1. In this case, the Epitropi Antagonismou (the Greek Competition Commission) (hereinafter also the 'Competition Commission') refers to the Court questions concerning whether and in what circumstances a dominant pharmaceutical company may, in order to limit the parallel trade in its products, refuse to meet in full the orders which it receives from pharmaceutical wholesalers.

2. There is however first an issue as to the admissibility of the reference, which turns upon whether the Greek Competition Commission constitutes a court or tribunal within the meaning of Article 234 EC so as to be eligible to refer questions to the Court.

3. The complainants in the main proceedings are Greek pharmaceutical wholesalers. The respondents are the pharmaceutical company, Glaxosmithkline PLC, and its subsidiary, Glaxosmithkline Aeve (formerly Glaxowellcome), which imports and distributes its products in Greece (hereinafter collectively referred to as 'GSK').

4. The main proceedings relate to the supply of three proprietary medicinal products, Imigran, Lamictal and Serevent, owned and manufactured by GSK (hereinafter, 'the products at issue').

5. Until November 2000, GSK met in full the orders which it received for the products at issue from the complainants and other pharmaceutical wholesalers. A substantial proportion of those orders were then exported by the wholesalers to other Member States of the European Union where the prices were much higher.

6. From early November 2000, however, GSK stopped meeting orders from pharmaceutical wholesalers and stated instead that it would supply hospitals and pharmacies directly. It alleged that the export of the
relevant products by wholesalers was leading to significant shortages on the Greek market. It subsequently reinstated supplies to wholesalers, but still refused to meet their orders in full.

7. That refusal formed the subject of proceedings before the Greek Competition Commission as a result both of complaints brought by the pharmaceutical wholesalers and of several applications made by GSK for the negative clearance of its distribution policy.

8. In August 2001, the Competition Commission adopted interim measures requiring the Greek subsidiary of GSK to meet in full orders which it received, which it has done to the extent of the supply received by it from its parent company. That supply has more than covered the consumption needs of the domestic market, but not the much larger orders which have been placed by wholesalers.

9. Following hearings at which the interested parties set out their positions orally and answered questions put to them, the Competition Commission has determined, by a decision of 22 January 2003, to suspend the case before it and to refer various questions to the Court of Justice.

10. In the order for reference, the Competition Commission notes that all of the Member States of the European Union intervene in the market to fix the prices of pharmaceutical products within their territories. The prices thus fixed vary from State to State, but those in Greece are consistently at the lowest levels prevailing anywhere in the European Union.

11. The Competition Commission proceeds on the basis that GSK enjoys a dominant position within the meaning of Article 82 EC on the relevant market in Greece in respect of at least one of the products at issue, Lamictal. It is uncertain, however, whether GSK's refusal to meet in full the orders which it receives from pharmaceutical wholesalers should be considered as an abuse within the meaning of that article.

12. It recognises that an agreement or concerted practice which restricts trade between Member States is regarded as a particularly serious breach of Article 81 EC, and is considered to have as its object to restrict competition, without any need to consider its effects upon the market, provided that they are not de minimis. On that basis, it might be thought that any policy by a dominant company to restrict exports would constitute abusive conduct per se.
13. The Competition Commission also notes, however, that unrestricted parallel trade can seriously undermine the financial and organisational interests of pharmaceuticals manufacturers, eroding their revenues and disrupting their organisational arrangements in those States which receive the parallel imports. Moreover, the benefit of the parallel trade would appear to accrue mainly to the undertakings engaged in such trade rather than the end consumers of the products traded. In any event, Member States are the effective purchasers of most pharmaceutical products, through socialised health schemes, and if it were their preference to pay less, they would set the price applicable on their national market accordingly.

14. The Competition Commission therefore wonders whether dominant pharmaceuticals manufacturers may justify a restriction of supply on a given national market as necessary to protect their legitimate business interests by limiting the scope of parallel imports, and, if so, what factors should be weighed in determining whether the justification is made out in a given case.

15. Accordingly, the Competition Commission refers 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 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 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:
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?

16. Four sets of written observations have been received from various of the complainants: one submitted by Synetairismos Farmakopoion Aitolias & Akarnanias (Syfait) and 15 others (hereinafter, 'the first complainants'); another submitted by Panellinios Sylogos Farmakapothikarion, K.P. Marinopoulos Anonymos Etaireia emporias kai dianomis farmakeftikon proionton, Jonas Stroumsas EPE and Farmakapothiki Pharma Group Messinias A.E. (hereinafter, 'the second complainants'); a third submitted by Farmakeftikon Syndesmos Anonymi Emporiki Etaireia (hereinafter, 'the third complainants'); and a final set submitted by Interfarm — A. Aggelakou & Sia O.E. and 39 others (hereinafter, 'the fourth complainants'). Written observations have also been received from GSK, the Commission and the Swedish Government. With the exception of the Swedish Government, all of those parties or sets of parties were present and made submissions at the hearing.
Admissibility

17. Under the second paragraph of Article 234 EC, only a 'court or tribunal of a Member State' may refer questions to the Court of Justice for preliminary ruling. It is clear from the Court's case-law that the concept of 'court or tribunal' is one of Community law.

18. A number of criteria have been identified in the case-law as relevant to the assessment whether a given entity constitutes a court or tribunal within the meaning of Article 234, such as whether the body is established by law, whether it is permanent, whether it applies rules of law, whether its jurisdiction is compulsory, whether it is independent, whether its procedure is *inter partes*, and whether its final decision is judicial in nature.

19. The Competition Commission considers that it meets those criteria. The Commission and GSK agree. The second and fourth complainants contested the admissibility of the reference in their written submissions. At the hearing, however, the second complainant changed its position, and accepted that the Competition Commission could refer questions under Article 234 EC. The Swedish Government makes no submissions as to the admissibility of the reference.

