JUDGMENT OF THE COURT OF FIRST INSTANCE IN *GLAXOSMITHKLINE*

Valentine Korah[*]

INTRODUCTION

The judgment of the Court of First Instance (CFI) in *GlaxoSmithKline Services Unlimited v European Commission*[1] (*GSK*) may not apply to many, or even any, products other than prescription medicines, but it is very important to those supplying medicines to wholesalers. More generally, if followed by the European Court of Justice (ECJ), it may take some contracts outside Art 81(1) of the EC Treaty so that it is not necessary to establish the application of Art 81(3) EC.

The pharmaceutical industry is closely regulated in each Member State. Each government controls at a different level the maximum price to be charged directly or indirectly to the national health service, and once a medicine is supplied in some Member States, it is illegal to withdraw it without ministerial consent. Consequently, wholesalers in the Member States where the maximum prices were lowest, bought additional quantities in order to sell them in those Member States where the maximum price was higher.

GW, a subsidiary of GSK operating in Spain, notified the European Commission of the conditions of sale to its wholesalers in Spain, relating to 82 medicines of which, according to GSK, eight were prime candidates for parallel trade (para 11). These conditions were countersigned by 79 out of 85 wholesalers who bought from GW and clause 4 imposed dual pricing for all 82 medicines. If purchase from the wholesalers was to be reimbursed by the national health insurance scheme,

* Professor Emeritus of Competition Law, University College London.
I am indebted to the Editors for permission to republish this article, first published in [2007] Competition Law Journal, 331 with minor amendments.

[1] (Case T-168/01) [2006] 5 CMLR 1623, appeal pending C-513/06 P. The numbers in round brackets are to the judgment of the CFI. In the quotations I have shortened the references to the cases cited by the CFI.

ie if made by pharmacies or hospitals, the maximum price allowed by Spanish law would be charged. In other cases a much higher price would be charged, set on objective grounds, without discrimination and irrespective of the destination. GW's main justification was that parallel trade prevented it from charging a higher price in countries where it was legal and, thereby, reduced the incentive to research and development (R&D) for a pharmaceutical company that had been a successful innovator. A second argument was that it would be impossible to ensure supply to each part of the common market with the amount needed there, as every part would be supplied from those Member States where the maximum price was lowest.

The Commission adopted a decision under Art 81(1) EC[2] condemning the agreement for having the object and effect of imposing higher pricing on medicines that were exported than on those to be consumed domestically (para 18). GSK appealed to the CFI.

AGREEMENT WITHIN ARTICLE 81 EC

The first ground of appeal was hardly controversial. In *Bundesverband der Arzneimittel-Importeure eV and European Commission v Bayer AG,*[3] Bayer had not asked the wholesalers not to export and, despite the continuing relationship between Bayer and the wholesalers, the ECJ accepted that there had been no meeting of minds within the meaning of Art 81(1) EC. On the other hand, GSK had obtained signatures to the conditions of sale. Clearly there had been an agreement between GSK and the wholesalers, even a contract. So, the CFI accepted that the failure of the Commission to refer to *Bayer* when finding that an agreement had been made did not amount to inadequate reasoning (paras 65-90). The Commission was not wrong to conclude that there was an agreement.

---

[2] Commission Decision 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), IV/37.380/F3 *EAEPC* (complaint) (2001) OJ L 302/1.

[3] (Cases C-2/01 P and 3/01 P) [2004] ECR I-23.

NOT ACT OF STATE

The CFI decided that the regulation by Member States did not amount to an Act of State – the national regulation did not require GSK to charge different prices (para 105). The pharmaceutical companies continued to compete in R&D and service (para 106). The regulation did not exclude all competition. It did not exclude Art 81 EC.

OBJECT OF RESTRICTING COMPETITION

The Commission's decision alleged that by clause 4, which imposed higher prices for medicines not paid for by the Spanish health insurance scheme, GSK sought to limit parallel trade and that it had that effect. GSK did not deny that its dual pricing was intended to deter parallel trade. It objected, rather, to the consequences for competition found by the Commission. The Commission said that the condition of sale restricted competition by object because it had an effect similar to an export ban, and the ECJ habitually treated export bans as infringing Art 81(1) EC.

