

CMS Adonnino Ascoli & Cavasola Scamoni CMS Albiñana & Suárez de Lezo
 CMS Bureau Francis Lefebvre CMS Cameron McKenna CMS DeBacker CMS Derks Star Busmann
 CMS von Erlach Henrici CMS Hasche Sigle CMS Reich-Rohrwig Hainz



European Pharmaceuticals Parallel Trade Review 2009

Repackaging and competition law cases have remained the focus of attention in the pharmaceutical parallel trade arena in recent months. We report on latest developments as at 2009 and also cover cases of wider interest relevant to international exhaustion of rights, customs procedures and regulatory issues, as well as parallel trade developments in other industry areas.

CMS has an experienced team of lawyers across the European Union and further afield which is able to advise on all aspects of parallel trade. If you would like further information please contact a lawyer in the relevant office using the contact details at the back of this publication.

Editors: Nick Beckett and Lucy Kilshaw, CMS Cameron McKenna LLP, London

Contents

Repackaging	4
Boehringer Ingelheim -v- Swingward, Court of Appeal, UK	4
Wellcome Foundation -v- Paranova, ECJ	6
Other national court decisions: Germany, Denmark and Finland	8
Poland: non compliance with ECJ	15
Exhaustion in Europe	16
Makro -v- Metro, ECJ	16
Leofelis -v- Lonsdale, High Court, UK	16
International Exhaustion	17
L'Oreal cases, EFTA Court	17
Honda -v- Neesam, High Court, UK	18
Microsoft, High Court, UK	20
Customs	21
Eli Lilly -v- 8pm, Court of Appeal, UK	21
Mulhens GmbH -v- SKB Perfumes, Finland	22
Competition Law	23
Greek references to ECJ: Sot. Lélos kai Sia	23
EU Commission consultation 2008	24
Glaxo dual pricing appeal	25
AstraZeneca appeal	26
Regulatory – Plant protection	27
Commission -v- French Republic, ECJ	27
News	28
Contact Details	30

Repackaging

Boehringer Ingelheim & others -v- Swingward & others, Court of Appeal, 21 February 2008

The long running parallel imports case continued in the Court of Appeal following the ECJ's judgment of April 2007, with an interim judgment in February 2008 in favour of the importers. The case concerned reboxing of original branded product, including de-branding (removal of the manufacturer's trade mark) and co-branding (addition of the repackager's trade mark). The main judgment by Lord Justice Jacob, with whom the other judges agreed, is relatively brief. There is little in the way of detailed reasoning, and the Court did not address a number of the points raised in argument.

Meaning of "damage to reputation"

Having summarised the earlier judgments, Jacob LJ held that the question to be determined was whether the defendants had complied with the fourth condition set out in *Bristol Myers Squibb -v- Paranova* in 1996, Cases C-427/93, C-429/93 and C-436/93 ("the BMS conditions"): was the presentation of their products "liable to damage the trade mark's reputation"? Based on the second ECJ judgment in this case, Case C-348/04 ("ECJ 2"), he held that this was a question of fact for the national court.

The claimants had argued for a wide interpretation of damage. They pointed out that under ECJ 2 it was held that damage could be caused to the reputation of the mark other than by shoddy packaging, such as by de-branding and co-branding. The ECJ had also held that it was "the repackaging of the trade-marked pharmaceutical products in itself which is prejudicial to the specific subject-matter of the mark, and it is not necessary in that context to assess the actual effects of the repackaging". On that basis, the claimants argued for a broad interpretation of damage, encompassing not only damage caused when the public are confused, but including erosion or dilution of the mark.

The Court of Appeal rejected the claimants' submissions.

Co-branding

Jacob LJ referred to the evidence of a parallel importer, Munro, whose co-branding of Atrovent and Becloforte, according to Jacob LJ, did no damage to the brand owner. He held that this was because Munro made clear that their brand was an importer's mark, which did not disparage the claimants' trade marks nor suggest that Munro had any connection with the manufacturer. In this context Jacob LJ referred by way of example to the retailer Harrods and the wine merchant Berry Brothers and Rudd, both of whom habitually place their name on everything they sell; he held that it is obvious that the manufacturer of goods should not be able to stop this, the reason being that no damage is caused.

Partial de-branding

Jacob LJ held that total de-branding could not be an infringement because there is no use of the mark. He also found that the trade mark owner is not entitled to any exposure of his mark after he has sold the product, and therefore partial de-branding, which gives the trade mark owner some exposure of his mark, is more than he has a right to insist upon and therefore cannot be damaging. Apparently recognising that this conclusion appears to conflict with ECJ 2's conclusion that partial de-branding is in principle damaging, Jacob LJ said that this must be understood in the context of damage being a question of fact.

Burden of proof

Counsel for Boehringer and GlaxoSmithKline argued that ECJ 2, which makes clear that it is for the parallel importer to prove compliance with the BMS conditions, meant that it was up to the defendants to prove the fourth BMS condition (presentation not liable to damage reputation) and that this burden had not been discharged. However, Jacob LJ rejected this contention, on the basis firstly that the case has gone beyond any question of initial onus of proof, and secondly that the defendants did lead evidence of what they were doing, and asked the Court to infer that no damage was thereby being caused.

Foreign cases

Jacob LJ did not believe it to be a useful exercise to go far into other national law cases (being *Sanofi-Aventis -v- Kohlpharma* in the German Supreme Court and *AstraZeneca -v- Paranova Denmark* in the Danish Supreme Court, both of which are summarised below), although he noted that in each case the parallel importer was successful and the relevant court held that damage could not be assumed.

Austrian reference to the ECJ

Jacob LJ referred to another reference to the ECJ by the Austrian Supreme Court in *Wellcome -v- Paranova* (see below). This case raised the issue as to whether there was an additional condition (referred to as “BMS 6”) with which parallel importers must comply in order for their acts to be non-infringing: a principle of “minimum intervention”. Jacob LJ was sceptical of this possibility, but considered that he had no option but to defer making a final decision pending the outcome of this ECJ reference.

Decision

The Court of Appeal held that the defendants had complied with BMS condition 4 and in particular that their activities by way of re-boxing and re-labelling had not caused damage to the reputation of the claimants’ trade marks. However, it deferred its final judgment pending the outcome of the Wellcome ECJ reference (see below). In fact there will now be no final decision of the Court of Appeal as it is understood that all parties have settled outstanding issues.

The law on repackaging of pharmaceutical products for parallel trade purposes has been the subject of numerous ECJ cases, the most significant being *Bristol Myers Squibb -v- Paranova*, 1996 and *Boehringer -v- Swingward* (two references). There are a number of established rules:

1. the manufacturer must not artificially partition the market (so in order to obtain access, the importer may make necessary changes to packaging);
2. the original condition of the product must be unaffected;
3. the names of the manufacturer and repackager must be stated on outer packaging;
4. the repackaging must not damage the reputation of the trade mark or its proprietor; and
5. the importer must give notice to the trade mark owner, and on request supply a sample pack.

Wellcome Foundation -v- Paranova, Case C-276/05, 22 December 2008

The ECJ made findings in a case referred by an Austrian court that:

- (i) In reviewing repackaging of branded products there is no principle of “minimum intervention”. The sole criterion on which the lawfulness of the new packaging is to be measured is whether it is such as to damage the reputation of the trade mark and its proprietor (assuming that the other criteria relating to repackaging of branded products have been met, as per ECJ case law, set out in *Boehringer -v- Swingward 1 and 2* and the BMS conditions).
- (ii) It is for the parallel importer to provide to the trade mark owner in its notice the information which is necessary and sufficient to enable the trade mark owner to determine whether the repackaging of the product under that trade mark is necessary in order to market it in the Member State of importation.