20. In my view, according to the information supplied in the order for reference, the Competition Commission clearly satisfies many of the criteria which the Court has in the past identified as relevant when considering whether a given body may be classified as a court or tribunal. It is permanently established by Article 8 of Law 703/77 on the control of monopolies and oligopolies and protection of free competition (hereinafter, 'Law 703/77') as the body competent for ensuring observance of the provisions of that law. It reaches its decisions by application of the rules of domestic and Community competition law. It has sole competence to impose the penalties provided for by Law 703/77. Its jurisdiction is therefore compulsory.

21. The factors thus far considered, whilst probably necessary for any judicial authority, would equally apply to an administrative enforcement agency. More distinctive of a court or tribunal is the hearing before the Competition Commission, at which both complainants and respondents may be legally represented and are accorded procedural rights similar to those enjoyed by parties to

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ordinary court proceedings. Such guarantees go some way to supplying the necessary inter partes element to the Competition Commission's decision-making process.

22. Despite the characteristics of the Competition Commission so far identified, it appears to me that a more detailed analysis none the less remains appropriate in order to determine whether its structure and composition are consonant with those of a judicial authority, and in particular with the structural guarantees of independence which are core identifying features of such authorities.

23. As appears from the order for reference, the Competition Commission consists of nine members, appointed by the Minister of Development for a three-year period. Four of the members are chosen by the Minister from lists of three candidates supplied to him by trade and industry bodies. The remainder comprise a member of the State Legal Service or other high judicial officer; two academics, one a lawyer and the other an economist; and two persons of acknowledged repute and relevant experience. The Minister selects the President of the Competition Commission from among its members.

24. Article 8(1) of Law 703/77 expressly designates the Competition Commission as an 'independent authority', and specifies that its members shall 'enjoy personal and operational independence' and are to be 'bound in the exercise of their duties only by the law and their conscience'. As the Competition Commission explains, the independence of its members is further guaranteed by the fact that they are prohibited from engaging in any professional activity relating to matters which arise before it.

25. Attached to the Competition Commission is a secretariat, the task of which appears to be to investigate cases arising before the Commission and to make written proposals to it as to how they should be resolved. According to the order for reference, the President of the Commission coordinates and directs the secretariat as an administrative superior in the exercise of disciplinary powers. The Competition Commission none the less attests to the full operational separation of its secretariat, indicating that neither the President nor the rest of the Commission has any involvement in the secretariat's proposals.

26. I have two specific doubts arising out of the structure and composition of the Competition Commission, as described. First, it must, in my view, be relevant when assessing whether a body is judicial in nature to consider how many of its appointees possess qualifications as lawyers or judges. In the case of the Greek Competition Commission, as the order for reference explains, the rules
stipulate the need for only two lawyers out of a total of nine members: one in the form of an academic lawyer and the other either a member of the State Legal Service, whether in service or not, or a former civil or administrative law judge. There is apparently no guarantee that the President will be legally qualified. In my view, the relatively limited number of posts on the Competition Commission which are specifically assigned to lawyers must give rise to some element of doubt as to its designation as a court or tribunal.

27. Secondly, and as regards the independence of the Competition Commission, my concern relates to the structural links which exist between the Competition Commission and its secretariat, which I have set out above.⁴

28. It is apparent from the Court's judgment in Gabalfrisa⁵ that operational separation between a judicial body and an administrative authority establishes judicial independence. In that case, the Court admitted a reference from a regional body in Spain responsible for the hearing of fiscal complaints partly on the basis that a separation existed between its functions and those of the State Tax Administration Agency whose departments adopted the decision forming the subject-matter of the complaint.⁶ In the present case, the functions of the Commission and the secretariat may be considered separate, according to the formula in Gabalfrisa, provided that the investigation of alleged infringements of Law 703/77, carried out by the secretariat, is distinguishable from the Competition Commission's adjudicatory role.

29. The issue at stake here appears to me to be closely related to the question whether the procedure of the Competition Commission can be qualified as *inter partes* in nature. Only if the secretariat has the necessary degree of separation from the Competition Commission can it qualify as a third party independent both of the party being investigated and of the Competition Commission as judge.

30. Although the order for reference indicates that the President does not in practice intervene to influence investigations carried out by the secretariat, he clearly enjoys some authority over the latter body. No mention is made of rules or other safeguards designed to guarantee the secretariat's investigatorial independence.

31. In the light of the two concerns which I have identified, the status of the Greek Competition Commission is in my view finely balanced. That body appears to me

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⁴ At paragraph 25
⁵ Cited above in footnote 2
⁶ At paragraphs 39 and 40 of the judgment.
to be situated very close to the border line between a judicial authority and an administrative authority having certain judicial characteristics.

32. On balance, however, I consider that it is sufficiently judicial in character to qualify as a court or tribunal for the purposes of Article 234 EC.

33. As regards the legal expertise of the body, I note that in addition to the two posts specifically reserved for lawyers, two further positions are to be held by persons of acknowledged repute with experience of issues of national and Community economic law and of competition policy. The representatives on the body are also described in the order for reference as persons of acknowledged repute and experience with regard to competition law. Taken together with the fact that members of the Competition Commission are explicitly bound to exercise their duties in accordance with the law, I am satisfied that the limited number of places reserved for lawyers or judges is not sufficient to rule out its judicial status. One might in any event expect a lower proportion of personnel holding purely legal qualifications to serve on a judicial body charged with operating in a complex technical field such as competition law, where there is a need for economic and commercial expertise alongside legal qualifications.

