Parallel trade in drugs

The Hellenic Competition Commission followed Advocate General Jacobs's lead – up to a point

*by **Lisa Arsenidou****

On 1 September 2006, the Hellenic Competition Commission (HCC) issued its ruling regarding GlaxoSmithKline's (GSK, formerly Glaxowellcome) distribution practices in Greece. This was the sequel to the *Syfait* referral to the ECJ where AG Jacobs's opinion in 2004 was deemed by some as the pharmaceutical industry's victory against parallel trade. As expected by many, the HCC followed this opinion and ruled that GSK's refusal to supply its Greek wholesalers in late 2000-early 2001 did not amount to an abuse under Community competition law. Nonetheless, the HCC found an abuse under article 2 of the Greek competition law, which has similar wording to article 82 of the EC treaty.

Background of the case

In 2000 and 2001, a number of Greek wholesalers filed complaints with the HCC accusing GSK of abusing its dominant position by refusing to meet their orders. The company also made several applications for negative clearance of its distribution policy to the HCC, which opened its own ex officio investigation into the issues.

For four months, from early November 2000, GSK stopped carrying out wholesalers' orders for three of its products in Greece: Imigran (for migraines), Lamictal (for epilepsy) and Serevent (for asthma). Instead, the company supplied hospitals and pharmacies directly, alleging that the wholesalers' export of the three products to member states where prices were higher was leading to significant shortages on the Greek market. The prices for these products in Greece are consistently the lowest within the EU, thus making exports to other member states appealing for wholesalers. Subsequently, GSK restored supplies to wholesalers but still refused to meet their orders in full.

In 2003, following hearings, the HCC decided to suspend its proceedings and refer various questions to the ECJ for a preliminary ruling. In essence, HCC inquired whether a dominant pharmaceutical company's refusal to meet in full the orders it receives from wholesalers might be justified in view of the company's legitimate commercial interests to limit parallel imports. The HCC also asked whether competition rules applied in the same way to markets that function competitively as to markets distorted by state intervention.

Advocate General Jacobs's decision

In 2004, AG Jacobs concluded that a dominant pharmaceutical company's supply restrictions did not necessarily amount to an abuse under article 82. Supply restrictions could be justifiable in defence of the undertaking's interests. The attorney general underlined that his conclusions were "highly specific" to the pharmaceutical sector. He based his findings on (1) pervasive price and distribution regulation, which differentiates the sector from all other industries producing readily traded goods; (2) the likely negative impact of parallel trade upon incentives to innovate; and (3) the absence of any benefits for end-consumers.

In 2005, however, the ECJ ruled that the HCC was not a court under article 234 EC and therefore rejected the reference as inadmissible without examining the substance of the case. This ruling, disappointing for some, was considered by others as a victory for parallel distribution in the European Community. At any rate, the HCC had to proceed to its verdict without any formal guidance other than the AG's opinion.

HCC decision

First, it has to be observed that the HCC's September decision exclusively concerns GSK's actions in the period from November 2000 to February 2001, when the company completely discontinued its supplies to the Greek wholesalers. The referral to the ECJ concerned wider supply restrictions and not a complete discontinuation of supply.

As a preliminary remark, the HCC stated that pharmaceuticals were "social products" because they affected citizens' health. Intense state intervention in the sector was required to sustain national health budgets.

The HCC also observed that in the absence of a single market in pharmaceuticals, parallel trade was thriving. Indeed, parallel trade was even endorsed by high-price member states because, apart from wholesalers in the exporting member countries and pharmacists in the importing member states, it also benefited health insurance funds in some importing member countries such as the UK, which has established a clawback system to recover a portion of the profit from pharmacists, and even end-consumers in other member states such as Germany.

No abuse in the light of balance of interests

Following AG Jacob's findings, the HCC stated that a refusal to supply by a dominant undertaking is not abusive per se. On the contrary, if there is objective justification for the refusal to supply, this would not be abusive. In order to conclude whether there is an abuse, it is necessary to weigh all sides' interests, including the interests of consumers, in the light of the principle of proportionality.

Next, the HCC weighed GSK's interests against the wholesalers' interests. It took the view that, like any other undertaking, a dominant undertaking is allowed to take measures to protect its legitimate commercial interests. The HCC found that GSK's behaviour sought to avoid profit loss and that this was a legitimate commercial interest. Conversely,

**Lisa Arsenidou is an associate with Wilmer Cutler Pickering Hale and Dorr LLP (Brussels)*

the wholesalers had a legitimate interest in seeking to increase their own profits through parallel trade.