GSK claimed that the Commission had not taken proper account of the relevant legal and economic context when examining the alleged restriction of competition. The CFI agreed:

> '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 on 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 La Technique Minière* … pp. 249 and 250; … *Consten and Grundig v. Commission* … at p. 343 … and *Oude Luttikhuis and Others …,* paragraph 20).' (my italics)

Only when an examination of the clauses of an agreement, carried out in their legal and economic context, does not reveal an anti-competitive object, is it 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.

The CFI went on to consider both tests. It said that in principle dual pricing intended to discourage parallel trade must be regarded as having the object of restricting competition (paras 115-116). Nevertheless, as GSK had argued, having regard to the legal and economic context that was not enough to establish an anti-competitive object (para 117).

At para 118, the CFI stated that Art 81(1) EC:

> 'constitutes a fundamental provision indispensable for the achievement of the missions entrusted to the Community, in particular for the functioning of the internal market, … and restricting competition between themselves or with third parties, from reducing the welfare of the final consumer of the products in question.'

Consequently, an intention to limit parallel trade in medicines or to partition the common market does not necessarily have the object or effect of restricting competition *to the detriment of the final consumer*. The analysis may be abridged when the clauses of the agreement reveal in themselves an effect on competition, but analysis is required when they do not.

It cited *Société Technique Minière v Maschinenbau Ulm GmbH*[4] (pp 248–251) and *Etablissements Consten SARL and Grundig-Verkaufs-GmbH v EC Commission*[5] (pp 342 and 343) and said that:

> '120 … The Court of Justice [in *Consten and Grundig*], contrary to the Commission's contention …, 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 the plea alleging that Article 81(1) was not applicable to vertical agreements. … The Court of Justice then carried out a competitive analysis abridged but real, during the course of which it held, that the agreement

[4] (Case 56/65) [1966] ECR 235.

[5] (Joined Cases 56/64 and 58/64) [1966] ECR 299.

> 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 342–343) …
>
> 121. … 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.'

The CFI went on to consider the context of the dual pricing: and its main characteristics:

(1) the national regulation of prices;
(2) on different bases;
(3) that the structural cause of the price differentials was the national regulation;
(4) fluctuations in exchange rates were a cyclical cause of the price differentials;
(5) the price differentials were the cause of parallel trade;
(6) some Member States, for example, the UK, pays the manufacturer's list price subject to a standard discount of 4 or 5% supposed to compensate for buying elsewhere at a lower price;
(7) patients rarely pay much for medicines.

At no point had the Commission considered national price control (para 133). So, it cannot be presumed that parallel trade helped final consumers. It benefited mainly the parallel traders and caused inefficiencies. The Commission should not follow analogies from its previous practice. For these and other reasons, in carrying out its judicial review, the Commission was wrong to state that the dual pricing had the object of restricting parallel trade.

This reasoning amounts to a radical change of view. In *Consten*, the ECJ did, indeed carry out an abridged market analysis, but it did not mention consumer welfare. That concept became popular in the Community institutions only with the modernisation of competition law starting with the group

exemption for vertical distribution agreements.[6] The judgment of the CFI is an important reinterpretation of the ECJ's judgment in 1966, which I welcome. Forty years on it should be possible to reconsider competition policy, and the Commission which now frequently considers consumer welfare is the institution responsible for competition policy.

It is not only the judgment in *Consten* that has been challenged. In many decisions, the Commission relied on the ECJ's judgment in *Miller International Schallplatten GmbH v EC Commission*[7] and stated that any attempts to restrict parallel trade had the object of restricting competition. The decisions spawned by *Consten* on the concept of 'object' were purely formal and did not establish any effect on competition.[8] It is not surprising that the Commission and several parallel traders have lodged an appeal.

