JUDGMENT OF THE COURT (Grand Chamber)

16 September 2008 *

In Joined Cases C-468/06 to C-478/06,

REFERENCES for a preliminary ruling under Article 234 EC from the Efetio Athinon (Greece), made by decisions of 3 March 2006 (C-468/06 to C-474/06), 17 March 2006 (C-475/06 and C-476/06) and 7 April 2006 (C-477/06 and C-478/06), received at the Court on 21 November 2006, in the proceedings

Sot. Lelos kai Sia EE (C-468/06),

Farmakemporiki AE Emporias kai Dianomis Farmakeftikon Proionton (C-469/06),

Konstantinos Xidias kai Sia OE (C-470/06),

Farmakemporiki AE Emporias kai Dianomis Farmakeftikon Proionton (C-471/06),

Ionas Stroumsas EPE (C-472/06),

* Language of the case: Greek.

Ionas Stroumsas EPE (C-473/06),

Farmakapothiki Farma-Group Messinias AE (C-474/06),

K.P. Marinopoulos AE Emporias kai Dianomis Farmakeftikon Proionton (C-475/06),

K.P. Marinopoulos AE Emporias kai Dianomis Farmakeftikon Proionton (C-476/06),

Kokkoris D. Tsanas K. EPE and Others (C-477/06),

Kokkoris D. Tsanas K. EPE and Others (C-478/06),

v

GlaxoSmithKline AEVE Farmakeftikon Proionton, formerly Glaxowellcome AEVE,

THE COURT (Grand Chamber),

composed of V. Skouris, President, P. Jann, C.W.A. Timmermans, A. Rosas, K. Lenaerts (Rapporteur) and A. Tizzano, Presidents of Chambers, R. Silva de

Lapuerta, K. Schiemann, J. Makarczyk, P. Lindh, J.-C. Bonichot, T. von Danwitz and A. Arabadjiev, Judges,

Advocate General: D. Ruiz-Jarabo Colomer,
Registrar: L. Hewlett, Principal Administrator,

having regard to the written procedure and further to the hearing on 29 January 2008,

after considering the observations submitted on behalf of:

— Sot. Lelos kai Sia EE (C-468/06), by S.E. Kiliakovou, dikigoros,

— Farmakemporiki AE Emporias kai Dianomis Farmakeftikon Proionton (C-469/06 and C-471/06), Konstantinos Xidias kai Sia OE (C-470/06), Ionas Stroumsas EPE (C-472/06 and C-473/06), Farmakapothiki Farma-Group Messinias AE (C-474/06) and K.P. Marinopoulos AE Emporias kai Dianomis Farmakeftikon Proionton (C-475/06 and C-476/06), by L. Roumanias and G. Papaïoannou, dikigoroi,

— Kokkoris D. Tsanas K. EPE and Others (C-477/06 and C-478/06), by G. Mastorakos, dikigoros,

— GlaxoSmithKline AEVE Farmakeftikon Proionton, by A. Komninos, D. Kyriakis, T. Kloukinas and S. Zervoudaki, dikigoroi, and by I. Forrester QC and A. Schulz, Rechtsanwalt,

— the Italian Government, by I.M. Braguglia, acting as Agent, assisted by F. Arena, avvocato dello Stato,

— the Polish Government, by E. Ośniecka-Tamecka, P. Kucharski and T. Krawczyk, acting as Agents,

— the Commission of the European Communities, by T. Christoforou, F. Castillo de la Torre and E. Gippini Fournier, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 1 April 2008,

gives the following

Judgment

1 These references for a preliminary ruling concern the interpretation of Article 82 EC.

2 The references were made in proceedings brought by Sot. Lelos kai Sia EE, Farmakemporiki AE Emporias kai Dianomis Farmakeftikon Proionton, Konstantinos Xidias kai Sia OE, Ionas Stroumsas EPE, Farmakapothiki Farma-Group Messinias AE, K.P. Marinopoulos AE Emporias kai Dianomis Farmakeftikon Proionton, and Kokkoris D. Tsanas K. EPE and Others, pharmaceuticals wholesalers, ('the appellants

in the main proceedings') against GlaxoSmithKline AEVE Farmakeftikon Proionton, formerly Glaxowellcome AEVE, ('GSK AEVE') in respect of the latter's refusal to meet those wholesalers' orders for certain medicinal products.

