European Court of Justice, 16 September 2008, GSK

COMPETITION LAW - ABUSE OF A DOMINANT POSITION

Abuse of a dominant position – Article 82 EC

- **An undertaking which, in order to put a stop to parallel exports carried out by certain wholesalers, refuses to meet ordinary orders from those wholesalers, is abusing its dominant position**

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.

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European Court of Justice, 16 September 2008

(V. Skouris, P. Jann, C.W.A. Timmermans, A. Rosas, K. Lenaerts and A. Tizzano, R. Silva de Lapuerta, K. Schiemann, J. Makarczyk, P. Lindh, J.-C. Bonichot, T. von Danwitz and A. Arabadjiev)

JUDGMENT OF THE COURT (Grand Chamber)

16 September 2008 (*)

(Article 82 EC – Abuse of dominant position – Pharmaceutical products – Refusal to supply wholesalers engaging in parallel exports – Ordinary orders)

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),

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,

dvocate 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. Mar-

inopoulos 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 reimportations 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 abovementioned 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.

OPINION OF ADVOCATE GENERAL
Ruiz-Jarabo Colomer
delivered on 1 April 2008 (1)
Joined Cases C-468/06 to C-478/06
Sot. Lelos kai Sia EE,
Farmakemporiki AE Emporias kai Dianomis Farmakeftikon Proionton,
Konstantinos Xidias kai Sia OE,
Farmakemporiki AE Emporias kai Dianomis Farmakeftikon Proionton
Ionas Stroumsas EPE
Ionas Stroumsas EPE
Farmakapothiki Farma-Group Messinias AE
K.P. Marinopoulos AE Emporias kai Dianomis Farmakeftikon Proionton
K.P. Marinopoulos AE Emporias kai Dianomis Farmakeftikon Proionton
Kokkoris D. Tsanas K. EPE
Kokkoris D. Tsanas K. EPE
v
GlaxoSmithKline AEVE Farmakeftikon Proionton
(Reference for a preliminary ruling from the Trimeles Efetio Athinon (Greece))
(Abuse of a dominant position – Parallel trade in medicinal products)

I – Introduction

1. Like a boomerang, questions referred to the Court of Justice and ruled inadmissible a couple of years ago (2) have now come back to it. A Greek court, the Trimeles Efetio Athinon (Court of Appeal, Athens), is seeking a reply to some fundamental questions of Community competition law relating to abuse of a dominant position, which is prohibited by Article 82 EC, and parallel imports of medicinal products from the Hellenic Republic to other Member States, where the reimbursement of the price paid for medicinal products dispensed under prescription is appreciably higher than that in Greece.

2. The reason for the dismissal of the reference did not preclude the Advocate General appointed on that occasion preparing an Opinion, (3) to which the parties in the proceedings before the referring court make extensive reference, almost to the point of turning it into the main focus of the debate.

3. This situation makes me uneasy, as I feel like Avellaneda writing the second part of somebody else's novel, and, like that author, I could be criticised for this, even if the circumstances are not comparable: I feel compelled to write this Opinion and I am fulfilling my professional duty in good faith and without any of the resentment which seems to have driven Avellaneda's plagiarism. (4)

II – The legislative framework

A – Community law

4. The EC Treaty contains two rules of competition law which are fundamental to the operation of the common market. While Article 81 EC prohibits collusion between rival companies, the first paragraph of Article 82 EC prohibits any abuse by one or more undertakings of a dominant position within the common market or a substantial part of it. The second paragraph sets out a non-exhaustive list of typical examples of such arbitrary conduct.

5. In the context of the facts in the main proceedings, certain pieces of secondary legislation are also relevant; Directive 89/105/EEC (5) contains measures aimed at harmonising methods of setting the prices of medicinal products. Article 2(1) and (2) provides that:

'The following provisions shall apply if the marketing of a medicinal product is permitted only after the competent authorities of the Member State concerned have approved the price of the product:

1. Member States shall ensure that a decision on the price which may be charged for the medicinal product concerned is adopted and communicated to the applicant within 90 days of the receipt of an application submitted, in accordance with the requirements laid down in the Member State concerned, by the holder of a marketing authorisation. The applicant shall furnish the competent authorities with adequate information. … the competent authorities shall … take their final decision within 90 days … In the absence of such a decision within the abovementioned period or periods, the applicant shall be entitled to market the product at the price proposed.

2. Should the competent authorities decide not to permit the marketing of the medicinal product concerned at the price proposed by the applicant, the decision shall contain a statement of reasons based on objective and verifiable criteria. …'

6. Even if it is not relevant to the facts of the case before the referring court because of its temporal scope, it is appropriate, in view of the possible future implications of the Court's judgment, to mention the second paragraph of Article 81 of Directive 2001/83/EC, (6) repealing Directive 92/25/EEC, (7) which provides that:

'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.'

7. The third paragraph of Article 81 makes it clear that the measures put in place for implementing this article must be justified on grounds of public health protection and be proportionate to the objective of such protection, 'in compliance with the Treaty rules, particularly those concerning the free movement of goods and competition'.

B – National legislation

8. Article 2 of Law No 703/1977 on the control of monopolies and oligopolies and the protection of free competition ('Greek Law on competition') essentially corresponds to Article 82 EC.

9. Under the second paragraph of Article 29 of Law No 1316/1983, amending Article 8 of Legislative Decree 96/1973, holders of an authorisation to market medicines are required to supply the market regularly with the goods which they manufacture or import.

10. Finally, Greek legislation requires that persons carrying out the business of pharmaceutical wholesaler obtain a licence and undertake to supply a defined geographical area adequately.

III – The facts in the main proceedings and the questions referred for a preliminary ruling

11. GlaxoSmithKline plc, a pharmaceutical research and manufacturing company established in the United Kingdom, distributes and warehouses its products in Greece through its subsidiary GSK AEVE (hereinafter collectively referred to as 'GSK'), which holds the parent company's marketing authorisation for the products in Greece. GSK AEVE therefore distributes goods bearing the trade marks Imigran, for migraine, Lamictal, for epilepsy, and Serevent, for asthma, which are all prescription medicines for which GSK holds the patent.

12. The appellants in the main proceedings had for a number of years acquired these medicines in various forms as intermediary wholesalers in order to supply them both to the Greek and to other markets, particularly Germany and the United Kingdom.

13. Citing a shortage of the three medicinal products referred to above, for which it declined to take any responsibility, GSK changed its system of distribution in Greece at the end of October 2000. It stopped meeting the appellants' orders from 6 November of that year and supplied the products to hospitals and pharmacies through the company Farmacenter AE.

14. When, in February 2001, GSK reinstated normal supplies it resumed supplying Imigran, Lamictal and Serevent to the wholesalers, albeit to a limited extent, but ended its involvement with Farmacenter AE. This conduct on the part of GSK angered the appellants and resulted in their bringing two types of legal action: an administrative action and a civil action.