The recognition that analysis may be abridged when the Common Market is divided is also welcome. Can that view also be extended to cartels to raise price by restricting supply? It may reduce the concern of some of the judges about the application of a rule of reason. The analysis of hard core restraints may be also be truncated in the absence of an unusual legal and economic context.[9]

EFFECT OF RESTRICTING COMPETITION

The CFI started analysing the effect on competition by considering the definition of the market. The Commission had not expressly defined the relevant market, but implicitly relied on the third level of the anatomical therapeutic classification frequently used in merger decisions. It is based on the malady to be remedied. Nevertheless, at para 159, the CFI stated that it was not manifestly wrong to consider that Spanish wholesalers who engaged in parallel trade might have been less interested in the therapeutic indication of

---

6 Reg. 2790/99. See also Commission Notice - Guidelines on Vertical Restraints (2000) OJ C 291/1.

7 (Case 19/77) [1978] ECR 131.

8 For example, Commission Decision of 16 May 1984 relating to a proceeding under Article 85 of the EEC Treaty (IV/30.658 - *Polistil/Arbois* (84/282/EEC)) (1984) OJ L 136/9.

9 For instance, fees to the Confederation of British Industries are based on annual turnover. This is how many careless in the 1030s were organised. The fees, however, were a tiny percentage. They were a method of ensuring that the larger members paid more for administration than smaller members. In form, but not in substance, the fee structure was a cartel.

each medicine than in whether there was a sufficient price differential between medicines that were reimbursed by the Spanish health insurance scheme and the market prices in the country of destination to render parallel trade lucrative. Consequently, it was not manifestly wrong to accept that all the medicines reimbursed by the Spanish health insurance scheme which are capable of being sold at a profit owing to the price differential constituted a product market.

The court was not saying that this is the only correct way to define the product market. Its jurisdiction is limited to judicial review. The Commission enjoys a margin of appreciation over complex economic matters such as market definition. Nevertheless, it may be worth considering the implications of such a definition. Few pharmaceutical companies would be dominant over all the patented medicines that can be the subject of profitable parallel trade. The issue might arise before a national court, rather than a competition authority and it might accept the sensible criterion of the CFI. Then any form of dual pricing could be considered only under Art 81 EC: not under Art 82 EC.

The CFI proceeded to consider that the appropriate counterfactual was the situation that would exist without the agreement (para 162). It was for the Commission to establish the effect on competition (para 169). Clause 4 restricted the freedom of action of participating undertakings, but not every restriction of freedom of action restricts competition – *Wouters v Algemene Raad van de Nederlandse Orde van Advocaten (Raad van de Balies van de Europese Gemeenschap intervening*[10] and *Métropole télévision (M6) v European Commission, supported by CanalSatellite*.[11] Any vertical agreement restricts freedom of action. Since the objective of the competition rules is to prevent harm to consumers of the products in question, the Commission has to establish consumer harm. The judgment does not consider whether *M6* can stand with *Wouters* – it merely cites both cases.

The Commission had considered that the dual pricing was discriminatory, contrary to Art 81(1)(d) EC and referred to the case-law under Art 82(c) EC (para 174). The CFI, however, considered that it had not been shown that the transactions were equivalent, especially important when the price difference was justified by variations in the conditions of marketing and the intensity of competition (paras 176-180).

[10] Often called '*Metropole*' (Case C-309/99) [2002] ECR I-1577, at para 97.
[11] (Case T-112/99) [2002] ECR II-2459, at para 171.

Dual pricing might indicate discrimination if conditions in the markets were sufficiently homogenous, but not where the parties agreed that the geographic markets were separate and characterised by different conditions, especially different national regulation.

GSK argued that the Commission had not shown in any other way that clause 4 had the effect of restricting competition. The CFI, having gone so far along with GSK's arguments, considered that the welfare of final consumers was in fact reduced. To the extent that patients paid for their medicines, they were final consumers, and to the extent that they were reimbursed, the health insurance scheme was a consumer. Parallel trade applied marginal pressure on prices in the countries of destination, and the Commission was entitled to infer that clause 4 contributed to the rigidity on the market (para 186). Some national health insurance schemes claw back some of the benefits of parallel trade, although the amount was marginal (para 188). So the Commission was entitled to find consumer harm (para 190). The CFI confirmed the decision that the dual pricing had the effect of restricting competition to the detriment of consumers (para 194).