The legal framework

Community legislation

3 Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems (OJ 1989 L 40, p. 8) lays down certain requirements for Member States when applying national measures to control the prices of medicinal products for human use or to restrict the range of medicinal products covered by their national health insurance systems.

4 The second to fourth recitals to that directive read as follows:

'Whereas Member States have adopted measures of an economic nature on the marketing of medicinal products in order to control public health expenditure on such products; whereas such measures include direct and indirect controls on the prices of medicinal products as a consequence of the inadequacy or absence of competition in the medicinal products market and limitations on the range of products covered by national health insurance systems;

Whereas the primary objective of such measures is the promotion of public health by ensuring the availability of adequate supplies of medicinal products at a reasonable cost; whereas, however, such measures should also be intended to promote efficiency in the production of medicinal products and to encourage research and development into new medicinal products, on which the maintenance of a high level of public health within the Community ultimately depends;

Whereas disparities in such measures may hinder or distort intra-Community trade in medicinal products and thereby directly affect the functioning of the common market in medicinal products[.]'

5 Article 81 of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ 2001 L 311, p. 67), as amended by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 (OJ 2004 L 136, p. 34), ('Directive 2001/83') provides:

'With regard to the supply of medicinal products to pharmacists and persons authorised or entitled to supply medicinal products to the public, Member States shall not impose upon the holder of a distribution authorisation which has been granted by another Member State any obligation, in particular public service obligations, more stringent than those they impose on persons whom they have themselves authorised to engage in equivalent activities.

The holder of a marketing authorisation for a medicinal product and the distributors of the said medicinal product actually placed on the market in a Member State shall, within the limits of their responsibilities, ensure appropriate and continued supplies of that medicinal product to pharmacies and persons authorised to supply medicinal products so that the needs of patients in the Member State in question are covered.

The arrangements for implementing this Article should, moreover, be justified on grounds of public health protection and be proportionate in relation to the objective of such protection, in compliance with the Treaty rules, particularly those concerning the free movement of goods and competition.'

National legislation

6 Article 2 of Greek Law 703/1977 on the control of monopolies and oligopolies and the protection of free competition (FEK A' 278) essentially corresponds to the provisions of Article 82 EC.

7 Under Article 29 of Greek Law 1316/1983, holders of an authorisation to market pharmaceutical products are required to supply the market regularly with the goods which they manufacture or import.

8 Furthermore, Greek legislation requires persons carrying out the business of pharmaceuticals wholesaler to obtain a specific licence and to supply the needs of a defined geographical area with a range of pharmaceutical products.

The main proceedings and the reference for a preliminary ruling

9 GSK AEVE is the Greek subsidiary of GlaxoSmithKline plc, a pharmaceuticals research and manufacturing company established in the United Kingdom ('GSK plc'). GSK AEVE imports, warehouses and distributes pharmaceutical products of the GSK group ('GSK') in Greece. As such, it holds the marketing authorisation in Greece inter alia for the medicinal products Imigran, Lamictal and Serevent for the treatment, respectively, of migraines, epilepsy and asthma ('the medicinal products in dispute'), which are available in Greece only on prescription.

10 Each of the appellants in the main proceedings had for a number of years bought those medicinal products in all their forms from GSK AEVE, in order to distribute them both on the Greek market and in other Member States.

11 Towards the end of October 2000, GSK AEVE altered its system of distribution on the Greek market, citing a shortage, for which it denied responsibility, of those medicines. From 6 November 2000 it stopped meeting the orders of the appellants in the main proceedings for the medicinal products in dispute and began itself to distribute those products to Greek hospitals and pharmacies through the company Farmacenter AE ('Farmacenter').

12 In December 2000 GSK AEVE applied to the Epitropi Antagonismou (Competition Commission) for negative clearance in the form of a declaration that its new policy of selling the medicines directly to Greek hospitals and pharmacies did not infringe Article 2 of Law 703/1977.

13 In February 2001, taking the view that the supply of medicines on the Greek market had to some extent normalised and that stocks at hospitals and pharmacies had been

reconstituted, GSK AEVE started once more to supply the appellants in the main proceedings and other wholesalers with limited quantities of the medicinal products in dispute and shortly afterwards brought its cooperation with Farmacenter to an end.

14 GSK AEVE then withdrew its application for negative clearance but in the course of February 2001 filed a new application for negative clearance in respect of its sales policy, which in turn was replaced in December 2001 by another such application. Following discussions with the Epitropi Antagonismou, GSK AEVE agreed to deliver quantities of medicines equivalent to national consumption plus 18%.