15. GSK started administrative proceedings when the Epitropi Antagonismou (Greek Competition Commission) dismissed the complaints concerning the changes in its distribution policy for medicinal products; for their part, the appellants in the main proceedings, which are associations of Greek pharmacists and other wholesalers, instituted proceedings on the same facts, seeking to establish that GSK had committed an abuse of a dominant position within the meaning of Article 2 of the Greek Law on competition and Article 82 EC.

16. A decision of the Epitropi Antagonismou ordering interim measures required GSK to meet the orders of the three products in question pending adoption of a final decision. However, as it was unsure how national law should be interpreted in the light of Community law, the regulatory body charged with overseeing competition in the Greek market stayed the proceedings and referred certain questions relating to the interpretation of Article 82 EC to the Court of Justice for a preliminary ruling, the reference being lodged at the Court's Registry under the number C-53/03.

17. The Court's judgment did not address the substance of the dispute because it found that the Court had no jurisdiction to answer questions referred by a body which is not a court or tribunal within the meaning of Article 234 EC, (8) but the Epitropi Antagonismou issued its decision on the appellants' complaints on 1 September 2006 and made the following findings: that GSK occupied a dominant position only in respect of Lamictal, since epilepsy sufferers found it difficult to adjust to other similar medication; that the GSK group of undertakings had infringed Article 2 of the Greek Law on competition only during the period from November 2000 to February 2001 but not subsequently; and that it had not infringed Article 82 EC.

18. The validity of the decision of the Epitropi Antagonismou has been challenged by the appellants before the Diikitiko Efetio Athinon (Administrative Court of Appeal, Athens), whose judgment is pending.

19. The civil proceedings were commenced when the current appellants filed petitions at the Polimeles Protodikio Athinon (Court of First Instance, Athens) on 30 April (9) and 30 October 2001, (10) and 5 March (11) and 11 November 2002. (12)

20. The appellants argued that GSK's conduct in interrupting supplies and distributing through Farmacenter constituted acts of unfair competition and an abuse of the dominant position of GSK on the market for the three products in question. The appellants sought an order that the products continue to be supplied to them in the quantities corresponding to the monthly average supplied by GSK to them between 1 January and 31 October 2000, plus 20%, and compensation in respect of the damage caused and loss of profits.

21. With the exception of the claim for loss of profits, which it held inadmissible, the Court of First Instance, Athens, gave judgment in these actions between January and October 2003, and dismissed them as unfounded, finding that the refusal to supply was justified and that consequently the accusation of abuse of GSK's dominant position became void.

22. The appellants in the national proceedings have appealed against these decisions to the Trimeles Efetio Athinon (Tripartite Court of Appeal, Athens), which, having waited in vain for the opinion of the Court of Justice on the questions referred to it by the Epitropi Antagonismou in Case C-53/03, has decided to stay the appeal proceedings and refer identical questions to the Court of Justice for a preliminary ruling, namely: (13)

'1. Where the refusal of an undertaking holding a dominant position to meet fully the orders sent to it by pharmaceutical 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 in-

tervention, 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 court or tribunal 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:

2.1. 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?

2.2. Is an approach entailing the balancing of interests appropriate, and, if so, what are the interests to be compared? In particular:

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

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

2.3. What other criteria and approaches are considered appropriate in the present case?'

IV – Procedural steps before the Court of Justice

23. All the orders for reference were lodged at the Registry of the Court of Justice on 21 November 2006. Pursuant to Article 43 of the Rules of Procedure of the Court of Justice, the President, by an order of 29 January 2007, ordered the cases to be joined, on account of the objective connection between them.

24. Sot. Lelos kai Sia EE (Case C-468/06), Farmakemporiki AE Emporias kai Dianomis Farmakeftikon Proionton and others (Cases C-469/06 to C-476/06) and Kokkoris D. Tsanas K. EPE and others (Cases C-477/06 and C-478/06) (the appellants in the main proceedings), GSK, the Polish Government and the Commission of the European Communities have submitted written observations within the time-limit indicated in Article 23 of the Statute of the Court of Justice.

25. At the hearing, held on 29 January 2008, the representatives of Farmakemporiki AE Emporias kai Dianomis Farmakeftikon Proionton and others, Kokkoris D. Tsanas K. EPE and others, GSK, the Italian Republic, which had not submitted written observations, the Republic of Poland and the Commission of the European Communities were present to submit their arguments orally and to reply to the questions put to them by the Court.

V – Analysis of the questions referred for a preliminary ruling

A – Preliminary matters

1. Objections to the formulation of the questions

a) Dominant position

26. I have already referred to the decision of the Greek Competition Commission of 1 September 2006, which found that GSK held a dominant position in respect of the medicinal product Lamictal, but not in respect of Imigran or Serevent. GSK, however, in point 5 of its written observations, disputes that this is the case, relying on two principal arguments: that it is impossible for it to act without regard for its competitors and that the relevant market is not the market in the relevant therapeutic area but the European market for all prescription medicines.

27. There is settled case-law on the clear separation of functions between the national courts and the Court of Justice in Article 234 EC proceedings, to the effect that the assessment of the facts of the case is a matter for the national court. (14)

8. As investigating the position of an undertaking in a particular market and defining the relevant market entail an examination of the facts, it must be left to the referring court and there can be no question of the Court of Justice giving its view on the matter.

29. The Trimeles Efetio Athinon must therefore assess whether the essential prerequisite for the application of Article 82 EC has been met, and, if it has not, dismiss the appeals which are before it.

30. However, as an appeal is pending against the decision of the Epitropi Antagonismou in the Greek administrative courts, in order to address the concerns of the referring court, we will have to assume that GSK holds a dominant position.

b) Meeting orders 'in full'

31. In its written observations, the appellant in the main proceedings Lelos kai Sia EE is critical of the way the first question is worded in that it uses the expression 'to meet fully the orders', which could cause confusion as it moves the debate from the context in which it arose to a more theoretical level on which the basis of any order sent to GSK, however exorbitant or excessive, would have to be assessed.

32. The other appellants also refer, albeit less emphatically, to the need to redefine the debate in its original terms, as it was presented in the Greek proceedings, given GSK's tendency to take the complaints of the Greek wholesalers to extremes and to structure its argument as if it were a question of meeting any order, however excessive.

33. I share the view of the parallel importers that it is appropriate to direct the debate towards the circumstances in which it arose, namely the supply by GSK of the medicinal products in question to these undertakings in the average monthly amounts supplied in the year 2000, plus 20%, as set out in the order for reference, for the following reasons: on the one hand, in Article 234 EC proceedings the facts are provided by the referring court and the Court of Justice should not interfere in this area; and, on the other hand, to depart

from this factual framework would render the response less helpful.

