JUDGMENT OF THE COURT (Third Chamber)

6 October 2009 *

In Joined Cases C-501/06 P, C-513/06 P, C-515/06 P and C-519/06 P,

FOUR APPEALS under Article 56 of the Statute of the Court of Justice, brought on 11 December 2006 in respect of the first two cases, and on 18 December and 13 December 2006 in respect of the latter two,

GlaxoSmithKline Services Unlimited, formerly Glaxo Wellcome plc, established in Brentford (United Kingdom), represented by I. Forrester QC, S. Martínez Lage, abogado, A. Komninos, dikigoros, and A. Schulz, Rechtsanwalt,

appellant,

the other parties to the proceedings being:

* Languages of the case: English.

Commission of the European Communities, represented by T. Christoforou, F. Castillo de la Torre and E. Gippini Fournier, acting as Agents, with an address for service in Luxembourg,

defendant at first instance,

supported by:

Republic of Poland, represented by E. Ośniecka-Tamecka, M. Kapko and K. Majcher, acting as Agents,

intervener in the appeal,

European Association of Euro Pharmaceutical Companies (EAEPC), established in Brussels (Belgium), represented by M. Hartmann-Rüppel and W. Rehmann, Rechtsanwälte,

Bundesverband der Arzneimittel-Importeure eV, established in Mülheim an der Ruhr (Germany), represented by W. Rehmann, Rechtsanwalt,

Spain Pharma SA, established in Madrid (Spain),

Asociación de exportadores españoles de productos farmacéuticos (Aseprofar), established in Madrid (Spain), represented by M. Araujo Boyd and J. Buendía Sierra, abogados,

interveners at first instance (C-501/06 P),

and

Commission of the European Communities, represented by T. Christoforou, F. Castillo de la Torre and E. Gippini Fournier, acting as Agents, with an address for service in Luxembourg,

applicant,

supported by:

Republic of Poland, represented by E. Ośniecka-Tamecka, M. Kapko and K. Majcher, acting as Agents,

intervener in the appeal,

the other parties to the proceedings being:

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European Association of Euro Pharmaceutical Companies (EAEPC), established in Brussels (Belgium), represented by M. Hartmann-Rüppel, Rechtsanwalt,

Bundesverband der Arzneimittel-Importeure eV, established in Mülheim an der Ruhr (Germany),

Spain Pharma SA, established in Madrid (Spain),

interveners at first instance (C-519/06 P),

THE COURT (Third Chamber),

composed of A. Rosas, President of Chamber, A. Ó Caoimh, J. Klučka (Rapporteur), U. Lõhmus and A. Arabadjiev, Judges,

Advocate General: V. Trstenjak,
Registrar: K. Malaček, Administrator,

having regard to the written procedure and further to the hearing on 18 March 2009,

after hearing the Opinion of the Advocate General at the sitting on 30 June 2009,

gives the following

Judgment

1 By their appeals, GlaxoSmithKline Services Unlimited ('GSK') (C-501/06 P), the Commission of the European Communities (C-513/06 P), the European Association of Euro Pharmaceutical Companies ('EAEPC') (C-515/06 P) and the Asociación de exportadores españoles de productos farmacéuticos ('Aseprofar') (C-519/06 P) request the Court to set aside in part the judgment of the Court of First Instance of the European Communities of 27 September 2006 in Case T-168/01 *GlaxoSmithKline Services* v *Commission* [2006] ECR II-2969 ('the judgment under appeal'), by which it annulled Articles 2 to 4 of Commission Decision 2001/791/EC of 8 May 2001 relating to a proceeding pursuant to Article 81 of the EC Treaty (Cases IV/36.957/F3 Glaxo Wellcome (notification), IV/36.997/F3 Aseprofar and Fedifar (complaint), IV/37.121/F3 Spain Pharma (complaint), IV/37.138/F3 BAI (complaint) and IV/37.380/F3 EAEPC (complaint)) (OJ 2001 L 302, p. 1) ('the contested decision') and dismissed the remainder of the action brought by GSK.

2 By that decision, the Commission found that Glaxo Wellcome SA ('GW'), a subsidiary of GSK, had infringed Article 81(1) EC by entering into an agreement with Spanish

wholesalers operating a distinction between prices charged to wholesalers in the case of domestic resale of reimbursable drugs to pharmacies or hospitals and higher prices charged in the case of exports of medicines to any other Member State. The Commission also rejected the request for an exemption of that agreement under Article 81(3) EC.

Background to the dispute

3 The facts of the present dispute, as set out in paragraphs 8 to 21 of the judgment under appeal, may be summarised as follows.

4 GSK is a company incorporated under the laws of England and Wales, established in Brentford (United Kingdom). It belongs to the GlaxoSmithKline group, one of the world's main producers of pharmaceutical products. GW is a company incorporated under Spanish law, established in Madrid (Spain), whose main activity is the development, manufacture and marketing of medicines in Spain.

5 By letter of 6 March 1998, GW notified to the Commission a document entitled 'General sales conditions of pharmaceutical specialities belonging to [GW] and its subsidiaries to authorised wholesalers' ('the agreement'), with a view to obtaining negative clearance or an exemption under Council Regulation No 17 of 6 February 1962, First Regulation implementing Articles [81] and [82] of the Treaty (OJ English Special Edition 1959-62, p. 87). By letter of 28 July 1998, GSK sent a supplementary notification.

6 The agreement applies to 82 medicines intended for sale to wholesalers established in Spain with whom GW has commercial relations outside any distribution network. Those wholesalers may intend to resell the medicines to Spanish hospitals or to Spanish

pharmacies, which dispense them to patients on presentation of a medical prescription. They may also intend to resell them in other Member States, through parallel trade, in which they engage on account of price differentials. The 82 medicines include 8 medicines described by GSK as being prime candidates for parallel trade, principally between Spain and the United Kingdom.

7 For those 82 medicines, Clause 4 of the agreement provides for two different prices and is worded as follows:

'(A) Pursuant to the provisions of subsections 1 (first paragraph) and 2 of Article 100 of Law 25/1990 of 20 December 1990 on medicinal products (BOE No 306 of 22 December 1990), the price of pharmaceutical products of [GW] and its subsidiary companies shall, in no event, exceed the maximum industrial price, established by the Spanish health authorities when the two factors which allow for the application of the said legal rules are present, namely:

— that the aforementioned pharmaceutical products are financed by the funds of the Spanish Social Security or by Spanish public funds,

— that the acquired pharmaceutical products are subsequently marketed at a national level i.e. through pharmacies or Spanish hospitals.

(B) In the absence of one of these two factors (i.e. in all cases where Spanish law gives full freedom to the laboratories to set the prices of their pharmaceutical products themselves), [GW] and its subsidiaries will fix the price of their pharmaceutical products according to real, objective and non-discriminatory economic criteria and completely irrespective of the destination of the product determined by the

purchasing warehouse. In particular, [GW] and its subsidiary companies will apply to their pharmaceutical products the price which, on the basis of their internal economic surveys, had been initially proposed to the Spanish health authorities and objectively updated taking account of the increase in the cost of living in accordance with the provisions of subsections 1 (first paragraph) and 2 of Article 100 of [Law 25/1990] and other prior Spanish legislation concerning setting of prices of medicines.'

8 By letter of 6 March 1998, GW sent the agreement to 89 wholesalers established in Spain, of whom 75, representing more than 90% of GW's total sales in Spain in 1998, subsequently signed the agreement. The agreement entered into effect on 9 March 1998.

9 The lawfulness of the agreement was subsequently disputed by, inter alia, Aseprofar, before the Spanish Competition Authority and the Spanish courts.

10 In addition, complaints that the agreement infringed Article 81(1) EC were lodged with the Commission by, inter alia, Aseprofar and EAEPC.

11 On 8 May 2001, the Commission adopted the contested decision, which provides:

'Article 1

[GW] has infringed Article 81(1) of the Treaty by entering into an agreement with Spanish wholesalers operating a distinction between prices charged to wholesalers in

the case of domestic resale of reimbursable drugs to pharmacies or hospitals and higher prices charged in the case of exports to any other Member State.

Article 2

The request by [GW] for an exemption of the agreement referred to in Article 1, pursuant to Article 81(3) of the Treaty, is rejected.

Article 3

[GW] shall immediately bring to an end the infringement referred to in Article 1 in so far as it has not already done so. It shall refrain from repeating any measure constituting this infringement and shall refrain from adopting any measure having similar object or effect.

