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An End to Parallel Imports of Medicines? Comments on the Judgment of the Court of First Instance in *GlaxoWellcome*

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In September 2006, the Court of First Instance of the European Union (CFI) issued its judgment in the case opposing GlaxoSmithKline (GSK) to the European Commission. The Commission had found that the dual pricing system introduced by GSK violated the European antitrust rules (Article 81 of the EC Treaty), because it constituted an agreement with wholesalers whose object was to restrict competition by blocking parallel imports of pharmaceuticals. For the Commission, the agreement could not be exempted and was therefore to be prohibited.

The CFI disagreed with the Commission and found that the agreement could qualify for an exemption. More importantly, the CFI ruled that, at least in the pharmaceutical sector, an agreement whose object is to prevent parallel imports by imposing a dual pricing system is not automatically contrary to Article 81, as it cannot be automatically inferred that the end consumer is harmed. This holding is highly questionable in view of the prior EU case law, prohibiting per se agreements with anticompetitive objects. Therefore, the change brought about by the CFI's judgment could have major ramifications on the innovative pharmaceutical industry which is vigorously opposed to the principle of parallel imports.

I. INTRODUCTION

In *GlaxoSmithKline Services v. Commission* (T-168/01),[1] the European Court of First Instance (CFI) reached a decision with potentially major implications for EU competition law and for the pharmaceutical sector.

In 1998, the multinational drug company GlaxoWellcome (now and hereafter GSK, for GlaxoSmithKline) decided to impose on its Spanish distributors a new contract whereby it would sell its medicines at the Spanish nationally mandated price only if these medicines were intended for resale by the distributors on the Spanish market.[2] Conversely, if the Spanish distributors intended to resell these medicines outside of Spain (i.e., if they intended to parallel import them[3]), then the contract price would be higher. It was acknowledged that this dual pricing scheme had as its main, if not sole, purpose the deterrence of parallel imports orchestrated by Spanish

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[1] The text of the judgment of 27 September 2006, by the CFI is available from <http://curia.europa.eu/jurisp/cgi-bin/form.pl?lang=en&Submit=Rechercher&alldocs=alldocs&docj=docj&docop=docop&docor=docor&docjo=docjo&numaff=T-168/01&datefs=&datefe=&nomusuel=&domaine=&mots=&resmax=100>.

[2] Had there been no contract imposed on distributors, but only a unilateral practice implemented by Glaxo, then Article 81 EC would not have applied. See C-2/01, *Bundesverband der Arzneimittel-Importeure v. Bayer and Commission* (Adalat case), (2004) ECR I-26.

[3] Technically, the Spanish wholesaler is first *exporting* the medicine out of Spain and then *importing* it to the country of destination, for example the United Kingdom. However, it is customary to use the broad term "parallel importers" to encompass anyone conducting this arbitraging operation.

distributors.[4] As a rational economic agent, GSK did not want its Spanish distributors to make a profit by buying the medicines at the Spanish low State-set price and reselling them at a higher price set by another government. Indeed, prior to the new contract,[5] the Spanish distributor would typically engage in parallel imports in order to benefit from the significant differences in prices of medicines between Spain and the United Kingdom. In both countries, these prices were controlled, albeit in a markedly different manner, by the national authorities.[6]

GSK had submitted its new contract to the Commission for clearance.[7] Unsurprisingly in light of its largely uniform practice,[8] the Commission answered that the contract breached Article 81 of the EC Treaty (hereafter EC) because it limited competition between Member States. The Commission found that the *object* of the contract itself was to limit competition, in particular trade of GSK medicines across EU frontiers.[9] It also refused to grant an exemption pursuant to Article 81(3) EC. The *GSK* decision was carefully drafted, taking into account prior decisions by the Commission, the Court of First Instance and the European Court of Justice (ECJ); it extended over more than 40 pages and reflected a solid understanding of the pharmaceutical sector.[10]

GSK appealed the Commission's decision to the CFI. On 27 September 2006, the CFI delivered its judgment in favour of GSK. The Court found that the Commission had not correctly appreciated the evidence submitted by GSK, chiefly as regards the conditions for an exemption as per Article 81(3).

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[4] The initial explanation given by GSK for its dual pricing contract clause was very different. See recital 21 of the Decision of the European Commission of 8 May 2001 in case IV/36.957/F3 [hereafter Commission decision], L 302/1 (17.11.2001). Eventually, GSK had to admit that its ultimate purpose was to discourage parallel trade. See recital 116.

[5] The new contract clause of March 1998 only received limited application. In October 1998, the Spanish competition tribunal ordered GSK to suspend its application. In September 1998, the Commission sent a warning letter and in May 2001 it found the dual pricing clause illegal. See recitals 23 to 28 of the Commission decision. During its limited time of application, GSK nonetheless realised additional profits of GBP 13 million. See recital 146.

[6] Although price controls played an important role in creating the price differential necessary for parallel imports, they were not the only factor. Indeed, currency fluctuations between the British pound and the Spanish peseta (ESP) significantly widening the price gap. The British pound appreciated by about 30% compared to the ESP. See recitals 53, 54, 142, 143, 164 to 166 of the Commission decision.

