# JUDGMENT OF THE COURT OF FIRST INSTANCE
(Fourth Chamber, Extended Composition)

27 September 2006 *

In Case T-168/01,

**GlaxoSmithKline Services Unlimited,** formerly Glaxo Wellcome plc, established in Brentford, Middlesex (United Kingdom), represented by S. Martínez Lage, lawyer, I. Forrester QC, F. Depoortere, A. Schultz, T. Louko and I. Vandenborre, lawyers,

applicant,

v

**Commission of the European Communities,** represented initially by P. Oliver, then by É. Gippini Fournier, acting as Agents,

defendant,

* Language of the case: English.

supported by

**European Association of Euro Pharmaceutical Companies (EAEPC),** established in Brussels (Belgium), represented initially by U. Zinsmeister and M. Lienemeyer, then by A. Martin-Ehlers, and finally by M. Hartmann-Rüppel, lawyers,

by

**Bundesverband der Arzneimittell-Importeure eV,** established in Mülheim an der Ruhr (Germany), represented initially by M. Epping and W. Rehmann, then by W. Rehmann, lawyers,

by

**Spain Pharma, SA,** established in Madrid (Spain), represented by P. Muñoz Carpena, B. Ortúzar Somoza and R. Gutiérrez Sánchez, lawyers,

and by

**Asociación de exportadores españoles de productos farmacéuticos (Aseprofar),** established in Madrid (Spain), represented initially by M. Araujo Boyd and R. Sanz, then by M. Araujo Boyd and J.L. Buendia Sierra, lawyers,

interveners,

APPLICATION for annulment 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 COURT OF FIRST INSTANCE OF THE EUROPEAN COMMUNITIES
(Fourth Chamber, Extended Composition),

composed of H. Legal, President, P. Lindh, I. Wiszniewska-Białecka, V. Vadapalas and E. Moavero Milanesi, Judges,

Registrar: C. Kristensen, Administrator,

having regard to the written procedure and further to the hearing on 7 June 2006,

delivers the following

## Judgment

### Legal and factual framework

*Community law*

1 Article 3(1)(g) EC provides that the activities of the Community are to include a system ensuring that competition in the internal market is not distorted.

2 Article 81(1) EC provides, in particular, that all agreements between undertakings which may affect trade between Member States and which have as their object or effect the prevention, restriction or distortion of competition within the common market are to be prohibited as incompatible with the common market.

3 Article 81(3) EC provides that the provisions of Article 81(1) EC may be declared inapplicable, inter alia, in the case of any agreement between undertakings which contributes to improving the distribution of goods or to promoting technical or economic progress, while allowing consumers a fair share of the resulting benefit, and which does not impose on the undertakings concerned restrictions which are not indispensable to the attainment of these objectives, or afford such undertakings the possibility of eliminating competition in respect of a substantial part of the products in question.

4 On 21 December 1988, the Council, acting on the basis of Article 100a of the EC Treaty (now, after amendment, Article 95 EC), adopted Directive 89/105/EEC relating to the transparency of measures regulating the prices of medicines for human use and their inclusion in the scope of national health insurance systems (OJ 1989 L 40, p. 8). The objective of that directive is to obtain an overall view of pricing arrangements and of direct and indirect controls on the prices of medicines which the Member States have adopted in order to control public health expenditure on such products, and to eliminate disparities in such measures, which may hinder or distort intra-Community trade in medicines and thereby directly affect the functioning of the common market in medicines. To that end, it establishes, as a first step, a series of requirements intended to ensure that all concerned can verify that the national measures do not constitute quantitative restrictions on imports or exports or measures having equivalent effect thereto. However, those requirements are not to affect either the policies of those Member States, or national policies on price setting and on the determination of social security schemes, except as far as it is necessary to attain transparency. The period within which Member States were to comply with that directive expired on 31 December 1989.

*Spanish law*

5 On 20 December 1990 the Kingdom of Spain adopted Ley 25/1990 del Medicamento (Law 25/1990 on medicines, BOE No 306 of 22 December 1990, p. 2643; 'Law 25/1990'). That law was amended, in particular, by Ley 66/1997 of 30 December 1997 (BOE No 313 of 31 December 1997, p. 38517) and, during the administrative procedure which led to the adoption of the decision contested in the present case, by Ley 55/1999 of 30 December 1999 (BOE No 312 of 30 December 1997, p. 46095).

6 On 23 February 1990, the Kingdom of Spain adopted Real Decreto 271/1990 de reorganización de la intervención de los precios de las especialidades farmacéuticas

de uso humano (Royal Decree 271/1990 on the reorganisation of intervention in the prices of pharmaceutical products for human use) (BOE No 53 of 2 March 1990, p. 6086; 'Decree 271/1990'). That decree was intended, in particular, to allow the Kingdom of Spain to comply with Directive 89/105/EEC.

7 The provisions of Title VIII of Law 25/1990 and Decree 271/1990 establish, in particular, a system of intervention on the part of the Spanish Ministry of Health and Consumption and the Comisión Interministerial de Precios de los Medicamentos (Interministerial Commission on the prices of medicines) attached to it (together 'the Spanish authorities'), on the maximum wholesale price of medicines reimbursed by the Spanish sickness insurance scheme.

*Background to the dispute*

8 The applicant, GlaxoSmithKline Services Unlimited ('GSK'), formerly Glaxo Wellcome plc, is a company incorporated under the laws of England and Wales and having its registered office in Brentford (United Kingdom). The GlaxoSmith Kline group, to which it belongs, is one of the world's main producers of pharmaceutical products. The group was formed following a concentration between Glaxo Wellcome plc and Smithkline Beecham plc, a transaction which the Commission, by a decision of 8 May 2000 (Case N IV/M.1846 — Glaxo Wellcome/Smithkline Beecham), declared that it did not oppose.

9 Glaxo Wellcome, SA ('GW'), a company incorporated under Spanish law and established in Madrid (Spain), is one of the Spanish subsidiaries of the GlaxoSmithKline group. Its main activity, directly and via its subsidiaries, is the development, manufacture and marketing of medicines in Spain.

10 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 General Sales Conditions') with a view to obtaining negative clearance or an exemption pursuant to 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 to the Commission.

11 The General Sales Conditions apply to 82 medicines intended for sale to wholesalers established in Spain with whom GW has commercial relations in Spain 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 to which the General Sales Conditions apply include eight medicines which, according to GSK, are prime candidates for parallel trade, principally between Spain and the United Kingdom. Those medicines are:

— an anti-allergy, Beconase;

— five anti-asthma products, Becloforte, Becotide, Flixotide, Serevent and Ventolín;

— an anti-epileptic, Lamictal;

— an anti-migraine, Imigran.

12 For all 82 medicines concerned, Clause 4 of the General Sales Conditions provides for two different prices, 'the Clause 4 A price' and 'the Clause 4 B price'. Clause 4 is worded as follows:

'(A) Pursuant to the provisions of subsections 1 (first paragraph) and 2 of Article 100 of [Law 25/1990], 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.'

13 By letters of 6 March 1998, GW sent the General Sales Conditions to 89 wholesalers established in Spain. Those letters contain, in particular, the following:

'Important: As proof of acceptance, please return to us a copy of the attached document duly signed. This should be in our possession before 13 March 1998'.

14 Seventy-five wholesalers, with sales accounting for more than 90% of GW's total sales in Spain in 1998, did as requested.

15 The General Sales Conditions entered into force on 9 March 1998.

16 Their lawfulness was subsequently disputed before the Spanish Competition Authority and the Spanish courts by two Spanish trade associations, Asociación de Exportadores Españoles de Productos Farmacéuticos (Aseprofar) and Asociación de Empresarios de Cooperativas Farmacéuticas, and also by a Spanish wholesaler, Spain Pharma, SA.

17 In addition, a number of complaints that the General Sales Conditions infringed Article 81(1) EC were lodged with the Commission by Aseprofar, supported by another Spanish trade association, Federación Nacional de Asociaciones de Mayoristas Distribuidores de Especialidades Farmacéuticas y Productos Parafarmacéuticos (Fedifar), by Spain Pharma and by two other trade associations, the Bundesverband der Arzneimittel-Importeure eV ('BAI') and the European Association of Euro Pharmaceutical Companies (EAEPC).

18 On 8 May 2001, the Commission adopted Decision 2001/791/EC 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), IV/37.380/F3 EAEPC (complaint)) (OJ 2001 L 302, p. 1; 'the Decision').

19 Article 1 of the Decision provides that GW 'has 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 to any other Member State'.

20 Article 2 of the Decision provides that the request for an exemption of the agreement is rejected.

21 Articles 3 and 4 of the Decision order GW to bring the infringement to an end immediately and to inform the Commission of the steps which it has taken in order to do so.

**Procedure**

22 By application lodged at the Registry of the Court of First Instance on 23 July 2001, GSK brought the present action.

23 By documents lodged at the Court Registry on 8, 12 and 16 November 2001, EAEPC, BAI, Spain Pharma and Aseprofar sought leave to intervene in support of the form of order sought by the Commission, in accordance with 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.

24 By documents lodged at the Court Registry on 28 November 2001, 14 December 2001 and 21 March 2002, GSK requested that certain items and secret or confidential information be excluded from the communication of the parties' submissions to the persons granted leave to intervene in the proceedings, in accordance with Article 116(2) of the Rules of Procedure.

25 By order of 27 November 2002, the President of the First Chamber granted the applications to intervene and reserved the decision on the merits of the requests for confidential treatment.

26 By order of 5 August 2003, the President of the First Chamber of the Court of First Instance granted in part the requests for confidential treatment and, for the remainder, rejected those requests.

27 When the Judge-Rapporteur was assigned to the Fourth Chamber owing to the change in the composition of the Chambers of the Court of First Instance on 1 October 2003, the case was reallocated to that Chamber.

28 By document lodged at the Court Registry on 25 March 2004, GSK requested that certain secret or confidential information be excluded from the communication to the interveners of its observations on the statements in intervention. That request was granted.

29 By letter of 16 April 2004, the Court requested GSK and the Commission to produce certain documents and to answer a written question, on the basis of Articles 49 and 64 of the Rules of Procedure. The parties complied with those measures of organisation of procedure within the prescribed period.

30 By document lodged at the Registry of the Court of First Instance on 7 May 2004, Spain Pharma requested permission, in accordance with Article 35(2) of the Rules of Procedure, to use the Spanish language in the oral procedure. After the parties had been heard, that request was granted.

31 By documents lodged at the Registry of the Court of First Instance on 27 May and 22 June 2004, GSK requested that certain secret or confidential information be excluded from the communication to the interveners of its and the Commission's answers to the Court's requests of 16 April 2004. That request was granted.

32 On 7 March 2006, the Court, in accordance with Article 14 of the Rules of Procedure and on a proposal from the Fourth Chamber, decided, after hearing the parties, to refer the case to the Fourth Chamber, Extended Composition.

33 On 15 March 2006, the Court of First Instance (Fourth Chamber), after hearing the report of the Judge-Rapporteur, opened the oral procedure.

34 By letters of 7 and 20 March 2006, the Court requested GSK, the Commission and the interveners to answer a number of written questions and to produce a document, pursuant to Articles 49 and 64 of the Rules of Procedure. The parties complied with those measures of organisation of procedure within the period prescribed for that purpose, with the exception of one question which GSK answered in a document lodged at the Court Registry on 6 June 2006. In the absence

of any objections by the parties, who were invited to comment on that point at the hearing, that document was placed on the file.

35 By a document lodged at the Court Registry on 28 April 2006, GSK requested that certain secret or confidential information be excluded from the communication to the interveners of its answers to the Court's requests of 7 and 20 March 2006. That request was granted.

36 By a document lodged at the Court Registry on 16 May 2000, Aseprofar requested leave to use Spanish during the oral procedure, in accordance with Article 35(2) of the Rules of Procedure. After hearing the parties, the Court granted that request.

37 The parties submitted oral argument and their answers to the questions put by the Court at the hearing on 7 June 2006.

**Forms of order sought by the parties**

38 GSK claims that the Court should:

— annul the Decision;

— order the Commission to pay the costs.

39 The Commission contends that the Court should:

— dismiss the application;

— order GSK to pay the costs.

40 Aseprofar submits that the Court should:

— dismiss the application;

— order GSK to pay the costs, including those incurred by Aseprofar.

41 BAI submits that the Court should:

— dismiss the application;

— order GSK to pay the costs, including those incurred by BAI.

42 EAEPC submits that the Court should:

— dismiss the application;

— order GSK to pay the costs, including those incurred by EAEPC.

43 Spain Pharma submits that the Court should:

— dismiss the application;

— order GSK to pay the costs, including those incurred by Spain Pharma.

**Law**

44 In support of the form of order which it seeks, GSK relies in substance on six pleas, which may be arranged according to whether they seek annulment in whole or, in the alternative, annulment in part of the Decision.

45 In support of its principal claim, whereby it seeks annulment of Article 1 of the Decision, which finds an infringement of Article 81(1) EC, GSK puts forward three pleas in law, alleging, respectively:

— failure to state sufficient reasons;

— infringement of Article 81(1) EC;

— misuse of powers, breach of the principle of subsidiarity and infringement of Article 43 EC.

46 In support of its alternative claim, whereby it seeks annulment of Article 2 of the Decision, which rejects its claim for an exemption under Article 81(3) EC, GSK relies on three pleas in law, alleging, respectively:

— failure to state sufficient reasons;

— infringement of Article 81(3) EC;

— breach of the principle of proportionality.

I — *The pleas seeking annulment of Article 1 of the Decision*

A — *The plea alleging inadequate reasoning*

1. Arguments of the parties

47 GSK claims, in substance, that the fact that the Decision makes no reference to the judgment of the Court of First Instance of 26 October 2000 in Case T-41/96 *Bayer* v *Commission* [2000] ECR II-3383 means that it is vitiated by inadequate reasoning.

48 The Commission, supported by the interveners, contends that this plea is unfounded.

2. Findings of the Court

49 Article 253 EC states, in particular, that decisions adopted by the Commission are to state the reasons on which they are based.

50 In order to state the reasons to the requisite legal standard, a decision of the Commission must disclose clearly the reasoning followed by that institution in such a way as to enable the persons concerned to understand the basis for it and the Court to ascertain whether it is well founded. On the other hand, such a decision is not required to go into all the relevant facts and points of law, since the question of compliance with Article 253 EC is assessed by reference to both the wording of the measure and its legal and factual context (Case 2/56 *Geitling* v *High Authority* [1957] ECR 2, at 16, and Case T-171/02 *Regione Autonoma della Sardegna* v *Commission* [2005] ECR II-2123, paragraph 73).

51 The need to state the reasons for its decisions therefore does not place the Commission under any general obligation to refer to a specific judicial decision in the decisions which it adopts.

52 In the present case, GSK merely asserts that the Decision is vitiated by inadequate reasoning in that it does not refer to a judicial decision.

53 Accordingly, the plea alleging that the reasoning on which the Decision is based is inadequate in that it does not refer to the judgment in *Bayer* v *Commission*, paragraph 47 above, must be rejected.

54 In so far as GSK intends in reality, by this plea, to challenge the content of the Decision, it must be observed that the examination of the existence and the scope of the reasons on which a Commission decision is based forms part of the review of essential procedural requirements and of the formal legality of that decision. It must therefore be distinguished from the examination of the merits of the grounds of the decision, which forms part of the review of its substantive legality (Case C-367/95 P *Commission* v *Sytraval and Brink's France* [1998] ECR I-1719, paragraph 67, and Case T-93/02 *Confédération nationale du Crédit Mutuel* v *Commission* [2005] ECR II-143, paragraph 67). To that extent, the plea is indissociable from the plea alleging infringement of Article 81(1) EC, which will be examined below.

B — *The plea alleging infringement of Article 81(1) EC*

1. Preliminary considerations

55 The application of Article 81(1) EC depends on a series of distinct conditions being satisfied (Case 56/65 *Société technique minière* [1966] ECR 235, at pp. 248 and 249, and *Bayer* v *Commission*, paragraph 47 above, paragraph 174), which must be proved by the person relying on that provision (Joined Cases C-204/00 P, C-205/00 P, C-211/00 P, C-213/00 P, C-217/00 P and C-219/00 P *Aalborg Portland and Others* v *Commission* [2004] ECR I-123, paragraph 78). It is thus necessary to establish, first, that there is an agreement between undertakings, a concerted practice or a decision of an association of undertakings; second, that that agreement, concerted practice or decision has as its object or effect the restriction of competition to an appreciable extent; and, third, that trade between Member States must be capable of being affected, the purpose of that last requirement being solely to determine the application of Community law (*Société technique minière*, p. 249; Joined Cases C-89/85, C-104/85, C-114/85, C-116/85, C-117/85 and C-125/85 to C-129/85 *Ahlström Osakeyhtiö and Others* v *Commission* [1993] ECR I-1307, paragraph 176; and *Bayer* v *Commission*, paragraph 47 above, paragraph 174).