Article 4

[GW] shall inform the Commission, within two months of notification of this Decision, of the steps which it has taken to bring the infringement to an end.

…'

Procedure before the Court of First Instance and the judgment under appeal

12 It is apparent from paragraphs 22 to 37 of the judgment under appeal that, by application lodged at the Registry of the Court of First Instance on 23 July 2001, GSK brought an action against the contested decision. By documents lodged at the Registry on 8 and 16 November 2001, EAEPC and Aseprofar sought leave to intervene in support of the forms of order sought by the Commission, under the second paragraph of Article 40 of the Statute of the Court of Justice and Article 115(1) of the Rules of Procedure of the Court of First Instance. By order of 27 November 2002, the President of the Court of First Instance granted those applications to intervene.

13 In the judgment under appeal, the Court of First Instance:

‘1. Annuls Articles 2, 3 and 4 of [the contested decision];

2. Dismisses the remainder of the application;

3. Orders [GSK] to bear one half of its own costs and to pay one half of the costs incurred by the Commission, including those relating to the interventions;

4. Orders the Commission to bear one half of its own costs and to pay one half of the costs incurred by [GSK], including those relating to the interventions;

5. Orders [Aseprofar] … [and EAEPC] … to bear their own costs.'

Forms of order sought in the appeal and procedure before the Court of Justice

14 By its appeal, GSK claims that the Court of Justice should:

— set aside the judgment under appeal in so far as it rejects GSK's claim for annulment of Article 1 of the contested decision, or take such other action as justice may require; and

— order the Commission to pay GSK's costs.

15 In its response to that appeal, the Commission simultaneously lodged a cross-appeal. It contends that the Court of Justice should:

— dismiss GSK's appeal in its entirety;

— set aside points 1 and 3 to 5 of the operative part of the judgment under appeal;

— give final judgment in the matter by dismissing the application for annulment in Case T-168/01 as unfounded; and

— order GSK to pay the costs of the Commission arising from the proceedings at first instance and on appeal.

16 In its response to the cross-appeal, GSK contends that the Court should declare the cross-appeal inadmissible or unfounded, or both, and order the Commission to pay the costs.

17 By its appeal, the Commission puts forward three claims that are the same as the last three set out in its response and in its cross-appeal in Case C-501/06 P, namely that the Court of Justice should:

— set aside points 1 and 3 to 5 of the operative part of the judgment under appeal;

— give final judgment in the matter by dismissing the application for annulment in Case T-168/01 as unfounded; and

— order GSK to pay the costs of the Commission arising from the proceedings at first instance and on appeal.

18 By its appeal, EAEPC claims that the Court of Justice should:

— set aside the judgment under appeal in so far as the Court of First Instance annulled the contested decision; and

— order GSK to pay the costs at first instance and on appeal.

19 By its appeal, Aseprofar claims that the Court of Justice should:

— set aside point 1 of the operative part of the judgment under appeal;

— give a final decision in Case T-168/01 by dismissing GSK's claims in their entirety and confirming the contested decision;

— set aside points 3 to 5 of the operative part of the judgment under appeal; and

— order GSK to pay the costs at first instance and on appeal.

20 By order of 17 December 2008, the President of the Court of Justice joined Cases C-501/06 P, C-513/06 P, C-515/06 P and C-519/06 P for the purposes of the oral procedure and judgment.

The appeals

21 For the sake of clarity and given their similarity, certain of the grounds of appeal put forward by the appellants will be considered separately, whilst others will be examined together.

Admissibility

Admissibility of the grounds of the separate appeals relating to Article 81(1) EC put forward by Aseprofar and the Commission, supported by the Republic of Poland

— Arguments of the parties

22 GSK claims that the appeals brought by the Commission and Aseprofar and the Republic of Poland's statement in intervention are, in essence, inadmissible, as they challenge the grounds and not the operative part of the judgment under appeal relating to Article 81(1) EC. GSK states that the grounds of appeal challenging the reasoning in the part of the judgment under appeal relating to Article 81(1) EC cannot, under any circumstances, affect point 2 of the operative part of that judgment, which confirms Article 1 of the contested decision to the effect that the agreement infringes Article 81(1) EC. GSK maintains that, further to the case-law relating to admissibility of

appeals, all the grounds of appeal intended to cast doubt on the Court of First Instance's reasoning relating to Article 81(1) EC are inadmissible.

— Findings of the Court

23 According to the Court's settled case-law, for an appellant to have an interest in bringing proceedings the appeal must be capable, if successful, of procuring an advantage to the party bringing it (orders in Case C-111/99 P *Lech-Stahlwerke* v *Commission* [2001] ECR I-727, paragraph 18, and Case C-503/07 P *Saint-Gobain Glass Deutschland* v *Commission* [2008] ECRI-2217, paragraph 48 and case-law cited).

24 In the present case, the Commission and Aseprofar contend that the Court of First Instance made an error of law in its assessment of the anti-competitive object of the agreement, but ask the Court to uphold point 2 of the operative part of the judgment under appeal and effect a replacement of grounds.

25 In those circumstances, as correctly pointed out by GSK, it is settled that the grounds put forward by the Commission and Aseprofar, first, cannot procure an advantage for them and, secondly, are not capable of affecting point 2 of the operative part of the judgment under appeal, which confirms the infringement of Article 81(1) EC.

26 Consequently, the separate appeals brought by the Commission and Aseprofar must be held to be inadmissible in so far as they are directed against the part of the grounds of the judgment under appeal relating to Article 81(1) EC.

GSK's submission as to the inadmissibility of the Commission's cross-appeal

— Arguments of the parties

27 GSK states, first, that the cross-appeal is inadmissible on the ground that the Commission has already appealed against the judgment under appeal in Case C-513/06 P. In its view, the appeal and the cross-appeal are two branches of the same form of challenging that judgment and may not be employed cumulatively.

28 Secondly, the cross-appeal, being identical to the appeal in Case C-513/06 P, is an abuse of procedure and therefore inadmissible. According to GSK, as the two actions relate to a dispute involving the same parties, pursue the same aims and are based on the same grounds of appeal, the later action, namely the cross-appeal, is inadmissible.

29 Thirdly, the cross-appeal is inadmissible because it challenges certain parts of the judgment under appeal which allow the form of order sought by the Commission. It is clearly inadmissible because a ground of appeal directed against the reasoning of a judgment under appeal which has no effect on its operative part is ineffective and must therefore be rejected.

30 The Commission contends, in particular, that most of the arguments relating to Article 81(1) EC involve questions concerning Article 81(3) EC, because they relate to the alleged specific features of the market which are relevant for both paragraphs. It states that those arguments should be understood as being arguments put forward in response to those advanced in GSK's appeal. The Commission adds that there are no provisions precluding the bringing of a cross-appeal where a separate appeal has already been lodged.

— Findings of the Court

31 Regarding the argument that the Commission may not bring an appeal and a cross-appeal cumulatively, as that would constitute an abuse of procedure, the Court notes, first, that there is nothing in the wording of Article 116 of the Rules of Procedure of the Court of Justice indicating that a party may not bring both an appeal and a cross-appeal against a judgment of the Court of First Instance, irrespective of whether that judgment relates to a number of cases and those cases have been joined. Secondly, although Cases C-501/06 P and C-513/06 P have been joined, they have not thereby ceased to be distinct cases.

32 Accordingly, GSK's line of argument cannot be accepted.

33 As to the argument that the cross-appeal is inadmissible because the party bringing it is challenging the reasoning of certain parts of the judgment under appeal and not point 2 of its operative part, the Court notes that, just as for an appeal, for an appellant to have an interest in bringing proceedings the cross-appeal must be capable, if successful, of procuring an advantage to the party bringing it.

34 However, as pointed out by the Advocate General in point 52 of her Opinion, the Commission stated during the proceedings that its line of argument in the context of the cross-appeal was intended mostly as a response to GSK's appeal. According to the Commission, such a line of argument must therefore be considered not as a cross-appeal for the purposes of Article 116(1), first indent, second alternative, of the Rules of Procedure of the Court of Justice, but as a form of order seeking dismissal of the appeal brought by GSK for the purposes of Article 116(1), first indent, first alternative, of those Rules of Procedure.

35 It must be borne in mind that, under Article 116(1) of the Rules of Procedure of the Court of Justice, the form of order sought in the response may seek to dismiss, in whole or in part, the appeal or to set aside, in whole or in part, the decision of the Court of First Instance, or seek the same form of order, in whole or in part, as that sought at first instance and may not seek a different form of order.

