The Court of Appeal has returned its judgment in parallel imports case Speciality European Pharma v Doncaster Pharmaceuticals. Antony Craggs, Principal Associate in our IP team, explains how the Court of Appeal's guidance develops the test of objective necessity laid down by the CJEU.

Introduction

The Court of Appeal has provided useful guidance in relation to parallel imports, on when it is permissible to rebrand goods from the trade mark used in the exporting EU member state to the trade mark used in the importing EU member state.

The test laid down by the Court of Justice of European Union (CJEU) in parallel imports case Boehringer Ingelheim v. Swingward [2002] FSR 61 was one of objective necessity: re-branding was permitted "if, without such repackaging, effective access to the market concerned, or to a substantial part of that market, must be considered to be hindered as the result of strong resistance from a significant proportion of consumers to relabelled pharmaceutical products" (emphasis added).

In the dispute before the Court of Appeal the branded market for the medicine REGURIN was only 8.61% of the total market for trospium chloride medicines, for which over 88% of prescriptions were written generically. Did this warrant re-branding? In the circumstances, it did.
In its 6 February 2015 judgment, *Speciality European Pharma Ltd v. Doncaster Pharmaceuticals Group Ltd & Another* [2015] EWCA Civ 54, the Court of Appeal explained that Doncaster could not compete with the generics on price and re-branding would not be practicable - indeed due to the regular interruptions of supply which are the lot of the parallel importer, it would be "verging on the irresponsible to encourage a doctor to prescribe a Doncaster brand".

Therefore, in determining whether it is necessary to re-brand, the court must consider what alternatives exist for the parallel importer, and whether they are realistic. A relatively small branded market may nevertheless warrant re-branding.

**Background**

Madaus GmbH manufactured trospium chloride, an anti-muscarinic agent for the treatment of over-active bladder symptoms. It sold it in two forms (20mg and slow release 60mg) via a distribution network in the EU under three brands in different jurisdictions including CÉRIS in France, URIVESC in Germany and REGURIN in the United Kingdom. Its exclusive distributor in the UK was Speciality European Pharma Ltd.

88.65% of prescriptions written for 20mg trospium chloride in the UK are written generically; 8.61% are written by reference to the REGURIN brand; and 2.74% are written by reference to other brands. 68% of prescriptions written for 60mg slow release trospium chloride are written generically, with the remaining written by reference to the REGURIN brand.

UK prescription rules allow a prescription written generically to be satisfied by a branded or non-branded product, but a prescription written for a brand, for example REGURIN, can only be satisfied by that branded product.

In 2005, Doncaster Pharmaceuticals Group Ltd purchased CÉRIS-branded trospium chloride and over-stickered the box with the name of the active ingredient. It did not use the trade mark REGURIN. It then imported the goods into the United Kingdom. In 2009, the patent for trospium chloride expired. As a result, a number of generic manufacturers entered the market. Doncaster Pharmaceutical's parallel import was unable to compete with the price of the generic trospium chloride. Further, due to UK prescription rules, it could not satisfy prescriptions written for the brand REGURIN.

Further, in 2010 a company related to Doncaster Pharmaceutical applied for a parallel import licence to import slow release trospium chloride 60mg branded URIVESC from Germany (a product which remains subject to a patent). In 2011, the Medicines and Healthcare Products Regulatory Agency refused the application on the basis that a third party used a similar name in the UK.
The Medicines and Healthcare Products Authority requires extended release products to be marketed under a brand name (so that they can be distinguished from one another as, for example, they may have different release properties). This prevented Doncaster Pharmaceutical from importing the URIVESC branded goods or over-stickering the goods with a reference to the active ingredient.

As a result of the above, on importing its CÉRIS or URIVESC-branded trospium chloride, Doncaster Pharmaceutical placed stickers on the packaging bearing the trade mark REGURIN. Consequently, Specialty European Pharma brought a claim against it for trade mark infringement. At first instance, it was successful. Doncaster Pharmaceuticals appealed to the Court of Appeal.

**Issue**

The question which fell to be decided by the Court of Appeal was: "[w]hen a pharmaceutical manufacturer markets the identical product in EU member state A under trade mark X and in EU member state B under trade mark Y, in what circumstances can a parallel importer take the goods (marked X) from state A to state B and re-brand them with mark Y?" In particular, does the parallel importer need to show that it is hindered from entering a substantial part of the market, or is it a higher burden, for example, that it is prevented from access to any part of the market?

**Law**

Article 34 of the Treaty on the Functioning of the European Union provides that "quantitative restrictions on imports and all measures having equivalent effect shall be prohibited between Member States". In principle, a trade mark which has territorial effect falls within the scope of this prohibition.

Article 34, however, is qualified by Article 36, which states that: "The provisions of Articles 34 ... shall not preclude prohibitions or restrictions on imports ... justified on grounds of ... the protection of industrial and commercial property [which includes trade marks] ... Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States."