[7] The submission for clearance by GSK occurred in March 1998; it was based on Article 2 Regulation No 17 of 6 February 1962 implementing Articles 85 and 86 of the Treaty. This Regulation was repealed by Article 43 of Council Regulation No 1/2003 16 December 2002 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty, (2003) OJ L 1/1, which entered into force in January 2003. Several wholesalers and parallel importers objected to the Commission, asking that GSK's request for clearance be denied. See recital 3 of the Commission Decision.

[8] See, e.g. Commission Decision 78/163/EEC in Case IV/28.282 (*Distillers*); Commission Decision 82/203/EEC in Case IV/30.188 (*Moët et Chandon*); Commission Decision 87/409/EEC in Case IV/31.741 (*Sandoz*); Commission Decision 91/335/EEC in Case IV/32.186 (*Gosme/Martell*).

[9] The Commission noted:

> "The Court of Justice (and Court of First Instance) have always qualified agreements containing export bans, dual-pricing systems or other limitations of parallel trade as restricting competition 'by object'. That is to say, prohibited by Article 81(1) without there being any need for an assessment of their actual effects." [Recital 124].

Even though the Commission found that the agreement had an illegal object, it nonetheless decided to verify the agreement's effects on competition (see recitals 125 to 135).

[10] See also the note by Laurence Idot, (2006) 11 Europe p.27-28.

Even if the Commission's decision was only invalidated on this narrow issue of exemption, several aspects of the CFI judgment deserve a detailed review since they insidiously alter former EU case law.

The article is divided in three sections that follow the reasoning of the CFI. The first one focuses on the *object* of the agreement between GSK and its Spanish distributors; the CFI found that the object of the agreement, viewed in its particular legal and factual context, was insufficient to draw a conclusion that the agreement was *per se* in violation of Article 81(1) EC. The second section discusses the CFI's analysis of the agreement's actual effect on competition; the CFI found that the agreement did have an anticompetitive effect, but only barely so. The third section scrutinises the CFI's finding that the GSK agreement did have a pro-competitive effect, which should have been taken into consideration by the Commission when it refused to grant an Article 81(3) exemption.

II. AGREEMENTS HAVING AN ANTICOMPETITIVE OBJECT

A. CUSTOMARILY APPLIED PRINCIPLES

It is traditionally accepted that an agreement whose *object* is to restrict competition is *per se* in breach of Article 81(1) EC; in other words, it is not necessary to check whether this agreement also has anticompetitive *effects*.[11] The CFI in *GSK* did cite several prior EU judgments which buttressed this rule.[12]

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[11] In *Consten and Grundig v. Commission* (C-56/64), (1966) ECR I-299, the Court of Justice (ECJ) first highlighted that:

> "for the purpose of applying Article 85(1), there is no need to take account of the concrete effects of an agreement once it appears that it has as its object the prevention, restriction or distortion of competition. Therefore, the absence in the contested decision of any analysis of the effects of the agreement on competition between similar products of different makes does not, of itself, constitute a defect in the decision." [p. 342]

It is worth noting that the contractual restriction at issue in *Consten and Grundig* was an absolute territorial protection equivalent to a ban on parallel imports.

In Case C-277/87, *Sandoz Prodotti Farmaceutici v. Commission*, (1990) ECR I-45, the ECJ agreed with the Commission that:

> "For the purpose of the application of Article 85(1) there is no need to take account of the concrete effects of an agreement when it has as its object the prevention, restriction or distortion of competition within the common market [. . .]. In such a case the absence in the Commission's decision of any analysis of the effects of the agreement from the point of view of competition does not constitute a defect capable of justifying a declaration that it is void." [point 3 of the summary]

In the *Aalborg Portland v. Commission* case (C-217/00), (2004) ECR I-123, the ECJ noted that:

> "For the purposes of applying Article 85(1) [now Article 81(1)] of the Treaty, there is no need to take account of the actual effects of an agreement once it appears that its aim is to restrict, prevent or distort competition within the common market" [paragraph 261].

In *Volkswagen* (T-62/98), (2000) ECR II-2707, the CFI wrote:

> "It is settled case-law that for the purpose of the application of Article 85(1) there is no need to take account of the actual effects of an agreement when it has as its object the prevention, restriction or distortion of competition within the common market. Consequently, it is not necessary to show actual anti-competitive effects where the anti-competitive object of the conduct in question is proved [. . .]. As the Court has just held, the Commission has proved that the applicant adopted measures whose object was to partition the Italian market [. . .]. The Commission was not therefore required to investigate the actual effects which those measures had on competition within the common market." [paragraph 178]

Among agreements which are viewed as having a *per se anticompetitive object* are those which partition market by prohibiting parallel trade.[13] This is particularly true when, by contract, distributors are ascribed to one geographical area and are prohibited from selling in another Member State. Contracts whose aim is to prohibit parallel trade across national borders are viewed as having an anticompetitive *object*. Contracts which impose conditions that make such parallel trade difficult are also considered as implementing an anticompetitive object.[14]

Historically, the EU administrative authorities and Courts have strongly promoted parallel imports, including in the pharmaceutical sector. Numerous decisions and court judgments have defended parallel importers against private and public obstacles. State measures to discourage parallel imports have repeatedly been ruled contrary to Article 28 EC.[15]

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cont.

