

GWA ARTICLES

Title: Parallel trade in pharmaceuticals within the European Union and the EEA

Law Area: Trade Mark Law

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What is parallel trade?

In your everyday life you can often find products on the market, such as detergents, tooth pastes, groceries etc., where the package is marked in a foreign language and sold at a significantly lower price than that which the stores would normally charge you for the same product. How can that be?

The answer is parallel trade. Parallel trade occurs when someone purchases goods in one country and imports them to another country, where they are distributed in parallel to the manufacturer's normal distribution channels in that country. Parallel trade will only occur when the purchase price for a product is significantly lower in one country compared to the price charged for same product in another country. When a manufacturer sells his products at different prices in different countries, there will always be an economic incentive for a third party to purchase the goods in the country with the lowest price and sell them in another country where the price is higher.

Within the European Economic Area (EEA) all movements of goods between the countries must be free and unrestricted. The purpose is, of course, to stimulate competition in the area which ultimately will lead to lower prices for the consumers. Consequently, parallel trade between the member states is strongly encouraged.

Once the manufacturer has put a product on the market in one member state, anyone is free to buy that product and parallel import it to another member state and market it there, using the same brand that the product was sold under in the first country. Under the European “Trade Mark Directive”¹, all member states must adhere to the same basic trade mark law principles. One of these principles is that the manufacturer’s exclusive right to use his trade mark for a product, is “exhausted” once the product has been put on the market. In other words, the trade mark owner may not prohibit the further commercialization of his products under the same trade mark within the EEA. If, for example, a tube of *Colgate* is marketed in one member state, the same toothpaste can always be imported to and sold in another member state as *Colgate*. There is no mystery here, it is after all an original Colgate product and it is being sold as such.

There are however some things that a parallel trader may not do. He may not interfere with the product or its packaging in any way, since the function of the trade mark is to guarantee that the consumer receives exactly the same product as the one that the manufacturer put on the market. Moreover, the parallel importer must not market the product in such a way that may damage the reputation of the trade mark.

It should be noted that the principle of free movement of goods only applies within the EEA region (the European Economic Area) – so called regional exhaustion - and that parallel import of goods from USA or from other countries outside this region will constitute a trade mark infringement.

It should also be noted that parallel trade is legal and should not be confused with sales of copies and other false products. Nevertheless, the parallel trade does facilitate the marketing of illegal copies as if they were original products traded in parallel. Such illegal sales may severely damage a trade mark’s reputation and its commercial value. A trade mark can represent a significant commercial value and is often the single most valuable asset in a company today. It is therefore important that manufacturers keep an attentive eye on the sale of their goods so that they may take the necessary legal actions promptly if their products are copied or their trade mark rights otherwise infringed.

¹ First Council Directive 89/104/EEC of 21 December 1988 to approximate the laws of the Member States relating to trade marks

Parallel trade of pharmaceuticals

The principles mentioned above also apply when pharmaceuticals are traded in parallel. However, the parallel trade of pharmaceuticals differs from such trade of other consumer goods in that the trade with pharmaceuticals is strictly regulated within the EEA. In all member states, a great number of rules and regulations govern production and marketing of pharmaceuticals. For instance, in Sweden a parallel trader must obtain a separate sales permit from the Swedish Medical Products Agency for each of the products that he wishes to import to the country and must also comply with all the MPA:s rules and instructions on packaging, labelling etc. Parallel trade with pharmaceuticals also differs from trade with other goods in the sense that it typically only occurs during the relatively short period of time when the patent for the product is in force, i.e. before the competition from manufacturers of generic products forces the price down to a level which renders further parallel import of the product economically uninteresting.

The price for a pharmaceutical may vary quite significantly within the EEA. The reason for these differences in price can often be found in the fact that the price for a pharmaceutical product in most countries is not set by the manufacturer but rather by the regulatory authorities in each country with the particular purpose that the price shall conform to the diverse subsidy systems for pharmaceuticals that exist within each Member State.

Not only the prices vary between different countries, but also the pack sizes. In one member state, the subsidy system may for instance stipulate that doctors at any given time may only prescribe a pharmaceutical in a pack size equal to 7 days consumption, whereas a doctor in another country may prescribe the pharmaceutical in a pack size equal to 30 days consumption. The pharmaceutical companies adapt to the specific conditions for each country and as a result, the same pharmaceutical may be sold in a package of 7 doses in one country while in another country it is sold in a package containing 30 doses.

Doctors in Sweden typically prescribe pharmaceuticals in larger pack sizes than doctors in southern Europe, which is a consequence of the different subsidy systems between the countries concerned, and prior to putting parallel imported

pharmaceuticals on the Swedish market, parallel traders usually choose to **repackage** such products into new, larger packages corresponding to the Swedish pack sizes.