The court did not consider the 'bagatelle Notice',[12] but referred to the minor harm to consumers, without considering whether it was outweighed by other detriments to consumers – the reduction in the incentive to R&D and the difficulty of ensuring that every Member State was sufficiently supplied, when the Member States where high prices were permitted were supplied from those with a tighter cap. Perhaps the CFI thought that any balancing should come under Art 81(3) EC, which leaves a heavy burden of proof on the parties to the agreement.

EXEMPTION UNDER ARTICLE 81(3) EC

After dismissing pleas based on misuse of powers, the CFI turned from paras 233–315 to the Commission's refusal to grant an individual exemption under Regulation 17.[13] Any kind of

[12] Commission Notice on agreements of minor importance which do not appreciably restrict competition under Article 81(1) of the Treaty establishing the European Community (2001) OJ C 368/13. Its application was excluded by G 11.

[13] Council Regulation (EEC) No 17/62 of 6 February 1962, first Regulation implementing Articles [85] and [86] of the Treaty (1962) OJ 87.

agreement may be exempted (*Consten* (paras 342, 343 and 347) and *Matra Hachette SA v Commission*,[14] para 234).

Judicial review

The party relying on Art 81(3) EC must demonstrate that all the conditions of Art 81(3) EC are satisfied by means of 'convincing arguments and evidence', and the Commission must examine those arguments and evidence (para 236). The Commission relied mainly on the first condition, 'contributing to improving production or distribution or promoting technical or economic progress.' GSK had argued that restricting parallel trade increased its incentive to innovate.

The CFI referred to its limited jurisdiction when faced with complex economic assessments. Its review is 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 must consider also whether the decision 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. The CFI referred also to the margin of discretion normally left to the Commission. It is subject to a restricted judicial review which takes the form of a balancing exercise carried out in the light of the general interest appraised at Community level. The CFI added that it should consider only facts that existed at the time of the decision. Consequently, reports prepared subsequently otherwise than for the purpose of the Commission's proceedings must be rejected.[15]

The Commission should have examined GSK's argument and evidence more carefully. It admitted much of it.

Loss of efficiency

The CFI objected that the Commission had not considered all the factual arguments and evidence that GSK had pertinently submitted. Nor was the decision supported by convincing

[14] (Case T-17/93) [1994] ECR II-595.

[15] I hope this does not include the excellent article by P Rey, J Venit, 'Parallel trade and pharmaceuticals: a policy in search of itself' (2004) 29 ELRev 153. Its value lies in its analysis, rather than in its statement of facts.

evidence. The Commission carried out no serious examination of GSK's 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. This is especially important under Art 81(3) EC. It should have examined whether parallel trade led to a loss in efficiency for the pharmaceutical industry in general, and GSK in particular. Only in the absence of any dispute in that regard could the Commission validly dispense with such an examination.

The CFI went on to stress the importance of interbrand competition:

> '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 crucial. In those circumstances the Commission should not have refrained from examining whether clause 4 could enable GSK's capacity for innovation to be reinstated.'

The CFI therefore concluded that the failure to carry out a proper examination of all the factual arguments and evidence vitiated the decision to refuse an exemption. The court quashed the operative part of the decision relating to Art 81(3) EC and ordered the Commission to take the necessary steps that were relevant at the time of its decision. The Commission is, therefore, examining the merits of an exemption under Regulation 17, although the Regulation has been abrogated.

The CFI's stress on the importance of inter-brand competition is contrary to the view of the Commission in many of its cases in the twentieth century. Many agreements imposing restrictions on a dealer competing in the territory of another dealer were condemned for restricting its freedom of action. The need to avoid free riding was stressed in the guidelines on vertical restraints in 2000.[16] I am delighted that in GSK the CFI should have made such a clear affirmation of the importance of interbrand competition.

[16] Commission Notice - Guidelines on Vertical Restraints (2000) OJ C 291/1.