15 Meanwhile, the appellants in the main proceedings and other pharmaceuticals wholesalers, as well as some Greek associations of pharmacists and wholesalers, applied to the Epitropi Antagonismou for a declaration that the sales policy of GSK AEVE and GSK plc in respect of the medicinal products in dispute constituted an abuse of a dominant position under Article 2 of Law 703/1977 and Article 82 EC.

16 On 3 August 2001, a decision of the Epitropi Antagonismou ordering interim measures required GSK AEVE to meet the orders of the appellants in the main proceedings for the medicinal products in dispute pending adoption of a final decision in the case. GSK AEVE lodged applications with the Diikitiko Efetio Athinon (Administrative Appeal Court, Athens) for a stay of execution and an annulment of that decision, which that court rejected.

17 Having been informed by GSK AEVE of the difficulties it faced in supplying the wholesalers with the quantities requested, the Ethnikos Organismos Farmakon (National Organisation for Medicines) published a circular on 27 November 2001 which obliged pharmaceuticals companies and all distributors of medicines to deliver quantities equivalent to those required for prescription medicines plus 25%.

18 Between 30 April 2001 and 11 November 2002, each of the appellants in the main proceedings brought an action before the Polimeles Protodikio Athinon (Court of First Instance, Athens), claiming that the conduct of GSK AEVE in interrupting supplies of medicinal products which had been ordered and distributing them through Farmacenter constituted unfair and anticompetitive acts and an abuse of the dominant position occupied by GSK AEVE on the markets for the medicinal products in dispute. In their applications, those appellants asked for GSK AEVE to be ordered, first, to supply them with quantities of medicines corresponding to the monthly average of those it had delivered to them in the period from 1 January to 31 October 2000 and, second, to pay them damages and compensate them for loss of profits. Some of the applications contained a more specific request for GSK AEVE to be ordered to continue supplies by providing quantities corresponding to the monthly average of medicines that it had delivered to them during the same period plus a certain percentage.

19 In view of both the complaints mentioned in paragraph 15 of this judgment and the request for negative clearance that were pending before it, the Epitropi Antagonismou by decision of 22 January 2003 asked the Court a series of questions relating to the interpretation of Article 82 EC in a reference for a preliminary ruling, which was registered at the Court Registry under the number C-53/03.

20 Between January and October 2003, the Polimeles Protodikio Athinon gave judgment on the actions commenced by the appellants in the main proceedings against GSK AEVE. Although it ruled that the actions were admissible, with the exception of the claims for compensation for loss of profits, that court dismissed them as unfounded, on the ground that the refusal on the part of GSK AEVE to supply was not unjustified and could thus not constitute abuse of that company's dominant position.

21 The appellants in the main proceedings appealed against those judgments before the Efetio Athinon (Court of Appeal, Athens). GSK AEVE cross-appealed in some of the cases. That court however suspended its examination of some of the cases before it pending the Court's decision in respect of the reference for a preliminary ruling made by the Epitropi Antagonismou.

22 By its judgment of 31 May 2005 in Case C-53/03 *Syfait and Others* [2005] ECR I-4609, the Court ruled that it had no jurisdiction to answer the questions referred by the Epitropi Antagonismou, since the latter was not a court or tribunal within the meaning of Article 234 EC.

23 Considering that, in order to deliver its judgments, it is necessary to have answers to the same questions which the Epitropi Antagonismou had referred to the Court, the Efetio Athinon has decided to stay the appeal proceedings and to refer the following questions to the Court for a preliminary ruling:

'(1) Where the refusal of an undertaking holding a dominant position to meet fully the orders sent to it by pharmaceuticals wholesalers is due to its intention to limit their export activity and, thereby, the harm caused to it by parallel trade, does the refusal constitute per se an abuse within the meaning of Article 82 EC? Is the answer to that question affected by the fact that the parallel trade is particularly profitable for the wholesalers because of the different prices, resulting from State intervention, in the Member States of the European Union, that is to say by the fact that pure conditions of competition do not prevail in the pharmaceuticals market, but a regime which is governed to a large extent by State intervention? Is it ultimately the duty of a national competition authority to apply Community competition rules in the same way to markets which function competitively and those in which competition is distorted by State intervention?

(2) If the Court holds that limitation of parallel trade, for the reasons set out above, does not constitute an abusive practice in every case where it is engaged in by an undertaking holding a dominant position, how is possible abuse to be assessed?