56 In the present case, since GSK maintains that the Commission applied Article 81(1) to conduct not constituting an agreement within the meaning of that provision, that is to say, a restrictive agreement, it must be borne in mind that the question of the existence of an agreement between undertakings and the question of the restrictive nature of such agreement are distinct and must be examined separately (see, to that effect, *Société technique minière*, paragraph 55 above, pp. 248 and 249).

57 In that regard, the Court hearing an application for annulment of a decision applying Article 81(1) EC must undertake a comprehensive review of the examination carried out by the Commission (Case 42/84 *Remia and Others* v *Commission* [1985] ECR 2545, paragraph 34, and *Bayer* v *Commission*, paragraph 47 above, paragraph 62), unless that examination entails a complex economic assessment, in which case review by the Court is confined to ascertaining that there has been no misuse of powers, that the rules on procedure and on the statement of reasons have been complied with, that the facts have been accurately stated and that there has been no manifest error of assessment of those facts (*Remia and Others* v *Commission*, paragraph 34, and *Aalborg Portland and Others* v *Commission*, paragraph 55 above, paragraph 279).

58 Furthermore, that review is carried out solely by reference to the elements of fact and of law existing on the date of adoption of the contested decision (Joined Cases 15/76 and 16/76 *France* v *Commission* [1979] ECR 321, paragraph 7, and Case T-395/94 *Atlantic Container Line and Others* v *Commission* [2002] ECR II-875, paragraph 252), without prejudice to the possibility afforded to the parties, in the exercise of their rights of defence, of supplementing them by evidence established after that date, but for the specific purpose of contesting or defending that decision (Case T-87/05 *EDP* v *Commission* [2005] ECR II-3745, paragraph 158; see also, to that effect, Case 75/84 *Metro* v *Commission* [1986] ECR 3021 ('*Metro II*'), paragraphs 75 and 78, and *Atlantic Container Lines and Others* v *Commission*, cited above, paragraph 254).

59 In the present case, it follows that the elements of fact that did not exist on the date of adoption of the Decision, in particular the figures relating to the period 2001/2005, and the evidence which did not exist at that date and which was not

established for the specific purpose of contesting or defending the Decision in so far as it concludes that there was an infringement, in particular the studies generally covering the effects of parallel trade in medicines in the Community, other than those produced during the administrative procedure, must be excluded from the discussion at the outset.

2. The existence of an agreement between undertakings

(a) Content of the Decision

60 The Commission found, at recital 109 to the Decision, that the General Sales Conditions constituted an agreement between GW and all the wholesalers who had subscribed to them.

(b) Arguments of the parties

61 GSK claims that the General Sales Conditions do not constitute an agreement.

62 It maintains that GW and the Spanish wholesalers who signed the General Sales Conditions did not manifest an independent will, in so far as the wholesale price of the medicines reimbursed by the Spanish sickness insurance scheme is imposed on them by the applicable Spanish regulations.

63 Furthermore, they did not manifest a concurrent will to restrict competition, but merely a concurrent will to sell and purchase medicines according to the terms set out in the General Sales Conditions.

64 The Commission, supported by the interveners, disputes the merits of those arguments.

(c) Findings of the Court

65 GSK's arguments lead the Court to examine, in the first place, whether GW and the Spanish wholesalers did manifest an independent will by reference to the Spanish regulations on the wholesale price of medicines reimbursed by the Spanish sickness insurance scheme and therefore whether the conduct with which the Commission was faced was indeed conduct on the part of undertakings and not conduct on the part of the State. Its arguments also lead the Court to examine, in the second place, should it prove necessary to do so, whether GW and those wholesalers manifested a concurrent will, and therefore whether the Commission was indeed faced with bilateral conduct and not with unilateral conduct.

Independence of wills

66 Article 81(1) EC applies only to anti-competitive conduct engaged in by undertakings on their own initiative (Case 267/86 *Van Eycke* [1988] ECR 4769, paragraph 16; Joined Cases C-359/95 P and C-379/95 P *Commission and France* v *Ladbroke Racing* [1997] ECR I-6265, paragraph 33; and Case C-198/01 *CIF* [2003] ECR I-8055, paragraph 45).

67 Where, in order to decide whether that provision is applicable, it is necessary first to evaluate the possible impact of national regulations, it must be determined whether those regulations leave any scope for competition that might be prevented, restricted or distorted by autonomous conduct on the part of undertakings (*Commission and France* v *Ladbroke Racing*, paragraph 66 above, paragraphs 32 and 35, and *CIF*, paragraph 66 above, paragraph 66).

68 Where it is clear, following that evaluation, that the regulations in question require that undertakings engage in anti-competitive conduct, or eliminate any possibility of competitive activity on their part, Article 81(1) EC does not apply (*Commission and France* v *Ladbroke Racing*, paragraph 66 above, paragraph 33, and *CIF*, paragraph 66 above, paragraph 67).

69 Where, on the other hand, it is clear that those regulations do leave scope for competition that might be prevented, restricted or distorted by autonomous conduct on the part of undertakings, Article 81(1) EC does apply (*Commission and France* v *Ladbroke Racing*, paragraph 66 above, paragraph 34, and *CIF*, paragraph 66 above, paragraph 56).

70 The possibility of excluding particular anti-competitive conduct from the scope of that provision on the ground that it is required by national regulations has been applied restrictively by the Community Courts (*CIF*, paragraph 66 above, paragraph 67, and Case T-513/93 *Consiglio Nazionale degli Spedizionieri Doganali* v *Commission* [2000] ECR II-1807, paragraph 60).

71 It is therefore necessary to determine whether, as GSK maintains, the Spanish regulations require GW to apply, in the contracts which it concludes with Spanish wholesalers, prices which differ according to whether or not the medicines which it sells to them will be reimbursed by the Spanish sickness insurance scheme.

72 It is quite clear that the Spanish regulations, which result from the provisions of Title VIII of Law 25/1990 in conjunction with those of Decree 271/1990, do not in any way determine the wholesale prices of medicines which are not reimbursable by the Spanish sickness insurance scheme. GSK has acknowledged, moreover, both in its written submissions and at the hearing, that that assertion, which followed by implication but necessarily from the fact that Law 25/1990, in the version applicable when the General Sales Conditions entered into force, was silent as regards those products, was expressly confirmed by the subsequent amendments to that law, as stated at recitals 37 and 139 to the Decision.

73 Thus, even on the assumption that GSK's argument, according to which the wholesale prices of medicines which are reimbursable by the scheme are fixed wholly independently by the Spanish authorities and are binding on GW and the Spanish wholesalers, is correct, contrary to the interveners' contention, the fact remains that the conduct consisting in establishing, by contract, a system of differentiated prices prohibiting the Spanish wholesalers dealing with GW from purchasing at that price (the Clause 4A price) medicines which they will resell in other Member States, and obliging them to purchase those products at a higher price (the Clause 4B price), is not imposed by the Spanish regulations. When questioned on that point at the hearing, moreover, GSK was forced to agree.

74 Accordingly, it cannot be accepted that the national regulations in question required GW to apply, in the contracts which it concluded with Spanish wholesalers, prices which differ according to whether or not the medicines which it sells to them will be reimbursed by the Spanish sickness insurance scheme.

Concurrence of wills

75 Article 81(1) EC applies only to bilateral or multilateral conduct on the part of undertakings (Case C-49/92 P *Commission* v *Anic Partecipazioni* [1999] ECR I-4125,

paragraphs 79 and 112) and such conduct may take the form of agreements, concerted practices or decisions of associations.

76 In order for there to be an agreement, it is sufficient that at least two undertakings have expressed their joint intention to conduct themselves on the market in a specific way (Case 41/69 *ACF Chemiefarma* v *Commission* [1970] ECR 661, paragraph 112; Case C-277/87 *Sandoz Prodotti Farmaceutici* v *Commission* [1990] ECR I-45, summary publication, paragraph 13; and *Bayer* v *Commission*, paragraph 47 above, paragraphs 67 and 173).

77 While it is therefore essential that the decisions in which the Commission applies Article 81(1) EC show the existence of a joint intention to act on the market in a specific way, those decisions, contrary to GSK's contention, are not required to establish the existence of a joint intention to pursue an anti-competitive aim.

78 In the present case, the Decision concludes that there is a joint intention expressed by GW and the Spanish wholesalers who subscribed to the General Sales Conditions to conduct themselves on the market in the manner specified in Clause 4 of those conditions, that is to say, to sell and purchase one or other of the 82 medicines to which those conditions apply at the Clause 4A price or the Clause 4B price, depending on whether the conditions laid down in point A of that clause are or are not satisfied.

79 Clearly, that conclusion is confirmed by the case-file, which shows, first of all, that GW adopted General Sales Conditions providing for a system of differentiated prices. Then, GW sent those General Sales Conditions to 89 wholesalers with whom it had commercial relations in Spain. On that occasion, it requested them, emphasising the importance which it ascribed to that request, to return a signed copy '[a]s proof of [their] acceptance', within a mandatory period. Those factual

elements reveal the intention expressed by GW to seek the Spanish wholesalers' agreement to its General Sales Conditions and, therefore, to make them an offer concerning those conditions. Last, 75 of the 89 wholesalers to whom that offer was made did as requested by GW, signing the General Sales Conditions and returning them to GW within the prescribed period. Those factual elements reveal the intention expressed by those wholesalers to accept GW's offer and thus to form an agreement with GW, as GSK acknowledged at the hearing.

80 None of the arguments put forward by GSK appears to be capable of upsetting that conclusion.

81 In particular, GSK cannot find support in the fact that the Commission did not adduce evidence of the existence of a formal prohibition on exports imposed by GW on the Spanish wholesalers or of conduct revealing the tacit acceptance of that prohibition by those wholesalers.

82 It is for the Commission to prove the infringements which it finds by adducing, in the decisions in which it applies the competition rules, precise and coherent evidence demonstrating convincingly the existence of the facts constituting those infringements (Joined Cases 29/83 and 30/83 *CRAM and Rheinzink* v *Commission* [1984] ECR 1679, paragraph 20, and Joined Cases C-2/01 P and C-3/01 P *BAI and Commission* v *Bayer* [2004] ECR I-23, paragraph 62).

83 That evidence may consist of direct evidence, taking the form, for example, of a written document (Joined Cases T-25/95, T-26/95, T-30/95 to T-32/95, T-34/95 to T-39/95, T-42/95 to T-46/95, T-48/95, T-50/95 to T-65/95, T-68/95 to T-71/95, T-87/95, T-88/95, T-103/95 and T-104/95 *Cimenteries CBR and Others* v

*Commission* [2000] ECR II-491, paragraph 862, and, on appeal, *Aalborg Portland and Others* v *Commission*, paragraph 55 above, paragraph 237), or, failing that, indirect evidence, for example in the form of conduct (*Bayer* v *Commission*, paragraph 47 above, paragraph 73, and, on appeal, *BAI and Commission* v *Bayer*, paragraph 82 above, paragraph 100).

84 In the present case, it was observed above that the Commission had relied on an exchange of documents showing, beyond all possible doubt, that GW had proposed to the Spanish wholesalers that they conduct themselves on the market in the manner specified in the General Sales Conditions and that most of them had agreed to that proposal. The Commission therefore saw no point, as it again emphasised at the hearing, in seeking other evidence, such as evidence of the conduct of GW and the conduct of those wholesalers.

85 Likewise, GSK cannot validly maintain, in essence, that the wholesalers approached by GW would ultimately have disagreed with GW.

86 Where, as in this case, the Commission has adduced evidence of the existence of an agreement, it is for an undertaking which has taken part in that agreement to adduce evidence that it distanced itself from that agreement, evidence which must demonstrate a clear intention, brought to the notice of the other participating undertakings, to withdraw from that agreement (see, to that effect, *BAI and Commission* v *Bayer*, paragraph 82 above, paragraph 63; *Aalborg Portland and Others* v *Commission*, paragraph 55 above, paragraphs 81 to 84; and Case T-61/99 *Adriatica di Navigazione* v *Commission* [2003] ECR II-5349, paragraphs 135 to 138).

87 In the present case, while it is true that some of the Spanish wholesalers who had subscribed to the General Sales Conditions expressed doubts as to the legality of those conditions, as stated at recital 12 to the Decision, there is no indication in the case-file that they distanced themselves from the agreement within the meaning of the case-law. Likewise, it is true that a number of them exported medicines purchased from GW at the Clause 4A price. However, it is also apparent from the

case-file that they eventually agreed, at GSK's request, to pay the invoices corresponding to the difference between that price and the Clause 4B price. In any event, those facts concern only a few wholesalers and it cannot be concluded that they all distanced themselves from the agreement which they had previously concluded with GW.

88 It is also true that three trade associations, Aseprofar, the Asociación de empresarios de cooperativas farmacéuticas and Fedifar, lodged complaints with the Commission and with the Servicio de defensa de competencia (service for the protection of competition), as stated at recital 3 to the Decision, and that the members of those associations, direct members in the case of the first two associations and indirect members in the case of the third, included some of the wholesalers who signed the General Sales Conditions. None the less, the mere fact that a number of trade associations whose members included, among others, some of the signatories of the General Sales Conditions, submitted such complaints cannot suffice to prove that all the wholesalers did not really intend, or no longer intended as from the date on which those complaints were lodged, to collude with GW.

89 Accordingly, it cannot be accepted that GW and the wholesalers who subscribed to the General Sales Conditions did not manifest a joint intention.

90 It follows from the foregoing that it is not apparent, on the basis of GSK's arguments, that the Commission was wrong to conclude that there was an agreement.

3. The existence of a restriction of competition

(a) Content of the Decision

91 The Commission found at recitals 116 to 143 and 189 to the Decision that Clause 4 of the General Sales Conditions had both the object and the effect of restricting competition.

92 The Commission began by examining the object of that clause and observed at the outset, at recital 116 to the Decision, that the clause sought to limit parallel trade between Spain and other Member States in the medicines sold by GW. The Commission also found, at recital 117 to the Decision, that a comparison between the Clause 4A price, applicable to medicines intended to be resold and reimbursed in Spain, and the Clause 4B price, applicable to medicines intended to be resold or reimbursed in other Member States, revealed that its application would have the effect, depending on the case, of excluding or impeding parallel trade.

93 The Commission then considered, at recitals 117 to 119 to the Decision, that Clause 4 of the General Sales Conditions produced effects tantamount to those of an export ban in a considerable number of cases while impeding parallel trade in other cases in very much the same way as a system of dual pricing. The Commission also considered, at recitals 120 to 123 to the Decision, that the existence in Spain of national regulations relating to the procedures for fixing the wholesale prices of medicines reimbursed by the national Spanish sickness insurance scheme was not capable of altering that analysis.

94 Last, the Commission observed, at recitals 124 and 125 to the Decision, that the Court of Justice and the Court of First Instance had always qualified agreements containing export bans, dual-pricing systems or other limitations of parallel trade as restricting competition 'by object', so that Clause 4 of the General Sales Conditions must be regarded as having the object of restricting competition.

95 The Commission proceeded to examine the effect of Clause 4 of the General Sales Conditions and considered at the outset, at recital 126 to the Decision, that the fact of establishing a higher wholesale price where the medicines were to be exported, to which the transaction costs connected with that operation (shipping, repackaging, etc.) had to be added, tended to limit the parallel trade that would be expected in the absence of that price.

96 The Commission then considered, at recitals 127 to 135 to the Decision, that Clause 4 did not merely neutralise a distortion of competition attributable to the Kingdom of Spain and was not justified by the existence of a specific regulatory context.

97 The Commission also found, at recitals 136 to 140 to the Decision, that the differentiated prices specified in Clause 4 of the General Sales Conditions had the effect, first, of restricting the freedom of action of the wholesalers operating in the Member State of origin of the parallel trade and, second, of restricting competition between those wholesalers and the distributors operating in the Member State of destination of that parallel trade.

98 The Commission finally referred, at recitals 141 to 143 to the Decision, to the extent to which currency fluctuations had contributed to parallel trade in medicines between 1996 and 1998, in particular between Spain and the United Kingdom.

(b) Arguments of the parties

99 GSK claims, in substance, that Clause 4 of the General Sales Conditions does not constitute a restriction of competition.

100 In the first place, it maintains that competition is distorted at the outset in the prescription medicines sector and that Clause 4 of the General Sales Conditions seeks only to neutralise that situation, which is attributable to the existence of national regulations governing the price of those medicines and also to the absence of Community rules designed to harmonise the national regulations.

101 In the second place, GSK submits that Clause 4 of the General Sales Conditions does not have the object of restricting competition and that the Commission has not demonstrated that it has the effect of doing so, in the light of the specific features of the relevant market and, more generally, of the legal and economic context in which Clause 4 applies.

