

European Court of Justice Finds Dominant Pharma Companies May Not Prevent Parallel Imports by Refusing to Meet “Ordinary” Orders from Wholesalers

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The European Court of Justice (ECJ) ruled on September 16¹ that pharmaceutical companies that occupy a dominant position with respect to a particular drug may not refuse to meet “ordinary” orders from wholesalers in order to stop parallel imports.

Parallel imports have long been a thorn in the side of pharmaceutical companies operating in Europe. Pharmaceutical pricing in most member states is subject to some degree of direct or indirect regulation; as a result, prices can vary significantly from one Member State to another. This creates arbitrage opportunities for drug wholesalers that ship the drugs they buy in those countries where the price is low to countries where the prices are higher—to the detriment of the manufacturer and its distributors in the higher-priced countries.

At issue in the case was whether GlaxoSmithKline’s Greek subsidiary could limit the amount of certain medications it sold to Greek wholesalers in order to prevent them from re-exporting the products to countries where the maximum selling price was higher due to national regulation.

The ECJ concluded that such a limitation by a dominant pharmaceutical company was potentially an illegal abuse under Article 82 of the EC Treaty.

However, the ECJ recognized that pharmaceutical companies have a legitimate interest in defending themselves against distortions caused by price controls in different Member States. The ECJ declared that a situation should not be created where, “in order to defend its own commercial interests, the only choice left for a pharmaceuticals company in a dominant position is not to place its medicines on the market at all in a Member State where the prices of those products are set at a relatively low level.” The ECJ therefore held that the dominant company’s obligation to supply its products was limited to “ordinary” orders from wholesalers.

The decision requires pharmaceutical companies that occupy a dominant position to tolerate a degree of parallel trade, but accepts that such companies may take “reasonable and proportionate” steps to limit its extent. The ECJ left it to the national courts to decide at what point a wholesaler’s orders become

¹ Decision of 16 September 2008 in Joined Cases C-468/06 to 478/06 – *Sot. Lelo kai Sia and others v. GlaxoSmithKline AEEV*.

“out of the ordinary,” stating simply that the requirements of the national market and the previous business relations between the dominant company and the wholesalers concerned should be taken into account. Moreover, the ECJ’s decision does not limit the ability of companies that are not dominant to defend themselves from parallel imports by unilaterally limiting their sales to wholesalers in a given country to the amount necessary to supply the domestic market, which ability the ECJ upheld in 2004.²

Determining whether a company holds a dominant position is not always straightforward. Particularly in the pharmaceutical industry, where patents are often found to convey market power, companies should be very careful when designing their responses to parallel imports by wholesalers.

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Decision of 6 January 2004 in Joined Cases C-2/01 P and C-3/01P – *Bundesverband der Arzneimittel-Importeure v. Commission*.