A previous ECJ case involving parallel trade of whisky, *Loendersloot -v- Ballantine* had spoken of the principle of minimum interference to original packaging. It was not entirely clear how this concept fitted with the concept of “damage” to the trade mark, which the ECJ had discussed in the *Boehringer* cases, deciding there that it was a question for national courts as to whether particular types of repackaging, such as de-branding and co-branding did in fact damage the trade mark.

Questions referred

The questions referred by the Austrian court were:

- 1(a) *Are Article 7 of the Trade Marks Directive and the case-law of the Court of Justice of the European Communities which has been pronounced on it, to be interpreted as meaning that proof that reliance on the trade mark would contribute to an artificial partitioning of the market must be furnished not only as regards the repackaging in itself, but also as regards the presentation of the new packaging?*

If the answer to this question is in the negative:

- 1(b) *Is the presentation of the new packaging to be measured against the principle of minimum intervention or (only) against whether it is such as to damage the reputation of the trade mark and its proprietor?*
- 2 *Are Article 7 of the Trade Marks Directive and the case-law of the Court of Justice of the European Communities which has been pronounced on it, to be interpreted as meaning that the parallel importer fulfils his duty of notification only if he informs the proprietor of the trade mark also of the State of export and the precise reasons for the repackaging?*

Question 1(a)

Question 1(a) referred to the first of the five BMS conditions. BMS Condition 1 provides that a trade mark owner may legitimately oppose the further marketing of a repackaged pharmaceutical product unless:

to do so would contribute to the artificial partitioning of the markets between Member States; such is the case, in particular, where the owner has put an identical pharmaceutical product on the market in several Member States in various forms of packaging and the repackaging is necessary in order to market the product in the Member State of importation, and is carried out in such conditions that the original condition of the product cannot be affected by it.

In the ECJ's second judgment in *Boehringer Ingelheim -v- Swingward* ("*Boehringer 2*"), the ECJ further held that "[t]he condition that the repackaging of the pharmaceutical product be necessary for its further commercialisation in the importing Member State is directed solely at the fact of repackaging and not at the manner and style of the repackaging".

The ECJ confirmed that it had already answered Question 1(a) in its second judgment in *Boehringer 2*.

Question 1(b)

Wellcome, and the Greek and Portuguese governments, both of which intervened in the case, relied heavily on the ECJ's judgment in Case C-349/95, *Loendersloot*, in which the ECJ held that "the person carrying out the relabeling must use means which make parallel trade feasible while causing as little prejudice as possible to the specific subject-matter of the trade mark right".

The ECJ referred to and restated the BMS conditions. It then noted that BMS Condition 5, which requires the importer to give notice to the trade mark owner, enables the trade mark owner to check that the packaging is not carried out in such a way as directly or indirectly to affect the original condition of the product and that the presentation after repackaging is not likely to damage the reputation of the trade mark.

The ECJ also noted that the condition that repackaging of the pharmaceutical product be necessary for its further marketing in the importing Member State is directed only at the fact of repackaging and not the manner and style of it, citing *Boehringer 2*.

The ECJ then explained that because the presentation of the new packaging of the product does not fall to be assessed against the condition of necessity, it must also not be assessed against a criterion of minimum adverse effect on the trade mark rights. The ECJ said that it would be inconsistent to accept that there is no need to ascertain whether the new packaging is necessary for the further marketing of the product, but at the same time to demand that the importer satisfy the criterion of the minimum possible adverse effect on trade mark rights.

Accordingly, the ECJ's answer to Question 1(b) was that, where it is established that repackaging of the pharmaceutical product is necessary for further marketing in the Member State of importation, the presentation of the packaging should be assessed only against the condition that it should not be such as to be liable to damage the reputation of the trade mark or that of its proprietor (BMS Condition 4).

Question 2

The ECJ noted *Wellcome's* argument that disclosure to the trade mark owner of the State of export and the precise reasons for the repackaging enables the latter to determine whether the repackaging is necessary.

The ECJ held that it is for the parallel importer to furnish the trade mark owner with the information which is necessary and sufficient to enable the trade mark owner to determine whether the repackaging of the product under that trade mark is necessary in order to market it in the Member State of importation. However, the kind of information to be provided depends on the facts of each case. It may, in exceptional cases, include the Member State of export, if the absence of that information would prevent the trade mark owner from evaluating the need to repackage. However, it should be borne in mind that the details provided may be used by the trade mark owner to enable him to detect weaknesses in his sales organisation and thus combat parallel trade in his products, and that parallel traders were entitled under the provisions of the EC Treaty to seek protection against such action.

Accordingly, the ECJ held only that it is for the parallel importer to provide to the trade mark owner the information which is necessary and sufficient to enable the latter to determine whether the repackaging of the product under that trade mark is necessary in order to market it in the Member State of importation.

Comment

This ruling comes as no surprise: the trend has been to favour parallel importers in recent case law. The point on notice is of significance to centrally authorised products. Under UK nationally licensed products, the marketing authorisation holder (usually within the same group of companies as the trade mark owner) will be told by the MHRA of the country of export. However, where products are centrally authorised by the EMEA there is common outer packaging (with appropriate language change) for each country and it can sometimes be difficult on inspection of the interior packs to tell from where the product has been imported. Despite the concerns of the ECJ expressed in relation to competition law concerns, trade mark owners should press for disclosure of the country of export where this could make a difference to the assessment of the repackaging from a trade mark perspective.

Other national court decisions on repackaging

There have been decisions of the highest courts in Germany and Denmark concerning repackaging, again, largely sympathetic to importers, notwithstanding the findings by the ECJ in *Boehringer 2* that de-branding and co-branding were in principle damaging to the trade mark. Also the German courts have decided that replica packages created by importers are to be permitted. Further, they have considered the question of damages in the increasingly rare circumstances in which trade mark infringement is found, and decided that the trade mark owner's right to damages will be forfeited if he does not raise objection to repackaging in a timely manner after receiving notice from the importer. One decision of the Finnish courts has found in the manufacturer's favour concerning co-branding, but this seems to run against the tide of current judicial opinion.

Germany

Sanofi -v- Kohlfarma, German Federal Supreme Court, 14 June 2007

STILNOX was sold in Germany in packs of 10 and 20 and in Spain in packs of 30 (three blisters of ten) by the manufacturer. The German pack bore a design of four blue vertical stripes, becoming lighter and narrower across the pack. The importer bought product in Spain and reboxed for sale in Germany. The new box had the STILNOX mark re-applied, and bore the importer's name KOHLPHARMA in a large stylised form. Also a single blue stripe design was used, but this was different from the trade mark owner's design.

The trade mark owner complained that the reboxing to some extent was not necessary (at least in relation to some blisters which could have been left in original packaging in a set of ten) and also complained about the design of the rebox.

The defendant argued that a standardised appearance of their products was of great importance (they also imported from Greece where the original packaging was of a different design).

The trade mark owner was successful at first instance, and on appeal to the Higher Regional Court. The lower courts found that repackaging was not necessary. A single blister of ten tablets could have been left in the original packaging. Although there would be "leftover" blisters and it may have been more economical to rebox entirely, the importer could not make changes to original packs simply because it was more economically advantageous. Further, the importer used the trade mark on their rebox in a way which was not the most considerate interference with the trade mark owner's right of identification. The blue stripes resembled the trade mark owner's product in a way which suggested that the trade mark owner may have created the pack. The trade mark owner did not have to tolerate the impression that this conveyed of a non-uniform appearance of his product on the market.

The appeal by the importer was successful. The Federal Court relied on *Boehringer 1* and *2*. It found that because of the difference in pack sizes, reboxing of the entire contents of the original packs was necessary and a distinction could not be made between some blister strips and others, as the lower court had done.