36 There is, however, nothing in the wording of that provision to indicate that Aseprofar, EAEPC or the Commission may not rely on grounds of defence in response to the specific pleas put forward by GSK in its appeal, to explain why the Court of First Instance erred in the interpretation and application of Article 81(1) EC and to explain what the interpretation of that provision should be.

37 It follows that, in response to the appeal brought by GSK in Case C-501/06 P, the Commission, and also Aseprofar and EAEPC, may seek the dismissal of GSK's appeal directed against point 2 of the operative part of the judgment under appeal.

38 Contrary to GSK's submissions, the fact that the Commission set out its grounds of defence in the part of its response entitled 'cross-appeal' is not such as to cast doubt on this conclusion. It is indisputable that importance should not be attached solely to the formal title of the part in which the Commission developed its line of argument, without regard to the actual content of that part. In the present case, irrespective of the terms used, it is clear that the part of the response entitled 'cross-appeal' seeks the dismissal of the appeal.

39 In the light of the aforegoing considerations, the GSK's objection of inadmissibility of the cross-appeal must be rejected.

GSK's ground of appeal relating to Article 81(1) EC

40 In paragraphs 114 to 147 of the judgment under appeal the Court of First Instance considered whether the Commission's principal conclusion, that Clause 4 of the agreement should be regarded as prohibited by Article 81(1) EC in so far as its object is to restrict parallel trade, could be upheld.

41 In paragraphs 114 to 116 of the judgment under appeal, the Court of First Instance found that the agreement intended to introduce a differentiated price system aimed at restricting parallel trade and must in principle be regarded having as its object the restriction of competition.

42 In paragraphs 117 to 119 of the judgment under appeal, however, the Court of First Instance found that, having regard to the legal and economic context, that objective of limiting parallel trade did not by itself establish a presumption that the agreement had an anti-competitive object. On the contrary, the Court of First Instance held that the application of Article 81(1) EC to the present case cannot depend solely on the fact that the agreement in question is intended to limit parallel trade in medicines or to partition the common market, which leads to the conclusion that it affects trade between Member States, but also requires an analysis designed to determine whether it has as its object or effect the prevention, restriction or distortion of competition on the relevant market, to the detriment of the final consumer.

43 In paragraph 121 of the judgment under appeal, the Court of First Instance stated that, while it is accepted that parallel trade must be given a certain protection, it is not as such but in so far as it favours the development of trade, on the one hand, and the strengthening of competition, on the other hand, that is to say, in this second respect, in so far as it gives final consumers the advantages of effective competition in terms of supply or price. Consequently, according to the Court of First Instance, while it is accepted that an agreement intended to limit parallel trade must in principle be considered to have as its object the restriction of competition, that applies in so far as the agreement may be presumed to deprive final consumers of those advantages.

44 The Court of First Instance went on to hold, in paragraph 122 of the judgment under appeal, that, taking account of the legal and economic context in which the agreement concluded by GSK is applied, it could not be presumed that those conditions deprived the final consumers of medicines of such advantages. It found that the Spanish intermediaries could keep the advantage in terms of price which parallel trade might entail, in which case that advantage would not be passed on to the final consumers.

45 In paragraph 133 of the judgment under appeal, the Court of First Instance criticised the fact that at no point did the Commission examine the specific and essential characteristic of the sector, which relates to the fact that the prices of the products in question, which are subject to control by the Member States and fixed by them directly or indirectly at what they deem to be the appropriate level, are determined at structurally different levels in the European Community and, unlike the prices of other consumer goods, are in any event to a significant extent shielded from the free play of supply and demand. It held, in paragraph 134 of the judgment under appeal, that that circumstance meant that it could not be presumed that parallel trade had an impact on the prices charged to the final consumers of medicines reimbursed by the national sickness insurance schemes and thus conferred on them an appreciable advantage analogous to that which it would confer if those prices were determined by the play of supply and demand.

46 On the basis of that analysis, the Court of First Instance, in paragraph 147 of the judgment under appeal, ultimately ruled that the principal conclusion reached by the Commission, namely that Clause 4 of the agreement must be considered to be prohibited by Article 81(1) EC in so far it has as its object the restriction of parallel trade, cannot be upheld. As the prices of the medicines concerned are to a large extent shielded from the free play of supply and demand owing to the applicable regulations and are set or controlled by the public authorities, it cannot be taken for granted at the outset that parallel trade tends to reduce those prices and thus to increase the welfare of final consumers. An analysis of the terms of Clause 4 of the agreement, carried out in that context, therefore does not permit the presumption that that provision, which seeks to limit parallel trade, thus tends to diminish the welfare of final consumers. In this largely unprecedented situation, it cannot be inferred merely from a reading of the terms of that agreement, in its context, that the agreement is restrictive of competition, and it is necessary to consider the effects of the agreement, if only to ascertain what the regulatory authority was able to apprehend on the basis of such a reading.

Arguments of the parties

47 By its appeal, GSK seeks to have point 2 of the operative part of the judgment under appeal set aside in so far as it dismissed its claim seeking annulment of Article 1 of the contested decision. GSK claims that the Court of First Instance interpreted Article 81(1) EC incorrectly in finding that the agreement had an anti-competitive effect.

48 It submits that the Court of First Instance was, however, correct in holding that the Commission's Article 81(1) EC analysis of the restrictive object of the agreement was vitiated by the failure to take account of the relevant legal and economic context. It adds, however, that the Court of First Instance should have also highlighted the same shortcoming in examining the effects of that agreement.

49 In GSK's view, the Court of First Instance should have found that the agreement could not have the effect of restricting competition in the sense of reducing consumer welfare.

50 In their responses to GSK's appeal, the Commission, Aseprofar and EAEPC contest all of the arguments put forward by GSK. They submit that, by the judgment under appeal, the Court of First Instance correctly found that there was an infringement of Article 81(1) EC.

51 However, whilst they argue that the ground of appeal relating to Article 81(1) EC put forward by GSK should be rejected, they take the view that the Court of First Instance made a number of errors of law in the assessment of the anti-competitive object of the agreement. They submit that an analysis of the legal and economic context, in accordance with the principles deriving from the Court of Justice's case-law, should have led the Court of First Instance to find that the agreement was anti-competitive by

virtue of its object. Since point 2 of the operative part of the judgment under appeal is, in their view, nevertheless well founded, they ask the Court for a replacement of grounds in that regard.

52 In its response to GSK's appeal, the Commission argues in particular that the Court of First Instance made an incorrect interpretation and application of the term 'object' in Article 81(1) EC.

53 According to the Commission, first, the Court of Justice and the Court of First Instance have always held that agreements intended to restrict parallel trade within the Community have as their object the restriction of competition. Secondly, in the judgment under appeal the Court of First Instance not only set a restrictive legal standard for the protection of parallel trade but also applied it erroneously and incompletely, without providing adequate reasons. It states that, in paragraphs 117 to 122 of the judgment under appeal, the Court of First Instance held that parallel trade between Member States must be protected only 'in so far as it favours the development of trade, on the one hand, and the strengthening of competition, on the other hand'. It criticises the Court of First Instance for having then ignored the fostering of trade, for having interpreted the strengthening of competition as requiring that parallel trade procure for final consumers the advantages of effective competition in terms of supply or price and for having failed to carry out any examination of the advantages in terms of supply arising from parallel trade.

Findings of the Court

54 As the Commission, Aseprofar and EAEPC all contend that the Court of First Instance committed an error of law in its assessment of the anti-competitive object of the agreement and ask the Court to uphold point 2 of the operative part of the judgment under appeal by effecting a replacement of grounds, it is appropriate to begin by considering their arguments before those put forward by GSK in support of its appeal.

55 First of all, it must be borne in mind that the anti-competitive object and effect of an agreement are not cumulative but alternative conditions for assessing whether such an agreement comes within the scope of the prohibition laid down in Article 81(1) EC. According to settled case-law since the judgment in Case 56/65 *LTM* [1966] ECR 235, the alternative nature of that condition, indicated by the conjunction 'or', leads first to the need to consider the precise purpose of the agreement, in the economic context in which it is to be applied. Where, however, the analysis of the content of the agreement does not reveal a sufficient degree of harm to competition, the consequences of the agreement should then be considered and for it to be caught by the prohibition it is necessary to find that those factors are present which show that competition has in fact been prevented, restricted or distorted to an appreciable extent. It is also apparent from the case-law that it is not necessary to examine the effects of an agreement once its anti-competitive object has been established (see, to that effect, Case C-8/08 *T-Mobile Netherlands and Others* [2009] ECR I-4529, paragraphs 28 and 30).

