

## Parallel Imports - Speciality European Pharma Ltd v Doncaster Pharmaceuticals Group Ltd

The term "parallel imports" describes the purchase of trade marked or patented goods in one member state of the European Union (EU) and the subsequent export of those goods to another member state for resale. Where EU law provides that a trade mark owner's rights are exhausted after goods bearing the mark are first put on sale with his consent anywhere within the European Economic Area (EEA), the practice of parallel importation is permissible, subject to compliance with certain principles and procedures.

A recent UK case, *Speciality Europe Pharma Ltd (SEP) v Doncaster Pharmaceutical Group (DPG) and Madaus GmbH* [2013] EWHC 3264 (Ch) has confirmed one of the significant principles with which parallel importers must comply. In this case DPG was a parallel importer, which re-branded drugs that had been imported into the UK from other member states of the European Union. DPG applied the REGURIN brand to its products and the High Court ruled that this infringed the trade mark rights of SEP, which was the exclusive licensee of REGURIN in the UK. DPG could only re-brand the product with the REGURIN mark where it was objectively necessary to gain effective access to the UK market. In this case the re-branding could not be justified and was held to be a tactic to simply piggy-back on SEP's marketing efforts.

### Commercial Background

The practice of parallel importation is driven by price differences among different member states of the EU. Prices for pharmaceutical products are generally set by the governments of each member state dependent on national policy considerations and the operation of social security systems. Parallel importers operate outside the distribution network set up by the manufacturer or his/her authorised distributor.

They seek to take advantage of price divergences between member states to profit from purchasing goods in low price markets and reselling them, at a discount, in higher price markets.

In order to comply with local legislation on the supply of pharmaceutical products in the market into which the goods are exported, parallel importers often need to repack the goods, e.g. so that the packet contains the correct number of pills, or to include a translated/modified product information leaflet.

### Legal Background

The Treaty on the Functioning of the European Union (TFEU), which established the EU and determines how it operates, provides at Article 34 that "Quantitative restrictions on imports and all measures having equivalent effect shall be prohibited between member states." Article 36 contains the following

proviso to that prohibition, namely that "Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States."

Article 5 of the European Trade Marks Directive provides that the proprietor of a trade mark has exclusive rights which may be infringed by the use of that trade mark without his consent. These exclusive rights are subject to limitations set out in Article 7 of the Directive as follows:

"1. The trade mark shall not entitle the proprietor to prohibit its use in relation to goods which have been put on the market in the Community under that trade mark by the proprietor or which his consent.

2. Paragraph 1 shall not apply where there exist legitimate reasons for the proprietor to oppose further commercialisation of the goods, especially where the condition of the goods is changed or impaired after they have been put on the market."

In *Bristol-Myers Squibb & Ors v Paranova A/S* [1997] 1 CMLR 1151, the Court of Justice of the European Union (CJEU) set out 5 conditions which a parallel trader needs to establish in order to avoid a finding of infringement under Article 7. A trade mark owner may legitimately oppose parallel trading in a pharmaceutical product if the importer has repackaged the product and reattached the original trade mark unless:

1. This would contribute to the artificial partitioning of the markets between member states;
2. It is shown that the repackaging does not affect the original condition of the product inside the packaging;
3. The new packaging clearly shows who repackaged the product and also shows the name of the manufacturer;
4. The way the product is repackaged will not damage the reputation of the trade mark or its proprietor, so that the packaging should not be defective, of poor quality or untidy; and
5. The importer gives notice to the trade mark owner before the repackaged product is put in sale and, on demand, supplies him with a specimen of the repackaged product.

Article 7 of the Directive does not apply in cases where the parallel importer has replaced the original trade mark with another mark for resale. In these scenarios, Articles 34 to 36 of the TFEU determine the respective rights of the trade mark owner and parallel importer.