34. On the question of the structural links between the Competition Commission and its secretariat, I consider that those links do not appear so pronounced as to outweigh the various other factors suggestive of judicial status. First, I do not consider it likely that the exercise of disciplinary power by the President over the secretariat would influence the conduct of any given investigation. Secondly, even if the opposite view were to be taken, it seems to me that the threat to operational separation during investigation is sufficiently guarded against by the hearing held by the Competition Commission, which would appear to accord sufficient opportunity to all parties to make their own submissions, thereby ensuring that a fair decision is finally taken.

35. I note that the Court has previously admitted a reference from a competition authority, the Spanish Tribunal de Defensa de la Competencia (Tribunal for the Defence of Competition). That body shared many of the same attributes as the Greek Competition Commission. It too was a permanent body established by law with responsibility for applying competition rules following an adversarial procedure. It also acted after receiving a report, in that case from a separate body.

8 — The procedure by which a proposal was made by a separate investigatory body can be found in the Report for the Hearing, at p. 4790.
36. I find nothing in the submissions of the second and fourth complainants which would cast any additional doubts on the admissibility of the reference.

37. Those complainants note first that, despite the assertion of independence contained in Article 8(1) of Law 703/77, the Competition Commission does not count among the five independent authorities which have been specifically provided for in the Greek Constitution since its revision in 2001. In consequence, the Competition Commission is not afforded the specific constitutional guarantees which such authorities enjoy. Its membership is not selected in accordance with the special procedure specified in the Constitution. Nor are its rules of procedure enshrined in legislation; instead they take the form of an inter-ministerial decision.

38. Secondly, they submit that the Competition Commission's rules of procedure are not currently in accordance with fundamental judicial principles, because they do not allow interested persons to intervene in proceedings before the Commission.

39. Thirdly, the complainants allege that the Competition Commission has failed to adjudicate upon their complaints within the six-month period laid down in the applicable legislation.

40. I do not find any of the complainants' contentions convincing. The fact that the Competition Commission does not qualify as a matter of Greek constitutional law as an independent authority detracts neither from the legislative confirmation of its independence nor from the safeguards designed to secure that independence in practice.

41. Further, it seems to me that judicial bodies may legitimately vary in the degree to which they allow an interested third party to intervene in proceedings without thereby jeopardising their status as a court or tribunal. In any event, the complainants appear to have been able adequately to participate in the main proceedings before the Competition Commission by registering their grievances as complaints.

42. Lastly, any delays in the hearing of a case cannot to my mind undermine the judicial nature of the body hearing it, although they may obviously undermine the quality of the justice dispensed.

43. I have so far considered the specific characteristics of the Greek Competition
Commission, as reported in the order for reference. It may be useful, however, briefly to consider the admissibility of the reference from the perspective of competition enforcement and in particular Regulation No 1/2003, which has introduced with effect from 1 May 2004 a system of decentralised enforcement for the Community competition rules.  

44. First, it is noteworthy that Regulation No 1/2003 recognises the possibility that Member States might confer the tasks of a competition authority upon bodies having judicial characteristics, and contains provisions designed to preserve the independence of such bodies.

45. Secondly, there are in my view several practical reasons in favour of admitting references from such bodies. Considerations of judicial economy would favour allowing a reference to be made at the earliest possible stage, thereby avoiding the need for subsequent proceedings before a reviewing court in order to enable a preliminary reference to be made. It is also at least arguable that a specialised competition authority having judicial characteristics might be better placed to identify the relevant issues of Community competition law than a generalist court charged with reviewing the decisions of the former body at a subsequent stage. With the decentralisation of Community competition law, the possibility for the judicially structured national competition authorities to refer questions to the Court of Justice would provide some additional safeguard of the uniformity of Community law. Moreover, it is now clear that national competition authorities are empowered and obliged to disapply national legislation which requires or facilitates conduct contrary to Article 81 (1) EC, or which reinforces the effects of such conduct, specifically with regard to price-fixing or market-sharing arrangements. That possibility might also commend a generous approach towards references from such authorities, so as to ensure that any uncertainties as to the applicable Community rules are clarified before national legislation is disappplied.

46. In my view, those practical considerations support my previous conclusion that the present reference should be regarded as admissible. Accordingly, I shall now proceed to consider the substantive issues raised by the Greek Competition Commission.

10 — Article 35 and recital 35.
11 — See, in particular, Article 35(4).
47. As a preliminary point, I note that some of the submissions before the Court concern market definition and dominance. The questions referred, however, are premised on the existence of a dominant position on the relevant markets. The Competition Commission has found the existence of dominance in respect of one of the products at issue, Lamictal, and has not sought the Court's guidance regarding the criteria relevant either to market definition or to the assessment of dominance. I shall therefore confine my Opinion to the issue of abuse under Article 82 EC which has actually been raised by the Competition Commission.

48. In that regard, the Competition Commission wishes to know, first, whether a dominant pharmaceutical undertaking must always be regarded as abusing its dominant position within the meaning of Article 82 EC simply because it fails to meet in full all the orders placed with it with a view to limiting its customers' export activity. Secondly, and if not, the Competition Commission enquires which factors will go to determine whether or not an undertaking is liable for such conduct.

49. The European Commission submits that such a restriction of supply is abusive unless the dominant undertaking can point to an appropriate and sufficiently substantial objective justification for its conduct. The Commission does not consider that any of the factors identified by the Greek Competition Commission could be relevant for the purpose of such a justification.

50. The European Commission supports its conclusion partly on the basis of the anti-competitive character of the conduct in question. A dominant undertaking is understood to abuse its position when it refuses to supply its goods and services with the aim of limiting or excluding actual or potential competitors from a given market and of reinforcing its position on that market. Given that any attempt by a producer to restrict supply in order to limit parallel trade is usually motivated by a concern to restrict intra-brand competition on the market of import, such a restriction is normally to be regarded as abusive. Partly, also, the Commission relies upon the market-partitioning object of the conduct at issue. The Court has consistently interpreted Articles 81 and 82 EC as prohibiting conduct aimed at dividing the common market.