See also C-219/95, *Ferriere Nord v. Commission,* (1997) ECR I-4411, at paragraph 31. More generally on Article 81(1) EC and the anticompetitive object of an agreement: Valentine Korah, *An Introductory Guide to EC Competition Law and Practice*, Hart Publishing, Oxford, 7th Edn, 2000, p.58-65.

[12] The *Sandoz Prodotti Farmaceutici* affair presents several analogies with the instant case. The Italian branch of the Sandoz group wished to prevent its Italian distributors from exporting its drugs to other Member States; it had printed the words "export prohibited" on all the invoices it sent to these distributors. On this ground alone, the Commission found that there was an agreement whose *object* was to compartmentalise the European market and thus to restrict competition (Decision 87/409/EEC). The ECJ easily agreed (see C-277/87, as note 11 above). The CFI did not attempt to distinguish the ECJ *Sandoz* judgment from its own – divergent – decision in *GSK*.

[13] In C-19/77, *Miller International Schallplatten v. Commission*, 1978 ECR I-131, the ECJ held:

> "... by its very nature, a clause prohibiting exports constitutes a restriction on competition, whether it is adopted at the instigation of the supplier or of the customer since the agreed purpose of the contracting parties is the endeavour to isolate a part of the market." [paragraph 7]

See also C-551/03, *General Motors,* (2006) not yet in ECR, at paragraph 67; C-96/82 *NV IAZ International Belgium and others v. Commission*, (1983) ECR I-3369, at paragraphs 23-25. See moreover Pierre Mercier et al., *Grands principes du droit de la concurrence*, Academia-Bruylant 1999, p. 112-113.

[14] At paragraphs 115 and 116 of the *GSK* judgment, the Court wrote:

> "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 restriction of competition (*Consten and Grundig v. Commission* . . . 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).
>
> 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-0000, paragraphs 67 and 68)."

[15] See e.g., C-15/74, *Centrafarm et Adriaan de Peijper v. Sterling Drug*, (1974) ECR I-1147; C-16/74, *Centrafarm et Adriaan de Peijper v. Winthrop*, (1974) ECR I-01183; C-104/75, *Adriaan de Peijper of Centrafarm,* (1976) ECR I-613; C-102/77, *Hoffmann-La Roche v. Centrafarm,* (1978) ECR I-1139; C-3/78, *Centrafarm v. American Home Products*, (1978) ECR I-1823; C-187/80, *Merck v. Stephar*, (1981) ECR I-2063; C-1/81, *Pfizer v. Eurim-Pharm*, (1981) ECR I-2913; C-247/81, *Commission v. Germany*, (1984) ECR I-1111; C-181/82, *Roussel Laboratoria v. Netherlands*, (1983) ECR I-3849; C-87/85, *Legia and Gysekinx – Cophalux*, (1986) ECR I-1707; C-434/85, *Allen and Hanburys v. Generics*, (1988) ECR I-1245; C-347/89, *Freistaat Bayern v. Eurim-Pharm*, (1991) ECR I-1747; C-209/91, C-71/94, *Eurim-Pharm GmbH v. Bundesgesundheitsamt*, (1993) ECR I-3723; C-232/94, *MPA Pharma v. Rhône-Poulenc*, (1996) ECR I-3671; C-427/93, *BMS v. Paranova*, (1996) ECR I-3457; *Eurim-Pharm v. Beiersdorf*, (1996) ECR I-3603; C-267/95, *Merck v. Primecrown*, (1996) ECR I-6285; C-379/97, *Pharmacia v. Paranova*, (1999) ECR I-6927.

See also the astute parallels drawn by the Commission between Article 28 and Article 81 in recitals 127 to 130 of its 8 May 2001 Decision.

B. NOVEL PRINCIPLE SET BY THE CFI IN THE *GSK* CASE?

The GSK contract had undeniably the object of impeding parallel trade by making such trade financially unattractive.[16] Its purpose was to quench, to the greatest extent possible, this trade by the Spanish distributors. Therefore, it should have led to the straightforward conclusion that the contract had a *per se* anticompetitive object in violation of Article 81(1).

Yet, for the first time in EU case law, the Court decided that an automatic condemnation of an anticompetitive contractual object could not be pronounced when it is not clear from the outset that the contract would harm the final consumers. In other words, the Court set the following principle: When an agreement has an anticompetitive object which, in all likelihood, will harm ultimate consumers, then this agreement is *per se* illegal as per Article 81(1). However, when the harmful effects on the ultimate consumer are not immediately obvious, it is necessary to verify the agreement's actual effects on the competition.

According to the CFI:

> "[T]he 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.
> 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."[17]

To complete its argument, the CFI added:

> "[T]he objective assigned to Article 81(1) EC [...] 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 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*, [...] 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*. [...]
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> [W]hile 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."[18]

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[16] Also largely undeniable was the prior conclusion that GSK's new sales conditions imposed on distributors constituted an "agreement between undertakings". Indeed, a majority of GSK's wholesalers had accepted these conditions and returned to GSK a copy of the signed contract. See recitals 12 and 109 of the Commission decision and paragraphs 75-78 of the CFI decision.