102 The Commission, supported by the interveners, disputes the merits of those arguments. It contends that it was correct to find that Clause 4 of the General Sales Conditions, which was capable of excluding or impeding parallel trade, had the object and the effect of restricting competition.

(c) Findings of the Court

103 GSK does not dispute the material accuracy of the facts on which the Commission relied for the purpose of applying Article 81(1) EC, but contests the Commission's assessment of those facts. All of the applicant's criticisms relate, in substance, to the consequences to be drawn, when analysing the existence of a restriction of competition, from the legal and economic context peculiar to the medicines sector. More particularly, its criticisms concern, in the first place, the competitive situation existing before Clause 4 of the General Sales Conditions was adopted and, in the second place, the restriction of competition attributed to that clause.

The competitive situation existing before Clause 4 of the General Sales Conditions was adopted

104 As GSK rightly asserts, the sector of medicines reimbursed by the national sickness insurance scheme continues to be characterised, in a number of Member States, by the existence of regulations which go beyond the mere regulation of an economic

activity, in particular in matters of prices (Case 181/82 *Roussel and Others* [1983] ECR 3849, paragraph 8). The coexistence of those different national regulations may distort competition (Joined Cases C-267/95 and C-268/95 *Merck and Beecham* [1996] ECR I-6285, paragraph 47). It tends, moreover, to favour a certain partitioning of the national markets on that point (see, by analogy, Joined Cases 40/73 to 48/73, 50/73, 54/73 to 56/73, 111/73, 113/73 and 114/73 *Suiker Unie and Others* v *Commission* [1975] ECR 1663, paragraph 24).

105 However, in accordance with the case-law cited at paragraphs 67 to 70 above, it is only where the sector in which the agreement is applied is subject to regulations which preclude the possibility of competition that might be prevented, distorted or restricted by that agreement that Article 81(1) EC is inapplicable.

106 In the present case, however, there is competition between producers of medicines, which is mainly concerned with parameters other than price, in particular innovation (*Roussel*, paragraph 104 above, paragraph 9), as GSK maintained in its written submissions and at the hearing.

107 Furthermore, there may be competition between a producer and his distributors, or between parallel traders and national distributors, which specifically takes advantage of the significant differences in price to which the national regulations in question contribute and which, where the medicines are protected by a patent which confers a temporary monopoly on its holder, is, until the expiry of that patent, the only form of price competition envisageable in respect of them, as GSK also maintained in its written submissions.

108 Accordingly, as the regulatory situation described by GSK is capable of restricting competition, but not of excluding it, it does not have the consequence of rendering Article 81(1) EC inapplicable.

The restriction of competition attributed to Clause 4 of the General Sales Conditions

109 As GSK claims that the Commission did not take proper account of the relevant legal and economic context when it examined the existence of a restriction of competition, it should be noted at the outset that the competition referred to in Article 3(1)(g) EC and Article 81 EC is taken to mean effective competition, that is to say, the degree of competition necessary to ensure the attainment of the objectives of the Treaty. Its intensity may vary to an extent dictated by the nature of the product concerned and the structure of the relevant market. Furthermore, its parameters may assume unequal importance, as price competition does not constitute the only effective form of competition or that to which absolute priority must in all circumstances be given (Case 26/76 *Metro* v *Commission* [1977] ECR 1875 (*'Metro I'*), paragraphs 20 and 21, and *CIF*, paragraph 66 above, paragraph 68).

110 Consequently, the characterisation of a restriction of competition within the meaning of Article 81(1) EC must take account of the actual framework and, therefore, of the legal and economic context in which the agreement to which that restriction is imputed is deployed. Such an obligation is imposed for the purpose of ascertaining both the object and the effect of the agreement (*Société technique minière*, paragraph 55 above, pp. 249 and 250; Joined Cases 56/64 and 58/64 *Consten and Grundig* v *Commission* [1966] ECR 299, at p. 343; and Case C-399/93 *Oude Luttikhuis and Others* [1995] ECR I-4515, paragraph 20).

111 Thus, when examination of the clauses of an agreement, carried out in their legal and economic context, reveals in itself the existence of an alteration of competition, it may be presumed that that agreement has as its object the prevention, restriction or distortion of competition (see *Société technique minière*, paragraph 55 above, pp. 249, 251 and 252, and *Consten and Grundig* v *Commission*, paragraph 110 above, p. 343), so that there is no need to examine its effect (*Consten and Grundig* v *Commission*, paragraph 110 above, p. 342, and *Commission* v *Anic Participazioni*, paragraph 75 above, paragraph 99).

112 Where that is not so, on the other hand, it is necessary to examine the effect of the agreement and to prove to the requisite legal standard that it actually or potentially prevents, restricts or distorts competition (*Société technique minière*, paragraph 55 above, pp. 249, 251 and 252, and Case C-7/95 P *John Deere* v *Commission* [1998] ECR I-3111, paragraphs 75 and 77).

113 In the present case, the Court will examine, in turn, GSK's arguments concerning the object and the effect of Clause 4 of the General Sales Conditions.

— The existence of an anticompetitive object

114 GSK does not dispute that Clause 4 of the General Sales Conditions was inserted with the intention of limiting the parallel trade between Spain and other Member States, in particular the United Kingdom, in 82 medicines sold by GW.

115 It follows from the case-law that agreements which ultimately seek to prohibit parallel trade must in principle be regarded as having as their object the prevention of competition (*Consten and Grundig* v *Commission*, paragraph 110 above, pp. 342 and 343; Case 19/77 *Miller International* v *Commission* [1978] ECR 131, paragraphs 7 and 18; Joined Cases 32/78, 36/78 and 82/78 *BMW Belgium* v *Commission* [1979] ECR 2435, paragraphs 20 to 28 and 31; and *Sandoz Prodotti Farmaceutici* v *Commission*, paragraph 76 above, paragraph 16).

116 It also follows from the case-law that agreements that clearly intend to treat parallel trade unfavourably must in principle be regarded as having as their object the restriction of competition (Joined Cases 96/82 to 102/82, 104/82, 105/82, 108/82 and 110/82 *IAZ and Others* v *Commission* [1983] ECR 3369, paragraphs 23 to 25; and Case C-551/03 P *General Motors* v *Commission* [2006] ECR I-3173, paragraphs 67 and 68).

117 However, GSK is correct to maintain that, having regard to the legal and economic context, the Commission could not rely on the mere fact that Clause 4 of the General Sales Conditions established a system of differentiated price intended to limit parallel trade as the basis for its conclusion that that provision had as its object the restriction of competition.

118 In effect, the objective assigned to Article 81(1) EC, which constitutes a fundamental provision indispensable for the achievement of the missions entrusted to the Community, in particular for the functioning of the internal market (Case C-126/97 *Eco Swiss* [1999] ECR I-3055, paragraph 36, and Case C-453/99 *Courage* v *Crehan* [2001] ECR I-6297, paragraph 20), is to prevent undertakings, by restricting competition between themselves or with third parties, from reducing the welfare of the final consumer of the products in question (Joined Cases T-213/01 and T-214/01 *Österreichische Postsparkasse and Bank für Arbeit und Wirtschaft* v *Commission* [2006] ECR II-1601, paragraph 115; see also, to that effect, *Consten and Grundig* v *Commission*, paragraph 110 above, p. 493, and Case 28/77 *Tepea* v *Commission* [1978] ECR 1391, paragraph 56). At the hearing, in fact, the Commission emphasised on a number of occasions that it was from that perspective that it had carried out its examination in the present case, initially concluding that the General Sales Conditions clearly restricted the welfare of consumers, then considering whether that restriction would be offset by increased efficiency which would itself benefit consumers.

119 Consequently, 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. As may be seen from the case-law cited at paragraphs 111 and 112 above, that analysis, which may be abridged when the clauses of the agreement reveal in themselves the existence of an alteration of competition, as the Commission observed at the hearing, must, on the other hand, be supplemented, depending on the requirements of the case, where that is not so (*Société technique minière*, paragraph 55 above, pp. 248 to 251, and *Consten and Grundig* v *Commission*, paragraph 110 above, pp. 342 and 343).

120 In particular, in *Consten and Grundig* v *Commission*, paragraph 110 above, which gave rise to the case-law cited at paragraphs 115 and 116 above, the Court of Justice, contrary to the Commission's contention in its written submissions, did not hold that an agreement intended to limit parallel trade must be considered by its nature, that is to say, independently of any competitive analysis, to have as its object the restriction of competition. On the contrary, the Court of Justice merely held, first, that an agreement between a producer and a distributor which might tend to restore the national divisions in trade between Member States might be of such a kind as to frustrate the most fundamental objectives of the Community (p. 340), a consideration which led it to reject a plea alleging that Article 81(1) EC was not applicable to vertical agreements (pp. 339 and 340). The Court of Justice then carried out a competitive analysis, abridged but real, during the course of which it held, in particular, that the agreement in question sought to eliminate any possibility of competition at the wholesale level in order to charge prices which were sheltered from all effective competition, considerations which led it to reject a plea alleging that there was no restriction of competition (pp. 342 and 343).

121 While it has been accepted since then that parallel trade must be given a certain protection, it is therefore not as such but, as the Court of Justice held, in so far as it favours the development of trade, on the one hand, and the strengthening of

competition, on the other hand (Case C-373/90 *X* [1992] ECR I-131, paragraph 12), 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 (*Tepea* v *Commission*, paragraph 118 above, paragraphs 43 and 56). Consequently, 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.

122 However, if account is taken of the legal and economic context in which GSK's General Sales Conditions are applied, it cannot be presumed that those conditions deprive the final consumers of medicines of such advantages. In effect, the wholesalers, whose function, as the Court of Justice has held, is to ensure that the retail trade receives supplies with the benefit of competition between producers (*Metro I*, paragraph 109 above, paragraph 40), are economic agents operating at an intermediate stage of the value chain and may keep the advantage in terms of price which parallel trade may entail, in which case that advantage will not be passed on to the final consumers.

123 That context is described in Section I of the Decision, which deals with the facts, and more particularly in Subsections F, entitled 'Parallel trade in pharmaceutical products with the Community — impact of national regulatory frameworks and currency fluctuations' and G, entitled 'Parallel trade in GW products within the Community — impact of the GW sales conditions'.

124 It is apparent on reading that description that the main characteristics of the legal and economic context are as follows, as GSK agreed both in its written submissions and at the hearing.

125 First, according to recitals 31, 36 and 50 to the Decision, the price of medicines reimbursed by the national health insurance schemes is not determined as a result of a competitive process throughout the Community but is directly fixed following an administrative procedure in most Member States and indirectly controlled by the other Member States.

126 Second, according to recital 31 to the Decision, at this stage the harmonisation of the applicable national provisions is limited. In fact, Directive 89/105 endeavours to provide that where the pricing of those medicines is provided for in national law it must be preceded by a transparent procedure and be based on objective and verifiable criteria. For the remainder, according to recital 50 to the Decision, national law may provide that various criteria are to be taken into account, depending on the policy pursued by the Member State concerned as regards public health and the financing of the national sickness insurance scheme, as Directive 89/105 also explains. That is the case, in particular, of Spanish law, which, according to recitals 37 and 38 to the Decision, provides for the direct fixing of a maximum wholesale price and the indirect fixing of a maximum retail price. United Kingdom law does not provide for the fixing of prices but, according to recitals 44 to 46 to the Decision, for control of pharmaceutical companies' profits.

127 Third, according to recitals 29 to 31 and 34 to the Decision, the differences between the applicable national provisions are a structural cause of the existence of significant price differentials between Member States.

128 Fourth, according to recitals 30, 32 and 53 to the Decision, fluctuations in exchange rates are a cyclical cause of those price differentials. That phenomenon, which potentially affected all Member States of the Community on 6 March 1998, the date on which GSK notified the General Sales Conditions to the Commission, still affected the United Kingdom, Denmark and Sweden on 8 May 2001, the date on which the Commission adopted the Decision, as stated at recital 53 to the Decision.

129 Fifth, those price differentials are themselves the cause of parallel trade in medicines in the Community, according to recital 29 to the Decision. As indicated at recitals 33 and 34 to the Decision, the main Member States of destination of that parallel trade are Denmark, the Netherlands and the United Kingdom.

130 Sixth, certain Member States have adopted provisions which, independently of the question whether they are intended to encourage parallel trade — which the Commission explains at recitals 31, 33, 34, 36 and 52 to the Decision, but which GSK disputes —, may have such an effect. That is notably the case in the United Kingdom, where, as stated at recital 49 to the Decision, the National Health Service automatically pays pharmacists a sum equal to the manufacturer's list price on the United Kingdom market, minus a standard discount of 4 to 5%, which is supposed to correspond to the savings made by pharmacists where they obtain their supplies elsewhere, at a lower price.

131 Seventh, as stated at recitals 31 and 51 to the Decision, the patient generally bears only a limited part, although this varies from Member State to Member State, of the price of the medicines reimbursed by the national sickness insurance scheme which he consumes. The national sickness insurance scheme bears the essential part. That is notably the case in the United Kingdom, where, according to recital 48 to the Decision, the patient pays GBP 6 per item, unless he belongs to a category exempt from such payment.

132 The Commission refers to certain aspects of that description when it examines the object of Clause 4 of the General Sales Conditions. It thus makes reference to that description, at recital 117 to the Decision, in order to establish the impact of that requirement on parallel trade, which is not disputed. It also refers to that description, at recital 121 to the Decision, in order to explain that, contrary to GSK's contention, the pharmaceutical companies have a power of negotiation in the Spanish procedure for setting the wholesale price of medicines.

133 At no point, however, does 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, which fix them directly or indirectly at what they deem to be the appropriate level, are determined at structurally different levels in the Community and, unlike the prices of other consumer goods to which the Commission referred in its written submissions and at the hearing, such as sports items or motor cycles, are in any event to a significant extent shielded from the free play of supply and demand.

134 That circumstance means that it cannot be presumed that parallel trade has an impact on the prices charged to the final consumers of medicines reimbursed by the national sickness insurance scheme and thus confers on them an appreciable advantage analogous to that which it would confer if those prices were determined by the play of supply and demand.

135 Incidentally, the Commission itself agrees with what is at first sight the ambiguous impact of parallel trade in medicines on the welfare of final consumers, since it states in Communication COM(1998) 588 final of 25 November 1999 on the single market in pharmaceuticals, which is cited at recital 161 to the Decision and referred to by the parties in their written submissions and in their answers to the written questions put by the Court, that unless parallel trade can operate dynamically on prices, it creates inefficiencies because most, although not all, of the financial benefit accrues to the parallel trader rather than to the health care system or the patient (p. 6).

136 Accordingly, it cannot be considered that examination of Clause 4 of the General Sales Conditions, which according to GSK is designed to ensure that the wholesale price set by the Kingdom of Spain is actually charged only for the medicines to which it was intended by law to apply, reveals in itself that competition is prevented, restricted or distorted.

137 None of the arguments of the Commission or the interveners appears to be capable of calling that conclusion in question.

138 In particular, the Commission is not entitled, as it did at recitals 118 and 119 to the Decision and in its written submissions, merely to draw parallels with the agreements which it has had occasion to examine in its previous practice in taking decisions and take the view that Clause 4 of the General Sales Conditions resembles those agreements or can be treated in the same way as them. Such an approach ultimately ignores the elements of legal and economic context described above, which are not present in the decisions adopted pursuant to Article 81(1) EC to which the Commission referred.

139 Furthermore, the Commission is not correct to claim that the existence of the Spanish regulations on the setting of the wholesale price of medicines is ultimately not decisive, owing to the power of negotiation which those regulations confer on the pharmaceutical companies, as it did in recitals 120 to 123 to the Decision and in its written submissions. Nor is it correct to submit that the coexistence of different State rules on that subject is also not decisive, in the light of the case-law (*BMW Belgium* v *Commission*, paragraph 115 above, paragraph 5, and Case T-175/95 *BASF* v *Commission* [1999] ECR II-1581, paragraphs 121 to 123 and 136), as it also did in its written submissions.

140 In effect, even on the assumption that the Spanish regulations confer a power of negotiation on the pharmaceutical companies, as the Commission and the interveners again maintained at the hearing, the fact remains that the existence of those regulations, and their coexistence with the regulations of other Member States, has a significant impact on an essential parameter of competition (see, by analogy, *Suiker Unie and Others* v *Commission*, paragraph 104 above, paragraphs 17 and 71), a contextual element which cannot be overlooked in the competitive analysis.

141 No parallel can therefore be drawn between the cases to which the Commission refers, which, as the Commission itself observed at the hearing, concerned price-freezing measures relating to new vehicles (*BMW Belgium* v *Commission*, paragraph 115 above, paragraph 5) or vehicle refinishing paints (*BASF* v *Commission*, paragraph 139 above, paragraph 123) in force in a single Member State of the Community, and the present case, which is characterised by the fact that the price of the products in issue, which is finally set by the Member States, falls structurally outside the play of supply and demand and is established at structurally different levels throughout the Community, notwithstanding a residual competition which may be revealed by parallel trade.