51. The complainants and the Swedish Government in essence agree with the Commission.
52. GSK submits that a restriction of supply by a dominant pharmaceutical undertaking in order to limit parallel trade does not amount to an abuse within the meaning of Article 82 EC. Such a restriction does not fall within the exceptional circumstances in which refusals to supply have been considered abusive. When assessed in its proper economic and regulatory context, given the specific circumstances of the pharmaceuticals industry in Europe, such restriction can be seen not to amount to an abuse, but rather to constitute the proportionate protection by an undertaking of its legitimate business interests.

Does the conduct at issue amount per se to an abuse?

53. As regards the first part of the first question referred, it appears to me correct, as the Commission and GSK submit, that a dominant pharmaceutical undertaking will not necessarily abuse its dominant position by reason of its refusal to supply in full the orders placed with it by pharmaceutical wholesalers even when its intention is thereby to limit parallel trade. That conclusion appears to me clearly to follow from the Court’s case-law to date regarding refusals to supply under Article 82 EC. Under that case-law, as is demonstrated by the following survey — which must inevitably be rather detailed — any obligation to deal pursuant to Article 82 EC can be established only after a close scrutiny of the factual and economic context, and even then only within somewhat narrow limits.

54. Confirmation that a dominant undertaking might in certain circumstances be obliged to supply its existing customers first came in the case of Commercial Solvents.13 The case concerned a refusal by Commercial Solvents to continue supplying a third party, Zoja, with raw materials which were essential for the production of a derivative, and which could only be obtained from Commercial Solvents. The refusal originated from Commercial Solvents’ decision to enter into competition with Zoja on the downstream market for the supply of the derivative. The Court held that an undertaking with a dominant position in the market in a raw material which reserves that material for manufacturing its own derivatives, and refuses to supply a customer which is itself a manufacturer of those derivatives abuses its dominant position, but only if it thereby ‘risks eliminating all competition on the part of this customer’.14

55. In United Brands,15 an undertaking which held a dominant position in the

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14 — Paragraph 25 of the judgment.
production of bananas ('UBC'), which it supplied under the brand name Chiquita, cut off supplies to a ripener/distributor when the latter, following a disagreement with the dominant undertaking, began promoting a rival producer’s bananas and taking less care in the ripening of UBC’s bananas. The Court considered it ‘advisable to assert positively from the outset 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 the 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’. 16

57. The BP case 19 involved a restriction of supply by a dominant petroleum undertaking during the period of oil scarcity in 1973 and 1974. BP challenged a decision of the Commission that it had abused its dominant position by restricting supply to one particular customer substantially and to a much greater extent than to other customers without there being objective reasons for its behaviour. The Commission considered that a dominant undertaking must distribute the quantities available of its product fairly amongst all its customers, subject to particularities or differences in their commercial situation. In the event of a generalised supply crisis, it must deal in the first place with its habitual customers and reductions in the supplies to purchasers in a period of shortage must be carried out on the basis of a reference period preceding the crisis. The Commission suggested that a year would be appropriate.

56. The Court considered such conduct to be incompatible with Article 82 EC ‘since the refusal to sell would limit markets to the prejudice of consumers and would amount to discrimination which might in the end eliminate a trading party from the relevant market’. 17 The Court also held, however, that even a dominant undertaking must have the right to take such reasonable steps as it deems appropriate to protect its commercial interests, provided its behaviour is proportionate to the threat and is not aimed at strengthening or abusing the undertaking’s dominant position. 18

58. Advocate General Warner considered the Commission’s formulation of the abuse to be unworkable, given the difficulty determining the proposed reference period and of ascertaining whether any differences between the customers might justify variations in their treatment. 20 The Court agreed that BP had not abused its dominant position. The customer in question had ceased to be a regular customer in the year

16 — Paragraph 182 of the judgment.
17 — Paragraph 183 of the judgment.
18 — Paragraphs 189 and 190 of the judgment.
20 — Page 1539, second column.
prior to the crisis. Given that it was therefore only an occasional customer when the crisis began, BP could not be expected to treat it in the same way as its traditional customers. The Court also doubted that a reference period could be applied at least in relation to a customer with whom commercial relations had ceased during such a period. Lastly, it noted that the customer in question was able to overcome the difficulties engendered by the crisis. It had therefore not suffered obvious, immediate and substantial competitive disadvantage or been placed at risk of elimination.

59. The Telemarketing case arose out of a claim before a Belgian court for an injunction to prevent a television broadcaster from refusing to sell television time to an undertaking which competed with it in the downstream market for telephone marketing. The broadcaster also refused to sell time to advertisers for advertisements which involved an invitation to make a telephone call unless the telephone number used was that of its own downstream telephone marketing operation.

60. The Court held, in response to a question referred by the national court, that an abuse within the meaning of Article 82 EC is committed where, without any objective necessity, an undertaking holding a dominant position on a particular market reserves to itself or its subsidiary another activity which might be carried out by another undertaking as part of its activities on a neighbouring but separate market, with the possibility of eliminating all competition from such undertaking. The Court noted that in such a case, the input withheld by the dominant undertaking would be indispensable for the activities of the other undertaking.

61. The cases so far considered all involved a failure to supply an existing customer. In a number of other cases, the Court has considered refusals to allow a third party to use its intellectual property or physical infrastructure for the first time.