The CFI did not hesitate either when it concluded, along with the Commission, that national regulations did leave enough "scope for competition to be prevented, restricted or distorted by autonomous conduct on the part of undertakings". See paragraph 67 of the *GSK* judgment.

[17] Paragraphs 110 to 111, emphasis added, parentheses in the citation omitted.

[18] Paragraph 118-121, emphasis added, parentheses in the citation omitted.

Applying this rule to the GSK agreement, the CFI noted that since the prices of medicines were either controlled or set in the countries of importation, it was highly likely that pharmacies in these countries would continue to sell the GSK medicines to consumers at this price, even though they had been able to acquire these medicines at a cheaper price from a Spanish parallel importer. In other words, intermediaries (in particular the Spanish parallel importers and the pharmacies) would probably pocket the benefit arising out of the price differential, while the consumer would continue to pay the same set price.

For the CFI:

> "[I]f 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, 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."[19]

As a result, the CFI reached the intermediate conclusion that the GSK agreement could not be said to violate Article 81(1) simply by reason of its anticompetitive object.

C. CRITICISM OF THE NEW PRINCIPLE SET FORTH BY THE CFI

The new rule set by the CFI requires, at a minimum, that competition authorities verify the *effects* of agreements (between undertakings) whose objective is to limit parallel trade, when there are reasons to suspect that, despite this objective, the final consumers will not be affected by the agreement.

Applied to the present situation, if consumers – which are to include both patients and sickness insurance schemes that pay for the patients' medicines – appear not to benefit from the parallel trade in medicines, for example because the prices, the quantity or quality of the medicines remain the same with or without parallel trade, then it is necessary to look into greater details into the circumstances of the case, to ascertain whether these contract clauses limiting parallel trade have any anticompetitive effect.

The reasoning of the CFI is a curious blend of different criteria. The CFI is saying that an anticompetitive object is not determinative when there are *indicia* that, despite this anticompetitive purpose, there is (or will be) no anticompetitive effect on the final consumer... and if so, one should check whether there is truly no anticompetitive effect.[20] In other words: if there *seems* (i.e. prima facie) to be no anticompetitive effect

[19] Paragraph 122, emphasis added, parentheses in the citation omitted.

[20] Another interesting question is: how can there not be *at least indicia* of anticompetitive effects when an agreement has an anticompetitive purpose? In most cases, one would imagine that when the purpose of the parties is to achieve an anticompetitive purpose, there should be at least prime facie evidence of anticompetitive effects. This is *a fortiori* true when the agreement has not yet been implemented and the question is whether the anticompetitive purpose will result in potentially anticompetitive effects. Here, the CFI appears to be crafting a specific exception just for the pharmaceutical industry: it is in the particular context of the pharmaceutical industry that the CFI generally assumes that anticompetitive objectives will not produce anticompetitive effects.

(but just an anticompetitive object), then Article 81(1) can only be infringed if the authority succeeds in showing that there is, nonetheless, an anticompetitive effect.

To avoid the obvious strains in this reasoning, the CFI should have stated, in much simpler terms, that violation of Article 81(1) will only be found when an agreement has anticompetitive effects.[21] Such a principle is sensible. The ongoing review of Article 82 EC emphasises the economic effects of abuses by dominant enterprises.[22] In the United States, Courts have long distanced themselves from *per se* prohibitions.[23] Yet, due to the prior EU case law and the clear language of Article 81(1), the CFI could hardly declare that it would, from now on, follow the US footsteps.

To achieve its goal, the CFI attempted a demonstration that purports to confirm prior case law, but in truth radically alters it. The cases that the CFI cites in an attempt to support its point of view in the *GSK* case do not stand for the conclusion of the CFI. The judgment refers to four prior decisions of the Court of Justice (i.e. the court of appeal against judgments of the CFI; hereafter ECJ).[24] However, none of these four decisions contain the new principle set forth by the CFI in the *GSK* case; indeed, none of these judgments state that an anticompetitive contractual object is insufficient to justify the application of Article 81(1) when circumstances suggest no anticompetitive effect.

True, these judgments do say that Article 81(1) requires that account be taken of the *economic context* to which the agreement is to apply. Appreciation for the context entails an understanding of "the products or services covered by the agreement, the structure of the market concerned and the actual conditions in which it functions".[25] There is nothing original about such a requirement to interpret an agreement with due consideration of its context;[26] to define the true object of an agreement, it is usually necessary to place it in its "real-life" context. Still, this does not mean that

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[21] If the agreement has not yet deployed its effect, for example because the parties to it have delayed its entry into force, then the "rule" would be: violation of Article 81(1) will only be found when an agreement *will* have an anticompetitive effect.

[22] See the various documents from the European Commission's on the review of Article 82 EC.