In particular:

(a) Do the percentage by which normal domestic consumption is exceeded and/or the loss suffered by an undertaking holding a dominant position compared with its total turnover and total profits constitute appropriate criteria? If so, how are the level of that percentage and the level of that loss determined (the latter as a percentage of turnover and total profits), above which the conduct in question may be abusive?

(b) Is an approach entailing the balancing of interests appropriate, and, if so, what are the interests to be compared?

In particular:

(i) is the answer affected by the fact that the ultimate consumer/patient derives limited financial advantage from the parallel trade and

(ii) is account to be taken, and to what extent, of the interests of social insurance bodies in cheaper medicinal products?

(c) What other criteria and approaches are considered appropriate in the present case?'

24 By Decision 318/V/2006 of 1 September 2006, the Epitropi Antagonismou ruled on the complaints lodged with it against GSK. In the decision it found that GSK did not occupy a dominant position on the markets for Imigran and Serevent in view of their interchangeability with other medicinal products, but that a dominant position existed with respect to Lamictal, on account of the fact that epilepsy sufferers may find it difficult to adjust to other medicines which treat that condition.

25 In the same decision, the Epitropi Antagonismou found that GSK had infringed Article 2 of Law 703/1977 during the period from November 2000 to February 2001, but that there had been no infringement of that article in the period after February 2001 and no infringement of Article 82 EC during either of those periods.

26 The appellants in the main proceedings have applied to the Diikitiko Efetio Athinon for an annulment of that decision.

27 By order of the President of the Court of 29 January 2007, Cases C-468/06 to C-478/06 were joined for the purposes of the written and oral procedures and the judgment.

The questions referred for a preliminary ruling

28 By its questions, which it is appropriate to examine together, the referring court essentially asks whether there is an abuse of a dominant position contrary to Article 82 EC if a pharmaceuticals company occupying such a position on the national market for certain medicinal products refuses to meet orders sent to it by wholesalers on

account of the fact that those wholesalers are involved in parallel exports of those products to other Member States.

29 In that context, the referring court asks the Court about the relevance of a series of factors, such as the degree of regulation to which the pharmaceuticals sector is subject in Member States, the impact of parallel trade on the pharmaceuticals companies' revenues, and the question whether that parallel trade is capable of generating financial benefits for the ultimate consumers of the medicinal products.

30 In its observations lodged before the Court, GSK AEVE contends that its refusal to supply the requested quantities of medicinal products to the appellants in the main proceedings does not constitute an abuse. First, it was not a case of an actual refusal inasmuch as, apart from a period of a few weeks between November 2000 and February 2001, GSK AEVE was always prepared to supply the wholesalers with sufficient quantities. Second, it did not put the wholesalers at risk of being eliminated from the market, since its supplies enabled them to cover all the requirements of the Greek market, and even requirements that went beyond those of that market.

31 According to GSK AEVE, the decisive factors for the question whether the conduct of a company that refuses to supply certain goods is abusive depend on the economic and regulatory context of the situation in question. Thus, in the case of a supply restriction in medicinal products in order to limit parallel trade, it is necessary to take into account the omnipresent regulation of prices and distribution in the pharmaceuticals sector, the negative consequences of an unlimited parallel trade upon the investments of pharmaceuticals companies in the field of research and development, and the minimal benefit of that trade for the final consumers of those products.

32 By contrast, the appellants in the main proceedings, as well as the Italian and Polish Governments and the Commission of the European Communities, maintain in their observations that the refusal by an undertaking in a dominant position to supply medicinal products to wholesalers with the aim of restricting parallel trade constitutes in principle an abuse of a dominant position within the meaning of Article 82 EC. According to them, none of the factors raised by the referring court and which were taken up by GSK AEVE to justify its refusal to supply is capable of altering the abusive nature of that practice.

The existence of a refusal to supply liable to eliminate competition

33 Article 82 EC prohibits any abuse by one or more undertakings of a dominant position within the common market or in a substantial part of it as incompatible with the common market in so far as it may affect trade between Member States. According to point (b) of the second paragraph of that article, such abuse may, in particular, consist in limiting production, markets or technical development to the prejudice of consumers.

