Parallel Import and Repackaging of Pharmaceutical Products in Turkey

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While the European Union has long determined its approach to trademark issues for parallel imports and repackaging of pharmaceuticals, Turkish courts and legislation lack a unified and established practice on the issue. In fact, the current regulatory regime in Turkey prevents parallel import and repackaging of pharmaceuticals.

Key aspects of trade mark law for pharmaceuticals

Pharmaceutical imports into Turkey are regulated under the Pharmaceutical and Medical Preparations Law numbered 1262 (Law numbered 1262), while parallel imports and the exhaustion of rights principle are regulated by the Decree Law on the Protection of Trade marks numbered 556 (Trade mark Decree Law). These legislative instruments aim to protect public health and intellectual property respectively. However, in practice the differing motivations also lead to contradictory outcomes in interpretation.

One of a company's most important assets is its trade mark portfolio. The key functions from a commercial trade mark portfolio are to:

- Exclusively identify and guarantee the commercial source or origin of products or services;
- Distinguish the trade mark owner from other establishments;
- Enable consumers to be certain that a purchased trade marked product has not been subject to interference by a third party, without the proprietor's authorization; and
- He or she will enjoy the same quality every time they purchase products from the same brand.

Legal systems generally allow trade mark holders to enjoy these functions by granting the right to prevent third parties from using its trade mark on goods or packaging, as well as prevent the goods being imported or exported. However, limitations apply to this absolute right, including the exhaustion of right principle.

Article 13 of the Trade mark Decree Law explicitly includes the national exhaustion principle as follows. The acts related with a product containing a registered trade mark shall not constitute a breach of the rights of a registered trade mark, where such acts have occurred after the product has been put on the market in Turkey by the proprietor or with his consent. The proprietor has the right, even within the provision of the first paragraph, to oppose further commercialization of the goods, especially where the condition of the goods is changed or impaired after they have been put on the market.

For a right to be exhausted under Article 13, goods must be sold in Turkey either by the trade mark owner, or by third parties with the owner's consent. It is agreed that what becomes exhausted is the right to first sell trade marked goods and not trade mark rights. Therefore, considering the fact that Turkey accepts the national exhaustion principle, the Trade mark Decree Law actually allows trade mark owners to prevent parallel import. If a third party imports goods to Turkey other than the goods in question, which have been already sold in Turkey, the trade mark right is not exhausted for the later goods. Therefore, the trade mark holder can prevent sale of those goods in Turkey.

However, the Court of Appeal interprets the exhaustion of rights in broader terms. In numerous decisions, it has concluded that if goods bearing the registered trade mark are put on the market in Turkey, the exhaustion of rights

occurs for all similar goods put on the market in other countries. Therefore, it is not possible to prevent importation or sale of original goods in Turkey, which have been put into the market of the other countries, unless the products are altered or damaged.

Parallel Importing of Pharmaceuticals

Parallel importing involves products being legally made (i.e. not pirated) abroad, but then imported without the intellectual property right-holder's permission. The concept has always been debatable due to the potential advantages which parallel importers gain, as well as possible loss of benefits for trade mark holders and the necessary changes which must be made to original packaging. These issues are particularly relevant for parallel imported pharmaceuticals.

Due to pharmaceutical pricing policies (based on consumer purchasing abilities) and the structures of state health and insurance practices, the same product is often marketed for different prices by different companies. Parallel importers buy original pharmaceuticals from one market at a lower price, then sell them in other markets for a higher price.

Trade mark holders argue that parallel imports harm trade marks' guarantee function. That is, the trade mark holder cannot guarantee the product's quality, since it cannot guarantee that products are kept under the right conditions during parallel importing, nor whether the packaging (including expiry date) has been manipulated.

On the other hand, parallel imports are arguably a strong tool for competition law, enabling international trade to function by preventing the trade mark holder from partitioning markets and allowing goods to move freely.

Parallel Importing in Turkey

Given Turkey's ongoing European Union harmonization process, the CJEU's decisions could potentially serve as valuable guides for Turkish courts and judges in developing a local approach. However, the current regulatory regime in Turkey prevents parallel import and repackaging of pharmaceuticals.

The Turkish Court of Appeal interprets parallel imports widely, failing to take into account the difference between goods which have already been put into the market and later imported goods. However, despite the more liberal judicial approach, pharmaceuticals are strictly regulated in Turkey, with close regulatory control over standards and pricing for manufacture, distribution, sale, promotion, imports and exports.

Accordingly, pharmaceuticals can only be imported and commercialized by the company which holds marketing authorization from the Ministry of Health. Marketing authorization is granted only to the Turkish subsidiary of the pharmaceutical manufacturer. Therefore, since it is only granted to one company, practically other companies are not allowed to import the pharmaceutical. These restrictions mean that parallel import of pharmaceuticals is not allowed in Turkey.

Labelling is also closely regulated by Law numbered 1262 and the Regulation on Packaging and Labeling of Pharmaceuticals (Regulation). The Regulation explicitly and strictly determines packaging requirements, also requiring packaging changes to be reviewed and approved by the Ministry of Health. Therefore, repackaging of pharmaceuticals is prohibited in Turkey.

When applying for marketing authorization, applicants must prepare sample packaging and submit this to the Ministry of Health for approval, together with other application documents. All information on the packaging and patient leaflets must be in Turkish, including:

- Name of the marketing authorization holder;
- Name of the laboratory where the pharmaceutical was manufactured;
- Marketing authorization number;

- Instructions for using the pharmaceuticals;
- Harmful or poisonous ingredients;
- Whether the pharmaceutical must be sold via a prescription.

Therefore, unless the current regulatory requirements are amended to allow parallel imported pharmaceuticals, the Turkish market will continue to be excluded from the economic benefits provided by parallel imports. For example, preventing division of markets and lowering the risks of companies abusing dominant positions.

Therefore, it seems that for now, Turkey will continue to watch European Union parallel import developments from a distance.

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