Repackaging of pharmaceutical products by parallel importers: ECJ's judgment in Case C-348/04 *Boehringer Ingelheim and Others v Swingward and Others*

BRUSSELS
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On April 26, the European Court of Justice ("ECJ") rendered its judgment in Case C-348/04 *Boehringer Ingelheim and Others v Swingward and Others* (the "Judgment"),[1] clarifying the scope of trademark owners' rights in relation to importers that tamper with or replace the original packaging of pharmaceutical products bearing a trademark. Modification or replacement ("repackaging") of the original packaging of imported products is often required in the pharmaceutical sector because of differing national regulations concerning, for example, box sizes. Importers have tended to exploit this situation by repackaging products in packaging displaying their own trade dress, and generally presenting the imported products as forming part of their own range of products. The ECJ's ruling sheds light on a number of fundamental issues left unanswered by its previous judgments in this area. The ECJ departed from the Opinion of Advocate General Sharpston and ruled in favour of trademark owners on all points raised, except for one.

Reflecting the ECJ's consistent case law,[2] Article 7(2) of Council Directive 89/104, provides that repackaging may constitute a "legitimate" reason for a trademark owner to oppose further marketing of repackaged pharmaceutical products.[3] As the ECJ recalled in *Boehringer I*: *"the specific-subject matter of a mark is to guarantee the origin of that product bearing that mark and […] repackaging of that product by a third party without the authorization of the proprietor is likely to create real risk for that guarantee*

[1] Cleary Gottlieb represented *Boehringer Ingelheim KG* and *Boehringer Ingelheim Pharma GmbH & Co.* KG.

[2] Case 102/77 *Hoffman la Roche & Co. AG v Centrafarm Vertriebsgesellschaft Pharmazeutischer Erzeugnisse GmbH* [1978] ECR 1139.

[3] Article 7(2) of the Council Directive 89/104/EEC of 21 December 1988 to approximate the laws of the Member States relating to trade marks (OJ 1989 L 40/1) provides that a trademark owner is entitled to prohibit the use by third parties of his trademark on goods sold in the Community *"[…] where there exist legitimate reasons […], especially where the condition of the goods is changed or impaired after they have been put on the market."*

of origin".[4] But the rights of trademark owners are not absolute: the so-called *Bristol Myers* conditions provide that repackaging must be allowed if:[5]

- the repackaging is necessary to permit importation (for example, because of national rules or established medical prescription practices based on standard package sizes);
- the repackaging does not adversely affect the original condition of the product;
- the presentation of the repackaged product is not such as to be liable to damage the reputation of the trademark and of its owner;
- the new packaging states by whom the product has been repackaged and manufactured;
- the trademark owner receives prior notice and a specimen of the repackaged product before it is put on sale.

The Judgement clarifies the interpretation of these conditions and addresses the allocation of the burden of proof between trademark owners and parallel traders. Further, the Judgement provides that several types of repackaging, such as "debranding" (removal of the original trademark) and "cobranding" (featuring the importer's trademark alongside the original trademark) fall within the scope of application of the *Bristol Myers* criteria.

I. BACKGROUND

The dispute concerned alterations to the packaging of pharmaceutical products of a number of companies by parallel importers for the purpose of commercializing those products in the United Kingdom. The alterations consisted in either attaching to the original packaging a label ("overstickering") setting out certain critical information, such as the name of the parallel importer and its parallel import license number, where wording in languages other than English remained visible and the trademark was not covered over, or repackaging of the product in boxes designed by the parallel importer ("reboxing"), either bearing the original manufacturer's trademark or simply the generic name of the product. In the latter case, the packaging inside the box bore the original trademark, but a self-adhesive label was attached indicating the generic name of the product and the identity of the manufacturer and the parallel import license holder. The pharmaceutical companies brought an action before the High Court of Justice of England

[4] Case C-143/00 *Boehringer Ingelheim and Others v Swingward and Others* [2002] ECR I-3759, ¶ 29.

[5] Joined cases C-427/93, C-429/93 and C-436/93 *Bristol-Myers Squibb e.a. v Paranova* [1996] ECR I-3457.

and Wales, which referred a number of questions to the ECJ for a preliminary ruling. Following the ECJ's findings,[6] the High Court ruled in favour of the trademark owners in the main proceedings. This decision was appealed to the Court of Appeal, which again referred the matter to the ECJ.

II. THE JUDGMENT

In response to the Court of Appeal, the ECJ held the following:

A. OVERSTICKERED PACKAGES

The importers and the Advocate General argued that the Bristol Myers criteria apply only to reboxing, as overstickering does not involve a use of the trademark, which is liable to impair the guarantee of origin, because there is no risk that the original condition of the product will be affected. However, the ECJ followed the line of reasoning in *Boehringer I* and rejected those arguments.[7] It clarified that the Bristol Myers conditions apply also to overstickering of imported pharmaceutical products, since reboxing and overstickering can be prejudicial to the specific subject matter of the mark and create real risks for the guarantee of the origin (¶¶ 29, 30, 32).

