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# EU Legal and Regulatory Update

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This section is intended to be a synopsis of recent developments and is not intended to be exhaustive. If any issue in this section is to be relied upon, specific advice should be sought. Please contact:

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# Parallel imports, trade marks and regulatory

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*Journal of Generic Medicines* (2007) 5, 79–84. doi:10.1057/palgrave.jgm.4950086; published online 24 July 2007

## PARALLEL IMPORTS

*Judgment of the Court of the European Communities, 26th April, 2007 (reference for a preliminary ruling from the court of Appeal — United Kingdom); Case C-348/04 Boehringer Ingelheim KG, Boehringer Ingelheim Pharma GmbH & Co. KG v Dowelhurst Ltd, and Glaxo Group Ltd v Swingward Ltd, and Glaxo Group Ltd, The Wellcome Foundation Ltd, v Dowelhurst Ltd, and SmithKline Beecham plc, Beecham Group plc, SmithKline & French Laboratories Ltd v Dowelhurst Ltd, and Eli Lilly and Co. v Dowelhurst Ltd.*

The second chamber of the European Court of Justice (ECJ) has issued its preliminary ruling on the repackaging of parallel-imported pharmaceutical products, which has been asked for by the Court of Appeal of England and Wales in a case involving Boehringer Ingelheim KG and Swingward Ltd.

A first preliminary ruling was issued in the same case (Case C-143/00 Boehringer Ingelheim and Others [2002] ECR I-3759) but the Court of Appeal of England and Wales, unsatisfied with the answers given by the Court, raised new questions before the ECJ about reboxing and repackaging.

This preliminary ruling refined the guidelines issued in Joined Cases C-427/93, C-429/93 and C-436/93 (The BMS case) in which the Court explained rules governing

the repackaging and/or reconditioning of parallel-imported products.

In the first Boehringer Case, the ECJ held that:

Article 7(2) of [the First Trademarks Directive]... must be interpreted as meaning that a trademark proprietor may rely on its trademark rights in order to prevent a parallel importer from repackaging pharmaceutical products unless the exercise of those rights contributes to artificial partitioning of the markets between member states.

Replacement packaging of pharmaceutical products is objectively necessary within the meaning of the court's case law 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.

A parallel importer must, in any event, in order to be entitled to repackage trademarked pharmaceutical products, fulfil the requirement of prior notice. If the parallel importer does not satisfy that requirement, the trademark proprietor may oppose the marketing of the repackaged pharmaceutical product. It is incumbent on the parallel importer [itself] to give notice to the trademark proprietor of the intended repackaging. In the event of dispute, it is for

the national court to assess, in the light of all the relevant circumstances, whether the proprietor had a reasonable time to react to the intended repackaging.

In this new preliminary ruling, the ECJ reminded the five requirements already set out by the BMS case in order to apply Art. 7(2) of directive no. 89/104 on trade marks, when repackaging consists of labelling the original packaging of a product. The holder may legitimately oppose further commercialisation of a pharmaceutical product imported from another member state in its original internal and external packaging with an additional external label applied by the importer, unless

- (1) it is established that reliance on trademark rights by the proprietor in order to oppose the marketing of the overstickered product under that trade mark would contribute to the artificial partitioning of the markets between member states;
- (2) it is shown that the new label cannot affect the original condition of the product inside the packaging;
- (3) the packaging clearly states who overstickered the product and the name of the manufacturer;
- (4) the presentation of the overstickered product is not such as to be liable to damage the reputation of the trade mark and of its proprietor; thus, the label must not be defective, of poor quality or untidy and
- (5) the importer gives notice to the trademark proprietor before the overstickered product is put on sale, and, on demand, supplies him with a specimen of that product.

Concerning the importance of style and manner of the repackaging, the Court once again referred to its reasoning in the BMS case:

the condition that the repackaging of the pharmaceutical product, either by reboxing the product and re-applying the trademark

or by applying a label to the packaging containing the product, be necessary for its further commercialization in the importing member state, as one of the conditions which, if fulfilled, prevent the proprietor under Article 7(2) ... from opposing such commercialization, is directed solely at the fact of repackaging and not at the manner and style of the repackaging.

Then, the ECJ specified one of the circumstances considered in the BMS decision, under which the parallel importation of repackaged goods may be stopped if the reputation of the holder or its trade mark is likely to be harmed. Here, the ECJ held that:

The condition that the presentation of the pharmaceutical product must not be such as to be liable to damage the reputation of the trademark and of its proprietor — as a necessary condition for preventing the proprietor, pursuant to Article 7(2), from legitimately opposing further commercialization of a pharmaceutical product, where the parallel importer has either reboxed the product and re-applied the trademark or applied a label to the packaging containing the product — is not limited only to cases where the repackaging is defective, of poor quality or untidy.

The Court also stated that it is up to the national courts to decide whether a parallel importer is damaging a trade mark's reputation when it

- does not affix the trade mark to the new exterior carton;
- applies either its own logo or a house style or get-up, or a get-up used for a number of different products;
- positions the additional label so as wholly or partially to obscure the proprietor's trade mark or
- fails to state on the additional label that the trade mark belongs to the proprietor or prints the name of the parallel importer in capital letters.

Moreover, the ECJ then specified that the burden of proof is on the parallel importer to state that

- reliance on trademark rights by the proprietor in order to oppose the marketing of repackaged products under that trademark would contribute to the artificial partitioning of the markets between member states;
- the repackaging cannot affect the original condition of the product inside the packaging;
- the new packaging clearly states who repackaged the product and the name of the manufacturer;
- the presentation of the repackaged product is not such as to be liable to damage the reputation of the trademark and of its proprietor; thus, the repackaging must not be defective, of poor quality or untidy;
- the importer must give notice to the trademark proprietor before the repackaged product is put on sale and, on demand, supply [it] with a specimen of their packaged product.