62. In Volvo v Veng, the Court held that it was not an abuse of a dominant position for a car manufacturer holding the registered designs for body panels for its cars to refuse to license others to produce such panels for use as replacements. The Court stated that the right of the proprietor of a protected design to prevent third parties from manu-

21 — Paragraphs 28, 29, 32 and 33 of the judgment.
22 — Paragraph 20 of the judgment.
23 — Paragraph 42 of the judgment.
24 — Paragraph 20 of the judgment.
25 — Case 311/84 CBEM v CLT and IPB (Telemarketing) [1985] ECR 3261.
26 — Paragraphs 25 to 27 and the operative part of the judgment.
facturing and selling or importing, without its consent, products incorporating the design constitutes the very subject matter of his exclusive right. A refusal to grant a licence therefore cannot in itself constitute an abuse. However, the exercise of the exclusive right might amount to an abuse if, for example, the dominant undertaking were arbitrarily to refuse to supply spare parts to independent repairers, were to fix prices for spare parts at an unfair level, or were to decide no longer to produce spare parts for a particular model of car which was still in wide circulation.28

63. Subsequently, in the Magill case,29 the Court confirmed the judgment of the Court of First Instance upholding a Commission decision that television broadcasters in Ireland had abused the dominant position which they held on the market for their television programme schedules, by invoking their copyright over such listings so as to prevent third parties from publishing a single weekly guide which would have competed with the guides which each broadcaster published to its own programmes. The Court considered the following circumstances relevant in demonstrating an abuse. First, the refusal by the broadcasters to allow use of the information relating to their schedules, which was an indispensable raw ingredient for a comprehensive weekly guide, prevented the appearance of a new product which the broadcasters did not offer and for which there was a potential consumer demand. Such refusal constituted an abuse under Article 82(b) EC.30 Secondly, there was no justification for such refusal.31 Thirdly, the broadcasters, by their conduct, reserved to themselves the secondary market of weekly television guides by excluding all competition on that market since they denied access to the basic information which was the raw material indispensable for the compilation of such a guide. 32

64. Another refusal to supply case was that of Bronner.33 The Court was asked whether it constitutes an abuse of a dominant position contrary to Article 82 EC for a newspaper group holding a substantial share of the market in daily newspapers to refuse to allow the publisher of a competing newspaper access to its home-delivery network, or only if that publisher purchases from the group certain additional services. The Court noted that in its judgments in Commercial Solvents and Telemarketing, it had found that a refusal to supply to a rival goods or services

28 — Paragraphs 8 and 9 of the judgment.
30 — Paragraphs 53 and 54 of the judgment.
31 — Paragraph 55 of the judgment.
32 — Paragraph 56 of the judgment.
indispensable to the rival's business would only constitute an abuse to the extent that the conduct in question was likely to eliminate all competition on the part of the rival. The Court then recalled the Magill judgment, and observed that even if such case-law on the exercise of an intellectual property right were applicable to the exercise of any property right whatever, it would still be necessary for finding an abuse not only that the refusal of the service comprising home delivery be likely to eliminate all competition in the daily newspaper market on the part of the person requesting the service and that such refusal be incapable of being objectively justified, but also that the service in itself be indispensable to carrying on that person's business, inasmuch as there is no actual or potential substitute for that home-delivery scheme. Such was not in fact the case.

65. Lastly, in the recent IMS Health case, the Court returned to the circumstances in which the refusal by a dominant undertaking to grant a licence to use its intellectual property might constitute an abuse under Article 82 EC. Following Magill, the Court stated that, in order for the refusal by an undertaking which owns a copyright to give access to a product or service indispensable for carrying on a particular business to be treated as abusive, it is sufficient that three cumulative conditions be satisfied, namely, that the refusal is preventing the emergence of a new product for which there is a potential consumer demand, that it is unjustified and that it is such as to exclude any competition on a secondary market.

66. It appears to me that the following points of present relevance can be derived from the Community case-law and practice to date. First, it is evident that a dominant undertaking will on occasion have an obligation to supply its products or services. Such is the case, for example, where an interruption of supply would seriously disrupt competition between the undertaking and the customer on a downstream market or between the undertaking and its actual or potential competitors on the market of supply. There is also a narrow range of circumstances in which a dominant undertaking will be obliged to open up its facilities or license its intellectual property rights to a third party for the first time. For such to be the case, some exceptional harm to competition must be shown.

67. Secondly, however, it is also clear that a dominant undertaking's obligations to supply under Article 82 EC are in various respects circumscribed. As the Court held in United

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34 — At paragraph 38.
35 — Paragraph 41 of the judgment.
36 — Paragraphs 42 to 44 of the judgment.
37 — Case C-418/01, judgment of 29 April 2004, ECR I-5039.
38 — Paragraph 38 of the judgment.
Brands, a dominant undertaking is not obliged to meet orders which are out of the ordinary, and is entitled to take such steps as are reasonable in order to defend its commercial interests. Similarly, in the BP case, a dominant undertaking was able successfully to defend before the Court a commercial policy which differentiated between customers in the allocation of scarce supplies. The Court has also consistently limited the obligation upon dominant undertakings by reference to the possibility of objective justification.

68. Thirdly, the factors which go to demonstrate that an undertaking's conduct in refusing to supply is either abusive or otherwise are highly dependent on the specific economic and regulatory context in which the case arises. The European Commission suggests as much in its recent Microsoft decision. A similar view has recently been taken by the Supreme Court in the United States.

69. In the light of that analysis, it appears to me clear that the first question referred must be answered in the negative: a dominant pharmaceutical undertaking which restricts the supply of its products does not necessarily abuse its dominant position within the meaning of Article 82 EC merely because of its intention thereby to limit parallel trade.

70. I consider it plausible, as the Commission submits, that an intention to limit parallel trade should be one of the circumstances which will ordinarily render abusive a refusal of supply on the part of a dominant undertaking. Such conduct is normally aimed at removing a source of competition from the dominant undertaking on the market in the Member State of import. Even assuming that a sufficient effect on competition could not in all cases be shown, an additional argument can be made in support of such a conclusion on the basis of the market-partitioning object of the conduct at issue.

