

# Case T-168/01

**GlaxoSmithKline Services Unlimited**

**v**

**Commission of the European Communities**

(Competition — Wholesale distribution of medicines — Parallel trade — Differentiated prices — Article 81(1) EC — Agreement — Restriction of competition — Object — Relevant market — Effect — Article 81(3) EC — Contribution to the promotion of technical progress — No elimination of competition — Proof — Statement of reasons — Subsidiarity)

Judgment of the Court of First Instance (Fourth Chamber, Extended Composition), 27 September 2006 . . . . . II - 2981

## Summary of the Judgment

- 1. Acts of the institutions — Statement of reasons — Obligation — Scope — Judicial review (Art. 253 EC)*
- 2. Actions for annulment — Pleas in law — Lack of or inadequate statement of reasons — Distinction from challenge to merits of the grounds (Arts 230 EC and 253 EC)*

3. *Actions for annulment — Commission decision adopted on the basis of Article 81(1) EC — Complex economic assessment — Judicial review — Limits*  
(Arts 81(1) EC and 230 EC)
  
4. *Actions for annulment — Subject-matter — Decision applying Article 81 EC — Acceptable evidence*  
(Arts 81 EC and 230 EC)
  
5. *Competition — Community rules — Substantive scope — Conduct imposed by national measures — Not included — Evaluation of actual scope for free competition*  
(Art. 81(1) EC)
  
6. *Competition — Agreements, decisions and concerted practices — Agreements between undertakings — Concept — Covering only bilateral or multilateral conduct — Existence of a joint intention as to the conduct to be adopted on the market — Sufficient condition*  
(Art. 81(1) EC)
  
7. *Competition — Agreements, decisions and concerted practices — Agreements between undertakings — Burden of proving the infringement borne by the Commission — Evidence of having distanced itself from the agreement borne by the undertaking relying on its intention to do so*  
(Art. 81(1) EC)
  
8. *Competition — Community rules — Substantive scope — Sector of medicines reimbursed by the national sickness insurance scheme — Included notwithstanding national intervention in matters of prices*  
(Art. 81(1) EC)
  
9. *Competition — Agreements, decisions and concerted practices — Adverse effect on competition — Criteria for assessment — Assessment by reference to the economic and legal context — Anti-competitive object rendering proof of anti-competitive effects unnecessary*  
(Arts 3(1)(g) EC and 81(1) EC)

10. *Competition — Agreements, decisions and concerted practices — Adverse effect on competition — Agreements intended to limit parallel trade — Criteria for assessment — Taking into account of effects for final consumers — Presumption of anti-competitive object — Limits — Sector of medicines reimbursed by the sickness insurances scheme — Not included*  
(Art. 81(1) EC)
11. *Competition — Agreements, decisions and concerted practices — Adverse effect on competition — Application of unequal conditions to equivalent services — System of differentiated prices — Assessment — Need to take account of the different regulatory framework depending on the Member States — Circumstance of medicines reimbursed by the national sickness insurance schemes*  
(Art. 81(1)(d) EC)
12. *Community law — Principles — Principle of subsidiarity — Application in the sphere of competition — Requirement of an effect on trade between Member States*  
(Arts 5, second para., EC and 81(1) EC)
13. *Competition — Agreements, decisions and concerted practices — Not allowed — Exemption — Conditions — Burden of proof — Scope — Examination by the Commission*  
(Art. 81(3) EC)
14. *Competition — Agreements, decisions and concerted practices — Not allowed — Exemption — Conditions — Complex economic assessment — Discretion of the Commission — Judicial review — Limits*  
(Art. 81(3) EC)
15. *Competition — Agreements, decisions and concerted practices — Not allowed — Exemption — Conditions — Improvement in the production or distribution of goods or promotion of technical or economic progress — Appreciable objective advantages of such a kind as to offset the disadvantages of the agreement for competition — Examination by the Commission*  
(Art. 81(3) EC)
16. *Actions for annulment — Action against a Commission decision on a request for negative clearance or exemption under Regulation No 17 — Judgment annulling act — Effects*  
(Art. 233, first para., EC; Council Regulations No 17 and No 1/2003)

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

distinguished from the examination of the merits of the grounds of the decision, which forms part of the review of its substantive legality.

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.

(see para. 54)

3. When it is dealing with an application for annulment of a Commission decision applying Article 81(1) EC, the Community judicature carries out, in accordance with Article 230 EC, a review of the lawfulness of that decision.

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.

In that regard, the Court must undertake a comprehensive review of the examination carried out by the Commission, 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.

(see paras 49-51)

2. 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

(see paras 57, 145)

4. Review by the Court dealing with an action for annulment of a decision applying Article 81 EC 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 paras 58, 245)

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.