This test has come to be referred to as the "artificial partitioning of the market". In Bristol-Myers Squibb v. Paranova [1997] FSR 102, the Court of Justice of the European Union explained that: "By stating that the partitioning in question must be artificial, the Court's intention was to stress that the owner of a trade mark may always rely on his rights as owner to oppose the
marketing of repackaged products when such action is justified by the need to safeguard the essential function of the trade mark, in which case the resultant partitioning could not be regarded as artificial" (emphasis added).

It then listed five conditions which needed to be satisfied by the parallel importer if the trade mark owner was not to be able to enforce its trade mark. These were summarised by Jacob LJ in Boehringer Ingelheim v. Swingward [2004] EWCA Civ 129 as follows:

"(1) Necessary to repackage to market the product;
(2) No effect on original condition and proper instructions;
(3) Clear identification of manufacturer and importer;
(4) Non-damaging presentation; and
(5) Notice."

(Emphasis added.)

For the purposes of the case at hand it fell to be determined whether, with respect to the first condition, it was necessary for Doncaster Pharmaceuticals to use the REGURIN trade mark to market its parallel import.

In Pharmacia & Upjohn SA v. Paranova A/S [2000] 1 CMLR 51, Upjohn marketed an antibiotic using the trade mark DALACIN in Denmark, Germany and Spain, DALACINE in France and DALACIN C in other EU member states. Paranova purchased antibiotic branded DALACINE and DALACIN C in France and Greece respectively, rebranded them DELACIN and imported them both into Denmark. Upjohn brought a claim for trade mark infringement. The matter was referred to the CJEU, which held that: "[t]his condition of necessity is satisfied if, in a specific case, the prohibition imposed on the importer against replacing the trade mark hinders effective access to the market of the importing Member State." (Emphasis added.)

"[H]inders effective access to the market" was expanded further by the CJEU in Boehringer Ingelheim v. Swingward [2002] FSR 61. A specific question raised by the reference was the existence among consumers of a resistance to re-labelled as opposed to re-packaged goods. The court held that: "[t]he answer ... must therefore be that replacement packaging of pharmaceutical products is objectively necessary ... if, without such repackaging, effective access to the market concerned, or to a substantial part of that market, must be considered to be hindered as the result of strong resistance from a significant proportion of consumers to re-labelled pharmaceutical products" (emphasis added).

The Court, therefore, needs to establish whether the parallel importer has been hindered from
access to a substantial part of the market; not access to the market as a whole.

**Decision**

Lord Justice Floyd gave the leading judgment, reversing the decision at first instance and concluding that Doncaster Pharmaceutical's use of the REGURIN trade mark to market its parallel import was necessary.

In summarising the law, he said:

"i) Subject to compliance by the importer with all of the BMS conditions, a trade mark owner may not enforce his mark against parallel imported goods which are re-branded if it is established that it is necessary to re-brand in order to gain effective access to the market.

ii) Effective access to the market is not achieved by being able to place some goods on the market.

iii) It may be necessary to re-brand where the parallel importer is not excluded from the whole of the market, but is merely excluded from a substantial part of it or from a significant proportion of consumers ...

iv) In determining whether it is necessary to re-brand, the court must consider what alternatives exist for the parallel importer, and whether they are realistic ..."

(Emphasis added.)

On the facts he reasoned that, in lieu of competing with the generics (which it could not do on price), Doncaster Pharmaceutical would have to satisfy branded prescriptions. It could not do this unless it established CÉRIS, URIVESC or its own brand in the United Kingdom. He concluded that this would not be practicable.

He pointed to the evidence of Mr Wilson on behalf of Doncaster Pharmaceutical, who said that: "I think it would be very difficult to convince a doctor to prescribe a brand when they know that quite frequently, due to matters beyond our control, that the supply will be interrupted. I think it would be a very difficult proposition to present to a doctor." Mr Wilson later characterised this as a "fool's errand".

Lord Justice Floyd concluded: "In my judgment, if the judge was going to reject Mr Wilson's evidence ... it was necessary to give some reason for doing so. This was not a solely commercial decision taken by Doncaster as a matter of their own commercial choice: it was an aspect of interstate trade which the free movement rules are there to protect. On the basis of the regular interruptions of supply which are the lot of the parallel importer, it would be verging
on the irresponsible to encourage a doctor to prescribe a Doncaster brand. If Mr Wilson says it is not realistic for a trader in his position to adopt an own brand, he should in principle be believed."

**Comment**

To date, the jurisprudence of the CJEU has tended to be construed as meaning that when assessing whether a trade mark owner can enforce its rights it is important to assess whether the parallel importer has access to a substantial part of the market.

In his leading judgment, Lord Justice Floyd has clarified this test. He explains that the focus is not what part of the market the parallel importer has access to, but what part of the market it does not. The question is then whether this is substantial. In this instance, 8.61% of the market (namely those prescriptions written for the REGURIN brand) was deemed substantial.

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