Dual Pricing Systems in Pharmaceutical Markets and EU Antitrust Law — after GlaxoSmithKline v Commission

THE SIGNIFICANCE OF THE JUDGMENT
On September 27, 2006 the European Court of First Instance ("CFI") rendered its long-awaited judgment in GlaxoSmithKline v Commission¹, also known as the Spanish Glaxo dual-pricing case. The case concerns a policy of GlaxoSmithKline ("GSK") to introduce general sales conditions under which wholesalers were to be supplied at different prices according to the place of resale.

The CFI ruled that a dual pricing scheme set up by a pharmaceutical manufacturer to reduce parallel trade between EU Member States is not per se prohibited under EU competition law. Such an agreement — or any other intended to limit parallel trade in medicines — will be unlawful only if it has actual or likely anti-competitive effects and harms consumers. Even in those cases, a pharmaceutical company is entitled to argue that the agreement may be exempted from the EU prohibition given the benefits it brings about, such as creating incentives for research and development.

In coming to this conclusion, the CFI took account of the significant differences in national pricing regimes and health care spending — differences that create the substantial price differences between Member States that make parallel trade in medicines so attractive.

The CFI’s judgment is the first from one of the Community Courts to rule specifically on (i) whether an agreement that hinders parallel trade in the pharmaceutical sector has either the object or effect of restricting competition, and (ii) even if restrictions on parallel trade restrain competition, whether off-setting benefits (such as the protection of innovation) outweigh the harms, so that there is no infringement of EU competition law.

¹ Case T-168/01, GlaxoSmithKline v Commission.
THE FACTS OF THE CASE
In March 1998, Glaxo Wellcome (now GlaxoSmithKline) notified the Commission of its new general sales conditions, seeking to secure an exemption or negative clearance under Article 81(3) EC.

The pricing scheme established by GSK had two elements. First, GSK would sell its medicines to Spanish wholesalers at no more than the price established by the Spanish health authorities, provided that the products were covered by Spanish reimbursement rules and they were marketed by the wholesalers through Spanish retailers or hospitals.

Second, if both conditions were not satisfied, the prices charged to wholesalers would be fixed by GSK “according to real, objective and non-discriminatory economic criteria” and irrespective of the destination of the products. In effect, GSK would set the price at the same level as it had first suggested to the Spanish authorities for adoption as the regulated price, adjusted for any increase in the cost of living.

In other words, GSK would operate with two prices. Products for sales in Spain would be supplied at the regulated price, while products for export would be sold at the price set by GSK, which was higher than the regulated price.

The system would apply to all 82 medicines that GSK marketed in Spain at the time. To implement the system, GSK sent its new general sales conditions to all wholesalers in Spain, requiring them to indicate their acceptance of the general conditions by returning a signed copy. Wholesalers accounting for more than 90% of GSK’s sales in Spain did so.

GSK’s objective was to protect its global margins in order to permit it to continue to support R&D activities, while allowing Spanish consumers to obtain the products — at the Spanish maximum price. The scheme was intended to limit the parallel trade between Spain and other Member States, in particular the UK, and remedy the adverse effects of the low prices established under Spanish regulations.

In May 2001, the Commission refused to exempt the price scheme and prohibited GSK from continuing it. The Commission held that by limiting parallel trade, the scheme was an agreement with both the object and the effect of restricting competition. The Commission also found that there was an element of negotiation between the manufacturer and the Spanish authorities in setting the maximum domestic prices, so that GSK could not argue that it had merely set the prices for products not covered by the price regulations.

The Commission refused an exemption under Article 81(3) EC on the basis that GSK had not demonstrated that the price scheme would contribute to promoting technical progress or improving the distribution of medicines. Since this first condition of Article 81(3) EC was not fulfilled, the Commission undertook only a summary examination of the remaining conditions.

In July 2001, GSK appealed to the CFI.

THE ISSUES TO BE DECIDED
Three main issues were raised before the CFI:

- is an agreement that seeks to limit parallel trade in medicines a per se infringement of Article 81(1) EC because it has an anti-competitive object?
- even if an agreement to limit parallel trade is not a per se infringement, may such an agreement nonetheless have the effect of restricting competition in the context of the pharmaceutical sector?
- if an anticompetitive effect can be demonstrated, could an agreement that seeks to limit parallel trade qualify nevertheless for exemption under Article 81(3) EC?

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2 The Spanish maximum industrial price was set under the process provided for in a Spanish Royal Decree of 1990. That process was commenced by a request from a pharmaceutical company for a price determination, supported by a full disclosure of relevant costs. The Royal Decree required the health authority to set a price that covered full costs (including R&D) and to provide for a suitable margin. After that price was set, the pharmaceutical company might later apply for increases.

3 Case No IV/36.954/F3 GlaxoWellcome.
Before addressing these issues the CFI confirmed, in line with the Commission’s findings, that GSK’s general sales conditions amount to an agreement. The fact that a small number of the wholesalers had contested the conditions’ legality was not sufficient to invalidate that conclusion.

**AGREEMENTS TO HINDER PARALLEL TRADE ARE NOT PER SE INVALID**

The CFI’s discussion of whether an agreement to limit parallel trade in medicines necessarily has an anti-competitive object demonstrates the substantial difference between its approach and that of the Commission. The CFI found that the most important feature of the pharmaceutical sector is that — unlike in other economic sectors — the prices of medicines that are reimbursed by national sickness insurance schemes are not freely determined by supply and demand, but rather are set or controlled by the Member States.