2. Approach

34. In the interests of a better understanding of this process, it would seem appropriate to look to the possibility, recognised in the case-law, (15) of reformulating the questions put by the Trimeles Efetio Athinon, since the first question seeks to establish whether GSK's refusal to supply, which is motivated by a desire to limit parallel trade, of itself constitutes an abuse of a dominant position when it is aimed exclusively at the elimination of its competitors in the wholesale distribution market.

35. However, the questions which follow relate to a series of circumstances which belong to the realm of possible justifications for the abuse, and consequently it would be more logical to transfer them to the second question, which asks about the correct criteria for assessing whether the conduct of GSK is excessive. Moreover, the written observations submitted in these preliminary ruling proceedings are inspired to a great extent by the Opinion of Advocate General Jacobs in Syfait and Others, which also deals extensively with the grounds for justifying the abuse.

36. This approach to the questions also permits me to address a current doctrinal debate, namely whether there are practices which are of themselves abusive, and to take the analysis of possible justifications further.

B – Abuses per se of a dominant position under Article 82 EC (the first question)

37. In the main proceedings, GSK is accused of having suspended sales of Imigran, Lamictal and Serevent to the wholesalers on the basis of an alleged shortage; it is also criticised for continuing to supply these competitors but only in quantities tailored to the requirements of the Greek market in order to prevent re-export to other European countries, in particular to Germany and the United Kingdom.

38. Before addressing the question of whether such conduct should be described as an abuse 'in itself' (per se), we must briefly look at how refusals to supply have been treated in Community case-law and at the effect that a clear intention to block parallel trade has as an aggravating factor in the assessment of the conduct. Once some light has been shed on the question of whether or not there is an abuse, our analysis can go on to focus on whether it can be described as an abuse per se.

1. Refusal to supply as an abuse

a) Community case-law

39. The factual background to the few judgments of the Court on this subject mean that they are of doubtful relevance to this case, where the wholesalers of the three medicines in question are facing a refusal by their only supplier, which is the holder of the manufacturing patent and a long-standing competitor in the distribution of these medicines. Nevertheless, it is worth mentioning a few of the most important decisions on Article 82 EC as they are of general application.

40. In Commercial Solvents, (16) Commercial Solvents stopped supplying aminobutanol to the Italian company Zoja, which manufactured ethambutol, a derivative of that raw material, in a market where the two undertakings were in competition with each other. The judgment held that the failure to meet orders was contrary to Article 82 EC because the dominant position enjoyed by Commercial Solvents in the manufacture of the substance, which allowed it to control the supply to manufacturers of derivatives, did not permit it to eliminate competition with its former customers simply because it had started to manufacture those derivatives itself. (17)

41. There are clear parallels between Commercial Solvents and the present case, since GSK initially stopped supplying the Greek wholesalers with its products with the aim of reorganising sales of the three disputed products through its own exclusive distributor in the country; about three months later it resumed supplies but limited the quantities supplied to the demand on the Greek domestic market.

42. In United Brands, which concerned 'Chiquita' bananas, (18) it was held that United Brands, in discontinuing sales of bananas to the Danish ripener-distributor Olesen for having taken part in an advertising campaign for its competitor, Dole, was in breach of competition law.

43. On that occasion the Court held that an undertaking in a dominant position for the purpose of marketing a product 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'. (19)

44. It is worth stressing the similarities between United Brands and the present case with regard to the dominant position of the undertaking and with regard to the competing wholesalers' respect for commercial practice or compliance with contracts; on the other hand, in the present case the level of supplies claimed by the appellants before the Trimeles Efetio Athinon, and whether it should be treated as ordinary or excessive, raises different problems. In United Brands this was not a matter of dispute and the Court therefore considered that Olesen's requests were normal. However, the right context for weighing up these matters is that of possible justifications for a refusal to meet all the orders of the parallel trading companies and consequently it is not appropriate to take this aspect any further.

45. In other cases, the Court of Justice has ruled on such a refusal, although this has been either in relation to factual situations which are too dissimilar to the present case or in a very different legal context. In the first category, it is worth mentioning the judgment in CBEM, (20) which extended to the services sector the prohibition on undertakings in a dominant position reserving to themselves, or to another company in the same group, the market for an ancillary activity carried out by another undertaking in a neighbouring but separate market; in the second category are judgments which deal with access to an essential facility, such as

Bronner, (21) or which relate to a refusal to grant an intellectual or industrial property licence, such as Magill (22) and IMS Health, (23) which are all very far removed from the circumstances of the present reference.

46. In short, the Commercial Solvents and United Brands cases show that a dominant undertaking which avoids supplying goods, particularly when there are no substitutes, as in the case of Lamictal, and reserves to itself the parallel export market, is committing an abuse under Article 82 EC. It now remains to be determined whether the intention to eliminate such parallel trade means that such an abuse can be designated an abuse per se under Community competition law.

b) Intent as an aggravating factor

47. Our point of departure is that it is an established rule of Community case-law that the concept of 'abuse' in Article 82 EC is an objective concept linked to the activities of undertakings in a dominant position (24) and, as such, is unaffected by any considerations relating to the intentions which prompted such behaviour. (25) Neither is it necessary that the abuse be blameworthy in order to fall within the scope of Article 82 EC. (26)

48. None the less, two important points should be borne in mind, which refine the above statements.

49. On the one hand, the possibility that subjective elements of the breach can often indicate that an anti-competitive outcome is being sought or even that they can constitute the abusive act itself cannot be entirely ruled out. (27)

50. On the other hand, the Court of Justice has confirmed the thesis developed by the Court of First Instance that, in view of the difference between Article 81(1) EC and Article 82 EC, which contains no reference to the anti-competitive effect of the abuse in question, in order to demonstrate that a breach of Article 82 EC has taken place it is sufficient to prove that the abusive conduct of the dominant undertaking tends to restrict competition or, in other words, is capable of having such an effect. (28)

51. Therefore, the closer the undertaking in a dominant position is to hindering competition in the market, the stronger the presumption of abuse. This is the key to solving the present dispute. Not even GSK has denied that its real aim is to eliminate the parallel exports by the wholesalers of the three medicines in dispute from Greece to other countries in the Community.

52. Moreover, as such restrictions on the volume of sales of the other distributors limit its rivals' market, within the meaning of subparagraph (b) of the second paragraph of Article 82 EC, there is a very strong indication that this conduct, and therefore the purpose behind it, contravenes the first paragraph of Article 82 EC. (29)

53. It is evident that the intention of GSK is contrary to the objectives of the Treaty, since it affects freedom of trade between Member States to an extent which might harm the attainment of a single market, as this is understood in the case-law and in Article 3(1)(g) EC, since it undoubtedly partitions national markets and impairs the structure of competition within the common market. (30)

54. In summary, the foregoing analysis shows that GSK has committed a serious infringement of the Treaty, which would merit being treated as an abuse per se, since it is difficult to identify any economic motive other than the elimination of the parallel trade of its competitors, the Greek wholesalers. (31) However, I have some doubts of a methodological nature about how the conduct of dominant undertakings should be evaluated, and it is therefore worth taking the analysis further.

