Pharmaceuticals & Parallel Importation in the EU

Given the different regulatory regimes and price differences from Member State to Member State, parallel imports of pharmaceuticals in the EU are nothing new. However, the balance of rights of trade mark holders and the right of parallel importers to exercise the principle of “free movement of goods” within the EU has come under scrutiny and appears recently to have shifted in favour of the parallel importers.

Choosing a trade mark for a new drug can be a difficult process, particularly in the pharmaceutical sector, given the need to find a mark which is sufficiently distant from existing marks, and looks and sounds right, in all target countries. When a brand name is researched, chosen and cleared for use, it needs to be registered as a trade mark before launch. The trade mark registrations and the goodwill that is generated in the brand name as a result of the investment and product efficacy can become very valuable assets.

The owner of a registered trade mark has exclusive rights which are infringed by unauthorised use of the trade mark, including importing goods under the trade mark or affixing it to packaging. Although the exclusive rights are subject to some limitations, the infinite lifespan of a registered trade mark compensates to some degree for the expiry of a patent when the expected tide of generic products sweeps in, on eventual loss of patent, SPC and data protection.

However, the threat to revenue is not always from generics or even third parties with their own competing brands. Increasingly, the threat is coming from the genuine product released for sale elsewhere in the EU. Parallel importers have had a legal decision of the High Court of England and Wales in their favour, concerning their use of the genuine product’s trade mark: Speciality European Pharma Ltd v Doncaster Pharmaceuticals Group Ltd & Madaus GmbH

Doncaster Pharmaceuticals Group imported a trospium chloride pharmaceutical into the UK from France where it was sold under the brand name CÉRIS. Doncaster over-stickered the box with the name of the active ingredient. There was no issue with this. However, Doncaster started over-stickering the boxes with the trade mark REGURIN, which was the registered trade mark under which the product was sold in the UK by the Speciality European Pharma (SEP) which was the exclusive licensee of the REGURIN mark in the UK. Doncaster also started to import the same product from Germany where it was sold as URIVESC and re-branded with REGURIN. SEP regarded these uses of the UK trade mark REGURIN as unacceptable and issued proceedings for trade mark infringement. Their claim was successful in the High Court but Doncaster appealed.

The outcome is that trade mark owners cannot enforce their registered trade mark against parallel imports if five conditions are met:

(1) it is necessary to repackage to market the product;

(2) there is no effect on original condition and proper instructions;
(3) the manufacturer and importer are clearly identified;
(4) the presentation is “non-damaging”; and
(5) the importer has given notice.

The judge considered as part of the “necessary to repackage” test (1) whether or not Doncaster could realistically compete for the *whole* of the market for trospium chloride without using the REGURIN trade mark. On the basis that there remained a proportion of the prescription market which was resistant to generics, and which demanded REGURIN, the Court of Appeal concluded that Doncaster Pharmaceutical’s use of the REGURIN trade mark to market its parallel import was “necessary”.

Unsurprisingly, the decision has attracted strong criticism and is not necessarily a “green light” for parallel importers. Cases turn on their own facts and as illustrated here, even the courts cannot agree, with the High Court deciding one way and the Court of Appeal deciding the other way.

There is no doubt that in using the trade mark already established in a territory, the parallel importer is in a better position than it would otherwise be. It can gain access to the entire market of a brand leader; gain the benefit of its research and investment without significant outlay; and gain immediate goodwill and recognition as long as the “necessary to repackage” test (1) is satisfied, and it adheres to the other rules.

However, companies selling the “original” pharmaceutical products may lose out, since they would be competing against parallel importers under the restrictions of their licence, which could include higher prices than parallel imports and minimum orders. Trade mark owners may lose out, as licences would become less attractive to distributors unless they can offer strong commercial incentives and low prices to potential licensees.

Notwithstanding this development, the trade mark owner still has the right to object if the five conditions above are not met. It is advisable to monitor in the marketplace and take action promptly if it appears that they may not have been.

It remains vital to register trade marks at the outset and to monitor the marketplace for infringements. In doing so, many third parties with similar products and similar brands can be easily eliminated, allowing a powerful presence in the brand to be built up. As a consequence, the trade mark will become so strongly associated with the product that customers may be reluctant to accept a generic product.

We have explained developments in relation to parallel importation of pharmaceuticals within in the EU in this AL Factsheet but, as noted, cases turn on their own facts. Any live situation will need individual assessment. Please contact us if you need more detailed information.