Because pharmaceutical prices are controlled by the Member States, it cannot be presumed that parallel trade will reduce prices or otherwise benefit patients or purchasing authorities. Absent a high likelihood of anticompetitive effects, hindering parallel trade in medicines can no longer be considered to be a per se infringement of EC competition rule.

**AGREEMENTS TO HINDER PARALLEL TRADE CAN HAVE AN ANTI-COMPETITIVE EFFECT**

The judgment does not mean that agreements to hinder parallel trade in medicines will be lawful. If, in the specific circumstances of each case, there is evidence that the agreement has adverse an effect on prices or quantities in the destination country, then the agreement will infringe Article 81(1) EC — as was the case in the GlaxoSmithKline case.

The CFI found that the price scheme did have an impact on competition in the destination country — principally the UK. It recognized that the impact of this price competition was marginal, but even that marginal price effect was sufficient to find an infringement of Article 81(1) EC given that the agreement covered a large number of products and a large network of wholesalers and the pre-existing price rigidity in the market.

**COULD THE SCHEME BE EXEMPTED UNDER ARTICLE 81(3) EC?**

Even agreements that hinder parallel trade and competition in medicines may be capable of exemption under Article 81(3) EC. GSK made several arguments to show that the advantages flowing from its policy, such as contributing to innovation and improving the distribution of medicines, outweighed any anti-competitive effect. The Commission rejected these, but the CFI found that the Commission did not adequately examine GSK’s request for exemption, and wrongly concluded that the conditions for exemption were not fulfilled.

In a strongly worded criticism of the Commission’s cursory analysis, the CFI said that the Commission failed to provide grounds for its conclusions, in particular given the relevance of the evidence submitted by GSK.

Specifically, the Commission failed to treat seriously GSK’s claims that parallel trade:

- has adverse effects on investing in, and financing, innovation;
- removes the possibility of having differentiated prices — so that consumers who are willing to do so will pay higher prices in order to finance R&D, or at least pay a contribution to R&D based on national preferences and standards of living; and
- leads to free-riding by intermediaries, bringing no real benefit to the consumer.

The CFI sets a high threshold for the Commission to overcome in future cases, leaving the door open for pharmaceutical manufacturers to argue for agreements that limit parallel trade to be exempted under Article 81(3) EC.

It is encouraging the see the CFI’s effort to assess GSK’s “relevant, reliable and credible” evidence of the adverse effects that parallel trade has on R&D, and the lack of benefit that parallel trade has for consumers. The CFI also pointed out that the Commission itself recognized the relationship between innovation, parallel trade and competition in the sector in its discussion documents on a single market in pharmaceuticals.

**THE OUTCOMES OF THE JUDGMENT**

The CFI’s strong criticism of the Commission and the evidence it relied on appears to lend strong support for a number of arguments made by GSK:
pharmaceutical manufacturers have a reasonable desire to protect R&D budgets by preventing low prices established under one country’s regulations being exported to other, higher priced, countries

- the loss in efficiency caused by parallel trade is lasting and appreciable, driven primarily by the coexistence of different national regulations and affecting a wide range of medicines

- pharmaceutical manufacturers have every interest to invest part of the surplus gained from limiting parallel trade in R&D, in the light of fierce competition through innovation; and this effect is sufficient to be taken into account under Article 81(3) EC.

Two of the CFI’s statements are worth reiterating here as they appear to set a particularly high threshold for the Commission in the context of the balancing exercise required under Article 81(3) EC.

First, according to the CFI, the effect of parallel trade on competition is “ambiguous” because it leads only to limited pressure on the prices of medicines, which comes at the cost of lost efficiency through any diminution in R&D, which plays a central role in pharmaceutical competition.

Second, this ambiguous effect means that it is improper to presume that because a pharmaceutical manufacturer holds a large market share for the products concerned, a restriction of parallel trade will necessarily lead to a substantial elimination of competition. The limited pressure on prices that might exist as a result of parallel trade must be balanced against the fierce competition in innovation and the price competition that emerges when generic products reach the market after patent expiry. In the words of the CFI, it is necessary to assess “what form of competition must be given priority with a view to ensuring the maintenance of effective competition” sought by the EC Treaty.

CONCLUSION

The CFI has further reduced the circumstances in which a restriction of parallel trade may amount to a breach of Article 81 EC by (i) rejecting the European Commission’s theory of per se infringement, (ii) pointing to the limited competition that derives from parallel trade, and (iii) laying down a high threshold for rejecting Article 81(3) EC arguments.

Two caveats are, however, necessary. When their parallel pricing strategies are challenged, companies will need to convince the European Commission, national competition authorities or national courts that, on the facts of each case, either there is no effect on competition in the destination market or that the agreement fulfils the conditions for exemption. The Greek Syfait® case, amongst others, suggests that this should be possible in the right circumstances. Secondly, the saga may continue should the European Commission appeal the GlaxoSmithKline judgment.

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5 The Greek competition authority was recently asked to rule GSK’s supply quota system, or be it in the context of an Article 82 assessment. It found GSK’s conduct objectively justified taking into account (i) the reduced level of competition on the market due to state intervention on pricing, (ii) its supplies on the Greek market exceeded national consumption. After reinstatement of supplies to wholesalers, GSK supplied its Greek subsidiary with the domestic needs of Greek pharmacies, hospitals and wholesalers plus 10%. Thereafter GSK increased the additional percentage to 25% to comply with a subsequent order from the national health authority applicable to all pharmaceutical companies, wholesalers and pharmacists., (iii) the fact that parallel trade seriously affects GSK’s profitability, (iv) the fact that consumers do not benefit from parallel trade, and (v) the general economic and regulatory framework within which pharmaceutical companies need to operate.