142 Last, it cannot be inferred from paragraph 75 of *General Motors* v *Commission*, paragraph 116 above, to which the Commission referred in its answer to the written questions put by the Court and at the hearing, that the situation of fact recalled in the preceding paragraph should be completely overlooked.

143 In fact, it follows from paragraph 75 of that judgment that the absence of fiscal harmonisation does not prevent the conclusion that an agreement intended to limit parallel trade in motor vehicles has the object of restricting competition, although, as the Commission observed at the hearing, the absence of such harmonisation has an effect on competition in that sector. On the other hand, it does not in any way follow that the State rules at issue in the present case are indifferent to the competitive analysis, when they have as their object to shield the pricing of medicines reimbursed by the national sickness insurance schemes from competition.

144 As regards the interveners, for their part, it does not avail them to rely as they did at the hearing on the fact that, in reality, the national regulations at issue are not intended to shield the pricing of those medicines from the play of supply and demand, but to compensate for the absence of competition caused by the weight of the pharmaceutical companies on the market and to ensure fair prices.

145 When it is dealing with an application for annulment of a Commission decision applying the competition rules, the Community judicature carries out, in accordance with Article 230 EC, a review of the lawfulness of that decision. The interveners' arguments rely on facts which are neither mentioned nor, a fortiori, examined by the Commission in the Decision. It is not for the Court to substitute itself for the Commission and examine them for the first time.

146 Furthermore, those arguments must be contrasted with GSK's arguments that the national rules on patents are intended to allow the pharmaceutical companies to recover their research and development ('R&D') costs by granting them a temporary monopoly, following which manufacturers of generic medicines restore competition on price, so that parallel traders, which operate on the market during the lifetime of the patents, are the vectors of artificial competition and not of effective competition within the meaning of Article 3(1)(g) EC and Article 81 EC.

147 Consequently, the principal conclusion reached by the Commission, namely that Clause 4 of the General Sales Conditions 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 General Sales Conditions, 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 therefore 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.

— The existence of an anti-competitive effect

148 In order to examine the effect of an agreement on competition, it is necessary, first of all, to define the relevant market or markets, from both a material and a geographic point of view (Case C-234/89 *Delimitis* [1991] ECR I-935, paragraphs 15, 16 and 18).

149 In the present case, as regards the relevant products market, the Commission considered at recitals 112 and 113 to the Decision that, taking into account GSK's observations that the nature and scope of parallel trade and the General Sales Conditions could give rise to the existence of a product market comprising all prescription medicines, it was not necessary to determine precisely GW's market shares for each of the 82 medicines involved. Since the Commission, at the hearing, cast doubt on the existence of the GSK observations on which those recitals are based, it must be held that a reading of the supplementary notification reveals that the Decision is not vitiated by an error of fact on that point.

150 As regards the relevant geographic market, the Commission finally considered, at recital 114 to the Decision, that it must be considered to be the national market, owing, in particular, to the existence in the Member States of the Community of different price and reimbursement regulations, different brand and packing strategies, different distribution systems and different prescribing habits.

151 The markets affected by the agreement were not expressly set out by the Commission. It may be inferred from recitals 112 to 114, 117 and 126 to the Decision, however, as the Commission confirmed in its answers to the written questions put by the Court, that these were, first, the Spanish market, where the

Spanish wholesalers may purchase medicines from GW, and, second, all the national markets of the Community where they may resell them, that is to say, those where the differential between the Spanish price and the domestic price is sufficient to make parallel trade lucrative.

152 GSK does not dispute the Commission's approach to the definition of the relevant geographic market, as it again confirmed at the hearing. It is therefore common ground that the geographic market, which is to be understood as the territory on which the objective conditions of competition relating to the relevant product are, if not the same, at least sufficiently homogeneous for all traders (Case 27/76 *United Brands* v *Commission* [1978] ECR 207, paragraphs 44 and 53, and Case T-83/91 *Tetra Pak* v *Commission* [1994] ECR II-755, paragraph 91), may in the present case be taken to be the national market, having regard in particular to the different regulations on the prices and reimbursement of medicines.

153 On the other hand, GSK disputes the Commission's approach to the definition of the relevant product market. It maintains that, having regard to the Spanish regulations in that regard, the Commission ought to have drawn a distinction between a regulated market, consisting of the medicines intended to be resold and reimbursed in Spain, and a free market, consisting of the medicines intended to be resold and reimbursed in any other Member State. However, that criticism does not appear to be well founded.

154 It follows from recitals 112 and 113 to the Decision that the Commission did not thoroughly investigate the question of the definition of the relevant product market. However, when questioned about the framework within which it had reasoned in practice, the Commission indicated in its answers to the written questions put by the Court that, while taking the view that it was not required to define the relevant product market in so far as it had been able to conclude that there was an anti-competitive object, it had made a summary definition of that market.

155 It also explained, in its written answers and then at the hearing, that, while not adopting an extremely detailed approach in that regard, it had ultimately adhered to the definition traditionally used in such matters, namely a definition based on the third level of the 'Anatomical therapeutic classification' (ATC) drawn up by the European Pharmaceutical Medical Research Association (EphMRA). As stated at recitals 16 and 110 to the Decision, that level corresponds to subgroups defined by reference to the therapeutic indication and the pharmacological properties of the medicines concerned.

156 Where the Court rules on an application for annulment of a Community measure, it falls upon it to interpret that measure itself, in particular where the institution which adopted it provides explanations of the way in which it should be understood (Case C-194/99 P *Thyssen Stahl* v *Commission* [2003] ECR I-10821, paragraphs 55 and 56). In the present case, a reading of the Decision as a whole reveals that the Commission, by implication but necessarily, reasoned within the framework of a market perceived as the market in medicines reimbursed by the Spanish sickness insurance scheme, in so far as they might be subject to parallel trade to other Member States of the Community. Thus, it was in a global manner that the Commission described the parallel trade in medicines sold by GW in Spain, at recitals 64 to 71 to the Decision, and the impact of the General Sales Conditions on that phenomenon, at recitals 72 to 75 to the Decision. It followed the same approach when it examined the restrictive effect of Clause 4 of those conditions, at recitals 117, 126, 137, 139 and 140 to the Decision, while concentrating its attention on a sample of eight medicines particularly suitable for parallel trade about which GSK had provided information to the Commission. It also followed the same approach, ultimately, when it evaluated the appreciable nature of that anti-competitive effect, at recital 144 to the Decision, and also the appreciable effect on trade between Member States, at recital 146 to the Decision.

157 As may be seen from paragraphs 13 and 14 of Commission Notice 97/C 372/03 on the definition of relevant market for the purposes of Community competition law (OJ 1997 C 372, p. 5, paragraphs 13 and 14), the Commission has undertaken to define the relevant product market principally by reference to demand substitutability and supply substitutability.

158 As regards the first aspect, it follows from Article 1(a) of Commission Regulation No 2790/1999 of 22 December 1999 on the application of Article 81(3) of the Treaty to categories of vertical agreements and concerted practices (OJ 1999 L 336, p. 21) that in the context of an agreement such as that at issue in the present case it is necessary to ascertain what products the buyer regards as interchangeable or substitutable by reason of their characteristics, their prices and their intended use.

159 It does not appear to be manifestly incorrect to consider that the buyer, that is to say, the Spanish wholesaler who might engage in parallel trade, is less interested, for that purpose, in the therapeutic indication and the pharmacological products of each of the medicines which he buys from GW than in the fact that all of those medicines are reimbursed by the Spanish sickness insurance scheme and that their price is therefore set by the Spanish authorities. Likewise, it does not appear to be manifestly incorrect to consider that the buyer is less interested in the price of each of the medicines as such than in the fact that there is a sufficient price differential to render parallel trade lucrative, for all of those medicines, between Spain and the Member State of destination. In those circumstances, it is not manifestly incorrect to accept that all the medicines reimbursed by the Spanish sickness insurance scheme which are capable of being sold at a profit owing to the price differential between Spain and the Member State of destination constitute a product market.

160 As regards the second aspect, it may be noted that, as is apparent from the observations of GSK on which the Commission relied at recitals 112 and 113 to the Decision, Clause 4 of the General Sales Conditions was conceived in order to address, in a global manner, the question of parallel trade in medicines sold by GW between Spain and the Member States to which parallel trade might be lucrative for the Spanish wholesalers.

161 Accordingly, the existence of the Spanish rules appears, from the point of view of both buyers and GSK, to be more a factor which confers unity on the relevant product market than an element which ought to serve to distinguish a market for

the distribution of medicines intended for domestic consumption, which would be regulated, from a market for the distribution of medicines intended for export, which would be free. In reality, the distinction suggested by GSK relates rather to the evidently territorial nature of the Spanish rules and the national dimension of the relevant geographic market, as, moreover, GSK acknowledged at the hearing.

162 It is necessary, in the second place, to examine the actual or potential effects of the agreement on competition. That examination entails a comparison of the competitive situation resulting from the agreement and the situation that would exist in its absence (*Société technique minière*, paragraph 55 above, p. 250, and *John Deere* v *Commission*, paragraph 112 above, paragraph 76).

163 In the present case, it must be observed at the outset that it follows from recitals 26 and 28 to the Decision that the application of the General Sales Conditions, which became applicable on 9 March 1998, was suspended on 16 October 1998 and remained suspended until the date of adoption of the Decision, as the parties recalled at the hearing. Consequently, the examination carried out by the Commission must be interpreted as being mainly devoted to their potential effects on competition, as the parties agreed at the hearing.

164 In that regard, GSK accepts that Clause 4 of the General Sales Conditions has, or may have, the effect of limiting parallel trade, but denies that it has or may have the effect of restricting competition. The main arguments which it puts forward concern, in substance, four aspects of the Commission's reasoning in the Decision. First, the fact that Clause 4 of the General Sales Conditions limits parallel trade and impinges on the freedom of action of the Spanish wholesalers does not in itself mean that it has the effect of restricting competition. Second, in the light of the legal and economic context in which Clause 4 operates, the fact that it establishes a system of differentiated prices does not in itself mean that it has the effect of restricting competition. Third, the Commission simply concluded that Clause 4 limited parallel trade, impinged on the freedom of action of the Spanish wholesalers and imposed

differentiated prices, so that it did not demonstrate to the requisite legal standard that that provision had the effect of restricting competition. Fourth, the Commission did not in any event take account of the fact that Clause 4 of the General Sales Conditions was confined to neutralising a distortion of competition attributable to the Kingdom of Spain.

165 The Court must determine whether those various criticisms reveal that the Decision was incorrect to find that Clause 4 of the General Sales Conditions had the effect of restricting competition.

166 First, it is common ground that, as stated at recital 126 to the Decision, Clause 4 has the effect of limiting parallel trade in medicines sold by GW in Spain. In numerous cases, it substitutes for a Clause 4A price significantly lower than the prices in force in certain Member States other than Spain a Clause 4B price for which the differential is less or non-existent. To that extent, it cancels or reduces the profits which the Spanish wholesalers might make by exporting the medicines.

167 However, it must be borne in mind that, considered in itself, the fact that an agreement has or may have the effect of limiting parallel trade admittedly affects trade between Member States but does not necessarily restrict competition. It is the repercussions which that restriction of parallel trade has or may have on one or other of the parameters of competition, such as the quantity in which a product is supplied or the price at which it is sold, that provides evidence of such a restriction (see, to that effect, *Tepea* v *Commission*, paragraph 118 above, paragraphs 41, 43 and 56).

168 Thus, the fact that in the absence of Clause 4 of the General Sales Conditions the Spanish wholesalers would be able to buy medicines at the wholesale price set by the Spanish authorities, independently of the Member State in which those medicines

are intended to be resold and of the national sickness insurance scheme by which they are intended to be reimbursed, and then to resell them in any Member State in which the price is sufficiently higher than the Spanish price to allow them to make a profit, taking into account the transaction costs, does not, independently of any examination of the extent to which parallel trade contributes to price competition, regard being had to the role played by the Member States in that regard, permit the conclusion that there is an effect restrictive of competition.

169 In consequence, GSK is correct to maintain that, after referring to the effect which Clause 4 of the General Sales Conditions has on parallel trade, the Commission was still required to demonstrate the effect on competition.

170 Second, it is not disputed that, as stated at recitals 137 to 139 to the Decision, Clause 4 of the General Sales Conditions has the effect of restricting the freedom of action of the Spanish wholesalers, in particular their freedom to choose their customers.

171 However, not every agreement which restricts the freedom of action of the participating undertakings, or of one of them, necessarily falls within the prohibition in Article 81(1) EC (Case C-309/99 *Wouters and Others* [2002] ECR I-1577, paragraph 97, and Case T-112/99 *M6 and Others* v *Commission* [2001] ECR II-2459, paragraph 76). In particular, any contract concluded between economic agents operating at different stages of the production and distribution chain has the consequence of binding them and, consequently, of restricting them, according to the stipulated terms, in their freedom of action. In the present case, whatever the price at which the Spanish wholesalers agree to buy a medicine from GW on the Spanish market (the Clause 4A price or the Clause 4B price), they are limited in their freedom of action since, from an economic point of view, they are not capable in the long term of reselling them at a lower price on the other national markets of the Community. However, as the objective of the Community competition rules is to prevent undertakings, by restricting competition between themselves or with third parties, from reducing the welfare of the final consumer of the products in question

(paragraph 118 above), it is still necessary to demonstrate that the limitation in question restricts competition, to the detriment of the final consumer. Incidentally, the Commission itself explained, at the hearing, that the limitation of the freedom of action of the Spanish wholesalers was difficult to envisage in isolation and constituted only the starting-point of its examination.

172 Consequently, GSK is correct to maintain that, after relying on the effect of Clause 4 of the General Sales Conditions on the freedom of action of the Spanish wholesalers, the Commission was still required to demonstrate how that provision had the effect of restricting competition to the detriment of the final consumer.

173 Third, it is not disputed that Clause 4 of the General Sales Conditions establishes a system of differentiated prices according to whether each of the 82 medicines concerned is intended to be resold and reimbursed in Spain or in any other Member State.

174 Although at first reading recital 139 to the Decision may appear ambiguous on that point, it is apparent on examination that the Commission took the view in that recital that such a system had a discriminatory effect on account of the destination of the products in question (the Spanish market, on the one hand, and the other national markets, on the other hand). A reading of the Commission's submissions confirms that interpretation. First, the system of differentiated prices established by GW is compared with a prohibitive discrimination on price according to the country of destination, the Commission taking the view that it results in applying dissimilar conditions to equivalent transactions within the meaning of Article 81(1)(d) EC. Second, the Commission refers to the case-law on Article 82(c) EC, the wording of which is identical to that of Article 81(1)(d) EC.

175 Article 81(1)(d) EC prohibits agreements which apply dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage.

176 In the present case, it is not open to doubt that the Spanish wholesalers are GW's trading partners and that GW imposes unequal conditions on them according to whether they resell those medicines in Spain or in other Member States of the Community. On the other hand, it is not demonstrated that those sales constitute equivalent transactions and that the constituent elements of Article 81(1)(d) EC are therefore satisfied.

177 It follows from the case-law to which the Commission refers that Article 82(c) EC does not preclude an undertaking in a dominant position from setting different prices in the various Member States, in particular where the price differences are justified by variations in the conditions of marketing and the intensity of competition, but prohibits it from applying artificial price differences in the various Member States such as to place its customers at a disadvantage and to distort competition in the context of an artificial partitioning of national markets (*Tetra Pak* v *Commission*, paragraph 152 above, paragraph 160 and the case-law cited). More generally, it follows from that case-law that, while the fact that an undertaking in a dominant position applies different prices may, in the absence of objective explanation, constitute an indicium of discrimination where those prices are applied on a particular geographic market, characterised by sufficiently homogeneous conditions of competition, that is not the case where they are applied on separate geographic markets, characterised by insufficiently homogeneous conditions of competition, regard being had in particular to the relevant regulatory framework (see, to that effect, *United Brands* v *Commission*, paragraph 152 above, paragraphs 44 to 56 and 207, 208, 225, 228 and 233, and *Tetra Pak* v *Commission*, paragraph 152 above, paragraphs 92 to 96 and 161, 164, 165, 167 and 170).

178 Those considerations may be transposed to the present case, where a producer and its wholesalers agree to apply different prices according to the Member State in which the products in question are intended to be resold and reimbursed. It is common ground that each of those Member States constitutes a distinct market, in so far as the relevant geographic market is national owing, in particular, to the differences in the national regulations on the prices and the reimbursement of the medicines in question. The Commission itself therefore found in the Decision that

where it supplied one or other of those national markets, a Spanish wholesaler operated, having regard in particular to the relevant regulatory framework, in conditions of competition which, as regards price, the parameter specifically concerned by Clause 4 of the General Sales Conditions, were heterogeneous.