71. In the present case, although an intent to partition the market is assumed, and even apparently admitted, the partitioning of the market is not the primary intent, but rather an inevitable consequence, given the characteristics of the market, of the attempt by GSK to protect what it sees as its legitimate commercial interests, by refusing to meet in full the orders which it receives. The issue of intent should therefore not deflect attention.
from the essential question whether such a refusal is in all the circumstances justified.

72. In any event, however, as the Commission submits, it is clear that the Community case-law provides dominant undertakings with the possibility of demonstrating an objective justification for their conduct, even if it is prima facie an abuse, and I now turn to the issue of objective justification. I would add that the two-stage analysis suggested by the distinction between an abuse and its objective justification is to my mind somewhat artificial. Article 82 EC, by contrast with Article 81 EC, does not contain any explicit provision for the exemption of conduct otherwise falling within it. Indeed, the very fact that conduct is characterised as an 'abuse' suggests that a negative conclusion has already been reached, by contrast with the more neutral terminology of 'prevention, restriction, or distortion of competition' under Article 81 EC. In my view, it is therefore more accurate to say that certain types of conduct on the part of a dominant undertaking do not fall within the category of abuse at all. However, given that the Commission has, in the light of some previous Community case-law, developed its submissions in terms of objective justification, it may be convenient for present purposes to assume that structure.

Is the conduct at issue capable of objective justification?

73. Given the negative response which I have proposed to the first part of the first question referred, it is necessary to consider also whether any of the various factors identified by the Competition Commission are of relevance when assessing whether conduct of the kind at issue might be capable of objective justification, namely: the fact that pure conditions of competition do not prevail in the European pharmaceutical sector; the percentage by which the supplies made available by the dominant undertaking exceed domestic consumption; the impact of the parallel trade upon the turnover or profits of the dominant undertaking; and the extent to which the ultimate consumer/patient and purchaser of the traded products derives a benefit from the parallel trade.

74. At first sight, it is difficult to refute the view of the European Commission that a restriction of supply in order to limit parallel trade should be capable of justification only in very limited circumstances. In most cases, the benefits of parallel trade are clear: such trade promotes intra-brand competition, reducing prices in the State of import to the benefit of consumers there. However, on a closer examination of the particular context of the European pharmaceutical sector, I am not convinced that the possibilities of justification are as narrow as the Commission suggests.

75. Indeed, several of the characteristics of that sector, alluded to by the Greek Competition Commission, appear to me to be relevant when considering the liability of a
dominant pharmaceutical undertaking which restricts supply in order to limit parallel trade.

76. The factors which should in my view be taken into account are first, the pervasive regulation of price and distribution in the sector; secondly, the likely impact of unmoderated parallel trade upon pharmaceutical undertakings in the light of the economics of the sector; and thirdly, the effect of such trade upon consumers and purchasers of pharmaceutical products.

77. In my view it is impossible, when assessing conduct of the kind at issue in the present proceedings, to ignore the pervasive and diverse regulation to which the pharmaceutical sector is subject both at national and Community levels, and which appears to me to set it apart from all other industries engaged in the production of readily traded goods.

78. Member States intervene to limit the prices payable for medicinal products within their territories. Such intervention aims to protect the budgets of the social health insurance funds, which meet most of the cost of such products. States intervene to varying degrees and by various methods in order to fix or influence the price of pharmaceutical products. Some States are prepared to allow pharmaceutical products to sell at a higher price than others. This may be in recognition, explicit or implicit, of the need to allow pharmaceuticals undertakings a sufficient return to provide an incentive for the research and development of new pharmaceuticals products. As a consequence, the price of pharmaceutical products in some Member States is typically much higher than in others. It is the price differentials between Member States which create the opportunities for parallel trade. In a recent Communication, published prior to the most recent enlargement of the European Union, the Commission predicted that enlargement would further increase such differentials. 41

79. The regulation of prices by the Member States is subject only to limited harmonisation by Community legislation. 42 In its 1998 Communication on the Single Market in pharmaceuticals, 43 the Commission concluded that the option of adopting a centrally

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41 — Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions, 'A Stronger European Pharmaceuticals Industry for the Benefit of the Patient — a Call for Action', COM (2003) 383 final, at p. 14

42 — Under Council Directive 89/105/EEC relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems. OJ 1989 L 38, p. 8. Member States are obliged to ensure that decisions on pricing and reimbursement are taken transparently in a non-discriminatory manner and within a precise time frame.

administered European pricing system for medicines was undesirable and currently impracticable. It noted that establishing an appropriate level of price across the Community would prove extremely difficult: low levels would benefit immediate health care expenditure objectives (at least in the Member States where prices are currently high), but would provoke a steady diminution of Europe's contribution to global pharmaceutical R&D investment, leading ultimately to disinvestment from the European economy. High levels would reduce access to consumers and payers in those countries where economic and social conditions mean that such prices cannot be afforded. Instead, the Commission has proposed various measures designed to lessen the distortions to the internal market resulting from price regulation of pharmaceutical products by the Member States.

81. In many Member States, pharmaceutical undertakings and wholesalers are subject to various additional duties under national law in order to guarantee the availability of medicinal products. For example, as the Greek Competition Commission explains in the order for reference, Greek law imposes upon some of the complainants a public service obligation constantly to maintain a full and diversified stock of pharmaceutical products appropriate for covering the requirements of a defined geographical area and for ensuring delivery of the required supplies very quickly throughout that area.

82. The second paragraph of Article 81 of Directive 2001/83 on the Community code relating to medicinal products for human use also now imposes the following obligation on pharmaceutical producers and their distributors:

'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.'

83. The national and Community regulation of the European pharmaceutical sector is in my view relevant in several respects when analysing conduct of the kind at issue.