34 The established case-law of the Court shows that the refusal by an undertaking occupying a dominant position on the market of a given product to meet the orders of an existing customer constitutes abuse of that dominant position under Article 82 EC where, without any objective justification, that conduct is liable to eliminate a trading party as a competitor (see, to that effect, Joined Cases 6/73 and 7/73 *Istituto Chemioterapico Italiano and Commercial Solvents* v *Commission* [1974] ECR 223, paragraph 25, and Case 27/76 *United Brands and United Brands Continentaal* v *Commission* [1978] ECR 207, paragraph 183).

35 With regard to a refusal by an undertaking to deliver its products in one Member State to wholesalers which export those products to other Member States, such an effect on competition may exist not only if the refusal impedes the activities of those wholesalers in that first Member State, but equally if it leads to the elimination of effective competition from them in the distribution of the products on the markets of the other Member States.

36 In this case it is common ground between the parties in the main proceedings that, 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 medicinal products in dispute are higher.

37 In respect of sectors other than that of pharmaceutical products, the Court has held that a practice by which an undertaking in a dominant position aims to restrict parallel trade in the products that it puts on the market constitutes abuse of that dominant position, particularly when such a practice has the effect of curbing parallel imports by neutralising the more favourable level of prices which may apply in other sales areas in the Community (see, to that effect, Case 26/75 *General Motors Continental* v *Commission* [1975] ECR 1367, paragraph 12) or when it aims to create barriers to re-importations which come into competition with the distribution network of that undertaking (Case 226/84 *British Leyland* v *Commission* [1986] ECR 3263, paragraph 24). Indeed, parallel imports enjoy a certain amount of protection in Community law because they encourage trade and help reinforce competition (Case C-373/90 *X* [1992] ECR I-131, paragraph 12).

38 In its written observations, GSK AEVE contends that the factors mentioned by the referring court in its questions constitute objective considerations, on the basis of which it cannot be regarded as an abuse for a pharmaceuticals company to limit supplies of medicines to the needs of a given national market when confronted with orders from wholesalers involved in parallel exports to other Member States where the selling prices of those medicines are set at a higher level.

39 In order to determine whether the refusal by a pharmaceuticals company to supply medicinal products to such wholesalers indeed falls within the prohibition laid down in Article 82 EC, in particular at point (b) of the second paragraph of that article, it must be examined whether, as GSK AEVE maintains, there are objective considerations based on which such a practice cannot be regarded as an abuse of the dominant position occupied by that undertaking (see, to that effect, *United Brands and United Brands Continentaal* v *Commission*, paragraph 184, and Case C-95/04 P *British Airways* v *Commission* [2007] ECR I-2331, paragraph 69).

The abusive nature of the refusal to supply

40 As a preliminary point, GSK AEVE observes, citing *United Brands Continentaal* v *Commission*, that a dominant undertaking is not under an obligation to honour orders that are out of the ordinary and that it may take reasonable steps in order to protect its legitimate commercial interests.

41 With regard more specifically to the pharmaceuticals sector, GSK AEVE argues, first, that the general logic behind protecting competition within a brand does not function in that sector, where the intervention of the public authorities of Member States prevents the manufacturers of medicines from developing their activities in normal competitive conditions.

42 On the one hand, the pharmaceuticals companies do not control the prices of their products, those prices being fixed at various levels by the public authorities, which are, at the same time, the buyers of the medicines wherever there are national health systems. Even where those prices are the result of negotiations between the authorities and the pharmaceuticals companies, the fact that those companies accept them does not in itself imply that the prices cover all the fixed costs connected with the

development of the pharmaceutical products. Moreover, even if such a system of agreed prices exists, Member States are still in a position to impose cuts in those prices.

43 On the other hand, the producers of medicines are subject to precise obligations with regard to their distribution. While pharmaceuticals companies are required by law to deliver their products in all Member States where they are authorised to do so, parallel exporters are free to shift their activities from one product or market to the next if the latter product or market offers a higher profit margin, which can lead to shortages in some exporting Member States. Thus parallel trade has negative consequences for the planning of production and distribution of medicines.

44 Second, GSK AEVE points out that parallel trade in medicines reduces the profits that pharmaceuticals companies can invest in research and development activities on which they depend in order to remain competitive and attractive to investors. By contrast, distributors which profit from parallel trade make no contribution to pharmaceutical innovation. Furthermore, in the Member States where the prices of medicines are fixed at relatively low levels, the marketing of new medicines might be affected if it became impossible for pharmaceuticals companies to hold back supplies with the aim of limiting parallel trade. In such circumstances, those companies would have an interest in delaying the launch of new products in Member States where the prices are low.