179 Consequently, GSK is correct to maintain that the finding of a difference in price is not sufficient to support the conclusion that there is discrimination. It is possible that GSK applies different prices because different markets exist and not so that different markets will exist.

180 Such an explanation is suggested by the Commission itself, moreover, which indicated in Communication COM(1998) 588 final, paragraph 135 above, that the pharmaceutical companies apply price discrimination to reflect the differences in the ability to pay (p. 4) and adds, generally, that it would be extremely difficult to establish an appropriate level of price across the Community, as the choice of a low level would benefit immediate health care expenditure objectives but would provide a steady diminution of Europe's contribution to global pharmaceutical R&D investment, and the choice of a high level would have the effect of reducing access to care by consumers and payers in countries where economic and social conditions mean that such prices cannot be afforded (p. 11).

181 Fourth, GSK maintains, in substance, that the Commission has not shown in any other way that Clause 4 of the General Sales Conditions had the effect of restricting competition.

182 That is not the case, however. On the contrary, the Commission concluded, following a relatively brief examination, as it acknowledged in its answer to the written questions put by the Court, which was none the less sufficiently complete in

the light of the facts of the case (see paragraph 119 above) and of GSK's arguments, that Clause 4 also had the effect of reducing the welfare of final consumers by preventing them from taking advantage, in the form of a reduction in prices and costs, of the participation of the Spanish wholesalers in intrabrand competition on the markets of destination of the parallel trade originating in Spain.

183 Thus, the Commission found, at recitals 72 to 75 to the Decision, that Clause 4 of the General Sales Conditions required the Spanish wholesalers who bought the medicines sold in Spain by GW to pay a higher price (the Clause 4B price) than the price set by the Spanish authorities, which they would have paid in the absence of the General Sales Conditions (the Clause 4A price). Clause 4 thus has the effect of reducing or cancelling, in numerous cases, the differential hitherto existing between the prices applicable in Spain and those applicable in other Member States of the Community. The number of cases concerned is significant, whether the costs incurred by the Spanish wholesalers when they engage in parallel trade (transport, repackaging, etc.) are disregarded or whether they are taken into consideration. GSK does not dispute those findings of fact.

184 Next, the Commission found, at recitals 48 and 51 to the Decision, that in some Member States an admittedly small part of the price of medicines covered by the General Sales Conditions was borne by the patient, who in that sense constituted a final consumer, within the economic sense of that term, of the products in question. The Commission also found, at recitals 49 and 51 to the Decision, that the remainder of the price of those medicines was reimbursed by the national sickness insurance scheme, which also constituted a final consumer of the products in question, in that it spread the economic risks borne for their health by those covered by the insurance schemes. The Court of Justice has already referred to the special nature, in that respect, of the trade in pharmaceutical products, namely the fact that social security institutions are substituted for consumers as regards responsibility for the payment of medical expenses (Case 238/82 *Duphar and Others* [1984] ECR 523, paragraph 20). GSK does not dispute those findings of fact, the importance of which the Commission recalled to mind in the context of the reasoning which it had applied in the Decision.

185 Even accepting that competition between the Spanish wholesalers who engage in parallel trade, or between those wholesalers and the distributors established on the market of the Member State of destination of the parallel trade, is limited to the point of allowing them to apply resale prices which are lower than the prices applied by those distributors only to the extent strictly necessary to attract retailers, as convincingly explained in some of the documents produced by GSK, the Commission was entitled to infer, as it did at recital 140 to the Decision, from the findings of fact set out in the preceding paragraphs that Clause 4 of the General Sales Conditions impeded that competition and, in substance, the pressure which in its absence would have existed on the unit price of the medicines in question, to the detriment of the final consumer, taken to mean both the patient and the national sickness insurance scheme acting on behalf of claimants.

186 It is true that, as the Commission observed at recital 133 to the Decision, and then in its answers to the written questions put by the Court and at the hearing, that pressure, considered at the individual level of one of the national markets affected by Clause 4 of the General Sales Conditions, such as the United Kingdom market, may be marginal. However, the Commission also observed, at recital 140 to the Decision, that the fact of impeding this pressure, by means of an agreement concluded with a significant number of Spanish wholesalers and affecting a significant number of products and national markets in the Community, contributed or could contribute, by a network effect, to reinforcing the pre-existing price rigidity on the market. Such reinforcement infringes Article 81(1) EC (see, to that effect, *Metro I*, paragraph 109 above, paragraph 22, and Case 209/78 *Van Landewyck and Others* v *Commission* [1980] ECR 3125, paragraph 139).

187 GSK has not adduced evidence of an error on that point. On the contrary, it acknowledged at the hearing that Clause 4 of the General Sales Conditions, although mainly intended to prevent the transfer of surplus to the wholesalers, might have the effect of reducing the admittedly restricted benefit which their participation in competition provides for the final consumer on the markets of destination of the parallel trade.

188 Last, the Commission found, at recitals 33, 34, 52 and 134 to the Decision, that some national sickness insurance schemes took advantage, to various degrees and according to different procedures, of parallel trade in order to reduce the cost of the medicines which they reimburse. Although GSK denies that the national measures to which the Commission refers have as their object to encourage parallel trade, it does not deny that they may have such an effect, as the Commission observed at the hearing, without being contradicted. Some of the documents which GSK produced, on the contrary, emphasise convincingly that that may be the case. GSK also acknowledges, most recently in its answers to the written questions and at the hearing, that some Member States have adopted measures in order to recover a proportion of the savings which pharmacists have made by means of parallel trade.

189 By focusing on the example of the United Kingdom, which in GSK's submission was the main target market for parallel trade in medicines sold in Spain by GW, the Commission was able to infer, at recital 134 to the Decision, that Clause 4 of the General Sales Conditions had the effect of depriving the national sickness insurance schemes of the advantage which they would have derived, in the form of a reduction in costs and even independently of any reduction in the retail price, from the participation of the Spanish wholesalers in intrabrand competition. Although it emphasised that that effect is minor, GSK also acknowledged its existence at the hearing. It also acknowledged that such an effect might be produced in Member States other than the United Kingdom.

190 Accordingly, it must be concluded that the Commission was entitled to find, in the light of elements whose relevance has not been validly called in question by GSK, that Clause 4 of the General Sales Conditions had the effect of reducing the welfare of final consumers by preventing them from taking advantage, in the form of a reduction in prices and costs, of the participation of the Spanish wholesalers in intrabrand competition on the national markets of destination of the parallel trade originating in Spain.

191 None of GSK's arguments appears to be capable of upsetting that conclusion.

192 In particular, its fundamental argument that Clause 4 of the General Sales Conditions is justified because it would neutralise a distortion of competition attributable to the Kingdom of Spain is unfounded. The fact that 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 (*Suiker Unie and Others* v *Commission*, paragraph 56 above, paragraph 620, and *CIF*, paragraph 66 above, paragraph 57).

4. Conclusion

193 It follows from the foregoing that GSK has not succeeded in calling in question the Commission's conclusion that the General Sales Conditions constituted an agreement within the meaning of Article 81(1) EC.

194 It also follows that, although the Commission's principal conclusion that Clause 4 of the General Sales Conditions has as its object the restriction of competition is incorrect, GSK has not succeeded in calling in question its subsidiary conclusion that that provision had the effect of depriving final consumers of the advantage which they would have derived, in terms of price and costs, from the participation of the Spanish wholesalers in intrabrand competition on the national markets of destination of the parallel trade originating in Spain.

195 Accordingly, the plea alleging infringement of Article 81(1) EC must be rejected.

C — *The plea alleging misuse of powers, failure to observe the principle of subsidiarity and infringement of Article 43 EC*

1. Arguments of the parties

196 GSK claims, in substance, that by prohibiting it from applying differentiated prices the decision ultimately requires it to apply the prices set by the Spanish authorities for the purposes of the wholesale of medicines intended to be resold in Spain and reimbursed by the Spanish sickness insurance scheme in the context of the wholesale of medicines intended to be resold in other Member States or reimbursed by other national sickness insurance schemes, which have their own price control systems. In doing so, it fails to observe the principle of subsidiarity. Furthermore, it infringes the right of establishment provided for in Article 43 EC. Last, in so far as the Commission's intention is thus to favour the convergence of the price of medicines in the Community, it is guilty of a misuse of powers.

197 The Commission, supported by the interveners, disputes the merits of this plea.

2. Findings of the Court

198 It should be observed, in the first place, that a decision is vitiated by misuse of powers only if it appears, on the basis of objective, relevant and consistent indicia, to have been taken with the exclusive or main purpose of achieving an end other than that stated (Case 8/57 *Aciéries belges* v *High Authority* [1958] ECR 245, at 255, and Joined Cases C-186/02 P and C-188/02 P *Ramondín and Others* v *Commission* [2004] ECR I-10653, paragraph 44).

199 In the present case, it is apparent from its written submissions that GSK is speculating as to the aim which it attributes to the Commission but does not rely on indicia on which it might be established to the requisite legal standard that the Decision was adopted with the exclusive or decisive aim of favouring the convergence of prices of medicines in the Community.

200 In the second place, the second paragraph of Article 5 EC provides that, in areas which do not fall within its exclusive competence, the Community is to take action, in accordance with the principle of subsidiarity, only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States and can therefore, by reason of the scale or effects of the proposed action, be better achieved by the Community.

201 In the context of Article 81(1) EC, the principle of subsidiarity is given concrete form by the limitation of the prohibition contained therein to agreements between undertakings, decisions by associations of undertakings and concerted practices which may affect trade between Member States. Thus, where a series of objective factors of law or fact makes it possible to foresee with a sufficient degree of probability that such conduct may have an influence, direct or indirect, actual or potential, on the pattern of trade between Member States, that conduct must be regarded as capable of affecting trade between Member States (*Consten and Grundig* v *Commission*, paragraph 110 above, p. 341, and Case C-359/01 P *British Sugar* v *Commission* [2004] ECR I-4933, paragraph 27), so that it is appropriate for the Community to take action, by reason of the scale and the effects of its action (see, to that effect, Case T-65/98 *Van den Bergh Foods* v *Commission* [2003] ECR II-4653, paragraphs 197 and 198).

202 Where that action takes the form of a Commission decision, the Commission is therefore acting in accordance with the principle of subsidiarity where it establishes to the requisite legal standard that trade between Member States is capable of being affected by the agreement between undertakings, the decision by an association of undertakings or the concerted practice the legality of which it is examining.

203 In the present case, the Commission found, in substance, at recitals 145 and 146 to the Decision, that Clause 4 of the General Sales Conditions was capable of affecting trade between Member States in so far as it established differentiated prices according to whether the wholesalers with whom GW had commercial relations in Spain intended that the medicines which they bought from GW would be resold in Spain or in other Member States of the Community, and GSK does not dispute that.

204 In the third and final place, Article 43 EC confers on the nationals of any Member State, to whom Article 48 EC assimilates companies or firms formed in accordance with the law of a Member State and having their registered office, central administration or principal place of business within the Community, the fundamental freedom (Case 246/80 *Broekmeulen* [1981] ECR 2311, paragraph 20, and Case C-19/92 *Kraus* [1993] ECR I-1663, paragraphs 28 and 29) to establish themselves in any other Member State on the same conditions as the nationals of that State and prohibits the maintenance or introduction of restrictions on that freedom.

205 Such restrictions consist in any national measures which, even though they are applicable without discrimination on grounds of nationality, are liable to place the nationals of other Member States in a less favourable legal or factual situation by comparison with that of the nationals of the Member State of establishment and thus to hinder or render less attractive the exercise of that fundamental freedom, subject to the exceptions provided for in the Treaty and those recognised by the Court of Justice (Case C-255/97 *Pfeiffer* [1999] ECR I-2835, paragraphs 18 and 19, and Case C-140/03 *Commission* v *Greece* [2005] ECR I-3177, paragraph 27).

206 In the present case, GSK seeks annulment of a decision applying Article 81(1) EC which was adopted by the Commission in the exercise of the powers conferred on it by the Community competition rules. By its nature, such a decision neither

constitutes nor contains any national measure capable of constituting a restriction prohibited by Article 43 EC. It is therefore pointless to claim that that decision constitutes an infringement of that provision (see, by analogy, as concerns Article 49 EC, order of the Court of Justice in Case C-171/05 P *Piau* v *Commission*, not published in the ECR, paragraph 58).

207 Accordingly, the plea alleging misuse of powers, failure to observe the principle of subsidiarity and infringement of Article 43 EC must be rejected in its entirety, as must GSK's form of order in so far as it seeks annulment of Article 1 of the Decision.

II — *The pleas seeking annulment of Article 2 of the Decision*

A — *The plea alleging inadequate reasoning*

1. Arguments of the parties

208 GSK claims, in substance, that the Decision is vitiated by insufficient reasoning, in that the Commission did not carry out an adequate examination of the factual arguments and the evidence submitted to it during the administrative procedure concerning the respective advantages and disadvantages of parallel trade and of Clause 4 of the General Sales Conditions for competition in the medicine sector, as it ought to have done in the light of the judgment in *Bayer* v *Commission*, paragraph 47 above.

209 The Commission, supported by the interveners, disputes the validity of this plea.

2. Findings of the Court

210 The question of the adequacy of the examination carried out by the Commission in a decision applying the competition rules is not a matter for the review of the existence or the extent of the reasoning in that decision but for the review of the merits of its grounds (*Commission* v *Sytraval and Brink's France*, paragraph 54 above, paragraph 67, and Case T-158/99 *Thermenhotel Stoiser Franz and Others* v *Commission* [2004] ECR II-1, paragraph 97).

211 In the present case, GSK claims that the Decision is vitiated by insufficient reasoning in that the examination of the factual arguments and the evidence submitted in support of its request for an exemption is inadequate. It therefore disputes not so much the reasoning in the Decision as the merits of the grounds devoted to the appraisal of that request under Article 81(3) EC.

212 Accordingly, the present plea relates in reality to the plea alleging infringement of Article 81(3) EC, which is examined below.

213 In so far as GSK also intends to claim that the Decision is insufficiently reasoned as regards the rejection of its request for an exemption, that criticism does not appear to be well founded. At recitals 147 to 188 to the Decision, the Commission explains, in a sufficiently developed manner to enable GSK to understand its reasoning and the Court to review it, that that request must, in the Commission's view, be rejected on the ground that evidence that the conditions necessary for the grant of an exemption, and primarily an efficiency gain, are satisfied was not adduced to the requisite legal standard.

B — *The plea alleging infringement of Article 81(3) EC*

1. Content of the Decision

214 The Commission found, at recitals 147 to 189 to the Decision, that GSK had not proved that the conditions for the application of Article 81(3) EC were satisfied in the present case.

215 With reference to the first conditions for the application of that provision, the Commission considered, at recitals 151 and 154 to 176 to the Decision, that GSK had not demonstrated to the requisite legal standard that the General Sales Conditions would contribute to promoting technical progress or to improving the distribution of medicines.

216 With reference to the second condition for the application of Article 81(3) EC, the Commission considered, at recitals 177 to 186 to the Decision, that GSK had not demonstrated to the requisite legal standard that a fair share of the benefits resulting from the General Sales Conditions would be reserved for consumers.

217 The Commission further stated, at recitals 187 and 188 to the Decision, that it was also not established that the General Sales Conditions did not impose restrictions which were not indispensable and did not eliminate competition in respect of a substantial part of the medicines in question.

2. Arguments of the parties

218 GSK maintains that the Commission's conclusion that it was not demonstrated that the conditions for the grant of an exemption were satisfied is vitiated by errors which justify annulment of Article 2 of the Decision.

219 Generally, it submits, in substance, that the Commission did not seriously examine the factual arguments and the evidence supporting its request for an exemption. It then puts forward a number of arguments relating to each of the conditions for the application of Article 81(3) EC.

220 As regards, first of all, the first of those conditions, GSK claims that the Commission did not seriously examine its factual arguments and its evidence that parallel trade would lead to a loss in efficiency by reducing its capacity to innovate, whereas Clause 4 of the General Sales Conditions would bring about a gain in efficiency by enabling it to increase its capacity for innovation. It contends that the Commission was incorrect to conclude that it was not shown that parallel trade was not linked to innovation and, in any event, that it had an appreciable effect on innovation. The applicant contends that it has demonstrated the existence of a contribution to the promotion of technical progress.

221 GSK further maintains that the Commission was incorrect to conclude that it was not demonstrated that Clause 4 of the General Sales Conditions would contribute to improving the distribution of medicines by limiting parallel trade, which leads to delays in placing products on the market in certain Member States and to a less than optimum allocation of the medicines offered for sale by GSK.