The lower court focussed on the idea that the importer's design was not necessary to market in Germany, and in judging the nature and manner of repackaging from the viewpoint of necessity, applied an incorrect test. It could not be assumed that the reputation of the trade mark has been damaged. The Federal Court found that there was no legal support for the lower court's findings.

Further it said that the requirement for the repackager's name to be printed on the rebox such that it can be seen by a consumer with normal vision applying a normal degree of attention (the requirement being met here) disproves the assumption made by the lower court that the design gives the impression that the trade mark owner created it. The averagely attentive consumer would see not only blue stripes but also the name of the importer. Therefore the view of the lower court that the trade mark owner was damaged because of the impression given of non uniformity of packs had no basis. The trade mark owner must tolerate non uniformity insofar as this is the consequence of parallel importation.

The lawfulness of the importer's new packaging did not depend on whether this serves the development of the importer's brand image. The key issue was whether the appearance of the packaging is liable to damage the trade mark, which was not the case.

LEFAXIN, German Federal Supreme Court, April 24, 2008

This case also concerned co-branding. The defendant bought the pharmaceutical with the active ingredient Simeticon in Austria where it was sold in packs of 30, 50 and 300 tablets under the trade mark LEFAXIN. The product was reboxed with the trade mark re-applied and sold in Germany in packs of 20. Under the statement 'Import, Reboxing and Distribution by:' the box bore the importer's name and its symbol which consisted of a green logo design, also overwritten with the importer's name.

The appellant, the German exclusive licensee, and the defendant agreed that the reboxing as such was "necessary" but the appellant complained that the reboxing by using the symbol of the importer was not necessary.

The licensee was not successful at first instance, but was so on an appeal to the Higher Regional Court in Hamburg, which found that the repackaging by use of the symbol was not necessary. While the importer was permitted to name himself as importer he was not permitted to use the box for marketing purposes and had done so here by printing his logo on the outer package.

The subsequent appeal by the importer was successful. The Federal Supreme Court stated that the requirement the repackaging be necessary was relevant only to the fact of repackaging and not to the way in which the repackaging was carried out. The question whether the parallel importer was permitted to place his symbol on the box is determined by asking whether this damages the function of the trade mark as an indication of origin.

The parallel importer neither damaged the reputation of the trade mark nor the function of the trade mark as an indication of origin if he applied to the outer packaging his own logo directly next to the necessary indication of the repackaging of the product and in such a way that the logo would be regarded by the relevant public as part of this indication.

Here the importer's logo was used in direct connection with the necessary statement 'Import, Reboxing and Distribution by:'. Therefore the relevant public would recognise the symbol as part of this indication and the function of the manufacturer's trade mark as an indication of origin was not damaged.

KLACID PRO, German Federal Supreme Court, October 2008

In this case the Federal Court considered package sizes. The Hamburg Court of Appeal, the specialist court dealing with parallel import cases in Germany, had previously decided that an importer had no automatic right to offer all package sizes for which there was a marketing authorisation. It had said that the key question was whether the specific package to be imported was marketable in Germany: for example, if the manufacturer distributes packs of 30 in Germany, an importer could not import a pack of 30 from another country and then repack for sale in Germany into an own box of 50, as this would not be necessary.

However, the Federal Court now appears to have come to the opposite view, saying that a parallel importer may not be hindered from entering "parts of the market". So if a parallel importer imports a package of 10 tablets he is – according to the Federal Court of Justice – forced to repackage in own new packages in order to be able to enter the market for a package size of, for example, 15 tablets. This would mean that the importer could repackage 100% of packages into his own boxes even if in the Member States of importation and exportation the same range of package sizes are available. Such scenario is conceivable if the importer decides to import, for example, packages of 10 tablets and rebox them into packages of 30 tablets and import packages of 30 tablets and rebox them into packages of 10 tablets, ie. the importer "cross-reboxes" the imported packages. The only circumstance in which such "cross-reboxing" is not conceivable is a situation where only one identical package size is available in both the Member States of importation and exportation. If only packages of 10 tablets are available in Member States of importation and exportation, the importer is obliged (under German law) to over sticker the original boxes since reboxing is then not necessary.

(In fact in the UK, this scenario of reboxing (including a single package size) has existed for a long while, since Mr Justice Laddie made a finding of fact in 2000 in the *Boehringer -v- Swingward* case that it was necessary, in order to access the market, for an importer generally to rebox rather than over sticker due to resistance by some consumers to foreign language on packs. This finding has yet to be challenged in a subsequent case.)

MICARDIS, German Federal Supreme Court, 13 December 2007

This case concerned the issue of replica packs in circumstances where the manufacturer's packaging was protected by a registered trade mark, which was separate from the trade mark protecting the brand name. Boehringer Ingelheim owned the mark MICARDIS and also had trade mark protection for a distinctive packaging design.

The defendant bought MICARDIS from Italy where it was sold in packages of 28 tablets, and reboxed for sale in Germany in packs of 56 and 98 tablets. The rebox was in the style of a replica pack, imitating Boehringer's original packaging. The trade mark MICARDIS was re-applied, with a footnote saying that MICARDIS was a trade mark of Boehringer. Also there appeared the usual statement saying that Boehringer was the manufacturer and that the defendant was the importer and repackager.

The parties agreed that reboxing was "necessary". However, Boehringer complained about the replica pack. It was unsuccessful at first instance, on appeal to the Higher Regional Court Hamburg and ultimately in the Federal Supreme Court. The Court stated that the parallel importer was allowed to replicate the design of the packaging even if the design was protected by a separate trade mark. Once the parallel importer has overcome the necessity criterion concerning reboxing, the importer should be free in his design of packaging as long as he did not damage the reputation of the trade mark owner or his trade mark. Boehringer's trade mark rights for MICARDIS as well as for packaging design were exhausted. Whether the replication of the design was necessary itself was irrelevant.

ASPIRIN II, German Federal Supreme Court, 12 July 2007

In this case the Federal Supreme Court dealt with the question as to whether the trade mark owner forfeits his right to a damages claim if he does not object promptly to a certain form of repackaging.

Since 1997 the defendant imported ASPIRIN into Germany from Greece, distributing 100 tablets in a bundle, which consisted of five Greek packs each of 20 tablets.

After the trade mark owner complained that the bundles were untidy, the defendant declared that he was planning to repackage the product in packs with 50 and 100 tablets by using a new outer package. By letter of 9 November 2000 the defendant informed the trade mark owner that the design of the rebox with 100 tablets had changed. Again by letter of 25 September 2002 the defendant gave notice of another change to the design of the rebox.

The trade mark owner complained that the reboxing infringed his trade mark rights, arguing that the reboxing was not necessary for distributing the medicine in Germany as packs of 100 tablets could be made by bundling five packs together. This was successful at first instance, and on appeal to the Higher Regional Court Hamburg.

The German Federal Court also acknowledged an infringement of trade mark rights. The repackaging was not necessary as a bundle package was possible and accepted by the market and especially the private consumer. The importer could not rebox simply because it was more economically advantageous than a bundle.

However the trade mark owner's damages claim was forfeited due to requirements of good faith. The Court stated an obligation on the trade mark owner to object to repackaging within a short time of being notified about the specific type of repackaging by the importer. The Court relied on several judgments of the European Court of Justice, especially *Boehringer 2*. It was the importer's obligation to notify the trade mark owner in advance of planned repackaging. The need to give notice gave warning to the trade mark owner but was also in the interests of the importer's rapid distribution of the repackaged product. If the trade mark owner failed to complain about a specific type of repackaging, the importer could trust in the fact that the trade mark owner would not base infringement claims on that packaging.

