European Court Opens a Small Window of Opportunity for Pharmaceutical Companies to Restrict Parallel Imports of Medicines

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On 6th January 2004, the European Court of Justice handed down its judgement in the *Bayer Adalat* case; a decision dealing with the controversial issue of parallel trade in pharmaceutical products. The implications of this case are potentially significant for the pharmaceutical industry, which has seen considerable so-called 'grey imports' from low-price countries, such as Spain, arrive in higher priced countries, such as the UK and Germany. For pharmaceutical manufacturers and their distributors, this decision opens a narrow window of opportunity to cut back on the level of this trade. For the parallel import industry, importing from lower priced EU countries outside of the manufacturer's formal distribution channels may become more difficult in future.

By now, most of us are familiar with the term 'parallel imports', seen by many pharmaceutical companies as a real threat to profits, and by the parallel importers as a multi-million pound opportunity to exploit price differences between EU member states. The European Commission views parallel imports as playing a vital role in invigorating the EU single market. The concept of compartmentalised national markets, where resellers are not free to sell to other countries, is inconsistent with the EU goal of a single market without internal frontiers. The European Commission's underlying policy is that consumers in high-price countries should have the opportunity to source elsewhere in the EU at more favourable prices. For several decades now, the European Commission has vigorously applied EU competition rules in pursuing companies that clipped the wings of parallel traders, not least in the pharmaceutical sector.

In a recent communication (30th December 2003), the European Commission has again confirmed that parallel imports of medicinal products are permitted in the EU. The basic applicable EU law principles reiterated by the Commission in this recent Communication are:

- Once a drug is placed on the market in any one of the EU member states, it can then be re-sold in any other part of the EU, provided that the drug concerned is the same or very similar to drugs already authorised for sale in the destination country

- If the manufacturer takes measures to prevent this trade he may well be infringing competition rules and be liable to significant fines

- The manufacturer cannot seek to rely on patent rights in the destination country to prevent import of the drug, provided that the manufacturer himself, or his authorised representative, placed the drug on the EU market in the first place

- The parallel importer may repackage the drug, subject to certain limitations, in order to meet the requirements of the country of destination

- The authorities in the country of destination cannot stop or restrict parallel imports unless such restrictions are strictly necessary to protect human health

The pharmaceutical industry has repeatedly criticised the European Commission for applying its parallel imports policy to a sector where public authorities play such a key role in determining price, leading to wide price variations between EU member states over which the industry has little control. However, the Commission has never accepted this argument as providing a basis to exempt the industry from what it views as a fundamental principle of EU competition law. The Commission has imposed significant fines for restrictions on parallel trade in a number of cases, but in the recent case of *Bayer Adalat*, the European Court of Justice found that the Commission had gone a step too far.

The *Bayer Adalat* case concerned the European distribution of Adalat, a drug manufactured and marketed by Bayer to treat cardiovascular diseases. Adalat was priced in France and Spain at some 40 per cent below the UK price. Bayer's French and Spanish wholesalers sought to exploit that difference by exporting Adalat to the UK outside Bayer's official distribution channel. The French and Spanish wholesalers ordered large quantities of Adalat from Bayer in excess of their domestic needs and subsequently exported the surplus to the UK. As a result of this parallel trade, the sales of Bayer's UK subsidiary dropped by almost 50 per cent.

Bayer reacted by adapting its supply policy, to the extent that it ceased to fulfil the increasingly large orders for Adalat placed by its wholesalers in France and Spain. Furthermore, Bayer implemented a quota system based on orders from those wholesalers in the previous year. Towards the wholesalers, Bayer argued that stock shortages necessitated the adjustment of its supply policy. Bayer did not indicate that the new supply policy was directed at tackling parallel imports into the UK. Following a complaint from the wholesalers concerned, the European Commission concluded that Bayer had violated EU competition rules (Article 81 (1) of the EC Treaty) by entering into an anti-competitive agreement with its wholesalers to ban exports to the UK.

The challenge to the Commission's decision ultimately centres on the question of 'what is an agreement and, in the absence of express consent on both sides, how should the Commission prove it'? If the French and Spanish wholesalers were to just go along with Bayer's new supply policy and continue their orders as before, does this mean that they 'agreed' with Bayer to restrict parallel exports to the UK in breach of EU competition rules?

In the *Bayer Adalat* case, the European Court of Justice found that the Commission failed to establish that the wholesalers agreed (even tacitly) to a ban imposed by Bayer to prevent parallel imports of Adalat into the UK. None of the documents submitted by the European Commission contained evidence proving either that Bayer intended to impose an export ban on its (French and Spanish) wholesalers, or that supplies were made conditional on compliance with that alleged ban. Therefore, the Court of Justice ruled that the European Commission had made an error in the legal assessment of the facts and wrongfully fined Bayer €3 million for breach of EU competition rules.

The *Bayer Adalat* ruling is likely to allow manufacturers some limited margin of manoeuvre to manage supplies in a way that could reduce parallel trade and avoid exploitation of price differences by traders. It will not be so easy in the future for the Commission to show that action taken by manufacturers on their own initiative and without the express agreement of their wholesalers/distributors may amount to an anti-competitive agreement. However, manufacturers who have a very strong market position in particular products will still be vulnerable to attack, even in the absence of any real or even apparent agreement. In addition, dominant players should be particularly mindful of EU competition rules prohibiting abuse of dominance if they seek to restrict parallel trade.

Clearly, the pharmaceutical industry will not be free from Commission scrutiny on this thorny issue in the future. Notwithstanding the setback the European Commission suffered in the recent Bayer case, it has announced that it will continue to scrutinise supply quota schemes that partition the single market along national lines. The law still leaves ample scope for investigations and infringement actions, and the Bayer case represents a very small opening for pharmaceutical manufacturers in an otherwise 'dead end'. In any event, pharmaceutical manufacturers, their wholesalers and distributors will still need to review with great care any measures taken to stem the flow of products to low-price EU member states. ◆

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