35 PP-pharmaceuticals 24/2/04 10:01 Page 35

Competition is the drug

The European Court of Justice decision in the case of pharmaceutical giant Bayer has implications for parallel imports in many other market sectors, report Catriona Hatton and Wim Nauwelaerts

On 6 January, the European Court of Justice (ECJ) issued a final decision in the *Bayer* Adalat case, which deals with the controversial issue of parallel trade in pharmaceutical products.

The judgment of the ECJ in joined cases C-2/01 P and C-3/01 P, *Bundesverband der Arzneimittel-Importeure* and *Commission of the European Communities v Bayer AG*, has potentially significant implications – not just for the pharmaceutical industry, but for any sector where price divergences between EU countries lead 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 (EC) views parallel imports as playing a vital role in invigorating the EU single market, as its 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, the EC has vigorously pursued companies that clipped the wings of parallel traders, not least in the pharmaceutical sector. In a recent communication, the EC confirmed that parallel imports of medicinal products is permitted, provided that the products concerned are the same or very similar to products that are already authorised for sale in the destination EU member state.

The pharmaceutical industry has repeatedly criticised the EC for applying its parallel imports policy, as well as EU antitrust rules, to a sector where public authorities play such a key role in determining price, leading to wide price variations between member states. However, the EC 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 EC has imposed significant fines for restrictions on parallel trade in a number of cases involving pharmaceuticals.

However, in the *Bayer* case, the ECJ found that the EC had gone a step too far.

The case concerned the European distribution of Adalat, a drug manufactured and marketed by Bayer to treat cardio-vascular diseases. Adalat was priced in France and Spain at 40% 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. They ordered large quantities of Adalat from Bayer in excess of their domestic needs and exported the surplus to the UK. This parallel trade caused sales of Bayer's UK subsidiary to drop by almost 50%.

Bayer reacted by ceasing to fulfil the increasingly large orders for Adalat from its wholesalers in France and Spain. It implemented a quota system based on orders from those wholesalers in the previous year, telling them 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, the EC concluded that Bayer had violated EU antitrust rules (article 81(1) of the EC treaty) by imposing an export ban as part of its commercial relations with Adalat wholesalers.

Article 81(1) prohibits anti-competitive agreements that have an appreciable effect on trade between member states. Genuinely unilateral conduct by a company, which does not involve a concurrence of wills between at least two parties, typically falls outside the scope of this prohibition. Such unilateral conduct could be reviewed under article 82 of the treaty and may infringe EC competition rules if the conduct constitutes an abuse of a dominant position on the relevant market.

In the *Bayer* case, the EC based its decision on article 81(1), which presupposes an agreement, rather than article 82. The challenge to the EC's decision ultimately centres on the question of what is an agreement, and, in the absence of express consent on both sides, how the EC should prove it.

European markets: parallel trading plays a vital role in the EU

If the French and Spanish wholesalers were just to 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 article 81(1)?

Article 81(1) may apply to anti-competitive distribution practices that, 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 ambit of article 81(1), the supplier must require from its dealers, as a condition of their future contractual relationship, that they comply with the supplier's new commercial policy aimed at achieving an anti-competitive goal.

In the *Bayer* case, the ECJ found that the EC had 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 wholesalers or that supplies were made conditional on compliance with that such a 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 that the wholesalers continued to distribute Adalat notwithstanding Bayer's altered supply policy did not prove the wholesalers' (tacit) acceptance of the alleged export ban. Therefore, the court upheld the initial decision of the European Court of First Instance, ruling that the EC had made an error in the legal assessment of the facts and had 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 that could reduce parallel trade and avoid exploitation of price differences by traders. The standard of proof for finding an agreement in the sense of article 81(1) is higher than the EC has thought, making it more difficult for the commission to challenge unilateral actions by companies that are not dominant.

Notwithstanding this setback, the EC has announced that it will continue to scrutinise supply quota schemes that partition the single market along national lines.

In any event, manufacturers and licensed distributors of pharmaceuticals and other goods, such as cars, will still need carefully to review measures taken to stem flow of products to low-price EU member states.

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