56 Secondly, to examine the anti-competitive object of the agreement before its anti-competitive effect is all the more justified because, if the error of law alleged by the Commission, Aseprofar and EAEPC turns out to be substantiated, GSK's appeal directed at the grounds of the judgment under appeal relating to the anti-competitive effect of the agreement will fall to be dismissed.

57 Consequently, it is appropriate to ascertain whether the Court of First Instance's assessment as to whether the agreement has an anti-competitive object, as referred to in paragraphs 41 to 46 of this judgment, is in accordance with the principles extracted from the relevant case-law.

58 According to settled case-law, in order to assess the anti-competitive nature of an agreement, regard must be had inter alia to the content of its provisions, the objectives it seeks to attain and the economic and legal context of which it forms a part (see, to that effect, 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, paragraph 25, and Case C-209/07 *Beef Industry Development Society and Barry Brothers* [2008] ECR I-8637, paragraphs 16 and 21). In addition, although the parties' intention is not a necessary factor in determining whether an agreement is restrictive, there is nothing

prohibiting the Commission or the Community judicature from taking that aspect into account (see, to that effect, *IAZ International Belgium and Others* v *Commission*, cited above, paragraphs 23 to 25).

59 With respect to parallel trade, the Court has already held that, in principle, agreements aimed at prohibiting or limiting parallel trade have as their object the prevention of competition (see, to that effect, Case 19/77 *Miller International Schallplaten* v *Commission* [1978] ECR 131, paragraphs 7 and 18, and Joined Cases 32/78, 36/78 to 82/78 *BMW Belgium and Others* v *Commission* [1979] ECR 2435, paragraphs 20 to 28 and 31).

60 As observed by the Advocate General in point 155 of her Opinion, that principle, according to which an agreement aimed at limiting parallel trade is a 'restriction of competition by object', applies to the pharmaceuticals sector.

61 The Court has, moreover, held in that regard, in relation to the application of Article 81 EC and in a case involving the pharmaceuticals sector, 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 Treaty's objective of achieving 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 article of the Treaty (Joined Cases C-468/06 to C-478/06 *Sot. Lélos kai Sia and Others* [2008] ECR I-7139, paragraph 65 and case-law cited).

62 With respect to the Court of First Instance's statement that, while it is accepted that an agreement intended to limit parallel trade must in principle be considered to have as its object the restriction of competition, that applies in so far as it may be presumed to deprive final consumers of the advantages of effective competition in terms of supply or price, the Court notes that neither the wording of Article 81(1) EC nor the case-law lend support to such a position.

63 First of all, there is nothing in that provision to indicate that only those agreements which deprive consumers of certain advantages may have an anti-competitive object. Secondly, it must be borne in mind that the Court has held that, like other competition rules laid down in the Treaty, Article 81 EC aims to protect not only the interests of competitors or of consumers, but also the structure of the market and, in so doing, competition as such. Consequently, for a finding that an agreement has an anti-competitive object, it is not necessary that final consumers be deprived of the advantages of effective competition in terms of supply or price (see, by analogy, *T-Mobile Netherlands and Others*, cited above, paragraphs 38 and 39).

64 It follows that, by requiring proof that the agreement entails disadvantages for final consumers as a prerequisite for a finding of anti-competitive object and by not finding that that agreement had such an object, the Court of First Instance committed an error of law.

65 However, where the grounds of a judgment of the Court of First Instance are contrary to Community law, that judgment need not be set aside if the operative part of the judgment appears to be well founded on other legal grounds (see, to that effect, Case C-30/91 P *Lestelle* v *Commission* [1992] ECR I-3755, paragraph 28, and Case C-294/95 P *Ojha* v *Commission* [1996] ECR I-5863, paragraph 52).

66 That is the case here. It suffices to note that in point 2 of the operative part of the judgment under appeal, the Court of First Instance confirmed Article 1 of the contested decision, by which the Commission had found that the agreement infringed Article 81(1) EC. Accordingly, it is not necessary to set aside point 2 of the operative part of the judgment under appeal.

67 In the light of all the aforegoing considerations, GSK's appeal must be dismissed as unfounded in so far as it seeks to establish that the agreement was compatible with Article 81(1) EC.

The grounds of appeal relating to Article 81(3) EC put forward by the Commission, EAEPC, Aseprofar and the Republic of Poland

68 Both in its appeal and in its response, the Commission puts forward a number of grounds relating to Article 81(3) EC. Some of the grounds and parts thereof are similar to the grounds put forward by EAEPC and/or Aseprofar in their respective appeals, and also by the Republic of Poland in its statement in intervention. The Commission and EAEPC also put forward additional, separate grounds relating to Article 81(3) EC.

The Commission's ground of appeal relating to distortion of the legal and economic context of the agreement

69 The Commission refers to its arguments relating to Article 81(1) EC by which it criticised the points of the judgment under appeal concerning the legal and economic context taken into account by the Court of First Instance, namely paragraphs 122 and 124 to 137 of the judgment under appeal. It maintains that Article 81(3) was applied incorrectly and on the basis of false specific features of the pharmaceuticals sector.

70 It adds that, in paragraph 104 of the judgment under appeal, the Court of First Instance held that the coexistence of the different national regulations in the medicines sector may distort competition. However, the possibility described in that paragraph then becomes a reality in paragraph 276 of the judgment, where the Court of First Instance held that the play of competition is distorted by the presence of the national regulations.

71 GSK states that it answered that question in its analysis of the ground relating to Article 81(1) EC.

72 The Court notes, first, that, in paragraph 122 of the judgment under appeal, the reference by the Court of First Instance to the situation where the advantage of parallel trade in terms of price is not passed on to final consumers was in relation to a hypothetical situation and not an actual one; this is not a distortion of the legal and economic context taken into account in the present cases.

73 Next, a reading of paragraphs 124 to 137 of the judgment under appeal relating to that context does not show that it was misconstrued by the Court of First Instance. In those paragraphs, the Court of First Instance discusses the principal characteristics of that context, which are, indeed, set out in the contested decision.

74 Lastly, in paragraph 104 of the judgment under appeal, the Court of First Instance found that the coexistence of the different national regulations may distort competition when it addressed the issue whether that coexistence made Article 81(1) EC inapplicable. In paragraph 105 of the judgment, the Court of First Instance stated that it was inapplicable only where the sector in which the agreement is applied was subject to regulations which preclude the possibility of competition that might be prevented, distorted or restricted by that agreement.

75 At that stage of its reasoning, the Court of First Instance did not have to determine whether or not the regulations in question actually did distort competition, in contrast to its subsequent finding in paragraph 276 of the judgment under appeal. There is accordingly no contradiction in reasoning in that regard.

76 This ground of appeal put forward by the Commission must therefore be dismissed as unfounded.

The grounds of appeal put forward by the Commission, EAEPC, Aseprofar and the Republic of Poland alleging incorrect application of the allocation of the burden of proof, the standard of proof required and the notion of 'promotion of technical progress'

77 The Commission's ground of appeal alleging incorrect application of the allocation of the burden of proof, the standard of proof required and the notion of 'promotion of technical progress' is broken down into five parts, some of which are similar to the grounds put forward by EAEPC, Aseprofar and the Republic of Poland.

— The first part of the Commission's ground of appeal

78 The Commission claims that the Court of First Instance misapplied the case-law relating to the allocation of the burden of proof and the standard of proof required in relation to Article 81(3) EC. It criticises paragraph 242 of the judgment under appeal, and also paragraphs 269 and 303 thereof, which refer to the case-law, criteria and principles applicable to the review of concentrations. There is, however, no analogy to be drawn between the examination of the anti-competitive effects of a concentration and that of the application of Article 81(3) EC.

79 Unlike the concentration cases, where the notifying parties do not, in its view, have any particular burden of proof, it is settled case-law that, in relation to Article 81(3), it is for the undertakings concerned to present to the Commission the evidence establishing that the agreement fulfils the conditions imposed by that provision. The Commission relies on Joined Cases 56/64 and 58/64 *Consten and Grundig* v *Commission* [1966] ECR 299, and Joined Cases 25/84 and 26/84 *Ford-Werke and Ford of Europe* v *Commission* [1985] ECR 2725, in support of its position.