In the USA, *Sylvania - Continental T.V., Inc. v GTE Sylvania Inc.*,[17] where dealers who invested were protected from free riders, is often cited as the judgment when the Supreme Court moved from formalistic analysis of restrictions of conduct to an analysis of the likely effects of conduct. Recently, in *Leegin Creative Leather Products, Inc. v PSKS, Inc., DBA Kay's Kloset … Kays* Shoes the Supreme Court[18] was prepared to overturn precedents extending over a century in order to apply a rule of reason to minimum resale price maintenance. It considered the circumstances in which the practice might avoid a free riding problem, and those in which it might support a price fixing cartel at dealer or producer level and concluded that, in the absence of a collusion at either level, the practice could be either pro- or anti-competitive. Consequently a per se rule was not appropriate and a court should examine the pro- and anti-competitive effects in each case.

CONCLUSION

This judgment will have to be included in every cases and materials book on EC competition, so many important points were made.

The distinction from *Bayer* demonstrates how narrow is the path that was opened up to avoid making an agreement or concerted practice.

The conclusion that the parties were not excused by an Act of State follows old law.[19] Only if the law requires conduct that infringes the competition rules is it excusable.

The most surprising point is that a realistic counterfactual, must be considered when deciding whether in its the economic context the object of the agreement is anti-competitive, but in *Consten* the ECJ did make an abridged analysis. This part of the judgment delights me. I am also delighted that it is only if consumer harm is caused that an agreement limiting freedom of action infringes Art 81(1) EC.[20]

---

[17] 433 U.S. 36, 53 L.Ed. 568. (1977).

[18] 551 U.S. 000 (2007).

[19] *Suiker Unie' UA v Commission* (Case 40/73) [1975] ECR 1663.

[20] I would prefer the institutions to look to total rather than consumer welfare, but the difference is important mainly when dealing with buying power. The interests of the foreclosed buyer should be relevant. In *Consten*, the court did not refer consumer harm under Art 81(1) EC.

At first I found it surprising that an agreement intended to limit parallel trade should be found to have the effect of restricting competition because of the loss to the UK national health scheme of the small discount on the payment to pharmacists made possible by parallel trade. The CFI described it as being minor. Was this a compromise within a divided court, or is the CFI still convinced that any balancing between positive and negative effects on competition must be done under Art 81(3) EC. Is it possible to reconcile *Wouters* with *M6* and *O2*[AQ: is this case: *O2 (Germany) GmbH & Co v European Commission* (Case T-328/03) *02 (Germany) GmbH & Co. v. Commission*, 2 May 2006. (T- 328-03). [2006] ECR II-1231, [2006] All ER (D) 13 (May)?], all of which were cited in the judgment? The issue may be less important now that national courts and competition authorities can apply Art 81(3) EC, but it affects the burden of a high standard of proof.

Other points to note are that the consumers who should not be harmed include the health insurance scheme. It is important that it is only when transactions are equivalent that Art 81(1)(d) EC is infringed by price differentials. If an agreement requires different prices to be charged in different markets, there is no discrimination (para 177). This had already been decided in relation to Art 82(c) EC and I hope it applies also to Art 81(1)(d) EC.

I welcome the view that the Market relevant to an agreement between a producer and wholesalers may be to products for which parallel trade is profitable and not only to substitutes at the consumers' level, especially when maximum prices or profits are capped by national legislation.

I also welcome the stress on the importance of interbrand competition.

The views of the CFI about judicial review under Arts 81(1), (3), 82 EC and the Merger Regulation[21] are congruent. Whoever bears the burden of proof must provide convincing arguments and evidence to support its views. It must get simple facts right, but the Commission has a margin of appreciation over complex economic matters. *Airtours plc v European Commission*[22] has had important implications outside the context of mergers.

[21] Council Regulation (EC) No 139/2004 of 20 January 2004 on the control of concentrations between undertakings (2004) OJ L 24/1 (EC Merger Regulation).

[22] (Case T-342/99) [2002] ECR II-2585.