[23] See recently *Illinois Tool Works v. Independent Ink*, 126 S. Ct. 1281 (2006); previously see *Continental TV Inc. v. GTE Sylvania Inc.*, 433 U.S. 36 (1977) and *State Oil v. Khan*, 522 U.S. 3 (1997).

[24] See C-56/65 *Société technique minière*, (1966) ECR I-235; C-56/64, *Consten and Grundig v. Commission*, (1966) ECR I-299; C-7/95, *John Deere v. Commission*, (1998) ECR I-3111; c-399/93, *Oude Luttikhuis and Others*, (1995) ECR I-4515.

[25] C-399/93, paragraph 10.

[26] See already the 1966 judgment in *Consten and Grundig* ("In order to arrive at a true representation of the contractual position, the contract must be placed in the economic and legal context in the light of which it was concluded by the parties." at p.343).

Similarly, on the application of Article 81 of the EC Treaty to technology transfer agreements, (2004) C 101/02, the Commission writes:

> "The assessment of whether or not an agreement has as its object a restriction of competition is based on a number of factors. These factors include, in particular, the content of the agreement and the objective aims pursued by it. It may also be necessary to consider the context in which it is (to be) applied or the actual conduct and behaviour of the parties on the market. In other words, an examination of the facts underlying the agreement and the specific circumstances in which it operates may be required before it can be concluded whether a particular restriction constitutes a hardcore restriction of competition." [paragraph 14]

See also the similar statement at paragraph 22 of the Commission Guidelines on the application of Article 81(3) of the Treaty (2004) C 101/97.

anticompetitive *effects* should always be present for the agreement to violate Article 81(1).

Similarly, the fact that EU authorities and courts tend to systematically ascertain both the object and the effect of an agreement does not mean that a violation of Article 81(1) cannot exist when only the object is anticompetitive. Authorities and courts have valid reasons to prefer decisions that fully analyse the facts at issue, even when they could as well rest their case on the easier finding of an anticompetitive object.

Hence, serious doubts have to be raised as to the legal soundness of the new principle set forth by the CFI in its *GSK* judgment. The next section of this article highlights the economic difficulties that this new principle generates.

III. Agreements Having an Anticompetitive Effect

A. Reasoning of the CFI

Because the Court accepted as credible GSK's argument that final consumers were not harmed by the new agreement preventing parallel trade of medicines,[27] it conducted a full analysis of the agreement's *effects* on competition. It was only reluctantly that it concluded that the agreement did have potentially anticompetitive effects (since the GSK agreement had been implemented only over a very short period,[28] only potentially anticompetitive effects were considered).

The effects on competition that the CFI was willing to take into consideration were mainly those concerning price and quantity:

> "[T]hat 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."[29]

Moreover, for the CFI, there had to be an effect "to the detriment of the final consumer",[30] and not just to the detriment of the intermediaries (distributors, importers and pharmacies).

Such detrimental effect on the final consumer was eventually identified in relation to two sets of facts.[31]

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[27] The CFI was also able to use against the Commission arguments that the latter made in another setting, that is its Communication COM(1998) 588 final of 25 November 1999 on the single market in pharmaceuticals. In support of the Commission's position, the CFI could instead have cited COM(2003) 839 final of 30 December 2003 on parallel imports of proprietary medicinal products for which marketing authorisations have already been granted.

[28] See note 5 above.

[29] Paragraph 167, emphasis added, parentheses omitted.

[30] Paragraphs 119 or 171.

[31] See paragraphs 182 to 195.

First, a few countries, in particular the United Kingdom, have realised that parallel imports can and should be used to the benefit of patients and public coffers. Nonetheless, achieving this goal may require an adaptation of the legal framework and regulatory incentives. Several countries apply various forms of discounts on the amounts due to pharmacists, the objective being to take into account the latter's ability to buy part of their supply at cheaper price from parallel importers.[32] As a result, these countries end up in paying slightly lower prices for medicines, whereas pharmacies are pushed into buying from parallel traders to avoid incurring a loss through the mandatory discount. Because the discount benefiting national insurance systems is tied to the existence of parallel imported medicines, the suppression of parallel trade could lead – assuming some legislative changes brought about by political pressure – to the suppression of the discount. Hence, for the CFI, the GSK agreement had (potentially) anticompetitive effect because it restricted the parallel trade that warranted the pharmacy discount imposed by certain Member States.[33]

The second circumstance recognised by the CFI as establishing an anticompetitive effect relates to the fact that, in some Member States, patients do pay a portion of the price of medicines. For the CFI:

> "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 [. . .] 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."[34]

In other words, parallel trade exercised some downward pressure on price and, if prices charged at pharmacies were even slightly lower than the usual prices, then both the patient (paying a percentage of this price out-of-pocket) and the sickness schemes paying the rest would derive a small monetary benefit.

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[32] For an explanation of the claw back mechanism applied to pharmacies' sales in the United Kingdom, see paragraph 49 of the Commission decision. For an explanation of the German mechanism, see the study by the University of Southern Denmark CAST, at 41 (July 2006).

[33] The CFI articulated the general framework, but abstained from exposing its financial impact on consumers:

> ". . . 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." [paragraph 130]

[34] Paragraph 185, emphasis added.