80 In response, GSK relies on Joined Cases C-204/00 P, C-205/00 P, C-211/00 P, C-213/00 P, C-217/00 and C-219/00 P *Aalborg Portland and Others* v *Commission* [2004] ECR I-123, paragraph 79, and the order in Case C-552/03 P *Unilever Bestfoods* v *Commission* [2006] ECR I-9091, paragraph 102, to support its contention that the Court of First Instance did not infringe the rules governing the burden of proof. In its view, only twice did the Court of First Instance refer to the rule applying to concentrations, first, by way of principal illustration to describe the Court of First Instance's review of the Commission's analysis under Article 81(3) EC and, secondly and in the alternative, to indicate that, when an undertaking has provided evidence, it is for the Commission to conduct a prospective analysis.

81 The Court of First Instance merely concluded that the Commission had not taken GSK's arguments seriously, contrary to what it should have done. GSK states that the Court of First Instance also referred to its judgments in Case T-86/95 *Compagnie générale maritime and Others* v *Commission* [2002] ECR II-1011, and Case T-65/98 *Van den Bergh Foods* v *Commission* [2003] ECR II-4653, which involved Article 81(3) EC. When the undertaking has shown that the conditions of that provision could reasonably apply, by putting forward relevant, reliable and credible arguments, the Commission is obliged to refute those arguments.

82 The Court notes, first, that in paragraphs 233 to 236 of the judgment under appeal, the Court of First Instance referred to the case-law, principles and criteria governing the burden of proof and standard of proof required in relation to requests for exemptions under Article 81(3) EC. It correctly stated that a person who relies on that provision must demonstrate, by means of convincing arguments and evidence, that the conditions for obtaining an exemption are satisfied (see, to that effect, Case 42/84 *Remia and Others* v *Commission* [1985] ECR 2545, paragraph 45).

83 The burden of proof thus falls on the undertaking requesting the exemption under Article 81(3) EC. However, the facts relied on by that undertaking may be such as to oblige the other party to provide an explanation or justification, failing which it is

permissible to conclude that the burden of proof has been discharged (see, to that effect, *Aalborg Portland and Others* v *Commission*, cited above, paragraph 279).

84 Secondly, in paragraphs 240, 241, 243 and 244 of the judgment under appeal, the Court of First Instance referred to the principles and criteria governing its review of a decision by the Commission taken in response to a request for exemption under Article 81(3) EC. It correctly stated that, when dealing with an application for annulment of such a decision, it carries out a restricted review of its merits.

85 This is fully in keeping with the principle that review by the Community judicature of complex economic assessments made by the Commission must necessarily be confined to verifying whether the rules on procedure and on the statement of reasons have been complied with, whether the facts have been accurately stated and whether there has been any manifest error of assessment or misuse of powers (*Aalborg Portland and Others* v *Commission*, cited above, paragraph 279).

86 The Court of First Instance added that it is not for it to substitute its economic assessment for that of the institution which adopted the decision whose legality it is requested to review.

87 The references thus made by the Court of First Instance do not reveal any error of law and do not lead to the conclusion that the case-law references in paragraph 242 of the judgment under appeal, relating to concentration cases, and the wording of paragraphs 269 and 303 of the judgment, could lead to a change in the allocation of the burden of proof or the standard of proof required in relation to Article 81(3) EC.

88 The first part of the ground put forward by the Commission in that regard must therefore be dismissed.

— The second part of the Commission's ground of appeal

89 The Commission criticises paragraphs 249 and 252 of the judgment under appeal, claiming that the Court of First Instance committed an error of law in finding that it is sufficient that an undertaking wishing to obtain an exemption under Article 81(3) EC show that it is probable that gains in efficiency may occur.

90 According to the Commission, that criterion is not in keeping with the Court's case-law. The Commission relies inter alia on the judgments of the Court of Justice in *Consten and Grundig* v *Commission* and of the Court of First Instance in *Compagnie générale maritime and Others* v *Commission* and *Van den Bergh Foods* v *Commission* in support of its argument that it is for the notifying party to establish that the restriction of competition gives rise to appreciable objective advantages.

91 GSK responds that the cases relied on by the Commission concern cartel cases and parallel trade in sectors other than the pharmaceuticals sector, where the measures in question had not generated intrinsic efficiency gains and where the undertakings had not submitted credible arguments about the existence of such gains. Moreover, the Court of First Instance's approach reflects Commission's decision-making practice in earlier cases, where it recognised that an agreement 'is likely to generate benefits' (Commission Decision 2004/841/EC of 7 April 2004 relating to a proceeding pursuant to Article 81 of the EC Treaty concerning case COMP/A.38284/D2 — Société Air France/Alitalia Linee Aeree Italiane SpA (OJ 2004 L 362, pp. 17), 'may have' efficiency gains (Commission Decision 2004/207/EC of 16 July 2003 relating to a proceeding under Article 81 of the EC Treaty and Article 53 of the EEA Agreement (Case COMP/38.369 — T-Mobile Deutschland/O2 Germany: Network Sharing Rahmenvertrag) (OJ 2004 L 75, p. 32)) or 'the benefits are … evident' (Commission Decision 2003/778/EC of 23 July 2003 relating to a proceeding pursuant to Article 81 of the EC Treaty and Article 53 of the EEA Agreement (COMP/C.2-37.398 — Joint selling of the commercial rights of the UEFA Champions League) (OJ L 291, p. 25)).

92 The Court notes that in paragraph 247 of the judgment under appeal the Court of First Instance rightly observed that, in order to be capable of being exempted under Article 81(3) EC, an agreement must contribute to improving the production or distribution of goods or to promoting technical or economic progress. That contribution is not identified with all the advantages which the undertakings participating in the agreement derive from it as regards their activities, but with appreciable objective advantages of such a kind as to compensate for the resulting disadvantages for competition (see, to that effect, *Consten and Grundig* v *Commission*, cited above, p. 348 and 349).

93 As the Advocate General observed in point 193 of her Opinion, an exemption granted for a specified period may require a prospective analysis regarding the occurrence of the advantages associated with the agreement, and it is therefore sufficient for the Commission, on the basis of the arguments and evidence in its possession, to arrive at the conviction that the occurrence of the appreciable objective advantage is sufficiently likely in order to presume that the agreement entails such an advantage.

94 The Court of First Instance therefore committed no error of law in paragraph 249 of the judgment under appeal in holding that the Commission's approach may entail ascertaining whether, in the light of the factual arguments and the evidence provided, it seems more likely either that the agreement in question must make it possible to obtain appreciable advantages or that it will not.

95 Moreover, the Court of First Instance made no error of law in paragraph 252 of the judgment under appeal in observing that it was necessary to determine whether the Commission was entitled to conclude that GSK's factual arguments and evidence, examination of which entailed a prospective analysis, did not demonstrate with a sufficient degree of probability that Clause 4 of the agreement would, by encouraging innovation, make it possible to obtain an appreciable objective advantage of such a kind as to offset the disadvantage which it entailed for competition.

96 The second part of the ground put forward by the Commission must therefore be dismissed as unfounded.

— The third part of the Commission's ground of appeal and EAEPC's second ground of appeal

97 The Commission criticises paragraphs 276 and 301, and also 162 to 169 and 281 to 293, of the judgment under appeal. It argues that the Court of First Instance applied Article 81(3) EC incorrectly in holding that the structural nature of the price differences leads to an 'aggravated' burden of proof and makes it unnecessary to examine the 'magnitude' of any gains in efficiency. According to the Commission, the Court of First Instance imposed a high standard on it for the analysis of GSK's arguments, on the ground that the situation faced by that company is structural.

98 The Commission states inter alia that, if, as the Court of First Instance states in paragraph 284 of the judgment under appeal, the phenomenon is structural only because there are different prices for the same medicinal product in the different Member States, then any phenomenon is structural, as it is quite uncommon to find a consumer good which costs the same throughout the Community. In its view, the problems in the pharmaceuticals sector are not more structural than in any other sector; it has never considered currency fluctuations to be only a significant factor aggravating another problem which is structural. Lastly, the scope of the Commission's obligations in the assessment of the evidence cannot depend on the regulatory context, contrary to the view taken by the Court of First Instance. In that sense there is contradictory reasoning in the judgment under appeal, in that, in paragraph 192, the Court of First Instance held that '[t]he fact the legal and economic context in which undertakings operate contributes to restricting competition cannot lead to acceptance of conduct on the part of those undertakings which, by preventing or restricting the competition which that context allows to subsist or to arise, in turn infringes the competition rules'.

