FREEMOVEMENT AND PARALLEL TRADE IN THE PHARMACEUTICAL SECTOR

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Article 3(c) of the EC Treaty sets as one of the fundamental objectives of the EC the creation of an internal market characterised by the abolition of obstacles to the free movement of goods.

The merits of this objective are understandable, but does it make sense in a sector where prices are directly or indirectly regulated by national governments?

The European Court of Justice has on various occasions answered in essence that its duty is to apply the law as it stands, regardless of whether prices in the pharmaceutical sector are regulated nationally. In *Merck v. Primecrown* (1996), it stated that even the imposition of national price controls "cannot justify a derogation from the principle of free movement of goods."

The Court of Justice has thrown the ball back to the Member States on the issue of harmonizing national price regulations. The Court has said that this harmonization cannot be achieved by means of the Court's case law. The Court stated in *Merck v. Primecrown* that "[i]t is well settled that distortions caused by different price legislation in a Member State must be remedied by measures taken by the Community authorities […]". (para 47).

The case law applying the principle of the free movement of goods has thus developed independently of any consideration of whether the regulatory context ought to influence its application.

The Commission published a Communication on December 30, 2003, summarizing the state of the case law in the two principal fields of relevance, namely the national regulatory requirements that can be imposed before authorizing imports of products lawfully traded in another Member State, and, secondly, the principles applicable to parallel traders' tampering with the original packaging of imported products lawfully traded in another Member State.

I will first review developments in the case law in the field of national authorizations required to import products.

The basic principle is that any restriction on the importation of a product lawfully traded in another Member State constitutes a restriction on the free movement of goods prohibited by Article 28 of the EC Treaty.

However, such a restriction may be lawful under Article 30 of the EC Treaty if it is necessary to protect public health and is the measure that achieves that purpose whilst restricting trade the least. In other words, the measure must be proportionate to the objective of protecting public health. (See case C-112/02 *Kohlpharma* of April 1, 2004, as the most recent pronouncement to this effect).

Concerning the marketing of pharmaceutical products in a Member State, Article 6(1) of Directive 2001/83 provides that no product may be placed on the market of a Member State unless it has obtained a marketing authorisation from that State or pursuant to the centralised procedure.

Articles 8 to 11 of the same Directive explain the procedure, documents and information necessary for the grant of a marketing authorisation.

There are derogations from these requirements for generic versions of products already covered by a marketing authorizations. Directive 2004/27 of March 31, 2004, which came into force on April 30, 2004, introduced the most recent amendments in this respect.

The Court has also introduced an exception to the requirements contained in the Directive for imported products lawfully marketed in the exporting Member State, provided it can be shown in each case that compliance with the requirements of the Directive is not necessary for the protection of public health.

The first case in the Court's long line of judgments on this topic was Case 104/75 ***De Peijper*** (1976] ECR 613), where the Court held that the authorities in the importing Member State may not require an importer to obtain a marketing authorization for an imported product already covered by a marketing authorization in the exporting Member State, if the importing authorities already have all the necessary information to determine the imported product's safety and efficacy because it is in every respect the same as a product already sold in the importing Member State or, if there are any differences, these have no therapeutic effect, in other words where the products are essentially identical.

Two products should be considered essentially identical, in particular, when they contain, qualitatively and quantitatively, the same active ingredients, have the same pharmaceutical form, are bioequivalents, and do not appear, in the light of scientific knowledge, to differ as regards their safety and efficacy (Case C-368/96 ***Generics*** [1998] ECR I-7967).

The most recent case on this topic which bridges the almost 30-year gap since *De Peijper* was rendered on April 1, 2004 in Case C-112/02 ***Kohlpharma***. Chiesi sells Jumex in Italy, manufactured using the same active ingredient used to manufacture Movergan, sold in Germany by Orion. In both cases, the medically active ingredient comes from the same Hungarian company Chinoin. However, while Orion obtains that active ingredient via a supply agreement with Chinoin, Chiesi obtains it via a licensing agreement with Chinoin.

Since the two products contain exactly the same active ingredient, Kohlpharma wished to import Jumex into Germany based on an extension of the marketing authorization for Movergan.

The German authority refused the request. It pointed to the Court's judgment in Case C-201 ***Smith & Nephew and Primecrown*** ([1996] ECR I-5819), saying that the Court had held that an existing marketing authorization for a domestic product could be extended to an imported product only if the two products have a common origin, or if the different manufacturers of those products are part of the same corporate group or, at least, manufacture those products pursuant to agreements concluded with the same licensor. It said this was not the case here, since Chiesi and Orion were not part of the same corporate group and only the former was linked to Chinoin by a licensing agreement.