222 As regards, next, the second condition for the application of Article 81(3) EC, GSK submits that the Commission was incorrect to conclude that it did not appear that a fair share of the benefits attached to Clause 4 of the General Sales Conditions would be reserved for consumers. It maintains that the Commission misidentified the consumers by including the wholesalers and by not taking fully into account the role played by the Member States in the sector concerned. Furthermore, the Commission manifestly erred in evaluating all the advantages which consumers could expect from its differentiated price system, by comparison with the situation in which they are as a result of parallel trade.

223 GSK further contends that it has clearly demonstrated that Clause 4 of the GSK was indispensable, within the meaning of the third condition for the application of Article 81(3) EC, to the attainment of the advantages which it expected for consumers.

224 Last, GSK submits that it has demonstrated that Clause 4 would not have the effect of eliminating a substantial part of competition, owing to the nature and intensity of competition, in accordance with the fourth condition for the application of Article 81(3) EC.

225 The Commission, supported by the interveners, disputes the merits of those arguments.

226 It claims, in the first place, that it carried out a serious and adequate examination of all the factual arguments and the evidence submitted by GSK in support of its request for an exemption.

227 It maintains, in the second place, that it was entitled to conclude that evidence of the existence of the conditions for the application of Article 81(3) EC had not been adduced by GSK.

228 In that regard, it contends, first, that GSK cannot merely claim that the agreement that it concluded with the intention or the effect of impeding parallel trade will allow it to maximise its commercial profits and to allocate a part of them to the financing of its R&D activities. It is incumbent on GSK, on the contrary, to establish, by adducing sufficient evidence to carry conviction, the existence of an objective, specific and direct causal link between the restriction of competition caused by the agreement and the efficiency gains apt to compensate for that restriction. In the present case, the Commission was entitled to find that such a causal link had not been demonstrated.

229 Second, the Commission contends that, even on the assumption that they were sufficiently specific to be capable of being taken into account, GSK's arguments that parallel trade disrupts the distribution of medicines and leads to delays in placing them on the market, difficulties which Clause 4 of the General Sales Conditions would redress, were not supported to the requisite legal standard at any time during the administrative procedure.

230 Third, the Commission is of the view, in substance, that the wholesalers must be counted among consumers and that they, like patients and the national sickness insurance schemes, may be considered to benefit from parallel trade. The Commission adds that, on the other hand, it has never been demonstrated to the requisite legal standard that consumers would also benefit from Clause 4 of the General Sales Conditions.

231 Fourth, the Commission submits that GSK's arguments do not reveal that, contrary to what the Commission found in the Decision, the indispensability of Clause 4 of the General Sales Conditions was demonstrated.

232 Fifth, the Commission likewise submits that GSK's arguments do not seriously call in question the finding that it was not demonstrated that Clause 4 of the General Sales Conditions would not ultimately eliminate competition in respect of a substantial part of the products in question.

3. Findings of the Court

(a) Preliminary considerations

233 Any agreement which restricts competition, whether by its effects or by its object, may in principle benefit from an exemption (*Consten and Grundig* v *Commission*, paragraph 110 above, pp. 342, 343 and 347, and Case T-17/93 *Matra Hachette* v *Commission* [1994] ECR II-595, paragraph 85), as the Commission, moreover, observed at recital 153 to the Decision and at the hearing.

234 The application of that provision is subject to certain conditions, satisfaction of which is both necessary and sufficient (*Remia and Others* v *Commission*, paragraph 57 above, paragraph 38, and *Matra Hachette* v *Commission*, paragraph 233 above, paragraph 104). First, the agreement concerned must contribute to improving the production or distribution of the goods in question, or to promoting technical or economic progress; second, consumers must be allowed a fair share of the resulting benefit; third, it must not impose on the participating undertakings any restrictions which are not indispensable; and, fourth, it must not afford them the possibility of eliminating competition in respect of a substantial part of the products in question.

235 Consequently, a person who relies on Article 81(3) EC must demonstrate that those conditions are satisfied, by means of convincing arguments and evidence (Joined Cases 43/82 and 63/82 *VBVB and VBBB* v *Commission* [1984] ECR 19, paragraph 52, and *Aalborg Portland and Others* v *Commission*, paragraph 55 above, paragraph 78).

236 The Commission, for its part, must adequately examine those arguments and that evidence (*Consten and Grundig* v *Commission*, paragraph 110 above, p. 347), that is to say, it must determine whether they demonstrate that the conditions for the application of Article 81(3) EC are satisfied. In certain cases, those arguments and that evidence may be of such a kind as to require the Commission to provide an explanation or justification, failing which it is permissible to conclude that the burden of proof borne by the person who relies on Article 81(3) EC has been discharged (*Aalborg Portland and Others* v *Commission*, paragraph 55 above, paragraph 79). As the Commission agrees in its written submissions, in such a case it must refute those arguments and that evidence.

237 In the present case, the Commission concentrated its examination on the first condition for the application of Article 81(3) EC, as, moreover, it stated in its written submissions and then at the hearing. It considered, at recitals 151 and 154 to 176 to the Decision, that the factual arguments and the evidence submitted by GSK during the administrative procedure did not demonstrate that that condition was satisfied.

238 The factual arguments and the evidence submitted by GSK for the purpose of establishing that consumers would be allowed a fair share of the benefit resulting from the General Sales Conditions and, consequently, that the second condition for the application of Article 81(3) EC was satisfied were rejected by way of consequence, as the Commission confirmed at the hearing. The Commission found, at recital 179 to the Decision, that as GSK had not demonstrated that the restriction of parallel trade actually achieved any of the benefits required under the first condition, the second condition could also not be fulfilled and therefore needed

no further examination. It was only subsequently, and solely in the interest of completeness, that the Commission responded, at recitals 180 to 186 to the Decision, to certain of the arguments put forward by GSK, with a view to establishing that the parallel trade would not give rise to a benefit of which a fair part would be allowed to consumers.

239 As regards the third and fourth conditions for the application of Article 81(3) EC, they were examined summarily, as the Commission indicated in its written submissions and then at the hearing, and were also essentially rejected by way of consequence. Thus, the third condition was rejected, at recital 187 to the Decision, on the ground that, as there was no evidence that the General Sales Conditions gave rise to advantages, it followed that there was no contribution whose indispensability could be analysed. The fourth condition was rejected, at recital 188 to the Decision, because GSK did not put forward any arguments concerning that condition which it had not already submitted and which had not already been rejected.

240 In those circumstances, it is for the Court to determine before all else whether the Commission was entitled to conclude that the factual arguments and the evidence supporting GSK's request for an exemption did not demonstrate that the first condition for the application of Article 81(3) EC was satisfied. Only if it is not the case must the Court also determine whether the Commission was entitled to conclude that it had also not been shown that the three other conditions for the application of that provision were satisfied.

241 In that regard, the Court dealing with an application for annulment of a decision applying Article 81(3) EC carries out, in so far as it is faced with complex economic assessments, a review confined, as regards the merits, to verifying whether the facts have been accurately stated, whether there has been any manifest error of appraisal and whether the legal consequences deduced from those facts were accurate (*Consten and Grundig* v *Commission*, paragraph 110 above, p. 347; *Metro I*, paragraph 109 above, paragraph 25; *Remia and Others* v *Commission*, paragraph 57 above, paragraph 34; and *Aalborg Portland and Others* v *Commission*, paragraph 55 above, paragraph 279).

242 It is for the Court to establish not only whether the evidence relied on is factually accurate, reliable and consistent, but also whether it contains all the information which must be taken into account for the purpose of assessing a complex situation and whether it is capable of substantiating the conclusions drawn from it (Case C-12/03 P *Commission* v *Tetra Laval* [2005] ECR I-987, paragraph 39, and Case T-210/01 *General Electric* v *Commission* [2005] ECR II-5575, paragraphs 62 and 63).

243 On the other hand, it is not for the Court to substitute its own economic assessment for that of the institution which adopted the decision the legality of which it is requested to review.

244 The Commission has, in particular, a margin of discretion which is subject to a restricted judicial review, in the operation consisting, once it has been ascertained that one of the criteria on which Article 81(3) EC makes provision for an exemption was satisfied, in weighing up the advantages expected from the implementation of the agreement and the disadvantages which the agreement entails for the final consumer owing to its impact on competition, which takes the form of a balancing exercise carried out in the light of the general interest appraised at Community level.

245 Furthermore, review of the Commission's decision is carried out solely by reference to the elements of fact and of law existing on the date of adoption of the contested decision, without prejudice to the possibility afforded to the parties, in the exercise of their rights of defence, to supplement them by evidence established after that date but for the specific purpose of contesting or defending that decision (see paragraph 58 above).

246 In the present case, it follows that the evidence which did not exist at the date of adoption of the Decision and which was not established for the specific purpose of contesting or defending it in so far as the Decision concludes that GSK's request for

an exemption must be rejected, in particular the factual information relating to the period 2001/2005 and the studies entitled 'Benefits to Payers and Patients from Parallel Trade' carried out by the University of York in May 2003, 'The Economic Impact of Pharmaceutical Parallel Trade in European Member States: A Stakeholder Analysis' carried out by the London School of Economics and Political Sciences in January 2004 and 'Parallel Imports and the Pricing of Pharmaceutical Products: Evidence from the European Union' carried out by M. Ganslandt and K.E. Maskus in February 2004, must, as the Commission properly states in its answers to the written questions put by the Court and at the hearing, be disregarded.

(b) Evidence of a gain in efficiency

247 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 offset the resulting disadvantages for competition (see, for a contribution towards improvement in production or distribution, *Consten and Grundig* v *Commission*, paragraph 110 above, pp. 348 and 349; Case T-7/93 *Langnese-Iglo* v *Commission* [1995] ECR II-1533, paragraph 180; and *Van den Bergh Foods* v *Commission*, paragraph 201 above, paragraph 139; see also, for a contribution towards the promotion of progress, *Matra Hachette* v *Commission*, paragraph 233 above, paragraphs 108 to 111).

248 It is therefore for the Commission, in the first place, to examine whether the factual arguments and the evidence submitted to it show, in a convincing manner, that the agreement in question must enable appreciable objective advantages to be obtained (see, to that effect, *Metro I*, paragraph 109 above, paragraph 43; *Metro II*, paragraph 58 above, paragraph 55; *M6 and Others* v *Commission*, paragraph 171 above,

paragraph 143; and Case T-231/99 *Joynson* v *Commission* [2002] ECR II-2085, paragraphs 48 and 49), it being understood that these advantages may arise not only on the relevant market but also on other markets (Case T-86/95 *Compagnie générale maritime and Others* v *Commission* [2002] ECR II-1011, paragraph 343).

249 That approach may entail a prospective analysis, in which case it is appropriate to ascertain 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 (see, to that effect, *Compagnie générale maritime and Others* v *Commission*, paragraph 248 above, paragraph 365, and *Van den Bergh Foods* v *Commission*, paragraph 201 above, paragraph 143; see also, by analogy, *Tetra Laval* v *Commission*, paragraph 242 above, paragraphs 42 and 43, and *General Electric* v *Commission*, paragraph 242 above, paragraph 64).

250 In the affirmative, it is for the Commission, in the second place, to evaluate whether those appreciable objective advantages are of such a kind as to offset the disadvantages identified for competition in the context of the examination carried out under Article 81(1) EC (see, to that effect, *Van Landewyck and Others* v *Commission*, paragraph 186 above, paragraphs 183 to 185).

251 In the present case, GSK claimed that Clause 4 of the General Sales Conditions would make it possible to secure advantages both upstream of the relevant market, by encouraging innovation, and on the market itself, by optimising the distribution of medicines. As those markets correspond to different stages of the value chain, the final consumer likely to benefit from those advantages is the same.

252 The Court must therefore determine, first of all, 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 General Sales Conditions would make it possible to obtain an appreciable advantage of such a kind as to offset the disadvantage which it entailed for competition, by encouraging innovation.

The existence of an appreciable objective advantage

253 Having regard to the nature of GSK's criticisms, it is appropriate, in the first place, to present the factual arguments and the evidence in support of its request for an exemption on this point and then, in the second place, to review the way in which the Commission examined them.

254 In the first place, recitals 90, 92 to 99, 151 and 154 to the Decision, and also recitals 64 to 68 to the Decision, to which they refer, briefly set out the arguments presented by GSK with a view to convincing the Commission that Clause 4 of the General Sales Conditions would enable innovation to be encouraged.

255 As may be seen from the Decision, those arguments centre on two axes, which are closely linked yet distinct. First, as indicated in the first sentence of recital 154 to the Decision, parallel trade in medicines marketed by GW in Spain leads to a loss in efficiency for interbrand competition, in so far as it reduces GSK's capacity for innovation. Second, as stated in the second and third sentences of that recital, Clause 4 of the General Sales Conditions will lead to a gain in efficiency for interbrand competition in so far as it will enable GSK's capacity for innovation to be increased.

256 As may also be seen from the Decision, those two axes of reasoning are developed in GW's notification, in GSK's supplementary notification and, above all, in a number of items of economic or econometric evidence submitted by GSK during the administrative procedure, in particular in response to the Commission's statement of objections. That evidence was placed on the file, principally in annexes to GSK's written submissions, the content of which it supports and supplements, and for the remainder in answers to the measures of organisation of procedure. They consist of the following documents:

— the study entitled 'Glaxo Wellcome's Spanish Pricing System: The Need for a New Approach to Parallel Imports', by London Economics;

— the study entitled 'Pharmaceutical Pricing in the EU — A note in response to the European Commission's Statement of objections concerning GlaxoWellcome's Spanish Pricing Agreements', by Frontier Economics;

— the study entitled 'The Adverse Effects of Parallel Imports on Consumer Welfare', by Professor P. Rey;

— the study entitled 'The Effects of Parallel Imports on Social Welfare I: Critique', by Frontier Economics;

— the study entitled 'The Effects of Parallel Imports on Social Welfare II: Critique', by Professor P. Rey;

— the presentation entitled 'Glaxo Wellcome's R&D budgeting process', by A. Baxter.

257 It is apparent upon reading the Decision as a whole and the other documents cited in the preceding paragraph that although GSK's arguments are divided between different documents, although their presentation may vary and although their content may be developed to a greater or lesser extent, particularly in the light of the aspect of the statement of objections against which the document containing them is directed, they are essentially as follows.

258 First, according to the documents produced by GSK, parallel trade in medicines marketed in Spain by GW entails a loss in efficiency. In effect:

— the sector for patented medicines reimbursed by a national sickness insurance scheme is characterised by the fact that innovation constitutes the determining parameter of interbrand competition;

— innovation in ensured by a level of R&D expenditure which is both substantial and higher than that which characterises most other industries; in GSK's case, that expenditure represents approximately 14% of its turnover, or approximately GBP 1.3 billion;

— as investment in R&D is costly, high-risk and long-term, it is mainly financed from the undertaking's own funds rather than by borrowing; in GSK's case it is financed exclusively from its own funds;

— R&D financing is dependent on current returns and also on anticipated returns; in GSK's case, the fact that its capacity for financing increased by 230 times in the 1980s and 1990s was made possible by the existence of very successful medicines, in particular Zantac, which accounted for 40% of its world-wide revenues until 1994;

— parallel trade has the effect of reducing the returns of the pharmaceutical company concerned (schematically, for each unit sold at a price of 100 in the country of origin there is a corresponding unsold unit at a price of 100 + n in the country of destination) and, thus, of impeding the possibility of applying, for all sales made in each national market, an optimum price, that is to say, a price set by reference to the preferences peculiar to each Member States;

— that impact is concentrated on certain products and on certain geographic markets; in GSK's case, the losses mainly affect certain medicines consumed in the United Kingdom;

— that impact is significant, owing to the significant differential existing between the prices in force in the various Member States of the Community; in particular, the differential between the Spanish price and the United Kingdom price was, in 1998, for the eight medicines principally concerned (paragraph 11 above), between a minimum of 21% and a maximum of 132%;

— in that regard, GSK provides estimates, containing confidential figures, of the loss of revenue caused by parallel trade from all Member States to the United Kingdom and concerning all of its medicines, and also relating to the loss of revenue caused by parallel trade from Spain to the United Kingdom and relating to the eight medicines principally concerned, for 1996, 1997 and 1998;

— parallel trade also has the effect of reducing the amount which GSK is authorised to deduct, by way of investment in R&D, from the amount of its profits taken into account for the purpose of determining whether it exceeds the maximum rate of return on investment set by National Health Service; in that regard, GSK provides estimates, containing confidential figures, of the amount of the reduction caused by parallel trade from all origins and parallel trade from Spain, in 1998;

— the fact that the pharmaceutical company continues to make what are apparently significant profits does not deprive those arguments of relevance, in so far as it is necessary to take account of the method of accounting for investments in R&D, the way in which they are spread over time, their average cost and the degree of risk which they entail;

— last, parallel trade has the effect of reducing the capacities for financing R&D; in that regard, GSK provides estimates, containing confidential figures, relating to the percentage of its pre-tax profits which it reinvests in R&D and to the reduction in its R&D budget to which the loss in revenue caused by parallel trade from Spain to the United Kingdom and relating to the eight medicines principally concerned correspond, for the years 1996 to 1998;

— the fact that that reduction is quantitatively limited does not deprive that argument of relevance, in so far as it concerns the impact of parallel trade from Spain to the United Kingdom and relating to the eight medicines principally concerned between 1996 and 1998 and in so far as a quantitatively limited reduction may in any event have significant qualitative effects, in particular by leading to less profitable or more risky projects being abandoned; GSK provides a list of nine projects abandoned for that reason;

— on the other hand, parallel trade has few positive effects, as parallel traders do not compete on price to any significant extent and keep for themselves a substantial part of the differential between the price in force in the Member State of origin and that applied in the Member State of destination, so that the downward pressure on prices is reduced and the final consumer ultimately derives only a limited benefit.