2. Recognition of abuses per se in the context of Article 82: a problem of methodology

55. Before setting out the arguments against accepting abuses per se, it is appropriate to address the development of the concept in Community case-law.

a) Case-law of the Court of Justice

56. To date the Court has identified three practices which, when carried out by undertakings in a dominant position, would inevitably constitute an abuse of their strength in the market, seemingly without any possibility of adducing evidence to the contrary by way of justification.

57. The Court had ruled to this effect in respect of exclusive supply obligations imposed on purchasers by a dominant company, whether stipulated without further qualification or in consideration for the grant of rebates. (32)

58. Loyalty rebates constitute the second of the practices which are always presumed to be abuses, since, unlike quantity discounts, which are linked solely to the volume of purchases from the manufacturer concerned, loyalty rebates, by offering customers financial advantages, tend to prevent them from obtaining their supplies from competing manufacturers. (33)

59. The third practice which is considered abusive per se concerns predatory pricing. According to the Court of Justice, prices below average variable costs (those which vary depending on the quantities produced) have no economic basis and therefore can only indicate an intention to eliminate a competitor and must consequently be regarded as abusive. (34) By contrast, prices below average total costs (fixed costs plus variable costs), but above average variable costs must be regarded as abusive if they are part of a plan for eliminating a competing undertaking. (35)

60. The reasoning in these judgments left no room for any justification on the part of the dominant undertaking. (36) However, more recent case-law, also relating to loyalty rebates, does not confirm the idea that these must always be regarded as abusive. Thus, in relation to discounts linked to individual sales targets in commercial passenger aviation granted to travel agencies by an undertaking in a dominant position on the United Kingdom market for air travel, the Court allowed the undertaking to demonstrate that its bonus system, which had the effect of eliminating competition, was economically justified. (37)

61. The Court is therefore prepared to allow dominant undertakings to defend themselves, even in areas

where it seemed to accept the existence of possible abuses per se, and in doing so it is in reality following the more traditional case-law developed independently of this line of decisions which establish a category of automatically abusive practices. (38) However, apart from specific statements focusing on the circumstances of each individual case, the Court has not given any general rules indicating that abuses per se do not fall within the article of the Treaty dealing with abuse of a dominant position. It might therefore be helpful to suggest some rules of this nature.

b) Abuses per se unsuited to Article 82 EC

62. For both legal and economic reasons, Article 82 EC is not appropriate to govern conduct branded as abusive per se.

i) Legal considerations

63. The structure of Article 82 EC, particularly in comparison with the preceding article of the Treaty, falls to be considered here.

64. Article 81 EC comprises three paragraphs which cover, respectively, the principle that collusive practices are prohibited, a statement that the main consequence of infringing the prohibition contained in paragraph 1 is that the agreement or decision is void and the possibility of obtaining an exemption, assuming that none has been obtained by virtue of a block exemption regulation adopted pursuant to Article 83(2)(b) EC in conjunction with Article 83(1) EC.

65. The examples of anti-competitive agreements listed in Article 81(1)(a) to (e) EC are traditionally likened to infringements per se of this provision and consequently they have no place in Article 81(3) block exemptions. (39) Although very problematic, there is still a possibility that such agreements can remain valid thanks to an individual exemption if the parties can show that their agreements meet the conditions set out in Article 81(3) EC. In this context, the United States Supreme Court has recently aligned its approach to resale price maintenance in vertical agreements with the proposition that they should be subject to the 'rule of reason', (40) thus departing from the rigour of its well-established case-law which, ever since a precedent laid down in 1911, (41) had held that such a practice was illegal per se because it contravened Section 1 of the Sherman Act.

66. In short, the provision itself offers undertakings various routes for challenging any assertion that the clauses of their agreements constitute infringements per se. This is not so in the case of dominant companies under the article of the Treaty relevant to them.

67. Drafted as it is, without a provision dealing with exemptions for certain abuses, an analysis of conduct requires undertakings holding a dominant position on a particular market to engage in a dialectical debate with the competition authorities, whether national or Community, and with the affected parties.

68. Each of these participants in the rhetorical debate brings evidence of its assertions, in accordance with the old Latin adage ei incumbit probatio qui dicit, non qui negat (the burden of proof is on him who alleges and not on him who denies).

69. This being the case, if certain conduct always gives rise to a legal presumption that an abuse has occurred, dominant undertakings would be deprived of their right to defend themselves, since, as I have indicated, the structure of Article 82 does not permit any exemptions; consequently, once the abuse has been proved, the finding of an infringement follows, unless there are adequate indications that it has not been committed.

70. Furthermore, the examples listed in subparagraphs (a) to (d) of the second paragraph of Article 82 EC do not operate as legal presumptions, unlike those in Article 81(1)(a) to (e). At most they should be understood, due to their underlying economic logic, as rebuttable presumptions which lighten the burden of proof for the party relying on them, (42) but never as substitutes for the dialectical debate which I have referred to above. In the same way that collusive practices per se under Article 81 EC were redeemed by Article 81(3) EC, the option of accommodating certain types of abuse under Article 82 EC by means of objective justification should remain open.

ii) Economic considerations

71. In the first place, to accept the idea of abuses per se of a dominant position would run counter to the proposition that it is necessary to examine each case within the economic and legal context in which it arose.

72. Secondly, from a purely economic perspective, the approach per se is too form-based, a defect criticised by some very informed commentators who advocate an alternative approach to Article 82 EC, which would focus on the effects of each abuse and involve a consideration of the specific circumstances by applying an 'analysis of the merits' (43) (or a 'rule of reason'). (44)

73. Allowing preconceived and formalistic ideas on abuse of a dominant position to prevail would mask the fact that sometimes dominance can benefit consumers. (45) This is the case when the strength of one operator reduces competition in a particular market, given that Article 82 EC does not include any provision whereby such operators can successfully defend themselves against the accusation of abuse by demonstrating the economic efficiency of their conduct, an absence which has been justly criticised. (46)

74. Thirdly and lastly, if, as has been said, it is common to divide the circumstances in which Article 82 EC applies into two categories, namely those that harm consumers (exploitative abuses) and those that harm actual or potential competitors (exclusionary abuses), (47) so that any anti-competitive conduct of a dominant undertaking is capable of constituting an abuse, (48) as there is no indication of the relative importance of these two aspects of Article 82 EC, (49) a defence of the dominant company based on economic results obtained might be advocated.

75. A mere comparison of the positive and negative consequences for consumers and for other operators in the same market provides sufficient information to draw the relevant conclusions.