ACERBON, German Federal Supreme Court, 18 October 2007

In this similar decision the Federal Supreme Court acknowledged the ASPIRIN II decision (see above).

The defendant, a parallel importer, planned to distribute the pharmaceutical ACERBON in Germany, having purchased from an unnamed country. He informed the appellant, the German representative of the manufacturer and owner of the trade mark ACERBON, about his plans. In his answer the appellant complained only about the user information but not about the planned use of the mark ACERBON.

Later on in legal proceedings the appellant complained that the use of ACERBON infringed his trade mark rights and sought financial relief. The Court held again that the trade mark owner's rights to damages claims were forfeited if he did not object to a certain form of repackaging within a short time. As he had not complained in his answer to the importer's original notice, he no longer had a right to claim damages.

Denmark

AstraZeneca AB -v- Paranova Denmark, Danish Supreme Court, 3 December 2007

This was an appeal from a decision of the Maritime and Commercial Court of 11 February 2005.

The product, whose generic name is Bambuterol, was sold by AstraZeneca in Denmark under the brand name BAMBEC in packs of 100. In France the brand name was OXEOL, sold in packs of 30. Paranova bought in France and repackaged (presumably reboxed) so as to remove the mark OXEOL from the outer packaging and to market as Bambuterol "Paranova" in packs of 105. Further the words "Bambuterol 'Paranova' corresponds to the pharmaceutical Bambec®" were affixed in small print. The usual statement as to manufacturer and importer was included on the outer packaging. The mark OXEOL remained on the inner packaging and the outer packaging noted this.

Later the packaging was amended to make the word "Paranova" smaller, to omit the reference to BAMBEC and to cover up the references to OXEOL on the inner and outer packaging.

The Court referred to the ECJ's judgment in *Boehringer 2*, in particular that de-branding and co-branding may in principle be damaging and that the national courts should make a decision. The Court found that national Danish trade mark law did not contain a prohibition on removing trade marks. The removal of a mark was not intended to damage the reputation of the trade mark or its owner.

The Court's view was that even if the name Bambuterol "Paranova" may have created the impression among some that Paranova was the producer, and that this concerns a generic and not a patented product (it was not clear whether product was still under patent) this name was not misleading and did not contravene good marketing practice. Account must be taken of the fact that the packaging showed AstraZeneca as the manufacturer and Paranova as the importer.

Using Paranova in the same font size as Bambuterol could not be illegitimate. Further the statement concerning the reference to BAMBEC was relevant consumer information which could not be considered an infringement. The fact that OXEOL was printed on the inner blisters did not mean that there was co-branding. Paranova succeeded and the earlier decision was annulled.

Finland

Organon -v- Paranova, Helsinki District Court, 5 October 2007

This case concerned the reboxing of MERCILON and MARVELON into different packaging sizes.

The trade marks were re-applied and Paranova's logo and company name in stylised form were also used.

There was also a dispute about lack of notice and the corporate entity within Organon to which notices should have been given. Further there was a dispute about acquiescence due to a delay between Paranova giving notice and Organon raising objection in relation to one product (77 working days). In that respect the Court found that Organon had lost its right to object.

The Court found that the national regulatory body had informed Paranova that it could not overstick in this instance and found that therefore repackaging was necessary. However following *Boehringer 2* the necessity requirement was not to be applied to the nature of the repackaging. The Court reiterated the findings of *Boehringer 2* on damage to a trade mark, referring to de-branding and co-branding. It also said that reputation may be damaged where the mark is used in a way which may create the impression of a commercial connection between the repackager and the trade mark owner, for example that the repackager's business is affiliated with the trade mark owner's distribution or that there is a special relationship between the two. In this connection the ECJ had said that there is a need to act fairly in relation to the legitimate interests of the trade mark owner (referring to the BMW case C-63/97).

On the external packaging was Organon's trade mark and a trade mark containing Paranova's logo and company name written in stylised form. The Court found that presenting the product name and the repackager's logo and the stylised company name on the front of the packaging in this manner connected the product with the repackager. This was not sufficiently clarified by the fact that above Paranova's trade marks there was a marking about the parallel import and re-packaging (presumably the compulsory notice). The co-branding created an assumption of a commercial or other special relationship between the manufacturer and the re-packager. Co-branding therefore damaged the reputation of the mark and damages and costs were ordered.

Poland – non compliance with ECJ

In the *Boehringer 2* ruling dated 26 April 2007, Case C-348/04, the ECJ stated that the fact that a parallel importer:

- (i) does not affix the trade mark to the new exterior carton (“de-branding”); or
- (ii) applies either his own logo or a house-style or get-up or a get-up used for a number of different products (“co-branding”); or
- (iii) positions the additional label so as wholly or partially to obscure the proprietor’s trade mark; or
- (iv) fails to state on the additional label that the trade mark in question belongs to the proprietor; or
- (v) prints the name of the parallel importer in capital letters;
- (vi) is, in principle, liable to damage the trade mark’s reputation.

At around the same time, on 1 May 2007, the Pharmaceutical Law, which regulates parallel trade in Poland, was amended. Following this amendment, a parallel importer may put on the Polish market an imported medicinal product under:

- (i) a name of a proprietary product used in the territory of Poland;
- (ii) a name of a proprietary product used in a country of origin; or
- (iii) a common or scientific name of a medicinal product used together with the trade mark or name of the parallel importer. This last possibility is contrary to the ruling in the *Boehringer 2* case.

It should be noted that Polish Industrial Property Law does not contain a direct legal basis entitling a trade mark proprietor to bring a claim in case of de-branding or re-branding. Trade mark protection under Polish law relates only to cases where the infringer uses a trade mark identical or similar to the protected mark. There are no provisions regarding repackaging of the product without affixing the original trade mark. Polish legal opinion is that in case of de-branding or re-branding, in order to affirm the infringement, the courts must interpret general rules regarding trade mark infringement in accordance with European Law (so-called indirect application of Community law). As in practice there are not yet any cases of de-branding or re-branding concerning medicinal products in Poland, this theory has not been tested.

Parallel trade has been growing significantly in Poland, according to recent IMS Health data. In 2008 sales of parallel imports rose by 89% and the number of products authorised for parallel trade in 2008 almost doubled, with the total number of authorised products standing at around 350. The first authorisations were granted in 2004. It is now estimated that parallel traded products account for approximately 0.5% of Poland’s pharmaceutical market. However, the decline in the value of the Zloty has reduced price competition and may stunt further growth.

Exhaustion in Europe

Makro -v- Metro

In 2008 the Dutch court referred a new case to the ECJ on exhaustion of rights, *Makro -v- Metro*, Case C-324/08. The questions are as follows:

1. In the case where goods bearing a trade mark proprietor's mark have previously been placed on the market within the EEA, but not by him or with his express consent, must the same criteria be applied in determining whether this has occurred with the (implicit) consent of the trade mark proprietor, within the meaning of Article 7(1) of First Council Directive 89/104/EEC of 21 December 1988 to approximate the laws of the Member States relating to trade marks, as are applied in the case where such goods have previously been placed on the market outside the EEA by the trade mark proprietor or with his consent?
2. If the answer to Question 1 is in the negative, what criteria – whether or not derived (in part) from the judgment of the Court of Justice in Case C-9/93 *IHT and Danzinger -v- Ideal-Standard and Wabco Standard* [1994] ECR I-2789, ... – must be applied in the first case referred to in that question in order to determine whether the trade mark proprietor has given (implicit) consent within the meaning of Directive 89/104/EEC?

The key case on consent concerning goods coming in from outside the EEA (international exhaustion) is *Zino Davidoff*, Case C-414/99 (see below). In this latest reference the Dutch Court is asking whether this interpretation of consent is the same when considering placement of goods on the market within Europe, and if not, to what extent the *Ideal Standard* case (which concerned a trade mark split between different parties) is relevant.