B. CRITICISM OF THE REASONING OF THE CFI

Both arguments of the CFI are seriously deficient.

The first argument centred on the discount calls for a lot of speculation. Governments can take into account a variety of factors when setting or controlling the price of medicines. Since the volume and financial impact of parallel trade cannot be precisely calculated, there is no perfect correlation between the level of parallel trade and the level of the discount imposed on pharmacies. Parallel trade is rather used as a political justification to justify a price cut. For some countries, it is an easier political argument than simply invoking a need to replenish social security budgets.

The second argument of the CFI focused on the marginal pressure on price caused by parallel trade[35] raises a different problem. The CFI did not refer to hard data to estimate this "pressure". It merely assumed it. In this assumption, the CFI is essentially doing the same as the legislator did when it posited that agreements with an anticompetitive object should be prohibited under competition law. It was – and still is – reasonable for the legislator to assume that parallel trade has a pro-competitive effect and that, therefore, agreements which are designed to block parallel trade are anticompetitive *per se*. As we saw in section II.B. above, the CFI went directly against this rule when dismissing the anticompetitive object due to the pharmaceutical context. Yet, at this next stage, the CFI is forced to reintegrate the assumption that parallel trade leads to marginal price pressure. The proof of an actual anticompetitive effect is still essentially lacking. If one admits that intermediaries are in a position to pocket the entire benefit arising out of the price differential because the price charged to end consumers is set or controlled by the State, then there is little reason to admit even "a marginal pressure" on prices.

Thus, the conclusion of an anticompetitive effect reached by the CFI is largely open to criticism.

A more convincing analysis would have required an investigation into the reasons for the alleged lack of competition at the consumer level. Pharmacies can play parallel importers against each other or against national distributors. Because competition is possible at this intermediate level, pharmacies should be able to derive a profit from the competition between distributors selling differentially priced medicines. If so, why are pharmacies not using this profit to attract more final consumers (patients)? One could imagine that a pharmacy which succeeds in securing cheaper supplies from a parallel importer would then use this saving to make offers designed to attract more patients, for example by offering discounts or maybe just better services (e.g., truly detailed medical advice, home delivery of medicines, information leaflets). Such a pro-competitive result should occur, unless the pharmacy is either legally prevented from offering these benefits to patients or the structure of the pharmacy market is such that pharmacies have no incentive to compete among themselves for clients.

[35] See paragraph 185-187.

The CFI did not delve into these issues. In any event, one may wonder whether it is wise to systematically check if and how the consumer will derive a benefit on the final market (here pharmacies) from competitive circumstances taking place on an upstream market. In a multitude of cases, it is not obvious that downward price pressure at an early point in the distribution chain will be passed on until the very final point of the chain. Market conditions can differ significantly at the various points of this chain and intense competition between undertakings occupying one level of the chain may not translate into competitive conditions at another level of distribution.

It is therefore problematic to introduce a principle whereby anticompetitive conduct is only prohibited when the end consumer is harmed. With such a principle, undertakings could get away with hard price-fixing cartels by arguing that, in any case, the final buyer would have paid the same price due to lack of competition at the final distribution level.

To revert to the special context of the pharmaceutical market, parallel imports have the potential to reduce prices at least in countries which only set maximum prices (typically maximum amounts that the patient will be reimbursed).[36] In such countries, pharmacies can sell medicines at a price below the maximum price and should have an incentive to do so in order to attract a greater number of customers. To realise this profit, pharmacies will seek cheaper parallel imported medicines. Profits will be made by the parallel importer, by the pharmacy and by the patient; health care budgets will be reduced. Of course, the drug manufacturer will incur a financial loss. Hence the next issue: Is such a loss acceptable or should it be precluded by the grant of an Article 81(3) exemption?

IV. Exemption under Article 81(3) EC

A. Argument of the CFI

Because the CFI ultimately reached the conclusion that the agreement imposed by GSK on its Spanish wholesalers had anticompetitive effects on final consumers, the Court had to go to the next stage of the Commission's decision and determine whether the Commission was right in refusing to grant an exemption as per Article 81(3) EC.

Four cumulative conditions have to be met for an exemption to be granted:

> "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

[36] Among economists, there is a long-standing controversy as to the – positive or negative – effects of parallel trade on price levels. Experts battle with numerous economic studies reaching different conclusions. Unfortunately, these conclusions appear in part dictated by the identity of study sponsor. See, e.g. the summary of available evidence provided in the CAST study, as note 32 above, especially at p.20. See further the listing of contributions on the subject of parallel trade in medicines at <http://www.euractiv.com/en/parallel-trade-medicines/article-117528>.