3. Proposed answer to the first question

76. In accordance with the foregoing, abusive conduct per se does not sit well with Article 82 EC, and consequently the first question put by the Trimeles Efetio Athinon should not be answered in the affirmative. I therefore recommend that the Court make an unambiguous declaration to the effect that Article 82 EC does not provide a basis for attributing abusive conduct per se to undertakings in a dominant position, even when it is clear from the circumstances of the case that there is both intent and an anti-competitive effect.

77. In view of the answer to the first question, the second question, which relates to possible objective justification of such conduct, must now be considered.

C – Justifications for conduct normally considered abusive (the second question)

78. First of all, I should like to call to mind the fact mentioned earlier that part of the first question belongs in the answer to the second because it relates to the grounds for exoneration of the types of practices listed in Article 82 EC. As I understand it, it is precisely the criteria for reversing an initial negative finding against an undertaking in a dominant position that the referring court is enquiring about.

79. Dominant undertakings accused of abuse can rely on three grounds to excuse their conduct: grounds relating to the market in which they are operating, (50) the legitimate protection of their business interests and proof of net positive economic effect. I will deal with each of these in turn, with reference to the facts before the referring court.

1. Market imperfections

80. GSK has argued that State regulation prevents it from carrying on its business in normal conditions of competition. It cites two factors justifying the limitations on the parallel exports of the Greek wholesalers: the setting of maximum sale prices for medicinal products, which is common practice in all the Member States, and the obligation to hold sufficient stocks to satisfy the domestic demand at all times.

81. The appellants in the main proceedings, the Polish Government and the Commission reject this analysis, with certain clarifications. Before embarking on an examination of the grounds for justification, it is appropriate to sketch out the distinctive features of the market in question.

a) Basic characteristics of the market

82. It has been correctly pointed out that the European pharmaceuticals market, defined as the trade in and distribution of products with or without patent protection, is characterised by a low level of harmonisation owing to State price intervention and to the existence of public systems for the reimbursement of patients' expenditure on medicinal products, which means that the price paid by the end-user is less important. (51)

83. The parties submitting observations in these reference proceedings are in agreement that all the Member States regulate the prices charged to patients by manufacturers in the sector by limiting the amounts reimbursed by the various social insurance bodies, thus containing public spending on health. They also agree that sale prices vary enormously between the Member States. Alongside this State financing system, there is another entirely private system in which pharmaceutical companies are free to charge the prices they choose for medicinal products: however, I detect a certain consensus that this model represents a very small percentage, although it does vary between countries.

84. Finally, another distinctive feature of this market should be noted, namely the number of patented medicines. Although this is not a reflection of State control, it is significant because the holders of these industrial property rights can more readily assume positions of dominance as these monopolies often act as barriers to entry of a legal and temporal nature. (52)

85. In this situation, GSK maintains that Member State price setting as well as the obligation to manage stocks to meet domestic demand constrain it to such an extent that the only means available to it to redress the situation from a business point of view is to make it more difficult for the Greek wholesalers to carry out parallel exports to countries where the amount reimbursed for each product far exceeds that obtainable in Greece.

b) Analysis of the grounds for justification

86. Although Community case-law has never accepted a justification based on the individual characteristics of the regulation of a particular market, I believe that there are circumstances where, on the basis of the effects of State control of the market, it might conceivably do so. GSK relies on two fundamental factors: price intervention and the duty to supply.

i) Member State price setting

87. On the subject of Member State policies for the reimbursement of the cost of medicines by social insurance bodies, the Court's judgment in Merck and Beecham (53) recognised that price setting may distort competition between Member States, but it went on to say that such a distortion brought about by State interference does not justify a derogation from the principle of free movement of goods. (54)

88. Although the prohibition contained in Article 28 EC cannot be invoked against undertakings, the obligation not to impede the objectives of the Treaty, and in particular freedom of trade between Member States, applies to them in the form of Articles 81 EC and 82 EC, which state that conduct which causes the artificial partitioning of national markets and impairs competition is incompatible with the Treaty. (55) It is therefore appropriate to mention the case-law of the Court of Justice on the free movement of goods, at least inasmuch as it concerns the partitioning of national markets.

89. In any event, the impact of pricing policies is diminished by Article 2(1) and Article 2(2) of Directive 89/105, (56) which apply to all forms of State intervention. (57) It is clear from Article 2(2) that the manufacturers of medicinal products are involved in a dialogue with the authorities responsible for setting prices, which must give reasons based on 'objective and verifiable criteria' for any decision not to permit the sale of the medicinal product at the price proposed by the applicant. Article 2(1) even contemplates deemed authorisation by administrative silence, as, in

the absence of a decision of the Member State within 90 days of the receipt of the application, the applicant is entitled to market the product.

90. However tough the negotiations, we should not forget the position of the pharmaceutical companies, particularly when they hold new patents, which usually mean an improvement for the patient receiving treatment using these medicines. This point is highly significant as it is in the interests of the Member States, which are under a duty to ensure that a high-quality public health system is provided for patients, to have at their disposal the best methods that the market can offer, provided that they can be obtained at a reasonable price. (58)

91. I realise that, with the passage of time, the advantage enjoyed by the holder of the pharmaceutical patent diminishes and the prices originally agreed with the health authorities have to be reduced. However, this evolution is quite normal and is due to other manufacturers offering substitutes which are therapeutically more effective, with each new product displacing its predecessor thanks to advances in research.

92. Furthermore, the price agreed must not be at a level which would cause companies in the sector to sell at below cost.

93. In summary, although the pharmaceuticals market does not operate under normal competitive conditions, the price regulation system is not completely free from the influence of the manufacturers, which negotiate prices with the Member State health authorities, enjoy a degree of strength in the market and are able to adapt easily to the vicissitudes of health policy, at least as far as medicines are concerned.

ii) The duty to supply

94. The second market regulation factor which, according to GSK, interferes with its normal activities in Greece and excuses the limitation on parallel trade concerns the duty to keep the Greek market adequately supplied at all times. GSK also maintains that this duty prevents it from meeting the orders from the wholesalers as they would like.

95. The scope of this duty requires some clarification, since some of the appellants in the main proceedings also regard themselves as under a duty to supply the market, and this is supported by the second paragraph of Article 81 of Directive 2001/83, referred to in point 6 of this Opinion. I cannot therefore see any reason why GSK should plead this duty in its defence.

96. Undoubtedly, the needs of patients in the Member State are not subject to sudden changes, except when there are epidemics or pandemics, and consequently the figures for numbers of patients suffering from each condition are reliable and give the companies a degree of predictability which allows them to adapt to the market.

97. In short, for the reasons set out above, the duty to supply cannot justify GSK cutting off supplies to its rival Greek wholesalers.

98. Therefore, having rejected the two grounds for exoneration put forward by GSK, we must rule out the idea that there are in this case objective reasons relating to State intervention in the market which would justify its conduct.