The question as to whether rights are exhausted within the EEA concerns the issues of consent and control by the trade mark owner and therefore also of potential relevance to this new reference is the previous ECJ judgment in *Peak Holding AB -v- Axolin-Elinor AB*, Case C-16/03. This case decided that goods bearing a trade mark cannot be regarded as having been put on the market in the EEA where the trade mark owner has merely imported them into the EEA with a view to selling them there or where he has offered them for sale to consumers in the EEA, in his own shops or those of an associated company, without actually selling them.

The judgment does not deal expressly with the issue of control and whether transfers of ownership of goods between related or closely linked companies constitutes a placement on the market, but the ECJ did refer to the trade mark owner realising the "economic value" of his trade mark. In the subsequent English High Court case of *Leofelis -v- Lonsdale* in 2007 the Court said that following this logic, the trade mark owner can only exhaust his rights by putting the goods beyond his control by a sale to an objectively independent third party. In that case, transfers of goods below market value between related companies could not exhaust the rights.

International Exhaustion

L’Oreal – EFTA cases

The EFTA Court gave judgment in July 2008 on the issue of international exhaustion following referrals by two courts in Norway (cases E-9/07 and E-10/07). The Court has confirmed a position which reflects the ECJ’s view in the *Silhouette* case, C-355/96, that Community law does not allow for a concept of international exhaustion of rights, but instead a concept of regional EEA-wide exhaustion.

Both cases concerned genuine REDKEN branded shampoo marketed by L’Oreal in the United States and imported into Norway without L’Oreal’s consent. The importers argued that under Norwegian law, a concept of international exhaustion of trade mark rights remained, a finding which the EFTA Court had itself made in its previous decision of *Mag Instrument Inc -v- California Trading Company Norway*, Case E-2/97 in 1997. The Norwegian and Icelandic governments supported the importers.

It was clear that when the Trade Marks Directive was implemented into Norwegian law, the government acknowledged the traditional position on international exhaustion, saying *“since international exhaustion is the approach which creates the greatest price competition on the Norwegian market and is, therefore, best for Norwegian consumers, the Ministry is of the view that there should be no aim to switch over to EEA regional exhaustion until the issue is elucidated in more detail in further consultation or by the EFTA Court or the ECJ.”*

This has now happened. The EFTA Court found that the *Mag Instruments* case was inconsistent with the subsequent ECJ *Silhouette* case, and that Article 7 of the Trade Marks Directive must be interpreted so as to preclude the unilateral introduction or maintenance of international exhaustion by Member States. While it was understandable that the EFTA Court and the ECJ had reached differing views, there must be a presumption that, in the interests of a homogeneous market across the EEA, provisions framed in the same way under the EEA Agreement and European law must be interpreted in the same way. Under the EEA Agreement there is an obligation for EEA member states to provide for exhaustion of rights as laid down by Community law.

It is therefore now clear that the EFTA position is consistent with the longstanding ECJ position, an assumption which many brand owners had probably already made.

Honda Motor Co -v- Neesam & others, High Court, 28 February 2008

In a case concerning parallel importation of branded Honda motorbikes from Australia to the UK, the Court found largely for the importer on the facts: Honda as the brand owner had impliedly consented to the sale of these items within the EEA, until its consent was withdrawn at a later date. The judgment is very long and considers in depth highly complex factual evidence: the key point is how the issue of consent was treated.

The ECJ made clear in 2001 in the case of *Zino Davidoff Case C-414/99*, that unless a trade mark owner had given unequivocal consent to the sale of its branded goods within the EEA, his rights would be infringed by any importation, sale or advertisements of such goods in the EEA. This case has been applied by the courts consistently. Consent is usually express but may be implied provided that it is unequivocally demonstrated.

Background

The High Court had in 2006 granted summary judgment to Honda in relation to imports of its motorcycles from the US and Hong Kong into the EEA. In the case of the United States the motorcycles had originally been sold by authorised Honda dealers outside their own territories and in breach of their dealership agreements. The position in Hong Kong was unclear. The dealers argued that Honda had consented to the bikes being imported into the UK because its subsidiaries in the countries of export and its authorised distributors had supplied the bikes (albeit in breach of their dealership agreements). The dealers further argued that Honda knowingly participated in parallel imports by taking no steps to control it and also actively had facilitated it.

These arguments were then rejected by the Judge who said "I cannot accept that a distributor or dealer who exceeds his authority, or breaks his contract in consenting to import into the EEA, can saddle the trade mark proprietor with the consequences of his excess of authority or breach." The *Zino Davidoff* case had decided that consent could not be assumed even where there were no contractual restrictions in place. Here where Honda had imposed restrictions the argument was even stronger. The evidence was not sufficiently clear to support any facilitation by Honda and even then the Judge stated that knowledge of a local sales representative of Honda would not amount to consent by Honda to export. Further, knowledge or a failure to police did not amount to consent.

The Judge in 2006 did not give summary judgment in relation to certain bikes imported from Australia in the light of evidence about correspondence between the relevant defendant, KJM Superbikes, and Honda Australia and Honda Australia's export agent, which he decided merited further investigation. The defendant had purchased from the agent, Lime Exports, which had in turn purchased from Honda Australia. KJM alleged that the dealings gave rise to consent on the part of Honda to importation into the UK.

At a further hearing in March 2007 the High Court dismissed an application on the part of the importers for a letter of request to be issued by the English Court to the Australian courts requesting examination of relevant witnesses in Australia, including Honda's ex-sales director. The judge was apparently of the view that the request was a "fishing expedition". On appeal on the point, and with only a week to go until the trial of the case, the importers succeeded in overturning this decision, the Court of Appeal finding that such evidence was potentially significant and that it would be unjust to refuse the request, given that the burden of proving consent rested on the importer.

This latest judgment was also given against the background of Honda's general manager having already admitted to having given false evidence earlier in the case. He had falsely claimed that Honda had no continuous contact with Lime and that Lime were verbally advised by Honda Australia not to sell products outside the Pacific islands. It emerged from the emails available on disclosure that this was untrue: Lime had a large credit facility with Honda Australia and Lime had made clear that bikes were going to various overseas markets, including some in Europe, none of which were Pacific islands. The manager admitted the untruths and that he had known this at the time, attempting to excuse his behaviour as an attempt to protect Honda Australia's reputation within the Honda group.

Not surprisingly the Court of Appeal felt it more important to uncover the facts of the case by allowing examination of the witnesses, even if that meant losing the trial date, which was postponed. This latest judgment completed the action.

Honda conceded that if there were consent by Honda Australia (which they denied) this would be equivalent to consent of the trade mark owner, Honda Japan.

Decision

Following consideration of a very large amount of detailed written and oral evidence the Court found that Honda had impliedly consented to sale within the EEA of these bikes prior to a certain date.

It was clear that the sales from Honda Australia to Lime Exports were for export and that Honda Australia knew that Lime would sell to other trade customers rather than individuals. From this the judge extrapolated that, unless Honda Australia specified otherwise, it consented to Lime reselling to business customers outside Australia and that if it wanted to exclude sales to the UK it should have done so. He did not believe that this was inconsistent with *Davidoff*, which had made clear that silence was not sufficient to imply consent, saying: "there is far more than silence in this case. This is not a case where, because the original vendor has not said anything, it is not possible to tell whether that vendor consented to onward sales."

At a certain point in time, Honda Australia began to ask Lime for information as to the destination of the bikes it was supplying. There was a dispute as to the relevant date – the burden of proof rested with Honda – and this was decided in KLM's favour. There was very little evidence of an express prohibition on sales to the UK, so the Court took the date as from when Honda began to ask Lime for destination information as the date when implied consent should be treated as withdrawn, being mid 2003.