The Court noted that the two products were manufactured using the same active ingredient supplied by the same undertaking and took it as given that the safety and efficacy of the two products did not differ significantly. The Court held that the importing authority could not refuse the extension of an existing marketing authorization in the importing Member State to the imported product, simply on the grounds that the two products do not have a common origin, if such extension could be made without any risk to public health.

The Court noted that common origin can be an important factor in determining if two products are essentially similar. However, common origin cannot be determinative of that question.

Importantly, the Court held that it is for the importer to demonstrate based on available and accessible information that the imported product does not differ significantly from the domestic product. However, where the importer does not have access to all this information, he should provide data that at least makes it plausible that the two products do not differ significantly in terms of safety and efficacy. It is then the duty of the importing authority to decide the issue, using all the necessary information already in its possession and the information it can obtain by cooperating with other national health authorities.

This idea of a national authority cooperating with an authority in another Member State was recently introduced into the Community Code with respect to the marketing of a generic in a Member State in which the reference product is not sold, but in circumstances where the reference product is or has been authorized in another Member State (Article 10 of Regulation 2001/83, as amended).

(As an aside, this provision renders the Court's judgment in Case C-223/01 *AstraZeneca* of October 16, 2003, without object, as the Court there held that the then existing provisions of Directive 2001/83 required that there be at least a valid marketing authorization in force for the reference product, even though the reference product need not be actually marketed there, before a generic product could benefit from the abridged authorization procedure).

This provision does raise an interesting issue with respect to parallel traded products. The next logical case to be argued before the Court of Justice could be one where a product is imported in a country where there is no existing marketing authorization for a substantially similar product. Based on the new provision concerning generics, an importer might argue that a separate marketing authorization in the importing Member State is not necessary because the imported product is already covered by a marketing authorization in the exporting Member State. In other words, the exporter could try to seek to extend the existing marketing authorization for that product in the exporting Member State to the importing Member State.

Such a case would put the entire national authorization system into question. Directive 2001/83 contemplates the availability of the mutual recognition procedure to the "holder of the authorization", *i.e.,* not to the parallel trader. A parallel trader requesting a parallel import licence in a country where the manufacturer has not yet obtained a marketing authorization

would be overtaking the manufacturer in the race to access national markets with the product in question.

But whatever the situation, the Directive still contemplates that a separate authorization must be obtained in each Member State before a product can be sold there. The only exception is for generic products that can rely on the abridged procedure by referring to a reference product in another Member State.

It is therefore arguable that the current scheme of Directive 2001/83 does not contemplate a parallel trader asking for the marketing authorization for the product in question in the exporting country to be extended to the importing country.

However, a possible application of the principles in *Kohlpharma* could lead the Court to hold that the authority in the importing Member State should cooperate with the authority in the exporting Member State to determine if the marketing of the imported product in the importing Member State poses a risk to public health. If not, refusing the grant of a parallel import licence might be deemed not necessary for the protection of public health, and therefore in violation of Article 28 of the EC Treaty.

Note also that Advocate General Tizzano in his Opinion in ***Kohlpharma*** (points 78 and 79) suggests that generic products may raise greater safety issues than parallel traded products, given that parallel traded products will always benefit from a marketing authorization already granted somewhere in the EU, which may not be the case for generics. As a result, the cooperation between authorities contemplated for generics in Directive 2001/83 as amended might arguably apply a fortiori to parallel traded products.

In other words, following this logic, it should be easier for parallel traded products to obtain an extension in the importing Member State of an existing marketing authorization elsewhere, than for generics to benefit from the abridged procedure.

Turning back to the other questions raised by the judgment in *Kohlpharma*, the issue of whether the common origin of two products should be a necessary condition for the extension of the marketing authorization from a domestic product to an imported product arose in ***Smith & Nephew and Primecrown*** ([1996] ECR I-5819).

The Court held in that case that the production of all the documents and information required by (now) Directive 2001/83 as a pre-condition to the granting of a marketing authorization is justified to protect public health only for products sold in a country for the first time.

The Court held that a product lawfully sold in a Member State and imported into another Member State as a parallel import of a product already covered by a marketing authorization in the importing Member State could not be deemed to be placed on the market for the first time.

The Court noted that, in the case at hand, the products had not been produced by companies within the same corporate group, unlike the products at issue in *De Peijper*, but held that the situation was similar because the products had a common origin as they were manufactured pursuant to agreements concluded with the same licensor.

However, the Court did not mean to establish the requirement of common origin as a prerequisite to a finding that two products should be deemed essentially similar. Rather, common origin was a factor that could facilitate that conclusion.