2. Protection of legitimate business interests

a) Analysis of the case-law

99. A quick analysis of the case-law shows that, so far, this is the only category of objective justifications to have really taken shape, as the fundamental debate over Article 82 EC has come down to the dichotomy between abusive practices and conduct intended to protect legitimate business interests. (59)

100. The refusal to meet fully the requests of the Greek wholesalers amounts to a refusal to supply, albeit partial, and I will therefore restrict myself to the few judgments of the Court relating to that subject.

101. United Brands accepted that the protection of legitimate business interests can be a means of defusing suspicions of abuse by an undertaking in a dominant position, by allowing them to take the necessary steps to protect such interests, provided that the essential proportionality between the reaction of the dominant companies and the attacks on their interests is preserved. (60)

102. However, the establishment of this principle was of no help to the American banana multinational, as the judgment found that the necessary conditions for legitimate protection were not present, precisely because the refusal to meet the orders of its customer and competitor Olesen was not proportionate. (61)

103. In another case, the Court considered a refusal to supply in times of shortage, during the oil crisis of the 1970s, (62) and allowed BP to reduce its supply of crude oil to an occasional customer, the Netherlands cooperative ABG, by a higher percentage than that applied to its traditional customers in order to avoid those customers being more seriously prejudiced, by comparison. (63)

104. Aside from the Community case-law, particular justifications have been put forward in other contexts. Thus, for example, the Commission accepts that a dominant producer can review its commercial relations when a customer changes its policy so that its main activity is the promotion of a competing brand. (64)

105. There is discussion among legal writers about other justifications, such as that of the unsatisfactory trading parties, that is to say, a trader who is on the verge of insolvency, commits systematic breaches of contract or is damaging to the image or the quality of the supplier's goods. (65) In these circumstances, common sense suggests that the wishes of any dominant undertaking to refuse orders should be respected.

b) The arguments put forward

106. All the arguments put forward by GSK in the observations submitted to the Court concerning reduced income due to loss of market share in favour of the wholesalers and its effect on recouping investment in research and development ('R&D') relate to the protection of legitimate interests.

107. Both GSK and some of the legal literature cite the enormous cost of investing in the R&D for the launch of a medicinal product; they add that the average time between obtaining the patent for the active ingredient

and the product becoming available for therapeutic purposes is 12 or 13 years, and consequently the period during which the marketing of the product produces returns is only 7 or 8 years. (66)

108. In these circumstances, they say, parallel trade and the manufacture of generic drugs once the patent protection has expired reduce their ability to recoup R&D costs.

109. I cannot see that there is necessarily any causal link between any possible negative impact on R&D investment and parallel trade, since, in the first place, GSK and the writers in question have not provided any information relating to the reasons for the period during which the patent is not revenue producing. However, this long delay is a result of the internal cost structures of pharmaceutical undertakings. In any event, as they consider the period during which the patent is profitable to be very short, they are experiencing how it feels to enjoy rights for a limited period only. I would even hazard a guess that there are other sectors in which something similar occurs in relation to this type of intangible property.

110. Secondly, although it would be logical to suppose that only the economic success of a patent ensures that more funding is obtained to keep up the research, R&D policy in the pharmaceutical sector has become central to the entire business. In this branch of the economy, it is only the constant search for innovatory medicines which helps companies to survive in a very competitive, globalised and lucrative market. But without a well-thought-out commercial policy, the most brilliant inventions run the risk of going unnoticed. That is why any research company must seek out the best ways of appealing to and reaching the consumer.

111. GSK was free to design its own distribution system in Europe. It decided on a strategy which incorporated the Greek wholesalers because it considered it more economically efficient and advantageous. It could have opted instead for a vertically integrated system for the distribution of its medicines, as it did in November 2000. Even though it was at liberty to restructure its distribution networks, as long as it respected normal commercial practice, in the present case GSK is being criticised for punishing the wholesalers for having taken better advantage of market conditions and preventing them from carrying out their export business.

112. Thirdly, looking at the figures provided in the literature referred to in point 107 of this Opinion, which show that the market share of the parallel importers increased from 1.8% to 6.8% between 1998 and 2003, (67) one has the impression that the real battle is about winning back these profit margins which the rivals of the big pharmaceutical companies have appropriated.

113. Against this background, I find the argument that the loss of income resulting from parallel imports of patented medicines acts as a disincentive misleading, since it is aimed only at seducing public opinion, which is sensitised to the vital importance of R&D for competitiveness, by shifting the focus from business rivalry to research policy, an area which the European Union has taken on since the Single European Act incorporated Title XVIII, 'Research and technological development', into the EC Treaty.

114. The European Union offers undertakings a favourable environment in this respect by encouraging them, through the granting of a block exemption for horizontal agreements of this type, (68) to minimise R&D costs because it realises that cooperation in this area and in the exploitation of the results promotes technical and economic progress by increasing the dissemination of know-how; it also avoids duplication of R&D work, stimulates advances through the exchange of complementary discoveries and encourages greater rationalisation of the manufacture of the products or application of the methods arising out of the R&D. (69)

115. Consequently, even if it were possible to justify the conduct, it would have to be considered disproportionate, since it eliminates competition in distribution within Europe by smothering parallel imports from Greece.

3. Net positive economic effect

116. The last of the defences put forward by the dominant undertakings relates to the efficiency in economic terms of the potentially abusive conduct (the 'efficiency defence'). The Commission's discussion paper on the application of Article 82 EC includes this in its line of approach, (70) responding to the legal writers who had lamented its absence. (71)

117. I understand from the observations submitted by GSK that its arguments relating to the perverse consequences of parallel trade in prescription medicines should be classified under this heading. GSK submits that it is not to the advantage of either patients or the social insurance bodies which reimburse medical costs. It contrasts this with the healthy profits obtained by the wholesalers from the sale of the goods in countries where the price paid by health insurance is higher than it is in Greece, whilst lamenting the loss of the large amounts of money which GSK itself no longer receives.

118. So, apart from the description of the 'horrors' caused by parallel trade, GSK does not indicate any positive aspect resulting from its restriction of supplies of medicinal products to the wholesalers, except that its profit margins recover, which is irrelevant for the purposes of classifying the conduct as an abuse, or for the purposes of justifying it, as the Polish Government correctly points out.

119. Even if one supports the view that undertakings in a dominant position are entitled to demonstrate the economic benefits of their abuses, GSK has not been able to point to anything capable of tipping the balance in its favour, despite the fact that matters relating to the welfare of patients and the reduction of public health costs are deserving of special attention in the main proceedings. Consequently, there is no need to look at proportionality, which would have been the final step in the analysis, had a justification been established.

4. Proposed answer to the second question

120. In the light of the foregoing, I recommend that the Court's reply to the second question should be that

when an undertaking in a dominant position reduces the number of wholesalers' orders which it processes to the levels necessary to meet demand in a domestic market, with the intention of preventing parallel imports to other Member States by such wholesalers, this in principle constitutes an abuse of a dominant position within the meaning of Article 82 EC.