KLM also amended its defence to include an Article 81 argument, which there was no time to hear, to the effect that the withdrawal of the consent given to Lime was anti-competitive.

The end result was that Honda lost in relation to bikes acquired by KLM prior to mid 2003 when it was found on the facts that consent had been withdrawn. However, Honda won in relation to consignments after that date, subject to any further hearing of the Article 81 issue.

Comment

Although, unusually, the Court of Appeal in the previous case of *MasterCigars -v- Hunter & Frankau*, which concerned importation of Cuban cigars into the UK from Cuba, had found in favour of the importer, this was on the basis of an unusual factual matrix which the Court said could only be consistent with consent having been given by the trade mark owner. This latest judgment seems to imply consent more easily on much less clear facts. There was no detailed consideration of the *MasterCigars* case.

Microsoft success in enforcement against parallel trade

In January 2009 the High Court found repeated breaches of its previous orders by a parallel importer who had persisted in infringing Microsoft's intellectual property rights by parallel importing software intended for one region of the world into another. The importer was given a number of concurrent jail sentences of up to nine months for contempt of court and also will face enforcement of a damages judgment in Microsoft's favour for GBP £2.5 million.

Customs

Eli Lilly -v- 8pm Chemists Limited, Court of Appeal, 24 January 2008

The Court of Appeal found that importation of trade marked goods into the UK from outside Europe (here Turkey) under customs procedures, for the purpose only of onward transit to other destinations outside Europe, could not infringe the trade marks.

Background

The marks were CIALIS, LILLY, EVISTA, HUMALOG and HUMULIN. The defendant was an English pharmacy which operated a website through which US customers could, with a prescription, purchase drugs at favourable prices. The US customer would order from a Canadian company, which then supplied from a company in Turkey. The Turkish company labelled Lilly's genuine Turkish product with a dispensing label which included essential information such as dosage and customer name, and an English PO box address in Slough together with the name "Complete Care Pharmacy". The Turkish language information leaflet was left inside. The product was placed in a small box addressed to the customer and then about 100 such boxes were parcelled up in a larger box and sent to the defendant in Slough, who released them from customs, paying no duty (as these were only goods in transit), and sent the individual items on to the US customers via Royal Mail. On arrival in the UK, Customs seized a package believing that the products may be counterfeit, which they were not.

The High Court granted in November 2007 an interim injunction in Lilly's favour, finding that there was an arguable case that the importation of various branded pharmaceuticals into the UK from Turkey for immediate re-export to the United States, was a trade mark infringement. Although the goods were for customs purposes regarded as outside the UK, the defendant's distribution method suggested to recipients that the goods had a UK origin. Lilly had argued that the customer was being deceived and that the product was given an aura of respectability which it would not otherwise have. Further, the product was probably distributed in this way to minimise risk of interference by US Customs. Lilly also claimed that some products were temperature sensitive and could become degraded.

The defendant had sought summary judgment in its favour and appealed to the Court of Appeal on the point as to whether there was a cause of action against them.

Customs regulations

Under Customs regulations there are various procedures under which goods in transit through the UK or stored in customs warehousing are not treated as goods within the UK for tax purposes. In particular the "inward processing procedure" allows non EEA goods to be imported into the UK and re-exported outside the EEA without paying duty. In the case of *Class International Case C-405/03* which concerned two other customs procedures, being external transit and customs warehousing, the ECJ decided that the "mere physical introduction" of goods into the EEA did not constitute "importing" for trade mark infringement purposes and therefore the trade mark owner could not object purely on this basis. However, if the goods were to be released on the EEA market there would be an importation.

Decision

The Court of Appeal gave summary judgment in favour of the defendant.

The essential function of Lilly's trade marks was not affected by the defendant's activities. No-one in Europe ever saw the trade marks. In the *Arsenal* case, Case C-206/01 the ECJ made clear that the exercise of trade mark rights is to be reserved to cases where use of the sign by a third party affects the functions of the trade mark, in particular guaranteeing to consumers the origin of goods.

Further the *Class International* case was decisive: there is no "import" for the purposes of the Trade Marks Directive. Although the Customs procedure used here was different to those procedures referred to in the *Class* case, in both instances there was no interference with the trade mark owner's right of first marketing in Europe. The goods were never in free circulation in the Community and were never used in the course of trade within Europe. *Class* was entirely consistent with two other ECJ cases, *Rioglass* Case C-115/02 and more recently *Montex* case C-281/05.

This point was clear, so there was no need for trial on factual issues. The judge had been wrong to consider that giving an impression to consumers that the goods were English in origin could make a difference and had overlooked the fundamental reasoning of previous case law.

Mulhens GmbH & Co KG & others -v- SKB Perfumes LLC, Court of Appeal, Helsinki

A very similar case was heard by the District Court of Helsinki, whose judgment was upheld by the Helsinki Appeal Court in December 2007. The defendants purchased branded fragrances in the US, including those bearing the marks BOSS and NAOMI CAMPBELL, which they brought into Finland using the customs warehousing procedure for onward transit to Russia. Following the ECJ's judgments in *Class International* and *Rioglass*, the Finnish courts found that the mere transit of branded goods from a non EEA country to another via a Member State did not involve the marketing of the goods and therefore did not infringe the trade mark.

Competition Law

ECJ rules on pharmaceutical stock allocation for dominant products, Cases C-468-478/06

On 16 September 2008 the ECJ ruled that dominant pharmaceutical companies are not entitled to refuse to meet ordinary orders from wholesalers in order to limit parallel exports by those wholesalers. The judgment does make clear that stock allocation in the pharmaceutical sector should not receive special treatment but leaves to national courts to determine when a wholesaler's orders are or are not "ordinary". At the same time, the ECJ accepted that a dominant company should be permitted to take reasonable and proportionate steps to protect its own commercial interests.

The ECJ case (entitled *Sot. Lélos kai Sia*) stems from a reference from the Athens Court of Appeal for a preliminary ruling on the application of Article 82 EC Treaty which prohibits the abuse of a dominant position. The case involved the Greek subsidiary of GlaxoSmithKline plc (GSK), which was restricting supply to wholesalers in order to limit their parallel trade activities. GSK claimed that export of stocks in Greece by wholesalers was leading to shortages in Greece.

The ECJ held that it would in principle be an abuse of a dominant position on the relevant market for medicinal products for the dominant undertaking to refuse to meet ordinary orders from wholesalers with the intention of putting a stop to parallel exports by those wholesalers. On the other hand, the ECJ held that it would be permissible for a dominant supplier to refuse to honour extraordinary orders, since this would be a reasonable and proportionate protection of its commercial interests. The judgment recognises that, if this were not the case, the only choice left to suppliers would be to abstain from any supply to low-price national markets.

The ECJ did not offer guidance on what is understood by "ordinary" or "extraordinary" orders other than to state that historical relations between the parties and the size of the orders compared to national demand are relevant factors; instead, the ECJ left the determination of this issue to the national court.

The ECJ considered the particular situation of the pharmaceutical industry and to what extent refusals to meet orders might be justifiable. On the whole, it rejected claims by GSK that the specific circumstances of the pharmaceutical sector justified its refusal to supply. In detail the ECJ found that:

- parallel exports of medicinal products from an EU Member State where prices are low to one where prices are higher do benefit final consumers because parallel exports open up in principle an alternative source of supply to buyers and enhance product choice;
- parallel trade in medicines is liable to exert pressure on prices and consequently create financial benefits for social health insurance funds and for patients;
- manufacturers have some influence on the sale and/or reimbursement price of their medicines through their price negotiations with Member States so state price regulation did not completely remove pricing from the usual considerations of supply and demand.