259 Second, according to the documents produced by GSK, Clause 4 of the General Sales Conditions will lead to a gain in efficiency. In effect:

— the cost of R&D is global and joint in that it corresponds to an activity carried out on a world-wide scale and that, for a significant proportion, it is not attributable to a specific production site or a specific product;

— the pharmaceutical companies do not control their prices in most Member States; they agree to serve a national market on condition that the price set by the public authorities allows them to cover their marginal costs, but they must still succeed, where they can, in covering their entire global and joint R&D costs;

— the differentiated pricing system provided for in Clause 4 of the General Sales Conditions will make it possible to cover the cost of R&D by ensuring that the prices are set, on each national market, at the level corresponding to the preferences of the final consumer, that is to say, ultimately of the Member State concerned; in particular, it will make it possible to prevent the price fixed by the Kingdom of Spain from being exported to the United Kingdom;

— the strong competitive pressure by innovation which prevails in the sector ensures that GSK will act as a rational economic operator by transforming, in so far as necessary, those additional profits into investment in R&D.

260 In the second place, the Commission found, at recitals 151, 154, 155 and 169 to the Decision, that it was not proved that parallel trade had a negative impact on GSK's R&D activities and, in any event, that it was not proved that parallel trade had an appreciable negative effect on those activities.

261 Thus, the Commission essentially examined, at recitals 157 to 168 to the Decision, whether it was demonstrated that parallel trade gave rise to a loss in efficiency, a question which it answered in the negative. It therefore did not consider it necessary to examine in detail whether it was demonstrated that Clause 4 of the General Sales Conditions entailed a gain in efficiency, as that question was addressed only on one specific occasion, at recital 156 to the Decision.

262 Having regard to the relevance of the factual arguments and the evidence submitted by GSK, 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 General Sales Conditions cannot be accepted as sufficient to support the conclusions which the Commission reached on those points.

— The relevance of the factual arguments and the evidence submitted by GSK

263 The factual arguments and the supporting evidence submitted by GSK appear to be relevant, reliable and credible, having regard to their content (*Cimenteries CBR and*

*Others* v *Commission*, paragraph 83 above, paragraph 1838), which is itself corroborated on a number of significant aspects by documents originating with the Commission.

264 Thus, Communication COM(1998) 588 final, paragraph 135 above, which is essentially devoted to enhancing the single market in the pharmaceutical sector, which is not at issue here, also records the relationship existing, in the Commission's opinion, between innovation, parallel trade and competition in the sector. A reading of that communication reveals that, apart from the statement cited at paragraph 115 above concerning the ambiguous impact of parallel trade on the welfare of final consumers, the Commission makes the following assertions:

— the pharmaceutical industry is based on research (pp. 3 and 11) and it is clear that in the patented medicines sector there is very fierce competition in terms of innovation (p. 16), which leads to a continuous flow of new products on the market (p. 11); on the other hand, there is relatively little dynamic competition on prices after the products have been launched (p. 16);

— the pharmaceutical industry must pay for investments in R&D (p. 14) and for that purpose it needs to achieve a sufficient level of profitability to be able to devote the necessary resources to R&D to develop innovative products (pp. 17 and 23);

— although the European pharmaceutical industry is a powerful industrial sector (the amount of European investments in R&D tripled in 1997 by reference to the 10 previous years), it shows a fall in apparent competitiveness, which is

confirmed although that situation is beginning to change; one of the reasons for that situation is that its global profitability and its financial profitability ratio appear to be higher in the United States than in the European Union (pp. 4 and 5);

— in order to finance its R&D activities, the pharmaceutical industry seeks to make profits at world-wide level (p. 3);

— there are significant differences between the Member States, both in general macroeconomic conditions (especially per-capita income and wealth) and in health systems; there seems to be a well-established positive link between health care expenditure and incomes, although that relationship is not perfect (pp. 3 and 4);

— there are important differences between Member States from the point of view of prices, which can be explained by a number of factors; one of the factors responsible for those differences appears to be the extent to which Member States rely on price control, although there are also conjunctural factors such as inflation and currency fluctuations (p. 4);

— in that regard, the change to the euro should help to provide a more stable environment for Member States participating in the economic and monetary union (EMU). However, it will also make price differentials in the existing European market much more visible, which could stimulate wholesalers and pharmacists to engage in cross-border transactions (pp. 6 and 7);

— it would be extremely difficult to establish a price level which would be appropriate for all the Community. A low level 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 (p. 11);

— the pharmaceutical companies charge different prices to take account of the differences in the ability to pay (p. 4).

265 Admittedly, those extracts concerning the role of innovation and the impact which parallel trade and price differentials, respectively, have on innovation must not be taken to mean that GSK's factual arguments are necessarily well founded, or to provide a complete and definitive picture of the Commission's position on that complex question. The fact remains, however, that they corroborate a part of those arguments and of the economic analyses in the supporting evidence, thus attesting to their reliability and their credibility.

266 In its answers to the written questions put by the Court, the Commission stated that Communication (1998) 588 final, paragraph 135 above, also indicated that, in spite of important differences in prices between Member States, it was necessary to adopt an approach consistent with the principles of the single market, which made it impossible to justify measures the effect of which would be to maintain or increase the partitioning of the common market along national lines (p. 18). The Commission further explained that the decision was consistent with that approach. However, that argument cannot be accepted. It presumes that an agreement

providing that patented medicines reimbursed by the national sickness insurance schemes will be sold at different prices on different geographic markets, according to the preferences of the final consumer who bears the cost, cannot be granted an exemption in any circumstances. Article 81 EC makes no such provision.

267 As regards, more generally, economic theory, the Commission submitted, as an annex to its defence, the 'Executive Summary' of a study dated 8 February 1999 by NERA for the Commission's Directorate-General 'Internal Market and Financial Services', entitled 'The Economic Consequences of the Choice of Regime of Exhaustion in the Area of Trademarks'. That extract, and in particular the considerations on p. 5, corroborate certain of the analyses put forward in the evidence submitted by GSK concerning the interest that a pharmaceutical company might have in applying different prices according to the market on which the medicines are sold and the particular preferences of final consumers.

268 In those circumstances, the Commission, which itself analysed the system of differentiated prices established by Clause 4 of the General Sales Conditions as discriminatory owing to the destination of the medicines concerned (paragraph 174 above), in the context of the examination which it carried out under Article 81(1) EC, cannot claim, as it did in its answers to the written questions put by the Court, that that question is not relevant in the context of the examination to be carried out under Article 81(3) EC. Nor can it maintain that GSK did not rely on it during the administrative procedure or during these proceedings. On the contrary, by repeatedly claiming that it intends to prevent the prices imposed in Spain from being exported to the United Kingdom, GSK refers in particular to the idea that it intends to establish differentiated prices in order to ensure that the sales which it makes in the United Kingdom will all be made at the price which that Member State allows it to charge and not at the price which the Kingdom of Spain imposes on it.

— The loss of efficiency associated with parallel trade

269 The Court notes that the conclusion that it has not been shown that parallel trade leads to a loss in efficiency by altering GSK's capacity for innovation is based on an examination, at recitals 155 to 161 to the Decision, which does not take into consideration all the factual arguments and evidence pertinently submitted by GSK, contrary to what the Commission maintained in its written submissions, and is not supported by convincing evidence. While the Commission is clearly not required to examine all the arguments submitted to it, it must, on the other hand, in accordance with the case-law cited at paragraphs 236 and 242 above, adequately examine all the evidence which is relevant and, so far as necessary, refute it by means of evidence capable of substantiating its conclusion.

270 Taken as a whole, those arguments revealed that the competitive problem faced by GSK and the solution which it had sought to apply were, according to GSK, as follows.

271 First, the medicines sector is characterised by the importance of competition by innovation. R&D is costly and risky. Its cost is simultaneously a fixed cost (it is not connected with the number of medicines sold), a joint cost (it is incurred upstream from production and distribution and, in part, is not linked with a particular medicine) and a global cost (it is not connected with a particular country). It is most frequently financed from an undertaking's own funds rather than from borrowing. It therefore requires an optimum flow of income. The optimisation of income may be ensured by adapting the prices of medicines to the preferences of final consumers, where those preferences differ. Price differentiation thus allows the cost of R&D to be recovered from the final consumers who are prepared to pay for it. That practice of differentiated prices, which is presented here in a simplified form, is known to economists as 'Ramsey Pricing'.

272 Second, the implementation of that practice in the medicines sector is characterised by certain particular traits. When medicines are protected by patents, their price may be maintained, in the particular interest of the producer, at a higher level than the marginal cost throughout the life of the patent. However, when those medicines are reimbursed by the national sickness insurance schemes, their price must, in the general interest, be maintained directly (price control) or indirectly (control of benefits) at a level which is not excessively higher than the marginal cost. The extent of that excess reflects the preference of the final consumer, that is to say, essentially, the national sickness insurance scheme. If the latter is relatively sensitive to the price of the medicine, the excess will tend to be small; if it is relatively insensitive to that price, the excess will tend to be significant. In practice, that degree of sensitivity depends on various parameters, such as the standard of living or the state of public finances. The fraction of the cost of R&D recovered by producers of medicines therefore varies from one Member State to another, according to the income which the applicable price makes available. In the present case, it is in the United Kingdom that GSK could, owing to the regulations applicable, recuperate the global and joint part of its R&D costs.

273 Third, parallel trade has the effect of reducing that income, to an uncertain but real degree. That practice, which economists know as 'free riding', is characterised by the fact that the intermediary leaves the role which he traditionally plays in the value chain and becomes an arbitrageur and thus obtains a greater part of the profit. The legitimacy of that transfer of wealth from producer to intermediary is not in itself of interest to competition law, which is concerned only with its impact on the welfare of the final consumer. In so far as the intermediary participates in intrabrand competition, parallel trade may have a pro-competitive effect. In the medicines sector, however, that activity is also seen in a special light, since it does not bring any significant added value for the final consumer.

274 Fourth, Clause 4 of the General Sales Conditions seeks to optimise income and to neutralise parallel trade. It limits the possibilities previously afforded to GW's wholesalers to sell, outside Spain, medicines bought at the price set with a view to reimbursement by the Spanish sickness insurance scheme. It therefore allows sales

in other Member States to be made at the price determined with a view to reimbursement by their respective national sickness insurance schemes. The fact that the profit is retained by the producer will in all likelihood give rise to a gain in efficiency by comparison with the situation in which the profit is shared with the intermediary, because a rational producer which is able to ensure the profitability of its innovations and which operates in a sector characterised by healthy competition on innovation has every interest in reinvesting at least a part of its surplus profit in innovation.

275 However, the very structure of recitals 155 to 161 to the Decision shows that the Commission, after acknowledging the importance of competition by innovation in the relevant sector, failed to undertake a rigorous examination of the factual arguments and the evidence submitted by GSK concerning the nature of the investments in R&D, the characteristics of the financing of R&D, the impact of parallel trade on R&D and the applicable regulations, but confined itself, as indicated at recital 155 to the Decision, to observations which, to say the least, are fragmentary and, as GSK rightly claims, of limited relevance or value.

276 Such an omission is particularly serious where the Commission is required to determine whether the conditions for the application of Article 81(3) EC are satisfied in a legal and economic context, such as that characteristic of the pharmaceutical sector, where competition is distorted by the presence of national regulations. That circumstance obliges the Commission to examine with particular attention the arguments and evidence submitted to it by the person relying on Article 81(3) EC.

277 Thus, the first sentence of recital 157 to the Decision, which deals with the factors at the origin of decisions relating to R&D, relies on one of the economic studies in the file, but gives it an incomplete and unconvincing reading. Admittedly, that study indicates effectively that parallel trade is not the main factor underlying decisions on

R&D. However, it immediately adds that those decisions are taken, in particular, according to the general level of current profits or the expected profitability of the products in the development pipeline, as indicated, moreover, in the second sentence of that recital. Those are factors in respect of which GSK maintains that parallel trade has a negative impact, which the Commission accepts in the third sentence of that recital. In those circumstances, the Commission could not omit to carry out a more thorough examination, in the light of the supporting evidence submitted.

278 The remaining part of recital 157 to the Decision, which merely sets out GSK's possible responses to the loss of efficiency that may be caused by parallel trade, by reducing other budgetary items or using a part of its substantial profits, does not take the place of a response to the arguments that GSK has every interest in investing in R&D, owing to the fact of the lively interbrand competition, which relies on innovation, and finds it impossible to recover the entire proceeds of that investment, in order to reinvest in R&D, because of parallel trade. It also disregards GSK's arguments that the extent of its profits must be qualified because of the way in which they are accounted for.

279 In those circumstances, the question of the degree of correlation between parallel trade and R&D could not be dealt with without a more thorough examination or be satisfied by the lapidary conclusion that it was not proved that there was a causal link between parallel trade (or its limitation) and R&D, as stated at recitals 151, 154, 155 and 159 to the Decision.

280 As the Commission took advantage, in its written submissions, of the ambiguity of the wording of recital 169 to the Decision, in order to explain that what GSK had failed to prove was no longer the existence of a link between Clause 4 of the General Sales Conditions and the gain in efficiency which it expected from that provision but the existence of a direct link between those two elements, it must be observed that that argument, which was raised most recently at the hearing, cannot be accepted.

That distinction is not to be found at recitals 155 to 161 to the Decision, to which recital 169 refers, since those recitals unreservedly conclude that there is no link between the General Sales Conditions and the contribution to the promotion of technical progress. Nor is that distinction provided for in Article 81(3) EC, which allows the exemption of agreements producing a gain in efficiency without distinction as to whether that effect is direct or indirect, and a distinction cannot in principle be drawn where the Treaty draws no distinction (*Consten and Grundig* v *Commission*, paragraph 110 above, p. 339). In accordance with the case-law cited at paragraphs 247 and 248 above, any advantage in the form of a gain in efficiency must therefore be taken into account, provided that it is objective and appreciable and that its existence is proved convincingly.

— The extent of the loss in efficiency associated with parallel trade

281 The subsidiary conclusion that it is not in any event demonstrated that parallel trade leads to an appreciable loss in efficiency by altering GSK's capacity to innovate is not convincingly supported and the examination on which its is based, set out at recitals 159 and 162 to 168 to the Decision, does not take into account all the relevant elements put forward in that regard. In essence, it follows from that examination that the loss in efficiency alleged by GSK is limited, first, in time, because it is to be explained less by the price differentials linked to the existence of different regulations in the Member States of the Community, as indicted at recitals 162 and 163 to the Decision, than by the currency fluctuations between 1996 and 1998, as stated at recitals 164 to 166 to the Decision. It also follows from that examination that it is limited in material terms, as indicated at recitals 167 to 169 to the Decision.

282 In that regard, irrespective of the fact that Spanish prices would not be considerably lower than the Community average, which is explained at recitals 162 and 163 to the Decision and the relevance of which is limited in so far as national prices are at structurally different levels owing to the regulatory power of the Member States in that regard and as it therefore manifestly does not appear to be satisfactory, from an

economic viewpoint, to reason by reference to a hypothetical Community average, it must be observed that the Commission did not carry out a serious examination before reaching the definitive conclusion, at recitals 164 and 165 to the Decision, that the parallel trade between Spain and the United Kingdom between 1996 and 1998 was of a punctual and limited nature.

283 As may be seen from its written submissions, GSK does not deny that the variations in exchange rates, in particular speculative movements against the GBP in the approach to the final stage of EMU, made a conjunctural contribution to parallel trade in medicines marketed by GW in Spain between 1996 and 1998. However, it maintains that that conjunctural impact, as marked as it could be, constitutes only an aggravating factor, since parallel trade is linked, independently of exchange rate fluctuations, to the fact that the coexistence of different national regulations is reflected in structurally different prices in the Member States of the Community.