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."[37]

The Commission had not assessed all four conditions, because it had ruled that GSK had not proved that its agreement satisfied the first condition (i.e., efficiency justification). The CFI found that the Commission was wrong in holding that GSK had not provided such a proof and therefore annulled the Commission's decision without analysing the three other conditions. Since only the first condition was subject to the Court's review, this article will also limit its scope to this first condition.[38]

Interestingly, the CFI did not admit unequivocally that the GSK agreement had one of the pro-competitive effects required by the first condition of Article 81(3). It only stated that the Commission had been wrong in rejecting the evidence submitted by GSK in favour of a "technical … progress". For the CFI, GSK had presented economic studies showing that pharmaceutical companies invest their sales profits in R&D leading to new and improved medicines. By maximising revenues through differential pricing, pharmaceutical companies are able to invest more into R&D and thus bring to market more medicines.[39] The CFI chided the Commission for not having conscientiously examined this pro-competitive effect as well as not having adduced the evidence that could have refuted this effect.[40]

B. CRITICISM OF THE CFI'S ARGUMENT

The reasoning of the CFI is highly questionable. There is no doubt that pharmaceutical companies invest in costly and risky R&D to bring new drugs to the market. It is even reasonable to assume that the greater profits they amass, the more they will invest in R&D, and the more new products will reach the market. However, it is unexpected that this alone would qualify as pro-competitive effect.

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[37] Paragraph 234 of the T-168/01 judgment.

[38] Nonetheless, one should wonder how is the Commission to concretely determine whether or not additional profits achieved through differential pricing in segregated markets are *indispensable* to achieve the efficiency of greater R&D investments.

[39] For more on this argument, from a pro-industry perspective, see for example Patricia M. Danzon, *The Economics of Parallel Trade*, (1998) 13(3) Pharmacoeconomics 293-304; and Danzon and Adrian Towse, (2003) 3 International Journal of Health Care Finance and Economics 183-205.

[40] Although this article is not concerned with procedural aspects, it is worth remarking that the CFI has moved the evidentiary threshold in its decision. According to settled case law, it is for the party applying for an exemption under Article 81(3) to demonstrate that all conditions are met. The Commission found that GSK had not met its burden of proof. It explained in detail why it rejected GSK's claim that prevention of parallel trade was necessary in order to fund more R&D. See recitals 154 to 169.

Despite these explanations, the CFI found that the Commission "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." Paragraph 275. Altogether, the standard imposed by the CFI appears so high that the decision as to whether or not the conditions of Article 81(3) are met could only be made by economic experts.

Obviously, all businesses that are based on innovation rely on money (whether from profits or borrowed funds) to finance innovation. Obviously again, these businesses all wish for more money and more profits in order to finance more innovation. Undeniably, the consumer derives a benefit from the greater number of innovative products that thus come to the market. Nonetheless, this has never been enough to excuse anticompetitive conduct[41] – otherwise one could justify price-fixing cartels, because they too lead to higher profits that can be (and sometimes are) reinvested in R&D.[42]

Maximised profits achieved through differential pricing (also called Ramsey pricing[43]) should *not per se* constitute a pro-competitive benefit, even if they will be *entirely* reinvested in R&D[44] – which, incidentally, is rarely the case. As the Commission rightly pointed out,[45] the allocation of sales revenues to R&D is a discretionary decision of pharmaceutical companies. Companies can as well use their additional profits to reward executives, to increase their dividends or to offer share buy-backs. We have seen this happen. Conversely, companies have the option to reduce existing expenses – say, for example advertising budgets – in order to finance more R&D projects, without the need for an increase in sales revenues.[46]

V. CONCLUSION

Even though the reasoning of the CFI is deeply flawed, the Court did identify true problems pertaining to the application of competition law to the pharmaceutical sector. These problems are indeed tied to drug pricing.

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[41] See for example the Commission Guidelines on the application of Article 81(3) of the Treaty at paragraph 54, stating that:

> "The causal link between the agreement and the claimed efficiencies must normally also be direct. Claims based on indirect effects are as a general rule too uncertain and too remote to be taken into account. [. . .] An example of indirect effect would be a case where it is claimed that a restrictive agreement allows the undertakings concerned to increase their profits, enabling them to invest more in research and development to the ultimate benefit of consumers. While there may be a link between profitability and research and development, this link is generally not sufficiently direct to be taken into account in the context of Article 81(3)."

[42] As the Commission rightly observes in its May 2001 decision:

> "Obviously, the generation of extra profits alone cannot justify an exemption. In this regard, GW's argument would mean that the first condition for exemption 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." [Recital 156].

[43] The theory developed by Frank Ramsey (1903-1960) was to set prices that maximise the sum of industry consumer surplus and profits. This goal can be achieved by having different prices that reflect the elasticity of each separate segment of demand.

[44] There is no hard evidence that more R&D will always and systematically yield more or better drugs. See, e.g. EAEPC (European Association of Euro-Pharmaceutical Companies), at 6-7 (June 2006).

[45] See recital 156.

[46] The Commission wrote: "Parallel trade may have some impact on revenue and profits. However, there is no reason why a pharmaceutical company should react to losses of revenue resulting from parallel trade by cutting the R&D budget rather than any other budgetary item. In this context, it should be borne in mind that the R&D costs take up around 15% of the turnover and that the remaining 85% goes into sales costs, administrative costs and profits." [Recital 157].