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.

5. Article 81(1) EC applies only to anti-competitive conduct engaged in by undertakings on their own initiative.

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.

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.

(see paras 66-70)

Where it is clear, following that evaluation, that the regulations in question

6. Article 81(1) EC applies only to bilateral or multilateral conduct on the part of undertakings and such conduct may take the form of agreements, concerted practices or decisions of associations.

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.

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 are not required to establish the existence of a joint intention to pursue an anti-competitive aim.

Where the Commission has adduced evidence of the existence of an agreement, it is for an undertaking which has taken part in that agreement and denies having committed an infringement 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 paras 82, 83, 86)

(see paras 75-77)

7. 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.

8. 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. The coexistence of those different national regulations may distort competition. It tends, moreover, to favour a certain partitioning of the national markets on that point.

That evidence may consist of direct evidence, taking the form, for example, of a written document, or, failing that, indirect evidence, for example in the form of conduct.

However, 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.

In the sector in question, 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.

(see paras 104-107)

9. 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.

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.

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, so that there is no need to examine its effect.

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.

(see paras 109-112)

10. Agreements which ultimately seek to prohibit parallel trade must in principle be regarded as having as their object the prevention of competition, while agreements that clearly intend to treat parallel trade unfavourably must in principle be regarded as having as their object the restriction of competition.

However, the mere fact that an agreement is intended to restrict parallel trade is not sufficient to support the conclusion that there is an infringement of Article 81(1) EC. In effect, the objective assigned to that provision 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.

Consequently, the application of Article 81(1) EC cannot depend solely on the fact that an agreement is intended to limit parallel trade 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. That analysis, which may be abridged when the clauses of the agreement reveal in themselves the existence of an alteration

of competition must, on the other hand, be supplemented, depending on the requirements of the case, where that is not so.

While it is accepted that parallel trade must be given a certain protection, it is therefore not as such but in so far as it favours the development of trade, on the one hand, and the strengthening of competition, on the other hand, that is to say, in this second respect, in so far as it gives final consumers the advantages of effective competition in terms of supply or price. 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 of competition.

Then, while it is accepted that an agreement intended to limit parallel trade must in principle be regarded as having 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.

However, it cannot be presumed that agreements intended to hinder parallel imports of medicines have the effect of

depriving final consumers of the advantages linked with those imports. In effect, the prices at which medicines are sold at retail level 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 various Member States, so that it cannot be presumed that parallel trade has an impact on the retail prices charged to the final consumers of medicines reimbursed by the national sickness insurance scheme and thus confers on final consumers an appreciable advantage analogous to that which it would confer if those prices were determined by the free play of supply and demand.

(see paras 115-122, 133, 134, 140)

11. Where it is common ground that, in the case of a given product, in this instance medicines reimbursed by the national sickness insurance schemes, each of the Member States constitutes a distinct market, owing to the differences in the national regulations on the prices and the reimbursement of the medicines in question, the fact that different prices are charged depending on the Member State in which the medicines are intended to be resold and reimbursed

is not sufficient to characterise discrimination for the purposes of Article 81(1)(d) EC.

(see paras 178, 179)

12. 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, so that it is appropriate for the Community to take action, by reason of the scale and the effects of its action.

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.

(see paras 201, 202)

13. Any agreement which restricts competition, whether by its effects or by its object, may in principle benefit from an exemption under Article 81(3) EC.

The application of that provision is subject to certain conditions, satisfaction of which is both necessary and sufficient. 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.

Consequently, an economic operator who relies on Article 81(3) EC must

demonstrate that those conditions are satisfied, by means of convincing arguments and evidence.

The Commission, for its part, must adequately examine those arguments and that evidence, 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. In such a case the Commission must refute those arguments and that evidence.

(see paras 233-236)

14. 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.

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.

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.

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.

(see paras 241-244)

15. 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.

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, it being understood that these advantages may arise not only on the relevant market but also on other markets and that they are not required to be a direct consequence of the agreement.

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.

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.

Last, 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, it must examine with particular attention the arguments and evidence submitted to it by the economic operator relying on Article 81(3) EC.

(see paras 247-250, 276, 280, 298, 301)

16. Pursuant to the first paragraph of Article 233 EC, the Commission is required to take the necessary measures to comply with a judgment annulling a decision determining a request for exemption under Regulation No 17.

To that end, although the notification procedure provided for in Regulation No 17 no longer exists under Regulation No 1/2003 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty, it falls upon the Commission to rule on the request for exemption by reference to the date of that request, in so far as the request remains before it.

(see paras 319, 320)