Parallel Trade Update – Kohlpharma

April 2004

DECISION OF EUROPEAN COURT OF JUSTICE IN THE KOHLPHARMA CASE

Introduction. In our Update of February 2004, we discussed the opinion of the Advocate General in Case C-112/02, *Kohlpharma GmbH* v. *Bundesrepublik Deutschland*. The decision of the European Court of Justice was published on 1 April. This decision has followed the opinion of the Advocate General.

Background. Full details of the case are set out in our Update. In summary, the Court was asked to consider the issue of "common origin". Prior to Kohlpharma, it had been necessary for a parallel importer to establish that there was a link between the manufacturer of the imported product and the local product, either because the manufacturers were part of the same group, or were common licensees. However, the Advocate General challenged the legal basis for that rule, stating that the only two criteria which needed to be fulfilled in the case of parallel imports were that the imported product had a marketing authorisation in another Member State and that the imported product and the local product were substantially identical. While common origin provided useful evidence that two products might be substantially identical, he did not consider that this was an essential prerequisite for parallel importation. Where, for example, the link was more tenuous (in Kohlpharma, one of the companies had a licence agreement with Chinoin, while the other only had a supply agreement for the active ingredient), parallel importation could still go ahead if the two products were substantially similar.

Decision of European Court of Justice. The decision of the Court is short and does not contain much legal reasoning. The Court has focused on the application of articles 28 and 30 of the Treaty, stating that these articles preclude the competent authorities from refusing to grant an authorisation to a parallel importer solely on the ground that the two medicinal products do not have a common origin. The refusal to issue an authorisation in such circumstances constitutes a restriction on the free movement of goods between Member States. Such a restriction is contrary to article 28 of the Treaty unless it is warranted by imperative needs, in particular the protection of public health. While the competent authorities must ensure that public health is safeguarded, the principle of proportionality must be applied.

In each case, the competent authorities must carry out a safety and efficacy assessment. If the result of that assessment is that the imported product can be placed on the market without any risk to public health, there is no basis for imposing an additional restriction on the basis of a lack of common origin. While the fact of

common origin may be an important element in establishing that there is no risk to public health, the absence of such common origin does not in itself constitute a ground for refusing the application.

The parallel importer may, for the purposes of assessing the safety and efficacy of the product, demonstrate by means of available or accessible information that the imported medicinal product does not differ significantly from the local product. Where the parallel importer does not have access to all of the necessary information but provides data that make it at least plausible that the two medicinal products do not differ significantly for the purpose of assessing their safety and efficacy, the competent authority must act in such a way that its decision as to whether to permit the parallel importation is taken on the basis of the fullest information possible, including information from other competent authorities.

Comment. The ECJ's decision is light on reasoning and does not appear to have addressed the implications of a parallel import regime based purely upon an assessment of "essential similarity". It has taken the view that, provided that the local product and the imported product do not "differ significantly" as to safety or efficacy, the imported product may be placed on the market without going through the marketing authorisation procedure. This confuses the rules on parallel importation with those on generic marketing authorisations, where the applicant is required to demonstrate that its product is essentially similar to that of an originator (indeed, at times, the ECJ refers to the parallel importation authorisation as a marketing authorisation). The effect of this decision would appear to be that a generic company could import a product from another Member State where it was authorised, that the importer contends is 'essentially similar' to a product locally approved, and the burden would be upon the competent authority in the country of import to allow this unless it could demonstrate that it has a significant difference from the local product approved under the Directive. On the other hand, a locally manufactured generic product would have to obtain a marketing authorisation having had the burden of demonstrating essential similarity and that the other conditions for approval apply, such as the expiry of the data protection period. However, since the existence of protection periods is based upon promoting public health through encouraging innovation, an import that undermines a protection period might be said to infringe the principle of safeguarding public health that the ECJ has said is the only basis for restricting import of the product.

We suspect that the decision may have raised more questions than it resolves and wait with interest to see how it is interpreted by national competent authorities.

* * * * *

If you have questions about this advisory, or other related issues, please feel free to contact your Arnold & Porter attorney or:

Ian Kirby	(+44) (0)20 7786 6160	Ian_Kirby@aporter.com
Ian Dodds-Smith	(+44) (0)20 7786 6216	Ian_Dodds-Smith@aporter.com
Tim Frazer	(+44) (0)20 7786 6124	Tim_Frazer@aporter.com
Amanda Wearing	(+44) (0)20 7786 6219	Amanda_Wearing@aporter.com