Member States control the price of medicines for at least three connected reasons. First, many medicines are vital to the health of citizens and, if patients had to fully bear their prices, many would have to choose between financial ruin or health injuries. Second, medicines are protected by patents, which allow the patent holder to impose monopoly prices in the absence of government intervention. Third, and perhaps more importantly, without publicly mandated sickness insurance and income-based insurance subsidies, only rich patients would be able to buy all drugs and poor patients would be unable to buy most of them, even when absolutely necessary.[47] This would lead to evident market failure: Without government subsidy of demand through insurance schemes, pharmaceutical companies would not invest in R&D for drugs that a majority of patients could not afford. This is observed, for example, with drugs intended for developing countries: If their government cannot or do not want to subsidise patient demand (through taxes or mandatory insurance systems), then the industry will not invest in R&D targeted on diseases mostly prevalent in developing countries.

Governments face a true quandary: they need to (indirectly) subsidise the costly R&D leading to new drugs, but they objectively cannot afford monopoly prices which would then be set by the patent holder in a free market. The inevitable result is government price control.

Paradoxically, such price control is a form of optimum Ramsey pricing. Ideally, governments are controlling the price of medicines so that it reflects the ability to pay of the insurance schemes that ultimately bear the cost of medicines. True, governments do take into consideration other factors, some more legitimate than others.[48]

Ultimately, the price set for a given country reflects the ability and willingness to pay of that country's – artificially reconstituted – demand. The problem arises when parallel imports are allowed. If the English government, for example, has decided that it wants comparatively high medicine prices,[49] then it should have its way. When parallel imports are allowed, the wishes of the government are defeated – possibly completely so, if the entire English demand can be satisfied by parallel imports.[50] The same is still

[47] If companies cannot segment their markets, for example because parallel imports are freely allowed, they will set their prices taking into account the very different capacities of their consumers (from rich patients in rich countries to poor patients in poor countries). It could be that profit maximisation would be reached by setting a high price affordable only to the rich patients in the rich countries, thus excluding all poorer patients in all countries.

[48] For example, most governments take into account the existence of a *domestic* pharmaceutical industry: countries with prosperous domestic pharmaceutical industry tend to accept higher prices than countries with no such domestic industry. Other factors are more related to the constant power fight between political parties.

[49] The reasons for this choice are multifaceted: the English government may find that its health care budgets can afford the high price; the country may derive other benefits, such as a higher tax bases from pharmaceutical companies located on its territory; the government may want the industry to invest into new drug development for the benefit of the patients.

[50] In reality, parallel imported medicines only account for a fraction of domestic sales, up to 8% in the United Kingdom in 1997. See recital 33 of the Commission decision. In 2003, the UK percentage reached 17% according to the CAST study, as note 32 above, at 45. The loss for pharmaceutical companies in the United Kingdom was estimated at £1.3 billion. See ABPI, (March 2006). However, for individual medicinal products, the market share of parallel importers may be much higher (up to 49% for a best-seller product). See, e.g. the CAST study at 39.

The market share of parallel traders may be dropping as pharmaceutical companies progressively reduce quantities supplied to wholesalers to the level needed to satisfy domestic demand (to the exclusion of foreign demand).

true in Spain. When the Spanish government imposes comparatively low prices, it wants to favour wide access to medicines by Spanish citizens; to reach its goal, the government sacrifices other legitimate objectives such as R&D promotion. Evidently, the Spanish goal is not to encourage broad access to medicines by patients in the United Kingdom. Even less so, is it to grant parallel importers a windfall.

When prices are essentially controlled by democratic governments (based on valid laws expressing the final compromise made between diverging values), then the logic of introducing competition through parallel trade is debatable. In such situation, this competition is only upsetting the balance deliberately crafted by these laws.[51]

Of course, one can also advance a more cynical view and argue that governments favour parallel imports to relieve their health care budgets, instead of taking the direct and less popular route of imposing direct price cuts to the pharmaceutical industry.[52] As the Commission put it: they are trying "to achieve the best of two worlds".[53] Additionally, the threat of parallel imports may cause pharmaceutical companies, in their negotiations with governments, to accept prices exhibiting smaller national disparities.[54] It is well known that pharmaceutical companies will go to great length to discourage parallel imports: accepting lower prices to dissuade parallel imports may be one way to achieve this goal. The CFI judgment makes such a sacrifice largely unnecessary.

[51] Nonetheless, it is not for private companies to take the matter into their hands and circumvent parallel imports by implementing anticompetitive schemes. As the Commission stated: "it is not for a private company to safeguard governmental policy choices by restricting competition." [Recital 179].

The change should come from the Member States themselves. For instance, one could envision the prices of pharmaceuticals to be harmonised at the Community level. Prices could still be different across Member States to take into account different ability to pay. Once harmonisation would be achieved, then parallel imports of pharmaceuticals could be legally banned.

[52] Indeed, as the Commission pointed out (recitals 133 and 134), the United Kingdom has adopted a dubious position, whereby it accepts comparatively high domestic drug prices, but still encourages parallel imports of foreign low-priced drugs.

[53] Recital 134.

[54] The CAST study also attempts to calculate what it refers to as indirect savings of parallel imports, that is either reductions of drug prices (applied by the manufacturer in the national market) or reduction in the rate of increase of these prices.