99 GSK refers to studies which, in its view, explain why pharmaceutical research and development ('R&D') can be financed only from operating income. It refers to the paragraphs of the judgment under appeal where the Court of First Instance referred to the Commission's conclusions as unsubstantiated, fragmentary and of little value.

100 EAEPC, for its part, criticises the judgment under appeal on the ground that it was for GSK to demonstrate that all the conditions for the application of Article 81(3) EC were satisfied and that the general considerations relied on by GSK were insufficient. It was not for the Commission to consider the promotion of innovation solely on the basis of those general considerations as appreciable objective advantages. EAEPC criticises inter alia paragraph 236 of the judgment under appeal on the ground that *Aalborg Portland and Others* v *Commission*, cited above, referred to by the Court of First Instance, does not imply that the rules governing the burden of proof no longer apply. The burden of proof applicable to Article 81(3) EC shifts to the Commission only if specific evidence has been adduced in the form of a presumption. General arguments, even those relating to the legal and economic context of the pharmaceuticals sector, cannot be based on such presumptions.

101 GSK contends in response that the Court of First Instance correctly required the Commission to examine the legal and economic context used as the basis for GSK's line of argument and evidence. The evidence adduced by it is not general and imprecise but, on the contrary, highlights the basic legal and economic context to be taken into account for the analysis to have any meaning. Lastly, the Court of First Instance applied the rules governing the burden of proof by asking the Commission to conduct a sufficiently in-depth examination of the facts and evidence submitted to it by GSK. GSK's evidence was sufficient to establish that an exemption could be granted for the agreement.

102 The Court notes that the examination of an agreement for the purposes of determining whether it contributes to the improvement of the production or distribution of goods or to the promotion of technical or economic progress, and whether that agreement generates appreciable objective advantages, must be undertaken in the light of the factual arguments and evidence provided in connection with the request for exemption under Article 81(3) EC.

103 Such an examination may require the nature and specific features of the sector concerned by the agreement to be taken into account if its nature and those specific features are decisive for the outcome of the analysis. Taking those matters into account, moreover, does not mean that the burden of proof is reversed, but merely ensures that

the examination of the request for exemption is conducted in the light of the appropriate factual arguments and evidence provided by the party requesting the exemption.

104 In holding, in paragraphs 276 and 303 of the judgment under appeal, that the Commission had erroneously failed to take into account certain aspects highlighted by GSK in its request, including in particular the specific structural features of the pharmaceuticals sector in question, and that such an omission vitiated the examination of GSK's request for exemption, the Court of First Instance did not err in law.

105 Moreover, with regard to the insufficient statement of reasons alleged by the Commission regarding paragraph 292 of the judgment under appeal, which refers to price differences and currency fluctuations, the Commission argues that it is impossible to ascertain, in that paragraph, the part of Communication COM(1998) 588 final of 25 November 1999 on the single market in pharmaceuticals to which the Court is referring. It is sufficient, however, to refer to the content of that communication, as summarised by the Court of First Instance in paragraph 264 of the judgment under appeal and not contested by the Commission, to identify the two points of that communication relating to price differences and currency fluctuations referred to by the Court of First Instance.

106 The third part of the Commission's ground of appeal and EAEPC's second ground of appeal must therefore be dismissed as unfounded.

— The fourth part of the Commission's ground of appeal

107 The Commission criticises paragraphs 292 and 293 of the judgment under appeal. According to the Commission, the Court of First Instance held there that currency fluctuations may justify a restriction of competition. That is an incorrect application of Article 81(3) EC.

108 In the Commission's view, Community legislation does not allow undertakings to rely on the effects of currency fluctuations in order to justify hindrances to parallel trade.

109 The Court observes that, in those paragraphs of the judgment under appeal, the Court of First Instance did not hold that an agreement which is restrictive of competition, intended to offset the effects of currency fluctuations, may be exempted under Article 81(3) EC.

110 The Court of First Instance merely held in those paragraphs:

'292 [It] must be observed that parallel trade is a phenomenon which may extend beyond the short period taken by the Commission, not only on account of the lasting nature of the price differentials which make it possible but also by reason of the cyclical nature of currency variations, in so far as they still exist. The Commission agrees in Communication COM(1998) 588 final …. It also acknowledges, in its defence, that currency fluctuations remain a reality in the case of the Member States which did not proceed to the third stage of [Economic and Monetary Union] in 1999, which specifically include the United Kingdom.

293 In that context, the sample of figures provided by GSK reveals a tendency. The Commission's question at recital 168 to [the contested decision], as to whether the figure provided by GSK concerning its overall lost revenue in 1998 might be exaggerated, does not call that conclusion in question. The figure provided in that regard on 14 December 1998 and 14 February 2000 remains higher than the figure for the two preceding years, as indicated at recital 67 to [the contested decision]. Furthermore, GSK's explanation that the figure previously supplied in that regard, on 28 July 1998, was an estimate, whereas the figure provided in December 1998 and in February 2000 was real and could be explained by the fact that the [agreement] had been applied between spring and autumn 1998, as may be seen from recitals 19, 23, 26, 64, 67 and 168 to [the contested decision], was sufficiently credible to merit serious examination.'

111 The fourth part of the ground put forward by the Commission must therefore be dismissed as unfounded.

— The fifth part of the Commission's ground of appeal, supported by the Republic of Poland, and the first part of Aseprofar's second ground of appeal

112 The Commission criticises paragraphs 255, 269, 274, 281, 297 and 300 of the judgment under appeal. It takes the view that that judgment misapplied the causal link necessary for the application of Article 81(3) EC in holding that the restriction of competition contributes to the promotion of technical progress because increased profits benefit the manufacturer and not the wholesaler. It observes, in that regard, that it is necessary to determine whether the restriction actually does contribute to the promotion of technical progress and not whether it gives rise to increased profits which may, if the undertakings wish, be invested in R&D. It is not sufficient that part of the increase in profits go to R&D expenditure and that it benefits manufacturers and not intermediaries. The Commission adds that, contrary to the approach adopted in Case 45/85 *Verband der Sachversicherer* v *Commission* [1987] ECR 405, in the judgment under appeal the Court of First Instance held that it is sufficient that part of the increase in profits go to R&D expenditure for that condition to be fulfilled. It argues that the Court of First Instance committed an error of law in allowing the condition relating to the improvement in the distribution of goods or in the promotion of technical progress to be fulfilled without there being any specific link between the restriction of competition and the advantage claimed.

113 GSK replies by highlighting the link between profits and investment in R&D. That link should be analysed in the light of global quantitative studies conducted over a long period, rather than over a few months.

114 Aseprofar also alleges an error on the part of the Court of First Instance in that regard. GSK's reasoning to the effect that parallel trade reduces its profits and therefore its R&D expenditure, and thereby its innovation as well, is hypothetical and general to the point

that it could apply to any restriction of competition in any R&D-intensive sector. The reasoning based on the alleged causal link between parallel trade and innovation is incorrect.

115 In support of its response, GSK explains the pharmaceutical companies' method for financing research. It also explains that patients residing in the United Kingdom do not benefit from parallel trade in medicinal products and submits that Aseprofar offers an overly simplified, distorted version of its position. The problem resides in the fact that the Commission did not bother to examine whether the agreement contained 'appreciable objective advantages'. It considers that Aseprofar's factual assertions are inadmissible and, in any event, unfounded. The Court of First Instance merely noted that GSK's arguments deserved consideration.

116 The Court points out that, in paragraphs 255 and 270 to 274 of the judgment under appeal, the Court of First Instance simply set out the structure of GSK's arguments and the substance of those relating to the efficiency losses associated with parallel trade.

117 In paragraph 269, the Court of First Instance, referring to paragraph 242, reiterated the scope of its review of the assessment carried out by the Commission.

118 In paragraphs 281, 297 and 303 of the judgment under appeal, the Court of First Instance held that the Commission had not taken account of all the relevant evidence produced by GSK regarding the losses in efficiency associated with parallel trade or the gain in efficiency procured by Clause 4 of the agreement, and concluded that the contested decision was vitiated by a failure to carry out a proper examination.

119 Those various factors do not show an error of law in that regard. There has been no distortion of GSK's arguments and no error of law as to the scope of the Court of First Instance's review of the Commission's assessment has been established.