The judgment appears to accept that a supplier's regulatory obligation to supply national demand can to some extent justify a limitation of supply to wholesalers, in that it may inform the analysis of what constitutes a reasonable refusal to honour an extraordinary order. The judgment is ambiguous on this point.

However, the ECJ side-stepped arguments put forward by GSK that it is necessary for pharmaceutical companies to limit parallel exports in order to avoid the risk of a reduction in their investment in research and development for new medicines.

The ECJ's judgment in this case limits the scope of stock allocation systems implemented by dominant companies, especially where they are aimed at preventing parallel trade by wholesalers. The pharmaceutical industry can nonetheless take comfort from the ECJ's finding that even dominant companies should be permitted to take steps that are reasonable and proportionate to the need to protect their own commercial interests, even if uncertainty remains concerning the definition of (extra)ordinary wholesaler orders and consequently of what constitutes an acceptable restriction of supply to a wholesaler. The ECJ has now offered some clarification, but the line between acceptable commercial behaviour and anti-competitive behaviour will remain in some cases a difficult one to draw.

The judgment concludes a series of legal proceedings relating to Glaxo's actions in Greece which began in 2000 and continued with the *Syfait* reference to the ECJ, Case C-53/03, in which, following an Advocate General's Opinion largely in favour of the pharmaceutical industry, the ECJ had refused to give judgment on procedural grounds. The conclusions reached here are less generous to the pharmaceutical industry than those reached by the Advocate General in the *Syfait* case, who had placed more emphasis on the special and regulated nature of the pharmaceutical market to justify restrictions on supply.

EU Commission consultation on parallel trade and counterfeiting

The European Commission ran a consultation between March and May 2008 in connection with counterfeit medicines. The Commission had initially suggested banning the repackaging of medicines as a possible option to assist in anti-counterfeiting. It commissioned a report from Europe Economics, published in October 2008, which examined parallel trade and its possible links with counterfeiting. The report concluded that parallel trade was of little benefit to consumers and recommended that both repackaging and relabeling of medicines be banned. The report highlighted possible safety concerns and the opportunities for counterfeiters to link into the legitimate supply chain by distributing what appear to be repackaged products or even by using genuine cartons discarded by parallel traders to distribute counterfeits. Not surprisingly, this report was supported by manufacturers but challenged by parallel traders who felt that it lacked evidence and credibility.

Since then, the European Commission has made clear that it does not intend to ban repackaging of medicines, saying that this is a legal activity within Europe. However, in December 2008 it proposed a new Directive to amend Directive 2001/83 regarding the prevention of entry into the legal supply chain of counterfeit medicines. The Commission states that the counterfeiting of medicines is a clearly increasing trend which threatens public health in the EU and that one of the reasons for counterfeits often remaining undetected is the complexity of the supply chain. While the draft Directive does not expressly address parallel trade as such, it does propose some measures which may impact on parallel trade and repackagers, for example:

- certain obligations for those in the supply chain other than wholesale dealers, such as brokers who do not handle product themselves;
- a legal basis for the Commission to mandate specific safety features on pack, such as a serialisation number or seal;
- a prohibition on removing, overlabeling or otherwise tampering with safety features on pack unless stringent conditions are met.

It also proposes many other measures, for example strengthened requirements for importation of active ingredients and more stringent audits and inspections. Further, this proposed Directive forms part of a wider pharmaceutical reform at European level which is to cover also the issues of information to patients and pharmacovigilance (safety monitoring).

Glaxo – dual pricing appeals awaited

There are a number of joined cases outstanding relating to Glaxo's dual pricing policy in Spain. In September 2006 the CFI gave judgment, finding that the Commission had been wrong to conclude that the object of Glaxo's pricing system was to restrict competition because the system sought to limit parallel trade from Spain. While the CFI had found that the dual pricing system did in fact restrict competition, it decided that the Commission did not take proper account of the specific nature of the pharmaceuticals sector nor examine with sufficient thoroughness whether the system might also have resulted in an economic advantage by contributing to innovation. Glaxo, the Commission and industry parties have appealed (Cases C-501, 513, 515 and 519), the cases being heard in March 2009. Judgment is awaited.

AstraZeneca appeal awaited

An appeal decision is also awaited on AstraZeneca's fine of EUR 60 million in 2005 relating to abuse of its dominant position regarding its LOSEC product. The European Commission had found that AstraZeneca had misused national regulatory procedures by selectively de-registering market authorisations for LOSEC capsules in Scandinavian countries and replacing the product with tablets in those countries, with the intent of blocking entry to those markets by parallel importers of the capsule product who would need to rely on such authorisations (in fact since then the regulatory rules have changed). Further, AstraZeneca was found to have misled a number of national patent offices and thereby secured additional patent protection for LOSEC through supplementary protection certificates, which delayed market access for generic products.

Regulatory – Plant protection

Commission -v- French Republic, Case C-201/06, 21 February 2008

Many parallel trade cases, particularly those within Europe, concern pharmaceutical medicines and the question arises as to what extent the same principles can be applied to other goods, especially those of a very similar nature, such as veterinary products and agrochemicals.

The ECJ gave judgment in February 2008 in a case concerning authorisations for imported plant protection products, which makes an interesting comparison with the case law relating to pharmaceuticals. Since the *Kohlpharma* case, Case C-112/02, it has been established that a parallel imported pharmaceutical product can benefit from the existing marketing authorisation granted to a reference product under a simplified procedure, despite the fact that there is no common origin with the reference product. Previously, it had been argued that a common origin was essential. Now, at least for pharmaceuticals, the test is a wider one as to whether the imported product is essentially the same. Although the common origin principle forms an important part of this test, it is not decisive.

The same issue arose in relation to plant protection products in this case brought before the ECJ by the European Commission. The marketing of plant protection products is governed by Directive 91/414/EEC, but this Directive does not contain any provision governing the conditions applicable to the granting of marketing authorisations for parallel imported products.

French national law had a requirement that for the purpose of obtaining an authorisation for a parallel imported plant protection product, the imported product must have a common origin with the reference product. "Common origin" meant that the products must be manufactured to the same formulation by the same company or by an associated undertaking or by a licensee. The imported product also had to be manufactured using the same active ingredients and have the same effect as the reference product, taking into account differences due to factors such as climate and plant health.

The Commission, relying on the *Kohlpharma* case sought a declaration from the Court that by stipulating this requirement as to common origin, France had failed to fulfil its obligations under Article 28 of the Treaty of Rome concerning freedom of movement of goods. The Commission argued that the requirement to show common origin went further than was necessary for protection of public health, animal health and the environment (one of the principle objectives of the Directive).

The ECJ disagreed, saying that in the area of plant protection the legislature had not adopted provisions similar to those in the pharmaceuticals field, which make it possible to verify whether a generic product is essentially identical to a reference product. It could not be said that the French national requirement to show common origin was a breach of Article 28. In *Kohlpharma*, the active ingredient had been sold to two different manufacturers in different Member States and the applicant for a parallel import authorisation was able to show that the medicinal product to be imported did not differ significantly from the reference product. While there was no reason why this rule could not also be applicable to plant protection products, this did not mean that a national law condition relating to common origin did constitute a barrier to free trade.

News

US bill to allow parallel trade

There are serious moves afoot to amend US law so as to allow parallel imports of prescription drugs. A bill entitled the "Pharmaceutical Market Access and Drug Safety Act of 2009" ("Official Title: A bill to amend the Federal Food, Drug and Cosmetic Act with respect to the importation of prescription drugs, and for other purposes") has been introduced and referred to Senate Health, Education, Labour and Pensions Committee. The bill has cross party support, being sponsored by Senator John McCain, among others.

