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European Court of First Instance (CFI) partly annuls European Commission's decision in GlaxoSmithKline (GSK)

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On 27 September 2006, in a long-awaited judgment 1/, the European Court of First Instance (CFI) partly annulled a 2001 decision of the European Commission finding that GSK's General Sales Conditions to its wholesalers in Spain infringed Article 81(1) EC (equivalent of Section 1 of the Sherman Act) and denying GSK an exemption under Article 81(3) EC. According to the CFI, the Commission erred in considering only the short-term, price-impact issues in its analysis in EC competition law while ruling out consideration of the issues raised by GSK as to the longer-term, anti-competitive impact on innovation of parallel traders' price arbitrage.

The CFI judgment is of particular interest to pharmaceutical companies as it examines the justification of steps they have taken to address the issue of parallel trade. Although the CFI considers that limitations on parallel trade may have restrictive effects, even in industries like the pharmaceutical sector where manufacturers are often not free to determine the price of their own products, it also recognizes that such limitations may constitute efficiencies by preserving pharmaceutical companies' incentives to invest in R&D. As such, the CFI judgment departs from the European Commission's customary approach that limitations on parallel trade should be considered as a quasi *per se* restriction of competition for which there exists no possible justifications. The judgment raises the standards of proof that the European Commission must respect in order to deny an Article 81(3) exemption to agreements between undertakings that may limit parallel trade in the pharmaceutical industry.

The case goes back to 1998, when GSK (then Glaxo Wellcome) notified its General Sales Condition for wholesalers in Spain to the European Commission. Under the General Sales Conditions, GSK's domestic sales to wholesalers were regulated by the prices imposed on products by the Spanish health authorities. However, GSK charged a higher price to wholesalers for products intended for export to other EU Member States. The European Commission considered that GSK's General Sales Conditions infringed Article 81(1) EC and were ineligible for an Article 81(3) EC exemption because they introduced a 'dual' pricing 'system' that limited parallel trade between Spain and those EU countries where products were sold at prices higher than those in Spain, such as the United Kingdom. GSK appealed the European Commission's decision to the CFI.

The CFI did not accept the European Commission's conclusion that GSK's General Sales Conditions had *the object* of restricting competition. The CFI found, rather, that it cannot be automatically

1/ Case T 168/01, GlaxoSmithkline Services v. Commission, 27 September 2006

presumed that limitations of parallel trade in the pharmaceutical industry infringe Article 81(1) EC in the absence of an analysis of the effect of the agreement. The CFI pointed out that, in most EU countries, the pharmaceutical industry is shielded from the free play of supply and demand due to the existence of State-price regulations. In this context, it could not be inferred that parallel trade would automatically contribute to price reductions that would be passed on to end-users.

The CFI did, however, accept the European Commission's analysis that GSK's General Sales Conditions had some restrictive *effects* on intra-brand competition among wholesalers that could, in turn, deprive social security authorities and end-users from some cost and price reductions. In the CFI's view, GSK's General Sales Conditions limited the pressure that Spanish wholesalers could have exercised on the price of UK wholesalers/distributors. Even if this pressure was likely to remain 'marginal', the CFI concluded that the General Sales Conditions still contributed to the maintenance of some price rigidity, to the detriment of social security schemes and consumers' welfare.

Nevertheless, the CFI considered that the European Commission should have balanced this reduction of intra-brand price competition with the longer term 'efficiencies' that limitations of parallel trade may bring to inter-brand competition on innovation. In particular, the CFI found that GSK presented '*relevant, reliable and credible'* arguments that parallel trade had a negative impact on the company's incentives and ability to invest in R&D, which the Commission did not sufficiently take into account.

The CFI accepted GSK's arguments that the medicines sector is characterized by fierce competition on innovation and high fixed R&D costs, which pharmaceutical companies are required to fund themselves and are uncertain to wholly recover because of the different State-price regulated systems of the EU Member States. In this context, the CFI found that GSK had made a convincing case that parallel trade could lead to a loss of efficiency that would alter GSK's ability to recover R&D costs and discourage innovation. GSK had also convincingly argued that, in view of the fierce competition on innovation in the pharmaceutical industry, profit increases from limitations of parallel trade would likely be re-invested, at least in part, in R&D to the end-user's benefit.

The CFI therefore concluded that the European Commission had failed to 'seriously' examine GSK's arguments concerning investment in R&D and annulled that part of the European Commission's decision concluding that Article 81(3) EC was inapplicable in the present case. The CFI ordered the European Commission to reconsider GSK's request for an exemption under Article 81(3) EC. In light of the CFI's judgment, it will be interesting to see what conclusions the European Commission will be drawn in this respect.

The willingness of this key EU court to consider the broader macroeconomic impact as a core aspect of EC competition law will be welcomed by innovative pharmaceutical companies. This industry has

been trying for some time, and with limited success, to communicate to authorities the corrosive effect upon European competitiveness of permissive parallel trade policies, in a region where drug companies rarely have much say about the prices they can charge. Coming, as it does, in the same month as the Commission's first European Pharmaceutical Forum on European innovation, the judgment supports the industry's view that the Commission's competition authority remit encompasses broad impact on innovation as well as narrow price arbitrage issues.

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