120 Furthermore, contrary to the Commission's assertions, it does not follow from *Verband der Sachversicherer* v *Commission*, cited above, that the existence of an appreciable objective advantage necessarily supposes that all of the additional funds must be invested in R&D.

121 The fifth part of the Commission's ground of appeal and the first part of Aseprofar's second ground of appeal must therefore be rejected as unfounded.

The grounds of appeal put forward by the Commission and EAEPC relating to distortion of the content of the contested decision and the Commission's ground of appeal relating to the possibility of referring to past events

122 The Commission claims, first, that the Court of First Instance distorted the content of the contested decision in holding that it examined the efficiency gains in only one recital of the contested decision. The Commission submits, secondly, that the Court of First Instance misapplied Article 81(3) EC in finding that it was not entitled to refer to past events in conducting a prospective analysis.

123 The Commission criticises paragraph 261 of the judgment under appeal, where the Court of First Instance held that the Commission had not considered it necessary to examine in detail whether it was demonstrated that Clause 4 of the agreement entailed a gain in efficiency, as that question was addressed only on one specific occasion, at recital 156 of the contested decision. It also contests paragraph 299 et seq. of the judgment, where the Court of First Instance held that it could not find, in a peremptory

and unsubstantiated manner, that the factual arguments and evidence submitted by GSK had to be regarded as hypothetical.

124 It observes that, in the contested decision, it dealt with the gain in efficiency and states that it gave a description of past events which prove that parallel trade does not have any clear link with R&D budgets. The Commission correctly relied on past events and on data relating to the years after the contested decision, contrary to the Court of First Instance's position on that point.

125 GSK considers that, faced with a decision in which the Commission refused to take due account of its cogent, credible arguments by giving a fair and well-reasoned response, it was not inappropriate and certainly not an error of law for the Court of First Instance to annul the contested decision in that regard.

126 According to EAEPC, the Court of First Instance artificially broke down GSK's line of argument into two parts. Contrary to what the Court of First Instance held in paragraph 255 of the judgment under appeal, GSK's argument that parallel trade gives rise to a loss in efficiency and that Clause 4 of the agreement leads to a gain in efficiency should not have been thus divided into two parts. The Court of First Instance should not have ruled, in paragraph 261 of the judgment, that the Commission did not examine in detail the second part of GSK's argument relating to Clause 4.

127 GSK contends that this argument put forward by EAEPC is neither appropriate nor relevant. It is formalistic in nature, as the Court of First Instance held, in paragraph 262 of the judgment under appeal, that 'the Commission's examination of the loss in efficiency associated with parallel trade, of the extent of that loss of efficiency and of the gain in efficiency associated with Clause 4 [of the agreement] cannot be accepted as sufficient to support the conclusions which the Commission reached on those points'. In any event, the contested decision was annulled not because of the construction of the line of argument but because of the insufficiency of the Commission's examination. GSK adds that its arguments were always focused on two themes, namely that parallel

trade leads to a loss in efficiency and that Clause 4 of the agreement leads to a gain in efficiency, and that the Court of First Instance rightly distinguished those two aspects of its arguments.

128 The Court finds first of all that, in the course of the review carried out by the Court of First Instance of the way in which the Commission examined the factual arguments and evidence submitted by GSK to show that there was an appreciable objective advantage, the Court of First Instance, in paragraphs 263 to 268 of the judgment under appeal, analysed first the relevance of those arguments and evidence. Secondly, in paragraphs 269 to 280 of the judgment, it considered the issue of whether there was a loss in efficiency associated with parallel trade, before dealing, thirdly, in paragraphs 281 to 293 of the judgment, with the extent of that loss in efficiency. Lastly and fourthly, the gain in efficiency associated with Clause 4 of the agreement was analysed in paragraphs 294 to 303 of the judgment.

129 That four-stage analysis, which preceded the balancing, in paragraphs 304 to 307 of the judgment under appeal, of the appreciable objective advantage identified in the restriction of competition and the drawbacks for competition which that restriction entails, is clearly intended, for the purposes of the present cases, to ascertain whether the Commission was correct in finding that there was no appreciable objective advantage and thus in rejecting an exemption under Article 81(3) EC.

130 The Court of First Instance thereby exercised its power of review to ascertain whether the Commission had made a manifest error of assessment and it is not apparent that any error of law was committed in the course of that review.

131 The Court of First Instance was thus able to find, in paragraph 261 of the judgment under appeal, that the Commission had essentially examined whether parallel trade would give rise to a loss in efficiency for competition and that the Commission had not considered it necessary to demonstrate in detail whether Clause 4 of the agreement would entail a gain in efficiency for competition. It therefore held, in paragraph 262, that the examination carried out by the Commission had not been sufficient.

132 Secondly, with respect to taking account of past events, it suffices to find, as observed by the Advocate General in point 247 of her Opinion, that the Court of First Instance did not rule out the possibility that the Commission could rely on such events, contrary to what the Commission maintains.

133 The grounds put forward by the Commission and EAEPC in that regard must therefore be rejected as unfounded.

The EAEPC's grounds of appeal alleging errors of interpretation

134 EAEPC contends that the Court of First Instance misinterpreted or failed to interpret the facts. In that regard it criticises in particular paragraphs 275 and 277 of the judgment under appeal. It states that the Commission had analysed GSK's specific arguments and held, correctly, that GSK had not demonstrated sufficiently the causal link between the reduction in parallel trade resulting from the insertion of Clause 4 of the agreement and the increase in innovation resulting from an increase in R&D expenditure. The Frontier Economics Study II, submitted by GSK, states that 'it has never been claimed that parallel trade is the key driver of R&D'. The Court of First Instance based its assessment on inaccurate facts, including the proposition that the only final consumers in the medical sector are patients, without taking into account the fact that national health systems must also be considered final consumers as well.

135 GSK replies, in essence, that the principal point in the Court of First Instance's reasoning was that, although restrictive effects were detectable, they were not immediately apparent and certainly could not be presumed, given the regulatory framework of the pharmaceuticals sector.

136 The Court finds, as pointed out by the Advocate General in point 280 of her Opinion, that it cannot be inferred from the judgment under appeal, including paragraph 277 thereof, that the Court of First Instance inferred from the Frontier Economics Study II a direct connection between parallel trade and expenditure on R&D.

137 There is moreover nothing in the judgment under appeal, in particular paragraph 275 thereof, to indicate that the Court of First Instance distorted the contested decision in finding that the Commission had failed to undertake a rigorous examination of the factual arguments and evidence submitted by GSK.

138 As held earlier in paragraph 130 of this judgment, the Court of First Instance exercised its power of review to ascertain whether the Commission had made a manifest error of assessment and it is not apparent that any error of law was committed in the course of that review.

139 The EAEPC's grounds of appeal alleging errors of interpretation must therefore be rejected as unfounded.

The grounds of appeal put forward by the Commission and Aseprofar alleging incorrect interpretation of the applicable standard of judicial review

140 The Commission's ground of appeal is broken down into two parts, the second part being in essence similar to one of Aseprofar's grounds of appeal.

141 In the first part of its ground of appeal the Commission contends that, in the judgment under appeal, the Court of First Instance did not find any inadequate statement of reasons or manifest error of assessment, but created a new category of reviewable error, namely the 'lack of serious examination', which is unknown in the case-law on judicial review in the context of Article 81(3) EC. It refers to paragraphs 269, 277, 281, 286 and 313 of the judgment under appeal. In its view, the Court of Justice has never applied the ground of 'lack of serious examination' and the Court of First Instance did not establish that there was a manifest error of assessment. A correctly defined burden of proof and standard of proof should have led the Court of First Instance to dismiss the action or, at the very least, to explain where the manifest error of assessment was made.

142 GSK responds by stating that the Court of First Instance criticises the Commission for not having made any assessment of its detailed, serious arguments, which does not change the nature of the judicial review which it must carry out. A failure to 'assess' those arguments is covered by the test of manifest error of assessment.

143 In the second part of the ground of appeal, the Commission, like Aseprofar in its own ground of appeal, contends that the Court of First Instance exceeded the proper level of judicial review by substituting its own economic assessment for that of the Commission, contrary to what it stated in paragraph 243 of the judgment under appeal. The Commission criticises in particular paragraph 278 of the judgment under appeal, where the Court of First Instance held that the Commission 'disregards GSK's arguments that the extent of its profits must be qualified because of the way in which they are accounted for'. Such reasoning is so succinct that it is impossible to know what the Court of First Instance is referring to.