121. However, the potentially abusive undertaking can point to any matters it considers relevant in order to justify its behaviour objectively, in particular:

– matters relating to market regulation which constrain it to behave in this manner, given that it is unable to change such regulation, disregarding, in the present case, the setting of prices for medicinal products and the obligation to maintain stocks in order to supply patients;

– evidence that its sole motivation was the protection of its legitimate business interests, which do not include, in the present case, the impact on incentives to innovate; and

– the economic benefits of the conduct in question.

122. Once the grounds for justification have been established, the proportionality test should not be overlooked, in other words, the behaviour must be shown to be both unavoidable and appropriate.

VI – Conclusion

123. In the light of the foregoing, and taking a different view from that taken by Advocate General Jacobs in Syfait and Others, I propose that the Court give the following answers to the questions referred to it by the Trimeles Efetio Athinon:

(1) Article 82 EC does not provide a basis for attributing conduct which is abusive per se to undertakings in a dominant position, even when the circumstances of the case show that there is intent and an anti-competitive effect caused by that conduct.

(2) The refusal of an undertaking holding a dominant position to meet fully the orders sent to it by pharmaceutical wholesalers by reason of its intention to limit their export activity and, thereby, the harm caused to it by parallel trade constitutes an abuse within the meaning of Article 82 EC. However, the undertaking may produce the relevant evidence in order to justify its behaviour objectively, in particular:

– matters relating to market regulation which constrain it to behave in this manner, given that it is not within its power to change such regulation, disregarding, in the present case, the setting of prices for medicinal products and the obligation to maintain reserves in order to supply patients;

– proof that its only purpose was to protect its legitimate business interests, which do not include, in the present case, the impact on incentives to innovate; and

– the economic benefits of the conduct in question.

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1 – Original language: Spanish.

2 – Case C-53/03 Syfait and Others [2005] ECR I-4609.

3 – Opinion of Advocate General Jacobs in Syfait and Others, delivered on 28 October 2004, which argued that the reference for a preliminary ruling was admissible.

4 – Writing under the pseudonym Alonso Fernández de Avellaneda, who was probably a little known priest named Alonso Fernández Zapata, in 1614 he published the 'Segundo tomo del ingenioso hidalgo Don Quijote de La Mancha' ('Second book of the ingenious knight Don Quixote of La Mancha'), understandably provoking the wrath of Cervantes who, in the real sequel to his tale, attacked the clumsy imitation. The fraudulent version is far inferior in terms of literary merit to the work it attempts to imitate, causing Fernando García Salinero in the 'Critical introduction to the work and its author', in Alonso Fernández de Avellaneda, El ingenioso hidalgo Don Quijote de La Mancha, Castalia, Madrid, 2005, p. 24, to describe it as 'a mockery of a book without the ingenuities of the picaresque, perhaps born out of personal spite'.

5 – Council directive 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).

6 – Directive 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).

7 – Council directive of 31 March 1992 on the wholesale distribution of medicinal products for human use (OJ 1992 L 113, p. 1).

8 – Thus distancing itself from the decision in Joined Cases C-110/98 to C-147/98 Gabalfrisa and Others [2000] ECR I-1577, which I have always considered to be wrong, and tending more towards the view which I advocate in my Opinion in the De Coster case (Case C-17/00 [2001] ECR I-9445); my Opinion of 22 November 2007 in Case C-393/06 Ing. Aigner, Wasser-Wärme-Umwelt (not yet published in the ECR) discusses the current state of this debate.

9 – Cases C-468/06, C-470/06, C-472/06, C-474/06, C-475/06, C-476/06 and C-478/06.

10 – Case C-473/06.

11 – Case C-477/06.

12 – Cases C-469/06 and C-471/06.

13 – The questions in Cases C-474/06 to C-478/06 are reproduced here, since the questions in the earlier cases (C-468/06 to C-473/06) mistakenly made reference to 'a national competition authority' rather than 'a national court or tribunal', probably because the questions referred to the Court of Justice by the Epitropi Antagonismou were transcribed literally, as the appellants explain in their observations in Cases C-469/06 to C-476/06.

14 – Case 36/79 Denkavit Futtermittel [1979] ECR 3439, paragraph 12; Joined Cases C-175/98 and C-177/98 Lirussi and Bizzaro [1999] ECR I-6881, paragraph 37; Case C-318/98 Fornasar and Others [2000] ECR I-4785, paragraph 31; and Case C-259/05 Omni Metal Service [2007] ECR I-4945, paragraph 17.