45 Third, GSK AEVE contends that parallel trade provides no genuine benefit to the ultimate consumers. Since the greater part of the price difference which makes the business profitable is taken up by intermediaries, parallel trade does not result in genuine pressure on the prices of medicines in the Member States where those prices are higher. Equally, in the case of Member States where certain medicinal requirements are covered by public tender, parallel importers are not in a position to reduce price levels in view of their sporadic presence on the market.

46 While recognising that the prohibition in Article 82 EC does not apply when the conduct of an undertaking in a dominant position is objectively justified, the Polish Government and the Commission point out that it is for that undertaking to establish that there are circumstances that are capable of justifying its practice.

47 The appellants in the main proceedings, as well as the Polish Government and the Commission, consider that Article 82 EC cannot be applied differently in the pharmaceuticals sector simply because the prices in that sector are directly or indirectly fixed by the public authorities. Even in the Member States where prices are low, the price of a medicinal product is the result of negotiations with the pharmaceuticals companies, which will not put their products on the market if the prices proposed are not acceptable to them. Furthermore, there is no causal link between the repercussions of parallel trade on the revenues of pharmaceuticals companies and those companies' investments in research and development. Finally, parallel trade in medicinal products brings clear advantages to patients and is likely to enable national social security systems to make savings.

48 The appellants in the main proceedings add that taking into account the justifications advanced by GSK AEVE would run counter to the Court's case-law relating to the free movement of goods, which accepts only the justifications listed in Article 30 EC.

49 It should be recalled that in paragraph 182 of its judgment in *United Brands and United Brands Continentaal* v *Commission* the Court held that an undertaking in a dominant position for the purpose of marketing a product — which cashes in on the reputation of a brand name known to and valued by consumers — cannot stop supplying a long-standing customer who abides by regular commercial practice, if the orders placed by that customer are in no way out of the ordinary. In paragraph 183 of the same judgment, the Court held that such conduct is inconsistent with the objectives laid down in Article 3(f) of the EEC Treaty (Article 3(g) of the EC Treaty, and now Article 3(1)(g) EC), which are set out in detail in Article 86 of the EEC Treaty (Article 86 of the EC Treaty, and now Article 82 EC), particularly in points (b) and (c) of the second paragraph of that article, since the refusal to sell would limit the

markets to the prejudice of consumers and would amount to discrimination which might in the end eliminate a trading party from the relevant market.

50 In paragraph 189 of the judgment in *United Brands and United Brands Continentaal* v *Commission*, the Court stated that, although the fact that an undertaking is in a dominant position cannot deprive it of its right to protect its own commercial interests if they are attacked, and that such an undertaking must be conceded the right to take such reasonable steps as it deems appropriate to protect those interests, such behaviour cannot be accepted if its purpose is specifically to strengthen that dominant position and abuse it.

51 It must be examined in this context whether, as GSK AEVE claims, particular circumstances are present in the pharmaceuticals sector, by reason of which the refusal by an undertaking in a dominant position to supply clients in a given Member State who engage in parallel exports to other Member States where prices for medicines are higher does not, generally speaking, constitute an abuse.

The consequences of parallel trade for the ultimate consumers

52 The first thing to consider is GSK AEVE's argument that parallel trade in any event brings only few financial benefits to the ultimate consumers.

53 In that connection, it should be noted 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 medicinal products in those latter States, which necessarily brings some benefits to the final consumer of those products.

54 It is true, as GSK AEVE has pointed out, that, for medicines subject to parallel exports, the existence of price differences between the exporting and the importing Member States does not necessarily imply that the final consumer in the importing Member State will benefit from a price corresponding to the one prevailing in the exporting Member State, inasmuch as the wholesalers carrying out the exports will themselves make a profit from that parallel trade.

55 Nevertheless, the attraction of the other source of supply which arises from parallel trade in the importing Member State lies precisely in the fact that that trade is capable of offering the same products on the market of that Member State at lower prices than those applied on the same market by the pharmaceuticals companies.

56 As a result, even in the Member States where the prices of medicines are subject to State regulation, parallel trade is liable to exert pressure on prices and, consequently, to create financial benefits not only for the social health insurance funds, but equally for the patients concerned, for whom the proportion of the price of medicines for which they are responsible will be lower. At the same time, as the Commission notes, parallel trade in medicines from one Member State to another is likely to increase the choice available to entities in the latter Member State which obtain supplies of medicines by means of a public procurement procedure, in which the parallel importers can offer medicines at lower prices.