84. First, such regulation sheds light on the reasonableness and proportionality of a restriction of supply. When pharmaceutical undertakings attempt to block parallel trade, they are not thereby seeking to entrench price differentials of their own making, but rather to avoid the consequences which would follow if the very low prices imposed upon them in some Member States were generalised across the Community.

85. Nor does a restriction of supply itself prevent wholesalers from exporting the supplies which they receive. Ordinarily, such a restriction would be inefficacious to prevent parallel trade where price differentials existed between Member States. Any quantities supplied in a low-price Member State would be exported, and there would be no point in the undertaking supplying that State at all. In the pharmaceutical industry, what prevents wholesalers from exporting products in their possession is apparently the imposition of public service obligations, which require them to maintain sufficient stocks to meet domestic demand. The market-partitioning effect associated with a restriction of supply results from the measures of the national authorities in the State of export.

86. Secondly, the legal and moral obligations to which dominant pharmaceutical undertakings are subject to maintain supply in each Member State cast doubt on the reasonableness and proportionality of requiring them to supply wholesalers in low-price Member States intending to export the quantities supplied. It is not clear that a pharmaceutical undertaking could withdraw from a Member State in which a low price was imposed upon it. It appears to me that two legal obstacles could stand in the path of such a withdrawal. On the one hand, dominant undertakings may be limited by Article 82 EC as to the circumstances in which they may terminate existing commercial relationships, at least without a reasonable period of notice. On the other hand, Article 81 of Directive 2001/83 requires pharmaceutical undertakings, within the limits of their responsibilities, to ensure appropriate and continued supplies of an authorised medicinal product actually placed on the market in a Member State to pharmacies and persons authorised to supply medicinal products so that the needs of patients in the Member State in question are covered. The precise parameters of that obligation remain to be worked out, but it appears to have some potential to limit the scope for a pharmaceutical undertaking to
withdraw a product which has already been marketed in a given State.

87. Thirdly, the regulation of the distribution of pharmaceutical products in Europe is based around a nationally segregated scheme, aimed at ensuring that sufficient supplies are available within each national territory, which imposes obligations upon both pharmaceutical undertakings and wholesalers, and which is specifically reinforced by the applicable Community legislation. The activities of the parallel traders cut across that scheme and, in the process, risk destabilising, in both the Member State of import and that of export, the arrangements which pharmaceutical producers and wholesalers are required to establish in pursuit of their public service obligations under national and Community law. The decision of a dominant pharmaceutical undertaking to limit the quantities which it makes available to those intending to engage in parallel trade must in my view be assessed against the backdrop of such obligations.

88. Finally, as I discuss below, the fact that Member States have adopted radically different price levels for pharmaceutical products in their territories, and are themselves the main purchasers of pharmaceutical products, casts doubt upon the notion that parallel trade will in fact benefit the purchasers of such products.

89. In my view, it is also relevant to consider some of the economic factors affecting the commercial policy of pharmaceutical undertakings. Innovation is an important parameter of competition in the pharmaceuticals sector.\footnote{Commission Decision of 8 May 2001 relating to a proceeding pursuant to Article 81 EC (Glaxo Wellcome) OJ 2001 L 302, p. 1, at point 155.} Substantial investment is typically required in the research and development of a new pharmaceutical product.\footnote{In a Report prepared for the Enterprise Directorate-General of the European Commission, 'Global Competitiveness in Pharmaceuticals – A European Perspective', A. Gambardella, L. Orsenigo and F. Pammolli state, at p. 38, that 'an R&D project for a new drug is likely to last 8-12 years, with a cost in the range of US$ 350-650 millions'.} The production of a pharmaceutical product is usually characterised by high fixed costs (to research and develop the product) and comparatively low variable costs (to manufacture the product once developed).\footnote{See id., footnote 1 on p. 3, where the authors state that 'manufacturing is not that important in this industry compared to R&D and commercialisation, which command the bulk of the investments'.} The decision whether to invest in developing a new pharmaceutical product will obviously depend in part upon whether the producer expects to be able to make sufficient profits to recoup the cost of investment. Once the investment is made, however, that cost is sunk. It is therefore rational for an undertaking to supply its products on any market where the price is fixed above variable cost. The mere fact that a product is marketed on a given market at a given price does not mean that a pharmaceuticals undertaking could recoup its total costs if that price were...
generalised across the whole of the Community. The issue could be tested if the national court were able to establish whether the price obtained by the dominant undertaking in a particular Member State did allow it to cover its fixed and variable costs and make a reasonable profit.

90. Those factors provide some insight into the possible consequences of prohibiting any restriction of supply by dominant pharmaceutical undertakings intended to limit parallel trade.

91. There would clearly be an incentive for such undertakings not to market products which might win for them a dominant position in Member States in which prices are fixed at a low level. As discussed above, the legal and moral obligations upon undertakings might render it difficult for them to withdraw products already marketed in those States. More credibly, they might delay the launch of new products in those States. The levels of output and consumer welfare generated by some pharmaceutical products would therefore fall within the Community.

92. Similarly, the regulatory negotiation of prices in low-price Member States would almost certainly become more difficult. There would be considerable pressure for prices to rise in those States if they were to be generalised, by process of parallel trade, across the Community. Such price rises as were agreed would again reduce output and consumer welfare in the States where they occurred. Moreover, they would effectively result in a redistribution of resources from consumers in the low-price Member States to those in the high-price Member States.

93. If low-price Member States were able to resist the pressure for price rises, and pharmaceuticals undertakings did not withdraw or delay products, the revenue generated by products in respect of which dominance was found would be cut. The incentive for a pharmaceutical undertaking to invest in research and development would to that extent be reduced, given the lower returns which such an undertaking could expect to enjoy during the period of its patent protection.