Further, the Court logically noted that if one of the Bristol Myers conditions is not fulfilled, the trademark owner may oppose the marketing of the products even if prior notice has been given.

Finally, the ECJ held that the holder's rights are damaged if it has not been given prior notice. As a consequence, the national court may decide a proportionate sanction including awarding damages.

This preliminary ruling shows the will of the ECJ to construe its role to the interpretation of Community Law and to let national courts applying Community Law to specific circumstances of the case.

Finally, one has to remark that upon the general issue of parallel imports and specifically in the pharmaceutical field since the Bayer Case (C-2/01 and 3/01), the extent of protection shifts slightly in favour of the trademarks owner.

***England and Wales High Court; 5th March, 2007, AAH Pharmaceuticals Ltd & Others v Pfizer Ltd & Unichem Ltd, [2007] EWHC 565(Ch)***

As the reader already knows, until recently pharmaceuticals were essentially supplied through number of wholesalers. But nowadays producers are changing their supply policy and look for direct control upon the distribution of their products, following a general economic trend, seeking closeness to the customer, to eliminate go-betweens that erode their margins and without saying, fighting against parallel importation of their own products. Indeed, wholesalers do not agree with such policies that jeopardise their business.

In this case, Pfizer Ltd, one of the main pharmaceutical producers, decided to retail products directly to pharmacies through Unichem Ltd, a former wholesaler in charge of the logistics now, and advised the other wholesalers that they would not be provided anymore with Pfizer products.

Then the wholesalers brought a complaint before the UK Office of Fair Trading (OFT) for breach of both national and EU competition law, to obtain an interim injunction to order Pfizer to supply them. The OFT refused to grant the order as (i) infringement of Art. 81 prohibiting cartels or Art. 82 of the EC Treaty preventing the abuse of dominant positions was not obvious and (ii) there was insufficient proof of irresistible harm.

The wholesalers then applied for an interim injunction before the High Court on the same grounds.

Without examining the case on the merits, the High Court balanced the consequences of the granting of the injunction with the risk of damaging the market structure raised by Pfizer's new distribution policy.

The High Court finally considered that: 'the disruption and reputational damage likely to arise from an injunction for Pfizer and UniChem were real and not readily capable of compensation'.

Assuming that this would be the less damaging solution, the Court decided to refuse to grant the injunction.

## TRADE MARKS

### ***ECJ, C-412/05 P, Alcon Inc v OHIM, Biofarma SA***

In 1998 Alcon applied for the community trade mark TRAVATAN for ophthalmic pharmaceutical preparations.

Biofarma raised an opposition against this application, alleging a likelihood of confusion with its prior Italian word mark TRIVASTAN for ‘pharmaceutical, veterinary and hygiene products; dietary products for infants or patients; plasters; materials for dressings; tooth fillings and dental impressions; disinfectants; herbicides and pesticides’.

Alcon asked Biofarma to prove its use of the trade mark in the relevant field. Alcon provided proof of use for a ‘peripheral vasodilator intended to treat peripheral and cerebral vascular disturbance and vascular disorders of the eye and ear’.

The Opposition Division considered that there was a likelihood of confusion and therefore refused Alcon’s application.

Alcon appealed before the Board of Appeal of the OHIM.

In a decision upheld both by the Board of Appeal and the Court of First Instance, Alcon appealed on various grounds, particularly challenging the notion that in respect of pharma products such as those in question, which were available in part on prescription, the relevant consumer should be the public at large rather than healthcare professionals.

In a previous issue of this journal (April 2007, 4(3), 222–229), we commented on the Advocate General’s opinion on this matter. She proposed the ECJ to dismiss the appeal, and the ECJ followed the opinion, whereas it admits that the Court of First Instance had not clearly determined the public to take into account in order to assess a likelihood of confusion.

Alcon raised, and was followed by the Advocate General on that matter, that the relevant public in the field of ophthalmologic products was composed of healthcare professionals rather than the average consumer, although the Court of First Instance only focused on the average customer in order to establish the likelihood of confusion.

The ECJ admitted that Alcon was partially right and that the Court of First Instance ruling was vitiated related to the public to take into consideration, as it first admitted that this public was composed of both end-users and healthcare professionals, but did not take that assessment into account in his following reasoning.

The ECJ, however, concluded that this mistake could not bring the Court to dismiss the judgment. The Court of First Instance found a likelihood of confusion in the mind of end-users, which had to be taken into account anyway — as in Italy, some ophthalmologic preparations are available on prescriptions whereas others are delivered ‘over the counter’ — and this was sufficient to establish the risk of confusion.

## REGULATORY

### ***French Administrative Supreme Court (Conseil d’Etat), 25th May, 2007, no. 288186***

The French Administrative Court cancelled two decisions of the French Health Authority (AFSSAPS), one granting a Marketing Authorisation for the so-called generic product and the other registering this product as a generic on the *repertoire des groupes génériques*, which is an official publication of all generic products classified by groups referring to an active substance.

According to the French Administrative Court, the product at stake could not be considered as bioequivalent to the reference product, whereas Art. L. 5121-1 5° of the French Health Code (*Code de la Santé Publique*) requires a product to be bioequivalent to another product in order

to be considered a generic of this reference product:

'generic medicinal product' shall mean a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal

product has been demonstrated by appropriate bioavailability studies.

Indeed, this text implements in French Law Art. 10 2. b) of Directive 2001/83 CE as modified by further statutes.

Therefore, the French Administrative Court ordered the French Health Authority to withdraw this product.