284 That argument is relevant and the evidence on which it is based is corroborated both by the extracts from Communication COM(1998) 588 final set out at paragraph 264 above and by the Decision itself. In effect, recitals 31, 32 and 53 to the Decision state that currency fluctuations, which by their very nature have a cyclical effect on parallel trade, constitute only a complicating factor of a phenomenon which is explained, in structural terms, by the existence, in the different Member States of the Community, of different prices for the same medicine.

285 Admittedly, that situation did not in itself prevent the Commission from considering that the parallel trade between the Kingdom of Spain and the United Kingdom between 1996 and 1998 was a special case caused essentially by the appreciation of the GBP against the Spanish peseta (ESP).

286 However, the figures cited by the Commission are too ambiguous to be capable of providing convincing support for that conclusion. According to the Decision, the GBP appreciated by 30% against the ESP between October 1996 and April 1998. During that period, the proportion which parallel imports from Spain represented by reference to all parallel imports into the United Kingdom remained stable in volume (approximately 40%), while those parallel imports increased in value (approximately GBP 20 million in 1996 and approximately GBP 42 million in 1998). As the Commission explained, most recently in its answers to the written questions put by the Court, that attests to the fact that the appreciation of the GBP gave rise to a flow of parallel imports from other Member States. However, that also confirms that, both before and after the appreciation of the GBP, the main part (approximately 40%) of parallel trade to the United Kingdom came from Spain, the remainder being shared among the other source Member States. It therefore does not constitute a sufficient response to GSK's argument that while the appreciation of the GBP undoubtedly exacerbated the problem caused by parallel trade from Spain, it does not in any way detract from the structural origin of that problem.

287 The argument put forward by the Commission in its answers to the written questions put by the Court, that the increase in parallel trade from Spain during the period 1996/98 may be explained by the expiry, on 6 October 1995, of the transitional period provided for in Articles 47 and 209 of the Act of Accession of the Kingdom of Spain, during which the holder of a patent could exercise the rights which it held under that patent to oppose the import of medicines marketed by itself or with its consent in Spain, does not alter that conclusion, since it clearly has no bearing on the period after the date of notification, to which GSK's arguments relate.

288 Last, as indicated at recitals 15, 18 and 55 to the Decision, GSK stated during the administrative procedure that although the General Sales Conditions are applicable to 82 medicines, eight of them were prime candidates for parallel trade. In addition, as indicated at recitals 22 and 35 to the Decision, GSK also stated that while the General Sales Conditions were applicable irrespective of the final destination of the medicines concerned, they were mainly aimed at parallel trade between Spain and the United Kingdom. GSK therefore essentially, albeit not exclusively, provided the Commission with figures relating, first, to the price differentials between Spain and

the United Kingdom, second, to parallel trade in Becloforte, Beconase, Becotide, Flixotide, Imigran, Lamictal, Serevent and Ventolín between Spain and the United Kingdom during the period 1996/98 and, third, to the impact which according to GSK parallel trade had on its income and its R&D budget. Those figures are set out at recitals 55, 59 to 67, 70, 83, 92, 98 and 99 to the Decision.

289 Furthermore, as indicated at recitals 70 and 71 to the Decision, GSK made clear that parallel trade lay outside formally audited distribution channels and added that the figures provided to the Commission were estimates which might not be reliable but which it could not further refine. Those allegations of fact, which were reiterated in the reply, were not disputed.

290 GSK is correct to maintain that those figures, quite apart from the fact that they are not derisory, must be regarded as a sample attesting not to a punctual and limited loss in efficiency but to a more general loss which was destined to continue.

291 As regards the first aspect, it must be borne in mind that when the Commission considered whether Clause 4 of the General Sales Conditions might present a disadvantage, while it agreed to concentrate on the eight medicines which were the main candidates for parallel trade between Spain and the United Kingdom, as it indicated at recitals 18, 56, 57 and 69 to the Decision, it also took account of the network effect linked with parallel trade in other medicines, between Spain and other Member States, as indicated at recitals 72 to 75, 117, 126, 140 and 144 to the Decision. It is specifically that network effect that rendered significant a restriction of competition which would have been marginal at the level of the United Kingdom alone, according to recital 133 to the Decision. However, the Commission provides no explanation of why it must follow a different approach when examining the question whether Clause 4 of the General Sales Conditions may present an advantage and concentrate exclusively on the figures provided to it by GSK, in the

light of the difficulty in ascertaining the reality of parallel trade and of the fact that it agreed to regard the figures provided by GSK as a sample.

292 As regards the second aspect, 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, paragraph 135 above. 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 EMU 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 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 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 General Sales Conditions had been applied between spring and autumn 1998, as may be seen from recitals 19, 23, 26, 64, 67 and 168 to the Decision, was sufficiently credible to merit serious examination.

— The gain in efficiency associated with Clause 4 of the General Sales Conditions

294 It must be observed that, as GSK correctly maintains, the Commission carried out no serious examination of its factual arguments and its evidence relating, not to the disadvantages of parallel trade, but to the advantages of Clause 4 of the General Sales Conditions.

295 In the light of the structure of GSK's arguments and also of the discussion of that point during the administrative procedure, the Decision could not avoid examining, first of all, whether parallel trade led to a loss in efficiency for the pharmaceutical industry in general, and for GSK in particular. Only in the absence of any dispute in that regard could the Commission validly dispense with such an examination (see, by analogy, *Compagnie générale maritime and Others* v *Commission*, paragraph 248 above, paragraph 345).

296 However, a comparison of the evidence provided by GSK with the other evidence invoked by the Commission in the Decision clearly reveals that in the medicines sector the effect of parallel trade on competition is ambiguous, since the gain in efficiency to which it is likely to give rise for intrabrand competition, the role of which is limited by the applicable regulatory framework, must be compared with the loss in efficiency to which it is likely to give rise for interbrand competition, the role of which is central.

297 In those circumstances, the Commission could not refrain from examining, second, whether Clause 4 of the General Sales Conditions could enable GSK's capacity for innovation to be reinstated and thus could give rise to a gain in efficiency for interbrand competition.

298 That, moreover, formed the very core of the prospective analysis which the Commission was under a duty to carry out in order to respond to GSK's request for an exemption. According to the consistent case-law cited at paragraph 247 above, it is necessary to determine whether the agreement prohibited on account of the disadvantage which it represents for competition (Article 81(1) EC) presents an advantage of such a kind as to offset that disadvantage (Article 81(3) EC).

299 The Commission was therefore still required to examine GSK's arguments relating to the advantages expected of Clause 4 of the General Sales Conditions. In that regard, recital 156 to the Decision, the only recital susceptible of attesting to an examination on that point, indicates essentially:

'[I]t is a matter of discretion for pharmaceutical companies to decide how much they wish to invest in R&D. Any savings they might hypothetically make by preventing parallel trade would therefore not automatically lead to higher R&D investments. It is conceivable that these savings might merely be added to the companies' profits. Obviously, the generation of extra profits alone cannot justify an exemption. In this regard, GSK's argument would mean that the first condition for [the application of Article 81(3) EC] would be fulfilled for every agreement that could be said to contribute to an increase in the revenues of a firm engaged in R&D. The condition would in any case be meaningless, since it is in the nature of any agreement restricting competition to be likely to increase a firm's earnings.'

300 However, GSK did not claim that the creation of additional profits would in itself justify an exemption. On the contrary, it maintained that parallel trade prevented it from making the profits necessary for the optimum financing of its R&D, that Clause 4 of the General Sales Conditions would enable it to increase its revenues and that it would have every interest, in the light of the fierce interbrand competition, of the central role played by innovation in that competition and of the methods of financing R&D, in investing a part of this surplus in R&D in order to overtake its competitors or to ensure that it would not be overtaken by them. In other words, it claimed that its General Sales Conditions should be exempted because they would have not merely the immediate effect of increasing its revenues, but above all the secondary effect of increasing its capacity for innovation. Furthermore, it maintained that that advantage must be compared with the fact that, when it was obtained by parallel traders, that surplus did not constitute an advantage, because, not being obliged to engage in genuine competition among themselves, the parallel traders reduced prices only to the extent necessary to attract retailers and therefore kept most of that surplus for themselves, as GSK again submitted at the hearing.

301 The Commission could not merely reject those arguments outright on the ground that the advantage described by GSK would not necessarily be achieved, as it did at recital 156 to the Decision, but was required, in accordance with the case-law, also to examine, as specifically as possible, in the context of a prospective analysis, whether, in the particular circumstances of the case and in the light of the evidence submitted to it, it seemed more likely that the advantages described by GSK would be achieved or, on the contrary, that they would not (*Compagnie générale maritime and Others* v *Commission*, paragraph 248 above, paragraph 365). It was not entitled to consider, in a peremptory manner and without providing proper arguments, that the factual arguments and the evidence submitted by GSK must be regarded as hypothetical, as it maintained most recently at the hearing.

302 Furthermore, when questioned on that point at the hearing, the Commission admitted on a number of occasions that it was appropriate to reason in terms of probability, while adding that it was necessary to be strict in that regard and claiming, essentially, that in the present case, in the light of the evidence submitted, and in particular the figures obtained by GSK, it seemed more probable that the advantage claimed would not be achieved. However, that is not the reasoning followed by the Decision.

303 It follows from the foregoing that the Decision is vitiated by a failure to carry out a proper examination, as the Commission did not validly take into account all the factual arguments and the evidence pertinently submitted by GSK, did not refute certain of those arguments even though they were sufficiently relevant and substantiated to require a response, and did not substantiate to the requisite legal standard its conclusion that it was not proved, first, that parallel trade was apt to lead to a loss in efficiency by appreciably altering GSK's capacity for innovation and, second, that Clause 4 of the General Sales Conditions was apt to enable a gain in efficiency to be achieved by improving innovation.

The balancing exercise

304 After concluding its examination of the factual arguments and the evidence submitted by GSK and finding that they did not demonstrate the existence of an

appreciable objective advantage, the Commission did not carry out the complex assessment (see paragraph 241 above) which would have been involved by the exercise seeking to balance that advantage against the disadvantage for competition identified in the part of the Decision devoted to the application of Article 81(1) EC, as it stated on a number of occasions at the hearing.

305 In effect, the Commission considered, at recital 151 to the Decision, that GSK had not proved that Clause 4 of the General Sales Conditions brought advantages and, at recital 152 to the Decision, that, in such circumstances, no balancing test was necessary, further stating that, in any event, even if it had to undertake such a balancing exercise, the disadvantages in that provision would outweigh the advantages.

306 As may be seen from the foregoing grounds, however, the Commission's conclusion that evidence of the existence of an appreciable economic advantage had not been submitted is vitiated by a failure to examine adequately the relevant criteria (paragraph 303 above). For its part, the Commission's finding that Clause 4 of the General Sales Conditions restricts competition is well founded only in so far as it finds that Clause 4 has the effect of depriving final consumers of medicines reimbursed by a national sickness insurance scheme of the advantage which they would have derived, in regard to prices and costs, from the participation of the Spanish wholesalers in intrabrand competition on the markets of destination of the parallel trade from Spain (paragraphs 147, 190 and 194 above).

307 Consequently, the Commission's conclusion that there is no need to carry out a balancing exercise, which would show in any event that the advantage associated with Clause 4 does not offset the disadvantage which it represents for competition, cannot be upheld. The Commission was required, first, to conduct an appropriate examination of GSK's factual arguments and evidence, in order to be in a position to carry out, second, the complex assessment necessary in order to weigh up the disadvantage and the advantage associated with Clause 4 of the General Sales Conditions.

Conclusion

308 It follows from the foregoing that the Commission could not lawfully conclude that, as regards the existence of a contribution to the promotion of technical progress, GSK had not demonstrated that the first condition for the application of Article 81(3) EC was satisfied. In those circumstances, there is no need to examine GSK's arguments relating to a contribution to the improvement of the distribution of medicines.

(c) Evidence of the advantage being passed on to the consumer, of the indispensability of Clause 4 of the General Sales Conditions and of the absence of the elimination of competition

309 As stated previously (paragraphs 237 to 239 above), it follows from the 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 General Sales Conditions and the absence of elimination of competition rest on the conclusion relating to the existence of a gain in efficiency.

310 In 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.

311 In so far as, when it examined whether Clause 4 of the General Sales Conditions would or would not eliminate competition for a substantial part of the products, the Commission further stated, at recital 188 to the Decision, that, in any event, for

several of the leading products affected by the General Sales Conditions, GSK held substantial market shares (for example, for Zofran, Flixonase, Zovirax and Imigran) in one or more Member States, it remains necessary to review that assessment.

312 In that regard, it must be observed that the Commission acknowledged at the hearing that it had not really resolved the question of GSK's market power and further stated that it would have had to continue with the analysis in order to determine that point.

313 In fact, owing to the particular legal and economic context of the sector under consideration, the fact of holding substantial market shares, which, moreover, is limited to certain of the relevant products, of which the Commission provided only four examples, clearly does not in itself make it possible to conclude, in a convincing manner, that competition would be eliminated for a substantial part of the relevant products.

314 In effect, irrespective of the question of the definition of the relevant products market, which has been debated by the parties, a number of elements relied on by GSK during the administrative procedure, and then in its written submissions, prevent such a conclusion from being reached automatically.

315 In particular, GSK's argument to which reference is made at recital 188 to the Decision, which refers to recital 104 to the Decision, was not so irrelevant that the Commission could refrain from making it the subject of a specific assessment under the fourth condition for the application of Article 81(3) EC. In effect, the fact that Clause 4 of the General Sales Conditions prevents the limited pressure which might exist, owing to parallel trade from Spain, on the price and the cost of medicines in the geographic markets of destination must be related to the facts, put forward by GSK and not disputed by the Commission, that competition by innovation is very fierce in the sector and that competition on price exists in another form, although by

law it emerges only when, upon expiry of the patent, manufacturers of generic medicines are able to enter the market. In those circumstances, it was still necessary, in accordance with the case-law cited at paragraph 109 above, to assess what form of competition must be given priority with a view to ensuring the maintenance of effective competition sought by Article 3(1)(g) EC and Article 81 EC.

4. Conclusion

316 It follows from the foregoing that the plea alleging infringement of Article 81(3) EC must be upheld and, consequently, that GSK's form of order must be granted in so far as it seeks annulment of Article 2 of the Decision, without there being any need to examine the plea alleging breach of the principle of proportionality.

317 Accordingly, the Decision must be annulled in so far as, in Article 2, it rejects GSK's request for an exemption.

318 As the possibility that the provisions of Article 81(1) EC are inapplicable to Clause 4 of the General Sales Conditions, pursuant to Article 81(3) EC, cannot be precluded, the Decision must also be annulled in so far as it orders GSK, in Article 3, to bring that infringement to an end immediately in so far as it has not already done so and, in Article 4, to inform the Commission of the steps which it has taken in order to do so.

319 Pursuant to the first paragraph of Article 233 EC, the Commission is required to take the necessary measures to comply with this judgment.

320 To that end, although the notification procedure provided for in Regulation No 17 no longer exists under Council Regulation (EC) No 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty (OJ 2003 L 1, p. 1), it falls upon the Commission, in the light of the partial annulment of the Decision and the retroactive effect thereof, to rule on the request for exemption presented by GSK by reference to the date of that request (see, to that effect, Case T-328/03 *O2 (Germany)* v *Commission* [2006] ECR II-1231, paragraphs 47 and 48), in so far as that request remains before it.

## Costs

321 Under the first subparagraph of Article 87(2) of the Rules of Procedure, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings.

322 The first subparagraph of Article 87(3) of the Rules of Procedure provides, in particular, that where each party succeeds on some and fails on other heads, the Court may order that the costs be shared or that each party bear its own costs.

323 In the present case, GSK was unsuccessful in its claim for annulment of Article 1 of the Decision. The Commission, supported by the interveners, was unsuccessful in its claim that the application should be dismissed in its entirety.

324 In those circumstances, the costs must be shared. GSK must bear one half of its own costs and pay one half of the costs incurred by the Commission, including those relating to the interventions. The Commission must bear one half of its own costs and pay one half of those incurred by GSK, including those relating to the interventions. The interveners must bear their own costs.

On those grounds,

THE COURT OF FIRST INSTANCE
(Fourth Chamber, Extended Composition)

hereby:

1. **Annuls Articles 2, 3 and 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));**

2. **Dismisses the remainder of the application;**

3. **Orders GlaxoSmithKline Services Unlimited 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 GlaxoSmithKline Services, including those relating to the interventions;**

5. **Orders the Asociación de exportadores españoles de productos farmacéuticos (Aseprofar), the Bundesverband der Arzneimittell-Importeure eV, the European Association of Euro Pharmaceutical Companies (EAEPC) and Spain Pharma, SA, to bear their own costs.**

Legal Lindh Wiszniewska-Białecka

Vadapalas Moavero Milanesi

Delivered in open court in Luxembourg on 27 September 2006.

E. Coulon H. Legal

Registrar President

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