The principles which apply in cases of rebranding have been

broadly set out in Case C-379/97 Pharmacia & Upjohn SA v Paranova A/S [2000] 1 CMLR 51. Pharmacia & Upjohn marketed an antibiotic under the trade mark DALACIN in Denmark, Germany and Spain, DALACINE in France and DALACIN C in other member states of the EU. Paranova purchased goods bearing the brand DALACINE in France and DALACIN C in Greece and imported them into Denmark under the trade mark DALACIN. The CJEU considered that, in order to avoid an artificial partitioning of the EU market by the claimant, Paranova could rebrand the goods for resale in Denmark if they would otherwise be denied effective access to this market, e.g. if a significant proportion of consumers exhibited strong resistance to relabelled pharmaceutical products, but that they could not rebrand the goods solely to obtain a commercial advantage, e.g. higher sales at the expense of the brand owner's marketing effort.

### **Speciality Europe Pharma Ltd ("SEP") v Doncaster Pharmaceutical Group ("DPG") and Madaus GmbH**

SPG marketed pharmaceutical products in the field of urology and urogynecology, including a treatment for over-active bladders, trossium chloride, which was manufactured by Madaus GmbH. This product was branded as C ris in France, uriVesc in Germany and Regurin in the United Kingdom.

DPG had for a long period of time imported trossium chloride into the UK from France and Germany and initially marketed these goods in the UK by over-stickering the C ris and uriVesc brands on the boxes with the name of their generic active ingredient, trossium chloride. After the product came off patent in 2009, DPG decided to rebrand the goods with the Regurin trade mark, which was registered in the UK in Madaus' name and for which SEP had been appointed the exclusive licensee in 2009. SEP issued proceedings against DPG in registered trade mark infringement.

Mrs Justice Asplin needed to decide whether it was objectively necessary for DPG to rebrand the product from C ris and uriVesc to Regurin in order to gain effective access to the UK market. It was decided that the market in this case should be defined by reference to the product, trossium chloride, rather than the brand Regurin. If the market were defined by reference to the brand name, all parallel importers would simply need to identify a part of a particular market satisfied by a brand, however small, in order to contend that they should be entitled to use the trade mark in question in order to gain access to that market. This reasoning would be circular and would fail to satisfy the principles of free trade between member states enshrined in Articles 34 - 36 of the TFEU which are concerned with the market for a particular product in a member state or a substantial part thereof.

The evidence put forward on DPG's behalf showed that they had access to a substantial part of the market even without the use of the Regurin trade mark. In a dispensing climate where the English National Health Service (NHS) was in favour of generically written

prescriptions, DPG had access to 90% of prescriptions written by reference to trossium chloride for the 20mg version of the product and 68% of prescriptions for the 60mg version of the product. Furthermore, there was no evidence of any significant resistance by pharmacists or consumers to the use of over-stickered products. DPG were simply seeking a commercial advantage, in terms of increasing their profit margin, by "piggy-backing" on Speciality's marketing efforts in order to sell their parallel imported product at a higher price under the Regurin brand.

### **Comment**

Although this decision does not apply any new doctrine of law, it is significant insofar as it highlights the importance of a thorough case-by-case analysis of whether parallel importers have the ability to re-brand their products with the registered trade mark in the country of export. Only where parallel importers would otherwise be denied effective access to the relevant market will their adoption of the registered brand name be regarded as objectively necessary so as to fall within the scope of Articles 34 to 36 of the TFEU.

DPG had argued that they had been shut out from the discrete prescription market for branded Regurin or, in the alternative, that the sector of the market met by Regurin trade marked goods was substantial not only in terms of percentage share, but also value, given the premium at which Regurin branded products were sold. However, where J Asplin defined the market by reference to the product rather than the brand, these arguments were of negligible weight.

If J Asplin had come to the opposite conclusion, on the basis of a finding that the market was defined by the brand rather than the product, or on the basis that the percentage of the market which DPG had been able to access was not substantial, DPG and other parallel importers would have rushed to rebrand their goods with the registered trade mark and the value of such marks would have become almost worthless once the product had come off patent. Where brands are often the only remaining asset of value post patent-expiry, such a decision would have severely compromised the ability of pharmaceutical companies to "evergreen" their IP rights, such as by adapting prescription-only products for sale over the counter.

In member states such as the UK, where the NHS favours prescribing by way of the generic name of a pharmaceutical compound rather than by way of its brand name, and resistance by pharmacists and consumers to over-stickered products appears low, parallel importers are likely to struggle to convince the courts that they need to adopt the registered brand name in order to access the market for the relevant goods. Instead, they will need to market these goods under the generic name or devise their own distinct brand for registration and use.