Furthermore, it is often found difficult and some times impossible to use the one and the same brand name for a pharmaceutical product in all countries. A name that works well in one country may be perceived as improper or offensive in another. In addition, a brand name that is used in one country may already be taken by someone else in another. Thus, it is not unusual that pharmaceuticals are marketed under different brands in different countries.

If a pharmaceutical is marketed under a different brand in the country it is bought in than the brand that is used for the same product in the country it is exported to, some parallel traders choose to **rebrand** the product to the trade mark used on the market in the member state it is imported to.

Some parallel traders can also be found to **co-brand** parallel traded pharmaceuticals, i.e. use its own brand together with the manufacturer's brand name in an attempt to increase the status of its own brand to the detriment of the original brand. Co-branding infringes the proprietary rights of the original trade mark and is prohibited unless the proprietor has consented thereto. Such an action is also prohibited as it may incorrectly be perceived that there exists an agreement or understanding between the parties with regard to the sale of the product. It is not only the use of the parallel trader's own brand together with the manufacturer's brand name that may infringe the proprietary rights of the original trade mark, but also the use of other distinctive features that may be seen as clear representations of the parallel trader.

To what extent may the trade mark proprietor then act against repackaging and rebranding? The proprietor's rights are expressed in Article 7 of the Trade Mark Directive, which stipulates that the trade mark proprietor is entitled to oppose further commercialization when there are legitimate reasons to do so. When does he have such reasons?

The European Court of Justice

The European Court of Justice (ECJ) is the highest authority when it comes to interpretation of trade mark law within the European Union. In its precedences, the ECJ has dealt in detail with **repackaging** of parallel imported pharmaceuticals. In *Bristol-Myers-Squibb (joint cases C-427/93, C-429/93 and C-436/93)*, the ECJ stated very clearly that repackaging in principle is not allowed but that a parallel importer nevertheless may repackage a product if the measure is *objectively necessary* in order that the parallel importer shall be able to sell the product in the member state to which it is imported. For instance, there may be legitimate reasons for repackaging if the existence of national rules or practices only allow certain pack sizes, if sickness insurance rules reimburse medical expenses only with respect to certain pack sizes or if only certain pack sizes are prescribed following recommendations by professional groups and sickness insurance institutions.

The ECJ also pointed out that since repackaging in itself is an interference with a proprietor's trade mark rights, the parallel importers must always choose such actions that cause the least interference. For instance, the trade mark proprietor has legitimate reasons to oppose replacement packaging where the parallel importer is able to use the original package in the country of import by affixing new labels to that packaging.

The ECJ has also in detail dealt with **rebranding** of parallel imported pharmaceuticals. In *Upjohn (C-379/97)* it stated that a parallel importer may also rebrand a pharmaceutical to the trade mark used for the pharmaceutical in the country of import, provided that such rebranding is *objectively necessary*. Rebranding can only be necessary where it is clear that rules or practices in the importing member state prevent the product in question from being marketed in that state under the trade mark used in the exporting member state. This would for instance be the case where a rule for the protection of consumers prohibits the use of the original brand name in the state import. The requisite of necessity is *not* satisfied if rebranding is done solely in order to obtain a commercial advantage.

In *Boehringer Ingelheim (C-143/00)*, the ECJ stated as a further example where repackaging or rebranding may be objectively necessary, that if there exists such a strong resistance from a significant proportion of the consumers against relabelled

pharmaceutical products on a market, or on a substantial part of it, repackaging or rebranding is necessary, *provided that* this resistance is so strong that it hinders effective access to the market in the member state of import.

The ECJ has not dealt with **co-branding** and it is therefore not clear when a parallel trader's use of his own features together with a manufacturer's trade marks on the packaging shall be considered as an improper co-branding. The issue of co-branding has however been put to the ECJ in *Boehringer Ingelheim II (C-348/04)* and the Court's decision is expected sometime during Autumn 2006.

Swedish courts

The Gärde Wesslau Law Firm represents several of the major pharmaceutical companies and regularly acts in Sweden on their behalf against parallel traders who infringe their trade mark rights by repackaging, rebranding or co-branding their products where such actions are not allowed. We are familiar with the cases on parallel trade that have gone to court in Sweden and the outcome of such litigations. Based upon our experience we can say that Swedish courts carefully adhere to the principles laid down by the ECJ. In cases where parallel traders have not been able to show that it has been objectively necessary for them to repack, rebrand or co-brand their products, the courts have prohibited such measures. You will find the same results if you look at the decisions taken by the courts in Denmark and Norway and several other European countries.

Summary

In the outset, trade mark holders have legitimate reasons to oppose that a parallel importer repackages or rebrands a parallel imported pharmaceutical. However, if a parallel importer is able to show that it is necessary to repackage or rebrand the product in order to get effective access to the market in the state of import, then the trade mark holder may have to accept this. Under no circumstances may a parallel importer use his own brands together with the brand name of the pharmaceutical.

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