This was clear, given that the Court added that the importing authority must verify in each cse that, despite their common origin, the two products, if not identical in all respects, have at least been manufactured according to the same formulation, using the same active ingredient, and that they also have the same therapeutic effects. If necessary, the authority in the importing Member State should cooperate with the national authority in the exporting Member State in order to obtain all the necessary information to make this determination.

If that is established, the Court explained that the imported product should be deemed to have already been placed on the market in the importing Member State and must be entitled to benefit from the marketing authorization covering the product already sold there, unless there are other imperative considerations relating to the effective protection of the life and health of humans that militate against that.

On the contrary, if the national authority concludes that the imported product does not satisfy all the criteria just described, the product cannot be regarded as having already been placed on the market in the importing Member State and the importer must satisfy all of the conditions set forth in Directive 2001/83 to obtain a new marketing authorization.

In sum, it seems evident that the argument that common origin was a necessary condition for a marketing authorization for one product to be extended to another product was not supported by the Court's judgment just described.

No different conclusion can be drawn from the Court's judgment in ***Rhône-Poulenc Rorer and May & Baker*** (Case C-94/98 [1999] ECR I-8789). Rhône Poulenc replaced the existing version of **Zimovane** by a newer version in the importing Member State, which was the United Kingdom. The marketing authorization covering the older version in the United Kingdom was revoked. The older version continued to be imported from other Member States into the United Kingdom.

The Court found that that the two versions were essentially identical, and that the existing parallel import licences should continue to be valid, even though the new version was developed and introduced in order to provide a particular benefit to public health that the older version did not provide and that that particular benefit would not be achieved if the old and new version were both on the market in the United Kingdom at the same time.

Importantly, the Court held that the parallel import licences should lapse only if the national authorities considered that, in normal conditions of use, the imported product posed a risk as to quality, efficacy or safety.

Other cases of the Court that I will comment briefly confirm these judgments and reflect variations in the application of the principles just discussed, namely that any regulatory requirement restricting the importation of products must be no more than necessary to protect public health.

Case C-172/00 ***Ferring*** ([2002] ECR I-6891 concerned the sale in Germany of a product called Minrin Spray by Ferring. The same product was imported into Germany by Eurim-Pharm. Ferring decided to sell a new version of the spray that no longer required the spray to be stored in a cool place. The Court held that German law could not provide for the automatic invalidity of the import license for Eurim-Pharm's imported Minrin Spray simply because Ferring had withdrawn its corresponding product from the German market.

The Court held that the parallel import license must remain valid unless it can be shown that this raises issues for public health. For example, if the product withdrawn from the importing

Member State is replaced by a newer version, one must assess whether the coexistence of the older imported version with the newer version raises issues for public health.

The Court reasoned that Ferring's withdrawal of Minrin Spray did not indicate any problems with its quality and efficacy. Indeed, the product continued to be sold in other Member States. Pharmacovigilance could be satisfied through cooperation with other Member States where a marketing authorization for the old product was still in force. Any health issue arising from the co-existence of the old and new product could be monitored, and did not require the automatic withdrawal of the licence for the old product.

In this connection, I would recall the Court's judgment in Case C-94/98 ***Rhône-Poulenc Rorer, May & Baker*** that health risks preventing the granting of a parallel import licence should relate to conditions of normal use. The Court may very well take the same approach to health risks justifying the withdrawal of a parallel import licence.

This case was confirmed by the Court in two judgments of May 8, 2003, in Case C-15/01 ***Paranova Läkemedel*** and C-113/01 ***Paranova Oy***, which concerned Losec. The companies selling Losec in Sweden and Finland obtained revocation of the corresponding marketing authorization because they intended to sell a new version of Losec, which was in tablet as opposed to capsule form. The Swedish and Finnish authorities also revoked the corresponding parallel import licences. They argued that they would otherwise be unable to comply with pharmacovigilance requirements. The Court simply repeated its holding in *Ferring*.

I shall now turn to the other topic addressed by the Commission's communication on parallel imports, namely the extent of the rights of parallel importers to modify the original packaging of imported products.

The principle that Article 28 bars any restriction on imports is the same as in the context of marketing authorizations discussed above. However, national regulations may be acceptable under Article 30 not because they are no more than necessary to protect public health, but rather because they are no more than necessary to protect the manufacturers' trademark rights.

A manufacturer has legitimate grounds to ensure that the contents of imported products contained in packaging that has been tampered with and that bears the manufacturer's

trademark have not been altered in a way that would undermine the trademark's indication of origin. This is central to a trademark right, which is designed to guarantee to consumers that products bearing the manufacter's trademark have been manufactured under the control of the manufacturer and that the products are all of the same quality.

