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Judgment of the Court of Justice in Cases C-468/06 to C-478/06

Sot.Lélos kai Sia EE and Others v. GlaxoSmithKline A EVE Farmakeftikon Proïonton

A PHARMACEUTICALS COMPANY IS ABUSING ITS DOMINANT POSITION IF IT REFUSES TO MEET ORDINARY ORDERS BY WHOLESALERS IN ORDER TO PREVENT PARALLEL EXPORTS

Whether orders are ordinary must be ascertained in the light of the needs of the national market in question and previous trading relations

GlaxoSmithKline A EVE is the Greek subsidiary of GlaxoSmithKline plc, a pharmaceuticals research and manufacturing company established in the United Kingdom. It imports, warehouses and distributes pharmaceutical products of the GSK group in Greece. As such, it holds the marketing authorisation in Greece for certain prescription-only medicines.

In November 2000 GSK A EVE stopped meeting the orders of the Greek wholesalers who buy the medicines in question for distribution in Greece and export to other Member States. The company cited a shortage of the products at issue, for which it denied responsibility, and, altering its system of distribution, it began itself to distribute those medicines to Greek hospitals and pharmacies.

In February 2001, taking the view that the supply of medicines on the Greek market had to some extent normalised and that stocks had been reconstituted, GSK A EVE started once more to supply the wholesalers with limited quantities of the medicinal products.

The wholesalers, as well as some Greek associations of pharmacists and wholesalers, then applied to the Greek competition commission (Epitropi Antagonismou) for a declaration that the sales policy of GSK A EVE and GSK plc in respect of those medicinal products constituted an abuse of the dominant position which those companies held on the markets for the medicinal products in question.

By judgment of 31 May 2005 in *Syfait and Others*¹, the Court held that it had no jurisdiction to reply to the questions referred by the Epitropi Antagonismou since that body was not a court or tribunal.

¹ Case C-53/03 [2005] ECR I-4609

In the meantime the wholesalers brought an action claiming that the sales policy of GSK AEVE breached both Greek and Community competition law. Taking the view that it needed an answer to the same questions as were referred by the *Epitropi Antagonismou*, the Athens Court of Appeal, before which the case is pending, referred questions to the Court on the compatibility of the practices in question with the Community rules.

The Court observes, first, that any abuse by an undertaking of its dominant position is prohibited as incompatible with the common market in so far as it may affect trade between Member States. Such abuse may, in particular, consist in limiting production, markets or technical development to the prejudice of consumers.

The Court finds that, in this case, by refusing to meet the Greek wholesalers' orders, GSK AEVE aims to limit parallel exports by those wholesalers to the markets of other Member States in which the selling prices of the medicines in dispute are higher.

The Court went on to consider whether, in the pharmaceuticals sector, there are particular circumstances which might, generally, justify a refusal to meet orders.

First, the Court points out that parallel exports of medicinal products from a Member State where the prices are low to other Member States in which the prices are higher open up in principle an alternative source of supply to buyers of the medicines in those latter States at lower prices than those applied on the same market by the pharmaceuticals companies. It therefore cannot be argued that the parallel exports are of only minimal benefit to the final consumers.

The Court then analyses the possible effect of State regulation of the prices of medicines on the assessment whether the refusal to supply is an abuse. The Court observes that the control exercised by Member States over the selling prices or the reimbursement of medicines does not entirely remove the prices of those products from the law of supply and demand. Although the degree of price regulation in the pharmaceuticals sector cannot therefore preclude the Community rules on competition from applying, the fact none the less remains that, in the case of Member States with a system of price regulation, State intervention is one of the factors liable to create opportunities for parallel trade. The Community rules on competition are also incapable of being interpreted in such a way that, 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.

It follows that, even if the degree of regulation regarding the price of medicines cannot prevent a refusal by a pharmaceuticals company in a dominant position to meet orders sent to it by wholesalers involved in parallel exports from constituting an abuse, such a company must nevertheless be in a position to take steps that are reasonable and in proportion to the need to protect its own commercial interests. In order to assess whether such steps are reasonable and proportionate, it must be ascertained whether the orders of the wholesalers are out of the ordinary.

Finally, the Court examines the impact of State regulation on the supply of medicinal products, and more particularly the argument put forward by GSK AEVE that undertakings that engage in parallel exports are not subject to the same obligations regarding distribution and warehousing as the pharmaceuticals companies and are therefore liable to disrupt the planning of production and distribution of medicines.

In that connection, the Court observes that, in cases where parallel trade would effectively lead to a shortage of medicines on a given national market, it would not be for the undertakings holding a dominant position but for the national authorities to resolve the situation, by taking appropriate and proportionate steps. However, a producer of pharmaceutical products must be in a position to protect its own commercial interests if it is confronted with orders that are out of the ordinary in terms of quantity.

The Court leaves it to the national court to ascertain whether the orders are ordinary in the light of both the previous business relations between the pharmaceuticals company and the wholesalers concerned and the size of the orders in relation to the requirements of the market in the Member State concerned.

It concludes that an undertaking occupying a dominant position on the relevant market for medicinal products which, in order to put a stop to parallel exports, refuses to meet ordinary orders is abusing its dominant position.

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Languages available: CS, DE, ES, EL, EN, FR, HU, IT, PL, SK

The full text of the judgment may be found on the Court's internet site

<http://curia.europa.eu/jurisp/cgi-bin/form.pl?lang=EN&Submit=rechercher&numaff=C-468/06>

It can usually be consulted after midday (CET) on the day judgment is delivered.

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