The bill would allow the importation of prescription drugs by wholesalers and pharmacies that register with the Department of Health and Human Services. It would also create a criminal offence for the importation of drugs in "knowing" violation of a vast array of regulations issued under the Food and Drug Act, including violations of any registration requirement, falsifications of any record required to be kept or provided to the government, and violations of any other regulatory condition concerning drug importation. Violations would be punishable by criminal fines and imprisonment of up to ten years.

The bill's sponsors argue that the legislation would save the USD 50 billion, which includes USD 10 billion in savings for the US government, over the next ten years, bringing consumers immediate relief and ultimately forcing the pharmaceutical industry to lower drug prices.

Opinions are polarised as to whether or not the Bill will be passed by Congress. Around five years ago a similar attempt failed to progress, in spite of being passed by the Senate. The current efforts have recently gained increased momentum from support in President Barack Obama's budget. Making health provision cheaper is at the top of the Obama-Biden health care agenda. First on the list of reforms that the Obama Administration plan to phase in is:

"lower drug costs by allowing the importation of safe medicines from other developed countries, increasing the use of generic drugs in public programs, and taking on drug companies that block cheaper generic medicines from the market."

Nevertheless, a number of commentators remain sceptical about whether or not the bill will make it beyond committee level. Many of those involved in the US pharmaceutical industry are opposed to the bill, with a wealth of blogs and websites in which they vociferously critique the bill and its implications. Key arguments used by industry insiders include concerns about an increase in drug diversion, an increase in counterfeit drugs entering the legitimate supply chain and a fear that importers and dealers will absorb any price differences, rather than passing savings on to the consumer.

Even if the bill is passed, there remain many issues to consider, include the thorny subject of repackaging. Hopefully the US could learn from the European experience and avoid the many years of litigation which has occupied the industry here.

Commission report on pharmaceutical industry

To much fanfare the European Commission published its preliminary report in the Pharmaceutical Sector Inquiry on 28 November 2008. Although the report is work in progress, the Commission claims to be 'shocked' that originator companies use patent rights and other legal measures to delay entry by generic companies.

The report explores innovators' actions against other innovators and shortcomings in the patent and regulatory systems. However, it reserves most criticism for innovators' actions against generics. The Commission claims that innovators use a 'toolbox' of measures against generics, ie. the use of ancillary patents, patent litigation, patent settlements, regulatory intervention and follow-on product switching. At the same time, the Commission acknowledges that the patent system is the cornerstone of commercial innovation.

The Commission continues to evaluate the evidence seized in a series of raids on companies in January 2008 and in response to questionnaires issued to pharmaceutical companies and other stakeholders. For maximum effect it also launched further raids on some companies a matter of days before the preliminary report. Although the report is an interim step, its likely direction is clear: the Commission wishes to remove obstacles to generic entry. In doing so, it will explore that fine line between the existence of rights and when enforcement of those rights infringes competition law. DG Competition can take direct initiatives to bring infringement proceedings in specific cases. It can also be expected to issue guidelines, a form of 'soft' law, on some areas of concern. Other measures, such as patent and regulatory regime reforms would require wider support in the Commission and from Member States. Parallel trade issues were not addressed.

Views of stakeholders were due by 31 January 2009 and over 70 responses were received. A final report is expected later this year.

Belgian Competition decision

Belgium's Competition Council released a decision on appeal in April 2009 which reflects the ECJ's latest case law on abuse of a dominant position. The Council confirmed a previous refusal by the Council's prosecutor to deny interim relief to Belgian drug wholesaler Bofar, whose sole business was parallel export of drugs from Belgium. Bofar complained that a number of leading pharmaceutical companies had refused to supply it with some or all of the drugs it had ordered, in abuse of their dominant position, and further, that they had colluded to reduce parallel trade.

The Council confirms, in line with the ECJ's decision in the references from Greece (Cases C-468-478/06) that although pharmaceutical manufacturers may hold a dominant position in a particular market, they are entitled to protect their business interests by limiting supplies to wholesalers intending to parallel trade. Refusal to deal did not constitute abuse in itself. Further, Bofar had not established a clear breach of competition law, the manufacturers having decided to stop or reduce sales to Bofar independently over several years. A full investigation of the complaint on its merits is still under way.

Contact Details

AUSTRIA

CMS Reich-Rohrwig Hainz
Vienna

Dr. Egon Engin-Deniz

Intellectual Property,
Competition and Regulatory

T +43 1 404 43-1550

F +43 1 404 43-91550

E egon.engin-deniz@cms-rrh.com

BULGARIA AND ROMANIA

CMS Cameron McKenna EOOD
Sofia

J. David Butts

Intellectual Property,
Competition and Regulatory

T +359 2 921 99-48

F +359 2 921 99-19

E david.butts@cms-cmck.com

FRANCE

CMS Bureau Francis Lefebvre
Paris

Antoine Gendreau

Intellectual Property,
Competition and Regulatory

T +33 1 47 38-5649

F +33 1 47 38-5544

E antoine.gendreau@cms-bfl.com

BELGIUM

CMS DeBacker
Brussels

Veerle Raus

Intellectual Property,
Competition and Regulatory

T +32 2 743 69-78

F +32 2 743 69-01

E veerle.raus@cms-db.com

Tom Heremans

Intellectual Property,
Competition and Regulatory

T +32 2 743 69-78

F +32 2 743 69-01

E tom.heremans@cms-db.com

CENTRAL AND EASTERN EUROPE

CMS Cameron McKenna
Dariusz Greszta Spółka Komandytowa
Warsaw

Agnieszka Deeg

Intellectual Property,
Competition and Regulatory

T +48 22 52 05-698

F +48 22 52 05-556

E agnieszka.deeg@cms-cmck.com

GERMANY

CMS Hasche Sigle
Hamburg

Dr. Jens Wagner

Intellectual Property

T +49 40 376 30-357

F +49 40 376 30-40539

E jens.wagner@cms-hs.com

CMS Hasche Sigle
Frankfurt

Stefan Lehr

Competition and Regulatory

T +49 69 717 01-415

F +49 69 717 01-40717

E stefan.lehr@cms-hs.com

ITALY

CMS Adonnino Ascoli
& Cavasola Scamoni
Rome

Laura Opilio

Intellectual Property,
Competition and Regulatory
T +39 06 47 81-51
F +39 06 48 37-55
E laura.opilio@cms-aacs.com

THE NETHERLANDS

CMS Derks Star Busmann
Utrecht

Willem Hoorneman

Intellectual Property and Regulatory
T +31 30 21 21-727
F +31 30 21 21-157
E willem.hoorneman@cms-dsb.com

CMS Derks Star Busmann
Brussels

Robert Bosman

Competition
CMS Derks Star Busmann
T +32 2 650 04-52
F +32 2 650 04-59
E robert.bosman@cms-dsb.com

SPAIN

CMS Albiñana & Suárez de Lezo, S.L.P.
Madrid

Jesús Alfaro

Competition and Regulatory
T +34 91 45 19-300
F +34 91 44 26-045
E jalfaro@cms-asl.com

SWITZERLAND

CMS von Erlach Henrici Ltd.
Zurich

Dr. Kaspar Landolt

Intellectual Property,
Competition and Regulatory
T +41 44 285 11-11
F +41 44 285 11-22
E kaspar.landolt@cms-veh.com

UNITED KINGDOM

CMS Cameron McKenna LLP
London

Nick Beckett

Intellectual Property and Regulatory
T +44 20 73 67-2490
F +44 20 73 67-2000
E nick.beckett@cms-cmck.com

David Marks

Competition
T +44 20 73 67-2136
F +44 20 73 67-2000
E david.marks@cms-cmck.com