144 Aseprofar adds that the Court of First Instance ought to have ascertained whether there was a manifest error of assessment rather than expressing an opinion different from that of the Commission and replacing the Commission's assessment with its own.

145 For the same reasons as those put forward concerning the first part of the Commission's ground of appeal, GSK denies that the review carried out by the Court of First Instance could have led to its assessment being substituted for that of the Commission.

146 As the Court has already stated in paragraph 85 of this judgment, the Community judicature exercises a limited power of review of complex economic assessments made by the Commission. In that regard the examination by the Community judicature must be confined to verifying whether the rules on procedure and on the statement of reasons have been complied with, whether the facts have been accurately stated and whether there has been any manifest error of assessment or misuse of powers.

147 In such a review, the Court of First Instance may ascertain whether the Commission provided a sufficient statement of reasons for the contested decision (see, to that effect, *Remia and Others* v *Commission*, cited above, paragraph 40, and Case C-7/95 P *Deere* v *Commission* [1998] ECR I-3111, paragraphs 28 and 29).

148 The Court of First Instance was therefore empowered to review the statement of reasons in the contested decision with regard to the factual arguments and relevant evidence submitted by GSK in support of its request for exemption.

149 Furthermore, the Court of First Instance merely found that the Commission had not taken into account all of GSK's factual arguments and relevant evidence and did not substitute its own reasoning for that of the Commission in respect of granting the exemption.

150 The Commission's two-part ground of appeal and Aseprofar's ground of appeal must therefore be rejected as unfounded.

The grounds of appeal put forward by the Commission and Aseprofar alleging an insufficient statement of reasons

151 The Commission contends that the reasons in paragraph 263 of the judgment under appeal are insufficient. That paragraph reads as follows:

'The factual arguments and the supporting evidence submitted by GSK appear to be relevant, reliable and credible, having regard to their content …, which is itself corroborated on a number of significant aspects by documents originating with the Commission.'

152 The Commission states that paragraphs 265 and 266 of the judgment under appeal aggravate the insufficient reasoning and states in that regard that, although the Court of First Instance held, in particular in paragraph 265, that Communication COM(1998) 588 final corroborates '…a part of [GSK's] arguments and … the economic analyses in the supporting evidence, thus attesting to their reliability and their credibility', it is not possible to ascertain which parts of that evidence are actually corroborated.

153 The Commission adds that the case-file does not contain any evidence showing that GSK is prevented from increasing its R&D budget in a scale equivalent to the very limited loss of profits caused by parallel trade in its products.

154 In the same vein, Aseprofar contends inter alia that the Court of First Instance did not explain why the core element of the Commission's reasoning was flawed, namely that the causal link between parallel trade and innovation had not been demonstrated.

155 In that regard, it is not apparent that the obligation to state reasons which the Court of First Instance has under Article 36 and the first paragraph of Article 53 of the Statute of the Court of Justice (see Case C-431/07 P *Bouygues and Bouygues Télécom* v *Commission* [2009] ECR I-2665, paragraph 42) has been infringed in the present case.

156 It must be borne in mind that, in paragraphs 255 to 259 of the judgment under appeal, the Court of First Instance examined the various factual arguments and evidence submitted by GSK. In paragraph 261 of the judgment, it found that in the contested decision the Commission had essentially examined whether it had been demonstrated that parallel trade led to a loss in efficiency, without deeming it necessary to examine whether it had also been demonstrated that Clause 4 of the agreement entailed a gain in efficiency.

157 In paragraph 262 of the judgment under appeal, the Court of First Instance added that, having regard to the relevance of GSK's factual arguments and evidence, the Commission's examination could not be accepted as sufficient to support the conclusions it had reached.

158 As stated earlier in paragraph 128 of this judgment, the Court of First Instance followed that assessment with an analysis of the relevance of GSK's factual arguments and evidence and an analysis of the loss in efficiency associated with parallel trade, of the extent of that loss in efficiency, of the gain in efficiency associated with Clause 4 of the agreement and of the balancing of those different aspects.

159 The grounds of appeal put forward by the Commission and Aseprofar in that regard must therefore be rejected as unfounded.

The grounds of appeal put forward by the Commission and Aseprofar relating to the other conditions for the application of Article 81(3) EC

160 The Commission criticises paragraph 309 of the judgment under appeal and considers that that judgment does not contain any reasoning concerning the condition that the restriction must be 'indispensable'.

161 Aseprofar further submits that the Court of First Instance committed a manifest error in paragraphs 235 to 240 of the judgment under appeal, where it stated that the Commission had concentrated its examination on the first condition for the application of Article 81(3) EC. The Court of First Instance did not assess the merits of the Commission's analysis of the arguments that a substantial part of the gains in efficiency would be passed on to consumers, who could thereby obtain an advantage. Similarly, the Court of First Instance ought to have considered whether the Commission had committed a manifest error in finding that GSK had not demonstrated that its restriction was indispensable for innovation. Moreover, contrary to what the Court of First Instance held in paragraph 315 of the judgment under appeal, the Commission was not required to refute arguments which GSK had not advanced concerning the condition relating to lack of substantial restriction of competition.

162 GSK argues in response that the purpose of judicial review is not to determine whether the Commission ought to have granted an exemption. Under Council Regulation No 17, the Commission alone is competent to carry out that assessment, which explains why the Court of First Instance linked the analysis of the second to fourth conditions for the application of Article 81(3) EC with the outcome of the analysis of the first condition. The Court of First Instance was correct in finding, in paragraph 309 of the judgment under appeal, that 'it follows from [the contested decision] and from the oral argument presented at the hearing that the summary conclusions which the Commission reached concerning the existence of a passing-on to consumers, the indispensability of Clause 4 [of the agreement] and the absence of elimination of competition rest on the conclusion relating to the existence of a gain in efficiency' and, in paragraph 310, that '[i]n so far as that conclusion is vitiated by illegality, in that it concerns the existence of a contribution towards the promotion of technical progress, those conclusions are themselves invalid'.

163 First of all, it is not for the Court of First Instance to substitute its economic assessment for that of the author of the decision whose legality it is requested to review. As stated in paragraph 85 of this judgment, the review by the Community judicature of the complex economic assessments made by the Commission is limited and confined to verifying whether the rules on procedure and on the statement of reasons have been complied with, whether the facts have been accurately stated and whether there has been any manifest error of assessment or misuse of powers.

164 In the course of such a review, when the Commission has not provided reasons in relation to one of the conditions laid down in Article 81(3) EC, the Court of First Instance must examine whether or not the statement of reasons in the Commission's decision relating to that condition is sufficient.

165 This is exactly what the Court of First Instance did in paragraph 309 of the judgment under appeal.

166 Secondly, the Court finds that the Court of First Instance did not distort the content of recital 187 of the contested decision in holding that the conclusions of the Commission, which had found that Clause 4 of the agreement was not indispensable, were insufficient because they were based on a finding that that clause did not give rise to an appreciable objective advantage.

167 The grounds of appeal put forward by the Commission and Aseprofar in that regard must therefore be rejected as unfounded.

168 It follows from all of the foregoing considerations that the appeals brought by GSK, EAEPC, Aseprofar and the Commission must be dismissed.

Costs

169 The first paragraph of Article 122 of the Rules of Procedure of the Court of Justice provides that, where the appeal is well founded and the Court itself gives final judgment in the case, the Court is to make a decision as to costs. Under Article 69(2) of the Rules of Procedure, which applies to appeal proceedings pursuant to Article 118 of those rules, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings. The first subparagraph of Article 118(3) provides, however, that where each party succeeds on some and fails on other heads, or where the circumstances are exceptional, the Court may order that the costs be shared or that the parties bear their own costs. The first subparagraph of Article 118(4) provides that the Member States and institutions which intervene in the proceedings are to bear their own costs.

170 In the present case, since GSK, EAEPC, Aseprofar and the Commission were each unsuccessful in their claims, they must bear their own costs relating to the respective procedures and the Republic of Poland must bear its own costs.

On those grounds, the Court (Third Chamber) hereby:

1. **Dismisses the appeals brought by GlaxoSmithKline Services Unlimited, formerly Glaxo Wellcome plc, the Commission of the European Communities, the European Association of Euro Pharmaceutical Companies (EAEPC) and the Asociación de exportadores españoles de productos farmacéuticos (Aseprofar);**

2. **Orders each party to bear its own costs relating to the respective procedures;**

3. Orders the Republic of Poland to bear its own costs.

[Signatures]