B. PRINCIPLE OF NECESSITY

The ECJ further clarified the scope of the necessity test laid out in its previous case law,[8] holding that the test applies only to the fact of repackaging, namely the decision to rebox or oversticker, and does not extend to the precise manner and style of repackaging adopted by the parallel importer (¶ 39).[9] Nevertheless, this solution is legally questionable since the principle of proportionality requires that *"a particular method of repackaging cannot be regarded as necessary if another method which interferes less with the trademark owner's rights will suffice to give the parallel importer*

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[6] See Case C-143/00 *Boehringer Ingelheim and Others v Swingward and Others*.

[7] Referring to the definition of "repackaging" at ¶ 7 of the *Boehringer I* judgment ("*any act affecting the original packaging, including the modification of the original labels, the addition of new labels, or the use of new packaging, regardless of whether the original trademark has been reaffixed on the new packaging*"), the ECJ held that the above definition also included the concept of overstickering (see ¶ 28 of the Judgment).

[8] See, for instance, Case C-379/97 *Pharmacia & Upjohn SA v Paranova A/S* [1999], ECR I-6927, ¶¶ 37-39, 43-44.

[9] The Advocate General had held in his Opinion that applying the test of necessity on the precise manner and style of repackaging would place an intolerable burden on national courts. The ECJ, also referring to the judgment of the EFTA Court in Case E-3/02 *Paranova v Merck* [2003] EFTA Court Report 2004, endorsed the Advocate General's view and ruled against the trademark owners on the point.

effective access to the market in the importing State".[10] As a result, it is arguable that a particular manner and style of repackaging should not be deemed necessary if alternatives are available that interfere less with trademark owners' rights.

C. BURDEN OF PROOF

The ECJ further clarified that parallel traders bear the burden of proving that all the Bristol Myers conditions are satisfied. This is a significant point since previous judgments suggested indirectly that the burden of proof should be a matter for national law. Nevertheless, with respect to two of those conditions (*i.e.* that the original condition of the product is not affected, and that the repackaging does not damage the reputation of the original trademark and of its owner), the ECJ held that the standard of proof is lower than in relation to the other conditions. Specifically, the importer must provide evidence that leads to a reasonable presumption that these conditions have been fulfilled. It will then be for the proprietor of the trademark to prove that the condition is affected or the trademark's reputation damaged (¶ 54).

D. DAMAGE TO REPUTATION

The ECJ ruled in favor of a broad interpretation of the condition that the presentation of the product must not be such as to be liable to damage the reputation of the trademark and of its owner, holding that defective, poor quality, or untidy packaging are mere illustrations of presentation that may satisfy this condition (¶ 44).[11] The Court specified that methods of repackaging such as debranding, cobranding, additional labels obscuring the original trademark, failing to state on additional labels that the original trademark belongs to the proprietor, or printing the name of the parallel importer in capital letters are in principle all liable to damage the reputation of the trademark. Nevertheless, the ECJ said whether the trademark's reputation has been damaged is a question of fact for the national court to decide on a case-by-case basis (¶ 47). As the ECJ did not provide any further guidance on this point, it is likely that this will be an issue of further litigation and divergence of opinion between national courts.

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[10] See Opinion of Advocate General Jacobs in combined cases C-443/99 *Merck Sharp & Dohme GmbH v Paranova Pharmaceutica Handels GmbH* and C-143/00 *Boehringer Ingelheim and Others v Swingward and Others*, ¶ 111; *Bristol-Myers Squibb*, cited in note 3, ¶ 55 and Case C-349/95 *Loendersloot v Ballantine* [1997] ECR I-6227, ¶ 46.

[11] Specifically, the ECJ reasoned, at ¶ 43, that also those circumstances can be *"such as to affect the trademark's value by detracting from the image of reliability and quality attaching to such a product and the confidence it is capable of inspiring in the public concerned […]"*.

E. LACK OF PRIOR NOTICE

Finally, the ECJ ruled that the failure of a parallel importer to give prior notice to the trademark proprietor constitutes an infringement of the proprietor's rights (¶ 56). The ECJ also held that the trademark owner's right to prevent imports of products marketed without prior notice is no different to its right to prevent imports of spurious goods (¶ 61) and that national measures that entitle the owner to claim financial remedies in such a situation are not in themselves contrary to the principle of proportionality (¶ 63). While the national sanction must be assessed by national courts on a case-by-case basis, in the light of the extent of the damage to the trademark owner and in accordance with the principle of proportionality (¶ 63), the ECJ specified the necessity that the sanction be *"sufficiently effective and a sufficient deterrent to ensure that Directive 89/104 is fully effective"*(¶ 64).

III. IMPLICATIONS OF THE JUDGEMENT

The Judgment is welcome insofar as it provides a clear answer to a number of fundamental questions. Nevertheless, significant litigation will still undoubtedly arise concerning the factors that may damage a trademark's reputation. While the Judgment provides guidance in principle, national courts must decide this point on a case-by-case basis. Disappointed parties could thus well be tempted to seek the ECJ's guidance in order to obtain support for their position.

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