New Options for Pharmaceutical Distribution in Europe? CFI Partly Quashes Commission Decision On Parallel Trade

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On 27 September 2006, the European Court of First Instance partially overturned the Commission's ban on Glaxo SmithKline's dual pricing system aimed at preventing parallel exports between EU Member States. Unlike the recent *Syfait* judgment (C-53/03), a case in which the ECJ was able to avoid answering the question of whether Article 82 of the EC-Treaty allows the imposition of limits on supplies to wholesalers in order to avoid parallel trade, the CFI had to show its colors on parallel trade issues in what became commonly known as the "*the Spanish dual pricing case*" (T-168/01).

In this case, Glaxo SmithKline (Glaxo) charged higher prices for medicinal products that were exported to other Member States. In particular, Glaxo stipulated in its general sales conditions that its medicinal products would be sold to Spanish wholesalers at prices that differentiated according to the various national reimbursement schemes. In reality, this meant that products reimbursed in other Member States would be sold at a higher price than those in Spain. Glaxo made no secret of the fact that its primary intention was to limit parallel export (§ 114 of the judgment). Under the old notification system Glaxo had voluntarily notified those general sales conditions to the Commission in order to obtain a decision declaring that these conditions do not constitute an infringement of Article 81(1) EC, or alternatively be exempted as an agreement contributing to promoting technical progress (Article 81(3) EC).

On 8 May 2001, the Commission decided that Glaxo's conditions did in fact infringe competition law, because they had as their object the restriction of competition. It also held that the conditions for an exemption were not satisfied.

Glaxo challenged the Commission's decision before the CFI. Since a large number of Spanish wholesalers explicitly agreed to follow the line of conduct proposed by Glaxo, the CFI concluded that the general sales conditions should indeed be considered an "agreement" for the purposes of EC law.

However, the CFI continued by stating - in accordance with Advocate General Jacobs' opinion in the *Syfait case* - that due to the special legal and economic context of the pharmaceutical sector, the Commission could not simply draw a parallel to cases that were outside the area of pharmaceuticals. The Court highlighted the fact that different national pricing and reimbursement systems hinder pharmaceutical companies from freely determining the prices of their own products. The CFI held that "*the prices of the products in question, […] are determined at structurally different levels in the Community and […] are in any event to a significant extent shielded from the free play of supply and demand.* " (§ 133 of the judgment)

Although it was accepted that an agreement intended to limit parallel trade could, in principle, be considered to have as its object the restriction of competition, that applied only in so far as the agreement could deprive final consumers of those advantages. The Court stressed the fact that parallel traders are "*economic agents* "

which keep the price advantage that parallel trade entails for themselves (§ 122 of the judgment). As a result, the advantage is not passed on to the final consumers. The CFI concluded, therefore, that the Commission could not rightfully decide that Glaxo intended to restrict competition.

Nevertheless, the CFI ruled that although Glaxo did not intend to restrict competition, the general sales conditions did have this effect. The European Commission had succeeded in demonstrating that Glaxo's general sales conditions "*had the effect of reducing the welfare of final consumers*" in all destination Member States. According to the Court, Glaxo focused its evidence too much on the UK market instead of on all destination markets. Inter-brand competition on the destination markets of the parallel trade indeed results in a reduction in prices and costs, even though the Court acknowledged this effect to be relatively marginal. In the Court's view, consumers would be negatively affected because Glaxo's dual pricing would prevent them from taking advantage of this reduction.

Finally, the Court agreed with Glaxo that the Commission did not examine Glaxo's request for an exemption thoroughly enough and referred to the fact that since Glaxo invested the financial advantage it made by using the dual pricing system in its research and development, the Commission should have adequately taken into account all the factual arguments and relevant economic evidence and should have further developed its position with regard to possible other conditions which the agreement could have fulfilled in order to be eligible for an exemption. The CFI therefore annulled the decision to the extent that it rejected Glaxo's request for an exemption. As a consequence, the Commission now has to re-consider whether Glaxo's general sales conditions can be exempted under Article 81(3) EC-Treaty (cf. § 320 of the judgment).

Although it can reasonably be expected that the judgment will be appealed before the ECJ, the CFI judgment shows – together with Advocate General Jacobs opinion in Syfait – the tendency of the EC courts to implement the "*more economic approach* " in the cases concerning the pharmaceutical markets. Furthermore, the judgment adds another step in dismantling the protection of parallel trade from its nimbus as a "*sacred cow of competition law*". As a consequence, the Commission will have to show that specific distribution arrangements indeed have as their effect a restriction of competition. Pharmaceutical companies, on the other hand, could demonstrate that their pricing fosters innovation and consequently be considered for an exemption under Article 81(3) EC. The new Commission decision will likely provide further guidance on this aspect.

Please click here for a link to the decision