94. The Commission suggests that pharmaceutical undertakings have a choice as to whether to market a product at a given price, and if they choose to do so, it must be assumed that the price in question is
commercially viable. As explained above,\(^9\) that conclusion in my view goes too far. An undertaking may agree to a price in one Member State, despite the limited opportunity which that price offers for the recoupment of the fixed costs associated with the development of a given pharmaceutical product, provided that variable production costs are met and that the price will not be generalised across the Community, eliminating the revenues generated in other Member States.

95. As a consequence, it is entirely conceivable that, if they cannot negotiate a price increase in low-price Member States, dominant pharmaceutical undertakings would respond to an obligation to supply parallel traders within a given Member State by removing existing products from the market in that State, if they were able to do so, and by delaying the launch of new products there. Price differentials would be replaced by a greater fragmentation of the market, with a differing range of products available from State to State.

96. Lastly, I consider it relevant to examine the effect which parallel trade has upon consumers and purchasers in the Member State of import. Ordinarily, the benefits of parallel trade are felt by those who are able to buy products at a lower price on the market for which the trade is destined. However, it appears that special features of the European pharmaceutical industry cast such benefits in doubt.

97. Parallel trade in pharmaceutical products does not necessarily result in any price competition discernible to the end consumers of such products. In many Member States, patients make only a small flat-rate contribution towards the price of pharmaceutical products which are prescribed to them. The remainder of the cost of purchasing the product falls to the system of social health insurance. In those States, parallel trade therefore does not produce any benefits for the ultimate consumers of the medicinal products which are thus traded.

98. Nor does parallel trade always result in price competition to the benefit of the public bodies which in fact purchase the traded products or of the taxpayers which contribute to those funds. In some States, for example, pharmacists have been entitled to receive payment for traded products at the rate applicable for products first supplied within the State in question. As a result, the price differential which gave rise to the parallel trade has been entirely absorbed as profit by those involved in the distribution chain. In response, some such States have
established claw-back schemes in order to recover a portion of the profit from pharmacists. The Commission acknowledged in its 1998 Communication that ‘unless parallel trade can operate dynamically on prices, it creates inefficiencies because most, but not all, of the financial benefit accrues to the parallel trader rather than to the health care system or the patient’. 50

99. In any event, given that public authorities purchase pharmaceutical products as well as playing a significant part in determining the price of those products, it cannot be assumed that the sole concern of the purchaser in a high-price Member State is to obtain lower prices. If the State did desire lower prices, it might be expected to play a greater part in reducing them directly. Such price competition as does result from parallel trade may, therefore, run counter to the preference of the purchaser.

100. In the light of all of the factors considered above, I consider that a restriction of supply by a dominant pharmaceutical undertaking in order to limit parallel trade is capable of justification as a reasonable and proportionate measure in defence of that undertaking’s commercial interests. Such a restriction does not protect price disparities which are of the undertaking’s own making, nor does it directly impede trade, which is rather blocked by public service obligations imposed by the Member States. To require the undertaking to supply all export orders placed with it would in many cases impose a disproportionate burden given the moral and legal obligations on it to maintain supplies in all Member States. Given the specific economic characteristics of the pharmaceutical industry, a requirement to supply would not necessarily promote either free movement or competition, and might harm the incentive for pharmaceutical undertakings to innovate. Moreover, it cannot be assumed that parallel trade would in fact benefit either the ultimate consumers of pharmaceutical products or the Member States, as primary purchasers of such products.

101. However, I regard the conclusion which I have reached here as highly specific to the pharmaceutical industry in its current condition and to the particular type of conduct at issue in the present proceedings.

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102. I think it is highly unlikely that any other sector would exhibit the characteristics which have led me to conclude that a restriction of supply in order to limit parallel trade is defensible in relation to pharmaceutical products. Equally, if the economic and regulatory context of the pharmaceutical sector in Europe were to change, it might then be necessary to reconsider the reasonableness and proportionality of restricting supply in a low-price Member State.

103. I also consider that conduct by a dominant pharmaceutical undertaking which more clearly and directly partitioned the common market would not be open to a similar line of defence. The proportionality of the restriction of supply derives in part from the very limited contribution which it makes, in the pharmaceutical sector, to market partitioning.

104. Lastly, I would note that the above analysis does not preclude the possibility that a restriction of supply by a dominant pharmaceutical undertaking might fall foul of the Court's established case-law on refusal to supply if it had negative consequences for competition arising other than as a consequence of its restriction of parallel trade.

Conclusion

105. For the reasons stated above, I am therefore of the opinion that the questions referred to the Court should be answered as follows:

(1) A pharmaceutical undertaking holding a dominant position does not necessarily abuse that position by refusing to meet in full the orders sent to it by
pharmaceutical wholesalers only by reason of the fact that it aims thereby to limit parallel trade.

(2) Such a refusal is capable of objective justification, and thus of not constituting an abuse, where the price differential giving rise to the parallel trade is the result of State intervention in the Member State of export to fix the price there at a level lower than that which prevails elsewhere in the Community, given the combined circumstances of the European pharmaceutical sector at the current stage of its development, and in particular:

— the pervasive and diverse State intervention in the pricing of pharmaceutical products, which is responsible for price differentials between the Member States;

— the regulation by the Community and the Member States of the distribution of pharmaceutical products, which establishes nationally demarcated obligations upon pharmaceutical undertakings and wholesalers to ensure the availability of adequate stocks of those products;

— the potentially negative consequences of parallel trade for competition, the common market, and incentives to innovate, given the economic characteristics of the pharmaceutical industry;

— the fact that end consumers of pharmaceutical products may not in all cases benefit from parallel trade and that public authorities in the Member States, as the main purchasers of such products, cannot be assumed to benefit from lower prices, given that they are themselves responsible for fixing prices within their territories.