In 1978, the Court held in Case 102/77 *Hoffman-la Roche v. Centrafarm* ([1978] ECR 1139) that an importer can remove a third party's product from its original packaging and place it in new packaging on which the importer has reaffixed the third party's trademark, provided that the importer could show that (i) it has not adversely affected the original condition of the product, (ii) it has warned the trademark holder in advance of the proposed repackaging, and (iii) it has identified the repackager on the new packaging.

Importers have exploited this holding to argue that EC law gives them a right to do whatever they wish to the original packaging of a pharmaceutical product, subject only to the three conditions just mentioned.

Trademark owners, on the other hand, have consistently claimed a right to have their products reach end-consumers in their original packaging, modified only to the extent necessary to permit their free circulation between EC Member States.

The Court sided with the trademark owners, holding in Case C-379/97 *Upjohn v. Paranova*, that Article 30 allows a trademark owner to exercise his national rights to block the sale of an imported product bearing his trademark, if its original packaging has been modified in a way that is not necessary to permit its sale in the importing Member State.

On April 23, 2002, the Court confirmed this principle and other important points in Cases C-443/99 *Merck, Sharp & Dohme v. Paranova* and C-143/00 *Boehringer Ingelheim v. Swingward and Dowelhurst*.

Surprisingly, the Commission describes the state of the law in the Communication in a way that reflects the Court's holding in *Hoffman-La Roche*, thereby suggesting that parallel traders may do what they wish provided they comply with the conditions set forth in that judgment.

It is therefore necessary to go back to what the *Merck* and *Boehringer* judgments say.

The Court stated that any form of repackaging of a product by a third party without the authorization of the proprietor "is likely to create real risks" for the guarantee of origin, which is a trademark's essential function . The Court also stated that a trademark owner's right to oppose the repackaging of products bearing its mark arises without needing to assess "the actual effects of the repackaging by the parallel importer".

The Court confirmed that a parallel trader can repackage a product when such repackaging is "objectively necessary" for the sale of the product in the importing Member State, taking account of the circumstances prevailing at the time of marketing in that state.

Objective necessity would exist if, without such repackaging, the imported product's access to the market of the importing state would be hindered. By contrast, objective necessity would be absent if the importer "is able to reuse the original packaging for the purpose of marketing in the Member State of importation by affixing labels to that packaging", provided the re-labeled products have effective access to the market concerned.

The Court also confirmed that repackaging is not objectively necessary "if it is based solely on the parallel importer's attempt to secure a commercial advantage".

The Court added that consumer resistance to relabelled packaging does not always constitute an impediment to effective market access, such as to make replacement packaging necessary, but that "there may exist on a market, or on a substantial part of it, such strong resistance from a significant proportion of consumers to re-labeled pharmaceutical products that there must be held to be a hindrance to effective market access. In those circumstances, repackaging of the pharmaceutical products would not be explicable solely by the attempt to secure a commercial advantage. The purpose would be to achieve effective market access".

The Court did not address the issue of proportionality, other than to state that the use of new packaging cannot be justified if an importer "is able to reuse the original packaging for the purpose of marketing in the Member State of importation by affixing labels to that packaging". The Advocate General added to the Court's statement by confirming 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 effective market access.

The Court's judgment contains no clear reference to generic rebranding constituting trademark infringement other than the statement that "the change brought about by <u>any</u> repackaging of a trade-marked product – creating by its very nature the risk of interference with the original condition of the product – may be prohibited by the trade mark proprietor". Also, the Court referred in the judgment to "repackaging" and uses this term of the judgment to cover generic rebranding.

The Advocate General was clearer on this point, stating that: "repackaging a product which bears a trade mark, whether or not the trade mark is re-affixed to the new external packaging or <u>simply removed and not replaced</u>, is a particularly intrusive form of trade mark infringement." The Advocate General concluded that the principles governing repackaging apply to generic rebranding as it is equally liable to prejudice the trademark's guarantee of origin.

Although these principles are clear, the Court of Appeal in London is preparing to send another set of questions to the Court of Justice in the same case to clarify in particular the following questions:

- Does the test of necessity apply only to the question whether repackaging is justified instead of relabelling of the original package, or should the test also apply to the different forms of repackaging available to the parallel trader?
- If several styles of new packaging are available, does the test of necessity require that the method of repackaging that least interferes with the trademark owner's rights be used?
- If necessity is not the correct test, is the correct test then whether the new external packaging damages the reputation of the trade mark?
- Does the test of necessity also apply to the range of relabelling options open to the parallel trader?