

Life Sciences - EC Competition

E-ALERT

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PARALLEL TRADE IN PHARMACEUTICAL PRODUCTS IN EUROPE: THE EUROPEAN COURT OF JUSTICE'S RULING IN *GSK v COMMISSION*

May a pharmaceutical company charge its wholesalers one price for products to be resold under the national healthcare reimbursement rules, and another, higher price for products to be resold in another EU member state? This was the question addressed by the European Court of Justice (ECJ) in its much-anticipated 5 October 2009 judgment in *GSK v Commission*. In a favourable ruling for the pharmaceutical industry, the ECJ largely upheld the 2006 judgment of the European Court of First Instance (CFI) finding that these dual pricing systems are not necessarily incompatible with the EC competition rules, but rather must be judged on a case-by-case basis in the light of the specific structural features of the pharmaceutical sector and the impact of parallel trade on the ability of pharmaceutical companies to fund R&D. The ruling also has favourable implications for other strategies used by pharmaceutical companies to control parallel trade, such as supply chain management systems.

FACTS

Under its sales conditions for Spain, GlaxoSmithKline (GSK) applied a dual pricing system whereby it charged its wholesalers a price not to exceed the price established by the Spanish health authorities for products covered by the Spanish reimbursement rules and sold on the Spanish market. However, for all other products, GSK charged its wholesalers a price set according to "real, objective and non-discriminatory economic criteria and completely irrespective of the destination of the product." As a practical matter, this system provided for sales in Spain at the price set by the Spanish government and for sales outside Spain at a higher price.

In 1998, GSK filed its sales conditions for Spain with the European Commission under the "notification" system, which has since been replaced by a system of self-assessment. In its notification, GSK sought a ruling that its dual pricing system either did not restrict competition within the meaning of Article 81(1), or was eligible for an exemption from the application of those rules pursuant to Article 81(3).

In May 2001, the Commission adopted a decision in which it found that GSK's pricing system restricted competition within the meaning of Article 81(1) and was not eligible for exemption under Article 81(3). The Commission did not fine GSK, but ordered it to abandon its pricing system. GSK appealed this decision to the CFI.

On 27 September 2006, the CFI partially annulled the Commission's decision on the following grounds:

- *Object of restricting competition.* The CFI rejected the Commission's argument that the dual pricing system had the *object* of restricting

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competition under Article 81(1). In other words, the Commission could not simply assume that the system harmed consumers. Instead, it had to show that the system had the *effect* of harming consumers.

- *Effect of restricting competition.* The CFI nevertheless upheld the Commission's finding that the dual pricing system had an anticompetitive effect on competition to the detriment of consumers under Article 81(1), as the dual pricing system hampered the ability of parallel traders to compete with wholesalers in other EC member states and deprived national health insurance systems of the benefits resulting from parallel trade, namely reduced costs for products.
- *Exemption under Article 81(3)?* As GSK's dual pricing system fell under Article 81(1), the CFI next considered whether the Commission was correct in concluding that the system was not eligible for exemption under Article 81(3). In order to justify an exemption, GSK bore the burden of putting forward "convincing" arguments and evidence showing that the dual pricing system is likely to result in "appreciable objective advantages" that outweigh any anticompetitive effect.

In its judgment, the CFI described the evidence presented by GSK as "relevant, reliable and credible" and noted that it was corroborated in many respects by documents originating with the Commission. Further, the CFI criticised the Commission's examination of this evidence as too cursory to support its conclusion that the system was not eligible for an exemption. Accordingly, the CFI annulled the part of the Commission's decision denying GSK an Article 81(3) exemption and referred the matter back to the Commission to conduct a more thorough assessment of GSK's evidence.

Both the Commission and GSK, among others, appealed the CFI's judgment to the ECJ. In June 2009, Advocate General Trstenjak issued her opinion on the case, which was broadly followed by the ECJ.

THE ECJ'S JUDGMENT

In its judgment, the ECJ held that the CFI made an error in law in holding that the dual pricing system did not have the object of restricting competition. The ECJ rejected the CFI's position that the Commission must go beyond merely showing a restriction on competition and must show harm to the final consumer. As the ECJ upheld the Commission's finding that the dual pricing system had the object of restricting competition under Article 81(1), it was not necessary for the ECJ to consider whether the system had the effect of restricting competition.

The ECJ next considered whether the CFI was correct to annul the Commission's decision holding that the dual pricing system did not qualify for an exemption under Article 81(3). On this point, the ECJ upheld the CFI's holding that the Commission's examination of GSK's evidence was too cursory to support its conclusion that the system was not eligible for an exemption.

WHAT IS THE PRACTICAL IMPACT OF THE ECJ'S JUDGMENT ON PHARMACEUTICAL COMPANIES?

The judgment is good news for pharmaceutical companies, particularly as it confirms the prior holding of the CFI that, in determining whether an Article 81(3) exemption applies, the Commission and national authorities must take into account the specific structural features of the pharmaceutical sector as well as the relevant evidence presented by the pharmaceutical company regarding the losses in efficiency associated with parallel trade, including the impact on R&D.

Prior to the CFI's judgment, the Commission and Community Courts had consistently condemned dual pricing systems as violations of competition law so that, in effect, they were treated as per se violations of the competition rules. For example, the Commission took the extreme position that a dual pricing system could only be justified

to the extent a company could demonstrate that all of the resulting profits were spent on R&D. This position was specifically rejected by the ECJ in its judgment.

Going forward, the Commission and national authorities will not be able to peremptorily dismiss the arguments of pharmaceutical companies, and must instead conduct a thorough, in-depth analysis of the evidence presented in order to determine whether a restriction of parallel trade satisfies the conditions for exemption under Article 81(3). Additionally, the CFI's use of terms such as "relevant, reliable and credible" to describe GSK's arguments and evidence suggest that the CFI is, at the very least, favourably inclined towards the pharmaceutical industry's arguments on parallel trade.

Of course, the endorsement by the Community Courts is qualified in the sense that the Courts did not hold that the dual pricing system was eligible for exemption under Article 81(3). As reviewing courts, the ECJ and CFI could only rule on whether the Commission's decision was well-founded, not on whether GSK's dual pricing system was eligible for exemption. As a practical matter, the judgment means that the Commission and national authorities will have to give serious consideration to evidence put forward by pharmaceutical companies to justify dual pricing systems.

While the ECJ's judgment only dealt with dual pricing systems, it is also relevant to other strategies used by pharmaceutical companies to limit parallel trade, particularly supply chain management systems. Under these systems, the pharmaceutical company limits the amount of product available to each wholesaler, often based on the local market demand. Typically, these systems are implemented on a unilateral basis by the pharmaceutical company so that Article 81 does not even apply because there is no "agreement" between the pharmaceutical company and the wholesalers that it supplies. However, in the event that such an agreement were found to exist, so as to make Article 81 applicable, the Courts' judgments indicate that such a system could be eligible for exemption under Article 81(3), particularly as most of GSK's arguments justifying its dual pricing system apply equally to a supply chain management system.

The ECJ's judgment in Case C-501/06 P, etc., *GlaxoSmithKline Services v Commission*, is available at <http://curia.europa.eu>.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our life sciences practice group:

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