57 Accordingly, without it being necessary for the Court to rule on the question whether it is for an undertaking in a dominant position to assess whether its conduct vis-à-vis

a trading party constitutes abuse in the light of the degree to which that party's activities offer advantages to the final consumers, it is clear that, in the circumstances of the main proceedings, such an undertaking cannot base its arguments on the premiss that the parallel exports which it seeks to limit are of only minimal benefit to the final consumers.

The impact of State price and supply regulation in the pharmaceuticals sector

58 Turning, next, to the argument based on the degree of regulation of the pharmaceuticals markets in the Community, it must first be examined whether State regulation of the prices of medicinal products has an impact on the assessment of whether a refusal to supply those products constitutes abuse.

59 It is clear that, in the majority of Member States, medicines, in particular those available only on prescription, are subject to regulation aimed at setting, at the request of the manufacturers concerned and on the basis of information provided by them, selling prices for those medicines and/or the scales of reimbursement of the cost of prescription medicines by the relevant social health insurance systems. The price differences between Member States for certain medicines are thus the result of the different levels at which the prices and/or the scales to be applied to those medicines are fixed.

60 The main proceedings relate to a non-harmonised area in which the Community legislature has limited itself, in adopting Directive 89/105, to placing Member States under a duty to guarantee that decisions in respect of the regulation of prices and reimbursement are taken with complete transparency, without discrimination and within certain specific time-limits.

61 In that respect, it should be noted, on one hand, that the control exercised by Member States over the selling prices or the reimbursement of medicinal products does not entirely remove the prices of those products from the law of supply and demand.

62 Thus, in some Member States, the public authorities do not intervene in the process of setting prices or limit themselves to setting the scale of reimbursement of the cost of prescription medicines by the national health insurance systems, thereby leaving to the pharmaceuticals companies the task of deciding their selling prices. Furthermore, even though the public authorities in other Member States set the selling prices of medicines as well, that does not in itself mean that the manufacturers of the medicines concerned have no influence upon the level at which the selling prices are set or the proportion of those prices which is reimbursed.

63 As the Commission has pointed out, even in the Member States where the selling prices or the amounts of reimbursement of medicines are set by the public authorities, the producers of the medicines concerned take part in the negotiations which are initiated by those producers and take their price proposals as a starting point and end with the setting of the prices and the amounts of reimbursement to be applied. As the second and third recitals to Directive 89/105 state, the task of the authorities when setting prices of medicines is not only to control expenditure connected with public health systems and to ensure the availability of adequate supplies of medicinal products at a reasonable cost, but also to promote efficiency in the production of medicinal products and to encourage research and development into new medicinal products. As the Advocate General indicated in points 90 to 93 of his Opinion, the level at which the selling price or the amount of reimbursement of a given medicinal product is fixed reflects the relative strength of both the public authorities of the relevant Member State and the pharmaceuticals companies at the time of the price negotiations for that product.

64 On the other hand, it should be recalled that, where a medicine is protected by a patent which confers a temporary monopoly on its holder, the price competition which may exist between a producer and its distributors, or between parallel traders and national distributors, is, until the expiry of that patent, the only form of competition which can be envisaged.

65 In relation to the application of Article 85 of the EEC Treaty (Article 85 of the EC Treaty, now Article 81 EC), the Court has held that an agreement between producer and distributor which might tend to restore the national divisions in trade between Member States might be such as to frustrate the objective of the Treaty to achieve the integration of national markets through the establishment of a single market. Thus on a number of occasions the Court has held agreements aimed at partitioning national markets according to national borders or making the interpenetration of national markets more difficult, in particular those aimed at preventing or restricting parallel exports, to be agreements whose object is to restrict competition within the meaning of that Treaty article (see, for example, Joined Cases 96/82 to 102/82, 104/82, 105/82, 108/82 and 110/82 *IAZ International Belgium and Others* v *Commission* [1983] ECR 3369, paragraphs 23 to 27; Case C-306/96 *Javico* [1998] ECR I-1983, paragraphs 13 and 14; and Case C-551/03 P *General Motors* v *Commission* [2006] ECR I-3173, paragraphs 67 to 69).

66 In the light of the abovementioned Treaty objective as well as that of ensuring that competition in the internal market is not distorted, there can be no escape from the prohibition laid down in Article 82 EC for the practices of an undertaking in a dominant position which are aimed at avoiding all parallel exports from a Member State to other Member States, practices which, by partitioning the national markets, neutralise the benefits of effective competition in terms of the supply and the prices that those exports would obtain for final consumers in the other Member States.