15 – For example, in Case 38/77 Enka [1977] ECR 2203; Case C-250/91 HewlettPackardFrance [1993] ECR I-1819; and Joined Cases C-223/99 and C-260/99 Agorà and Excelsior [2001] ECR I-3605.
16 – Joined Cases 6/73 and 7/73 Istituto Chemioterapico Italiano andCommercial Solvents v Commission [1974] ECR 223 ('Commercial Solvents').
17 – Commercial Solvents, paragraphs 25 and 26.
18 – Case 27/76 United Brands and United Brands Continentaal v Commission [1978] ECR 207 ('United Brands').
19 – United Brands, paragraph 182.
20 – Case 311/84 [1985] ECR 3261('Telemarketing').
21 – Case C-7/97 [1998] ECR I-7791.
22 – Joined Cases C-241/91 P and C-242/91 P RTEand ITP v Commission [1995] ECR I-743 ('Magill').
23 – Case C-418/01 [2004] ECR I-5039.
24 – Case 85/76 Hoffmann-La Roche v Commission [1979] ECR 461, paragraph 91; Case 322/81 Michelin v Commission [1983] ECR 3461, paragraph 70; and Case C-62/86 AKZO v Commission [1991] ECR I-3359, paragraph 69.
25 – An idea on which practically all commentators are agreed; Schröter, H., 'Artikel 82', in Schröter, H., Jacob, T. and Mederer, W. (eds), Kommentar zum Europäischen Wettbewerbsrecht, Nomos, Baden-Baden, 2003, p. 905.
26 – Case 6/72 Europemballage and Continental Can v Commission [1973] ECR 215 ('Continental Can'), paragraphs 25 to 27.
27 – Gleiss, A. and Hirsch, M., Kommentar zum EWG-Kartellrech, 3rd edition, Verlagsgesellschaft Recht und Wirtschaft, Heidelberg, 1978, p. 347.
28 – Case C-95/04 P British Airways v Commission [2007] ECR I-2331, paragraph 30, relating to the judgments of the Court of First Instance in Case T-203/01 Michelin v Commission [2003] ECR II-4071, paragraph 239, and Case T-219/99 British Airways v Commission [2003] ECR II-5917, paragraph 293.
29 – Schröter, H., op. cit., p. 959.
30 – Case 22/78 Hugin v Commission [1979] ECR 1869, paragraph 17, and Case 31/80 L'Oréal [1980] ECR 3775, paragraph 27.
31 – This approach is echoed to a certain extent by legal writers; Koenig, C. and Engelmann, C., 'Parallel Trade Restrictions in the Pharmaceuticals Sector on the Test Stand of Article 82 EC – Commentary on the Opinion of Advocate General Jacobs in the Case Syfait/GlaxoSmithKline', ECLR, No 6/2005, p. 341.
32 – Hoffmann-La Roche v Commission, paragraph 89.
33 – Joined Cases 40/73 to 48/73, 50/73, 54/73 to 56/73, 111/73, 113/73 and 114/73 Suiker Unie and Others [1975] ECR 1663, and Michelin v Commission, paragraph 71.
34 – AKZO v Commission, paragraph 71, and Case C-333/94 P Tetra Pak v Commission [1996] ECR I-5951, paragraph 41.
35 – AKZO v Commission, paragraph 72.
36 – Loewenthal, P.-J., 'The Defence of "Objective Justification" in the Application of Article 82 EC', World Competition, No 28(4), 2005, p. 470.
37 – Case C-95/04 P British Airways v Commission, paragraph 69.
38 – Tetra Pak v Commission, paragraph 37; Case C-250/92 DLG [1994] ECR I-5641, paragraph 52; and Case 26/75 General Motors v Commission [1975] ECR 1367, paragraphs 20 and 22.
39 – Hence Article 4, relating to 'black' clauses, of Commission Regulation (EC) No 2790/1999 of 22 December 1999 on the application of Article 81(3) of the Treaty to categories of vertical agreements and concerted practices (OJ 1999 L 336, p. 21).
40 – Decision of 28 June 2007, Leegin Creative Leather Products, Inc. v PSKS, Inc (No 06-480); Llorente, C., 'La decisión del Tribunal Supremo de los EEUU en el caso Leegin', in Gertrude Ryan Law Observatory, Special Edition No 2, Actualidad Jurídica Aranzadi No 736, p. 2 et seq.
41 – Decision of 3 April 1911, Dr. Miles Medical Co. v John D. Park & Sons Co. (220 U.S. 373).
42 – On the use of such presumptions of fact, see Paulis, E., 'The burden of proof in Article 82 cases', in Hawk, B.E., Annual Proceedings of the Fordham Competition Law Institute, Juris Publishing, Inc., New York, 2007, p. 470.
43 – I am borrowing the Spanish translation of the English expression 'rule of reason' from Arruñada, B., 'Economía y Derecho en la nueva política comunitaria de competencia', in Beneyto Pérez, J.M. and Maillo González-Orús, J. (eds), El nuevo Derecho comunitario y español de la competencia, Bosch, Barcelona, 2002, p. 53.
44 – Report by the Economic Advisory Group on Competition Policy (EAGCP) 'An Economic Approach to Article 82', July 2005, available at http://ec.europa.eu/comm/competition/publications/studies /eagcp_july_21_05.pdf, pp. 5 and 6.
45 –
P., 'The criterion of economic performance in the antitrust policies of the United States and the European Economic Community', in Greaves, R. (ed.), Competition Law, Ashgate/Dartmouth, Aldershot (United Kingdom), 2003, p. 214, points out the risk associated with the abuse per se rule, also outside the context of the dominant position.
46 – Pelkmans, J., European Integration: Methods and Economic Analysis, Longman, London, 1997, p. 194.
47 – The Commission's 'DG Competition discussion paper on the application of Article 82 of the Treaty to exclusionary abuses' deals only with exclusionary abuses; it can be consulted at http://ec.europa.eu/comm/competition/antitrust/art82/discpaper2005.pdf. This has not gone without criticism: Díez Estella, F., 'El Discussion Paper de la Comisión Europea: reformas en la regulación del artículo 82 del Tratado CE?', Gaceta Jurídica de la Unión Europea y de la Competencia, No 242, May 2006, p. 24.
48 – Hildebrand, D., The Role of Economic Analysis in the EC Competition Rules, Kluwer, The Hague, 1998, p. 62.
49 –

underlying purpose to which Article 82 EC is expressly directed has been criticised in Whish, R., 'Rethinking Article 82 EC', Concurrences: Revue des droits de la concurrence, No 4/2005, p. 18, which likens this absence of guidance to leaving Article 82 EC 'like a ship without a rudder'. On the other hand, Schröter, H., op. cit, p. 813, argues, on the basis of Hoffmann-La Roche, Michelin and L'Oréal, that the provision tends above all to protect competition as an institution, and this indirectly benefits competitors, the dominant undertaking's trading partners and consumers.

50 – In the discussion paper referred to earlier, at paragraph 80 the Commission requires that the conduct be necessary for reasons of safety or health; this escape route for dominant undertakings strikes me as too narrow and I therefore propose a broader one, linked to the market.

51 – Myhre, J.W., 'The pharmaceutical sector – Article 81 EC and Article 82 EC – Imperfect tools for an imperfect market?', in Johansson, M., Wahl, N. and Bernitz, U. (eds), Liber amicorum in honour of Sven Norberg: a European for all seasons, Bruylant, Brussels, 2006, p. 378.

52 – Pelkmans, J., op. cit., p. 193.

53 – Joined Cases C-267/95 and C-268/95 [1996] ECR I-6285, paragraph 47.

54 – Ibid.

55 – Hugin v Commission, paragraph 17.

56 – Described in point 5 of this Opinion.

57 – Article 1(1) of Directive 89/105.

58 – Second and third recitals in the preamble to Directive 89/105.

59 – Van Bael, I. and Bellis, J.-F., Competition Law of the European Community, 4th edition, Kluwer, The Hague, 2005, p. 907.

60 – United Brands, paragraphs 189 and 190.

61 – United Brands, paragraph 191 et seq.

62 – Case 77/77 BP v Commission [1978] ECR 1513 ('Oil crisis').

63 – Ibid., paragraphs 32 and 33.

64 – Commission Decision 87/500/EEC of 29 July 1987 relating to a proceeding under Article [82] of the [EC] Treaty (IV/32.279 – BBI/Boosey & Hawkes: Interim measures) (OJ 1987 L 286, p. 36), point 19.

65 – Van Bael, I. and Bellis, J.-F., op. cit., p. 957.

66 – Krapf, E., Parallelimporte von Arzheimitteln und europäisches Kartellrecht – eine Untersuchung von Vertriebssystemen zur Verhinderung des Parallelhandels, Shaker, Aquisgrán, 2006, pp. 107 and 108.

67 – Krapf, E., op. cit., p. 2

68 – Commission Regulation (EC) No 2659/2000 of 29 November 2000 on the application of Article 81(3) of the Treaty to categories of research and development agreements (OJ 2000 L 304, p. 7).

69 – Recital 10 in the preamble to Regulation No 2659/2000.

70 – European Commission, op. cit., paragraphs 84 to 91.

71 – Loewenthal, P.-J., op. cit., pp. 464 and 465.