Parallel bars?

Catriona Hatton and Wim Nauwelaerts, of Hogan & Hartson LLP Brussels, look at the implications for parallel trade of the recent European Court ruling on Adalat

On January 6 the European Court of Justice issued a final decision in the Bayer Adalat case, which deals with the controversial issue of parallel trade in pharmaceutical products. The implications are potentially significant, not just for the pharmacy, but also other sectors where price divergences between EU countries give rise to parallel trade.

Parallel imports are products imported into one EU Member State from another, outside the manufacturer's formal distribution channels. The European Commission views parallel imports as being vital in invigorating the EU single market, as they prevent the compartmentalisation of national markets.

The EC's underlying policy is that consumers in high-price countries should be able to source from elsewhere in the EU at better prices. In a recent Communication, the EC confirmed that parallel importing of medicinal products is permitted, provided the products are the same or very similar to those already authorised for sale in the destination EU Member State.

The pharmaceutical industry has repeatedly criticised the EC for applying its parallel imports policy and EU antitrust rules to a sector where public authorities play such a key role in determining price, leading to wide price variations between EU Member States. 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 restricting parallel trade in a number of cases involving pharmaceuticals. In the recent case of Bayer Adalat, however, the European Court of Justice found that the Commission had gone a step too far.

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. French and Spanish wholesalers ordered large quantities of Adalat from Bayer in excess of their domestic needs and exported the surplus to the UK. As a result, sales of Bayer's UK subsidiary almost halved.

Bayer reacted by adapting its supply policy, ceasing 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. Bayer's argument to the wholesalers was that stock shortages necessitated the adjustment of its supply policy and 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 EC concluded that Bayer had violated EU antitrust rules (Art. 81 [1] of the EC Treaty) by imposing an export ban as part of its commercial relations with Adalat wholesalers.

Art. 81 (1) prohibits anticompetitive agreements which have an appreciable effect on trade between EU Member States. Genuinely unilateral conduct by a company, which does not involve agreement between at least two parties, typically falls outside the scope of this prohibition. Such unilateral conduct could be reviewed under Art. 82 of the EC Treaty and may infringe EC competition rules if the conduct constitutes an abuse of a dominant position on the market.

In the Bayer case, the EC based its decision on Art. 81 (1), which presupposes an agreement, rather than Art. 82. 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 they 'agreed' with Bayer to restrict parallel exports to the UK in breach of Art. 81 (1).

Art. 81 (1) may apply to anticompetitive distribution practices which, although apparently adopted unilaterally by a manufacturer in the context of its contractual relationship with its dealers, receive at least the tacit acquiescence of those dealers. However, for a distribution agreement by tacit acceptance to be within the remit of Art. 81(1), the supplier must require from its dealers that they comply with the supplier's new commercial policy aimed at achieving an anticompetitive goal.

In the Bayer Adalat case, the European Court of Justice found that the Commission failed to establish that the wholesalers acquiesced in a ban imposed by Bayer to prevent parallel imports of Adalat into the UK. None of the documents submitted by the EC 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 the alleged ban.

On the contrary, the Court took the view that Bayer's unilateral supply policy did not depend on the co-operation of the wholesalers, who attempted to make Bayer believe – by switching their patterns of ordering – that the needs of their national markets had grown. The mere fact the wholesalers continued to distribute Adalat despite Bayer's altered supply policy did not prove the wholesalers' tacit acceptance of the alleged export ban. Therefore, the Court of Justice upheld the initial decision of the Court of First Instance by ruling that the EC had made an error in the legal assessment of the facts and wrongfully fined Bayer €3 million for breach of EU antitrust rules.

The Bayer Adalat ruling is likely to allow manufacturers some limited margin of manoeuvre to manage supplies in a way which could reduce parallel trade and avoid exploitation of price differences by traders. The standard of proof for finding an agreement in the sense of Art. 81 (1) is higher than the Commission thought, making it more difficult for it to challenge unilateral actions by companies which are not dominant.

In any event, manufacturers and licensed distributors of pharmaceuticals and other goods will still need to carefully review measures taken to stem the flow of products to low-price EU Member States.

Catriona Hatton is a Partner at Hogan & Hartson. E-mail: CHatton@HHLAW.com