The HCC agreed with the advocate general that the balance leant towards the interests of the pharmaceutical industry, in view of the prevailing economic and regulatory context for that industry in the European Community. In particular, the HCC concluded that GSK's behaviour was not abusive under article 82 but was justified for the following reasons:

(1) There was no rigorous competition in the pharmaceutical sector in the European Community because of state intervention in pricing and distribution.
(2) The quantities that GSK supplied on the Greek market exceeded demand.
(3) Parallel trade affected the company's profits.
(4) End-consumers did not benefit from parallel trade.

Moreover, GSK did not infringe article 82 because its refusal to supply did not create any disadvantages for the complainants and, in any event, it did not lead to their elimination from the market. According to a witness from the wholesalers' side, the profit losses of his company were around 10%, which the HCC considered small. Other witnesses testified that they even had made profits from parallel trade of other pharmaceutical products during the pertinent period.

No internal market for pharmaceutical products

By way of addressing the issue of effect on trade between member states, the HCC further concluded that regulatory distortions of competition in the pharmaceutical market could not be tackled, on a lasting basis, through article 82.

It observed that the Community legislator's ultimate aim is to establish and reinforce the internal market. This could not be achieved under price regulation since the internal market was linked to entrepreneurial freedom which (in turn) was based on allowing prices to be determined by the rules of supply and demand. If, because of price regulation, this freedom does not exist, the application of article 82 is barely justifiable.

The existing distortion of the competitive situation on the market for pharmaceutical products at Community level is the result of price disparities between the various member states. The HCC observed that these issues need to be dealt with at Community level. The European Community has to take the necessary measures either to create an internal market for pharmaceutical products or to regulate parallel trade prices.

Dissenting opinion

One member of the HCC considered that GSK had violated article 82. Community competition law was applicable in the sector and could not be ruled out by pervasive regulation.

Parallel trade should be encouraged because it could benefit end-consumers, either directly (at least, in some countries) or indirectly through benefits accrued by health insurance funds. GSK intended to "punish" its wholesalers for engaging in parallel trade. There were after all no shortages on the Greek market. Moreover, it was not shown that parallel trade really affected GSK's R&D budget. In contrast, consumers in other member states were damaged by GSK's practices. Refusal to supply in the present case was an extreme form of supply restriction that was not justified by profit loss given the consumer benefits from parallel trade.

Abuse of dominance under Greek law

Rather surprisingly, the HCC nevertheless found that the refusal to supply, which was justifiable under European law, was in breach of Greek competition law. This time the balance of interests leant towards patients' welfare in Greece, which the HCC does not appear to have examined in its article 82 assessment. According to the HCC, there were no shortages on the Greek market to such an extent as would justify GSK's behaviour. GSK's actions caused supply disruptions on the Greek market, putting Greek patients at risk. Parallel trade leading to revenue losses, as well as to a decrease of the company's R&D budget, could not outweigh the potential risk to patients' health. Therefore, the HCC concluded that GSK had committed an abuse under Greek law. Due to the very short duration of the infringement and the lack of any evidence of consequences on the Greek market, the HCC did not impose a fine but only threatened one in the order of 3% of GSK's gross revenues, if the company were to adopt such behaviour again.

Abuse or a market definition issue?

This issue might have been easier if the HCC had adopted a different product market definition. In its recent judgment on GSK's dual pricing system in Spain, the CFI confirmed the Commission's market definition of "all the medicines reimbursed by the Spanish sickness insurance scheme which are capable of being sold at a profit owing to the price differential between Spain and the member state of destination". The CFI noted that traders are more interested in the existence of sufficient price differentials between member states rather than in therapeutic indications. In such a wholesale market, GSK would not have been dominant. The HCC could thus have avoided a complicated analysis which led to inconsistent results under Community and Greek law.

Parallel trade and competition law

By stating that the application of Community competition law in the pharmaceutical sector is difficult to justify, the Hellenic Competition Commission went a step further than the advocate general, who had restricted his conclusions to the possibility of objective justification of a prima facie unlawful refusal to supply. Condensed as it may be, the reasoning of the HCC helps to bring to the surface the substance of the issue of parallel imports in the pharmaceutical sector. As the industry tries to keep distribution under control to reduce parallel trade, the lack of a single pharmaceutical market and the distortion of competition due to price differentials should be addressed at Community level to avoid the risk of divergence between national and European law. Until then, the question remains: is competition law the appropriate tool to deal with private measures to limit parallel imports in the pharmaceutical sector?

References

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