer.

However, while the infringement trial was ongoing the generic company was still able to file Type-II variation applications with the Ministry of Health. As a result of two different Type-II variations being filed by the generic company during the trial, the court experts were completely confused as to who had supplied the advanced product information. Consequently, despite one court expert report acknowledging finding patent infringement, the IP Court was hesitant to grant the precautionary injunction and finally rejected the case due to another court expert report finding non-infringement.

Rather surprisingly, following the IP Court's decision, the generic pharmaceutical had not been launched; however, another generic pharmaceutical – which allegedly had a co-marketing relation with the generic subject to the patent infringement action – had been launched. The Ministry of Health had used this as the basis for decreasing the price of the originator’s product, claiming that the first generic had already come to market.

The issue was that the originator company could not find a single generic product on the market despite major efforts. When the matter was raised before the ministry, it referred to an invoice for the generic pharmaceutical as proof of launch (although the parties did not see this invoice).

The originator company evaluated filing an administrative application with the ministry, based on Article 4 of the Communiqué on Pricing Medicines, which requires the launch of the generic into the market in order to decrease the price of the original product.

Another issue which emerged was that the generic had a different pharmaceutical form from the originator's product. According to the definition given in the Communiqué on Pricing Medicines, one of the conditions to be deemed a generic of an original pharmaceutical is to have the same pharmaceutical form as the original: "Products featuring pharmaceutically analogous/similar characteristics cannot be regarded as the generics of the original product."

Therefore, serious doubt arose as to the generic quality of the pharmaceutical in question. The originator company also brought this issue before the ministry. The response of the pricing department was remarkable as it agreed that the different pharmaceutical forms should be deemed an obstacle to generic application; however, since the marketing authorisation had already been granted by the licensing department, the issue was not resolved.

Finally, the originator company has applied to the Ministry of Health under Article 11 of the Administrative Procedure Act seeking withdrawal of the price decrease decision. According to the law, the ministry must respond to this demand within 60 days. In case of a negative response or no response, the originator company must file an administrative action against the ministry or accept the situation.

In addition to the commercial concerns of a pharmaceutical company suing the Ministry of Health, it is quite challenging to provide proof in such cases as the allegedly generic pharmaceutical is not even available for testing.

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