67 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, when assessing, in the case of Member States with a system of price regulation, whether the refusal of a pharmaceuticals company to supply medicines to wholesalers involved in parallel exports constitutes abuse, it cannot be ignored that such State intervention is one of the factors liable to create opportunities for parallel trade.

68 Furthermore, in the light of the Treaty objectives to protect consumers by means of undistorted competition and the integration of national markets, 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.

69 It follows that, even if the degree of regulation regarding the price of medicines cannot prevent any 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.

70 In that respect, and without it being necessary to examine the argument raised by GSK AEVE that it is necessary for pharmaceuticals companies to limit parallel exports in order to avoid the risk of a reduction in their investments in the research and development of medicines, it is sufficient to state that, in order to appraise whether the refusal by a pharmaceuticals company to supply wholesalers involved in parallel exports constitutes a reasonable and proportionate measure in relation to the threat that those exports represent to its legitimate commercial interests, it must be ascertained whether the orders of the wholesalers are out of the ordinary (see, to that effect, *United Brands and United Brands Continentaal* v *Commission*, paragraph 182).

71 Thus, although a pharmaceuticals company in a dominant position, in a Member State where prices are relatively low, cannot be allowed to cease to honour the ordinary orders of an existing customer for the sole reason that that customer, in addition to supplying the market in that Member State, exports part of the quantities ordered to other Member States with higher prices, it is none the less permissible for that company to counter in a reasonable and proportionate way the threat to its own commercial interests potentially posed by the activities of an undertaking which wishes to be supplied in the first Member State with significant quantities of products that are essentially destined for parallel export.

72 In the present cases, the orders for reference show that, in the disputes which gave rise to those orders, the appellants in the main proceedings have demanded not that GSK AEVE should fulfil the orders sent to it in their entirety, but that it should deliver them quantities of medicines corresponding to the monthly average sold during the first 10 months of 2000. In 6 of the 11 actions in the main proceedings, the appellants asked for those quantities to be increased by a certain percentage, which was fixed by some of them at 20%.

73 In those circumstances, it is for the referring court to ascertain whether the above-mentioned orders are ordinary in the light of both the previous business relations between the pharmaceuticals company holding a dominant position and the wholesalers concerned and the size of the orders in relation to the requirements of the market in the Member State concerned (see, to that effect, *United Brands and United Brands Continentaal* v *Commission*, paragraph 182, and Case 77/77 *Benzine en Petroleum Handelsmaatschappij and Others* v *Commission* [1978] ECR 1513, paragraphs 30 to 32).

74 Those considerations equally deal with the argument raised by GSK AEVE, namely the impact of State regulation on the supply of medicinal products, and more particularly the argument 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.

75 It is true that in Greece, as is apparent from paragraph 8 of this judgment, national legislation places pharmaceuticals wholesalers under an obligation to supply the needs of a defined geographical area with a range of pharmaceutical products. It is equally true 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 that were consistent with national legislation as well as with the obligations flowing from Article 81 of Directive 2001/83.

76 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. Such could be the case, in a given Member State, if certain wholesalers order from that producer medicines in quantities which are out of all proportion to those previously sold by the same wholesalers to meet the needs of the market in that Member State.

77 In view of the foregoing, the answer to the questions referred should be that Article 82 EC must be interpreted as meaning that an undertaking occupying a dominant position on the relevant market for medicinal products which, in order to put a stop to parallel exports carried out by certain wholesalers from one Member State to other Member States, refuses to meet ordinary orders from those wholesalers is abusing its dominant position. It is for the national court to ascertain whether the orders are ordinary in the light of both the size of those orders in relation to the requirements of the market in the first Member State and the previous business relations between that undertaking and the wholesalers concerned.

Costs

78 Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the national court, the decision on costs is a matter for that court. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.

On those grounds, the Court (Grand Chamber) hereby rules:

Article 82 EC must be interpreted as meaning that an undertaking occupying a dominant position on the relevant market for medicinal products which, in order to put a stop to parallel exports carried out by certain wholesalers from one Member State to other Member States, refuses to meet ordinary orders from those wholesalers, is abusing its dominant position. It is for the national court to ascertain whether the orders are ordinary in the light of both the size of those orders in relation to the requirements of the market in the first Member State and the previous business relations between that undertaking and the wholesalers concerned.

[Signatures]