Dominant Companies May Not Refuse Ordinary Orders With The Aim Of Restricting Parallel Trade - ECJ Judgment in *GlaxoSmithKline AEVE*

Brussels
October 1, 2008

On September 16, 2008, the European Court of Justice ("ECJ") rendered its much-awaited judgment in Joined Cases C-468/06 to C-478/06 *Sot. Lélos Kai Sia EE (and Others) v GlaxoSmithKline AEVE* clarifying the application of Article 82 EC to a dominant company's reduction of customary supplies to wholesalers aimed at restricting parallel trade.

The proceedings were unusual in that they involved the opinions of two Advocates General, who, four years apart, took opposite views on whether the highly regulated nature of the pharmaceutical sector justifies supply limitations by dominant companies aimed at restricting parallel trade. The ECJ ruled that the degree of State regulation of the pharmaceutical sector does not preclude the application of Article 82 EC in such circumstances. However, the ECJ tempered this finding by recognizing that dominant pharmaceutical companies are entitled to protect their commercial interests in "*a reasonable and proportionate way*" against orders "*of significant quantities of products that are essentially destined for parallel export*". More specifically, the judgment holds that:

- A dominant pharmaceutical company cannot refuse to satisfy ordinary orders of existing wholesalers "*for the sole reason*" that these wholesalers export part of their purchases to other Member States.

- A dominant pharmaceutical company may refuse to meet an order that is "*out of the ordinary*" even if the refusal is openly designed to restrict parallel trade.

- An order is out of the ordinary if it is "*out of all proportion*" to the volume previously ordered "*by the same wholesalers to meet the needs of the [local] market*". Two factors are therefore relevant for assessing whether orders are "out of the ordinary": (i) "*the size of those orders in relation to the requirements of the [local] market*"; and (ii) "*the size of those orders in*

relation to the previous business relations" of the parties. In case of a dispute, the matter must be resolved by the national courts.

The judgment only addresses the circumstances in which a refusal to supply existing customers "*for the sole reason*" that they engage in parallel trade amounts to an abuse. The judgment's finding that even in these circumstances a refusal may potentially be justified implies *a fortiori* that no violation of EC competition law should arise if:

- A dominant company refuses to supply an existing customer with quantities in excess of those ordinarily purchased by that customer.

- A dominant company refuses to supply a new customer.

Finally, this also suggests that no violation of EC competition law should arise if a dominant company refuses or reduces supplies to an existing customer for reasons other than to restrict parallel trade that are objective and substantiated, such as, *e.g.*, preventing disruptions of supply chains or responding to declining local demand.[1]

I. BACKGROUND

Having ascertained that Greek wholesalers were selling surplus amounts of certain pharmaceuticals in Germany and in the United Kingdom, GlaxoSmithKline ("GSK") sought, through its Greek subsidiary GSK AEVE, to restrict exports by first suspending supplies of the relevant products to these wholesalers, and then resuming supplies, but only in quantities sufficient to satisfy domestic demand. Greek wholesalers affected by these decisions, as well as some Greek associations of wholesalers and pharmacists, started proceedings before the Greek Competition Commission and civil jurisdictions, alleging that GSK AEVE's sales policy constituted an abuse of a dominant position under EC and Greek competition law.

The Greek Competition Commission referred to the ECJ a number of questions concerning the interpretation of Article 82 EC. In these proceedings, Advocate General Jacobs in 2004 took the view that an undertaking's reduction of supplies aimed at restricting parallel trade could be objectively justified in light of the highly regulated

[1] This is however without prejudice to the potential application of stricter national competition laws, including provisions concerning economically dependent undertakings. See recital 8 and Article 3(2) of Council Regulation No 1/2003.

nature of the pharmaceutical sector. For procedural reasons, the ECJ however declined to address the Greek Competition Commission's questions.[2]

Proceedings in the Greek civil courts continued in parallel. After the Athens Court of First Instance found the wholesalers' allegations unfounded, an appeal was brought before the Athens Court of Appeals. The Court decided to ask the ECJ the same questions concerning the interpretation of Article 82 EC that the Greek Competition Commission had unsuccessfully raised. On April 1, 2008, Advocate General Ruiz-Jarabo Colomer advised the Court to qualify the limitation of supplies as abusive, contrary to Advocate General Jacobs's opinion four years before.

II. THE JUDGMENT

The ECJ cited its judgments in *Commercial Solvents* and *United Brands*[3] for the principle that the refusal by a dominant company to meet the orders of an existing customer is abusive where, without any objective justification, that conduct is liable to eliminate a trading party as a competitor (para. 34).

1. Restrictions Of Parallel Trade in Pharmaceuticals Restrict Competition

Addressing the issue of whether a refusal to meet orders aimed at restricting parallel trade can be considered anti-competitive, the ECJ found that:

- There may be an effect on competition in the Member State where the refusal takes place ("*if the refusal impedes the activities of those wholesalers in that first Member State*") (para. 35);

- There may also be an effect in the destination market if the refusal "*leads to the elimination of effective competition from [the wholesalers] in the distribution of the products*" in these destination markets (para. 35);

- The curbing of parallel trade has been found anti-competitive in other sectors (*i.e.*, motor vehicles) (para. 37);

[2] Case C-53/03 *Syfait and Others* ("*Syfait*") [2005] ECR 4609. The ECJ found that it lacked jurisdiction because the Greek Competition Commission did not meet the prerequisite that it be a court or tribunal.

[3] Joined Cases 6/73 and 7/73 *Istituto Chemioterapico Italiano Spa and Commercial Solvents Corp v Commission* [1974] ECR 223 and Case 27/76 *United Brands and United Brands Continentaal v Commission* [1978] ECR 207.

- In the field of Article 81, the Court has on several occasions held as anti-competitive agreements aimed as partitioning national markets (para. 65).

The ECJ found that there are no grounds for treating restrictions to parallel trade in pharmaceuticals differently. In particular, the ECJ rejects GSK's argument that parallel trade in pharmaceuticals "*in any event brings only few financial benefits to the ultimate consumers*". To the contrary, in the ECJ's view, "*parallel exports…open up in principle an alternative source of supply [in the destination markets], which necessarily brings some benefits to the final consumer of these products*" (para. 53). According to the ECJ, these "benefits to the final consumer" result from (i) the general price pressure that parallel imports exert in the destination market; and the (ii) the additional choice that parallel imports represent for entities that purchase through public procurement procedures (para. 56).

2. State Regulation of the Pharmaceuticals Sector Does Not Objectively Justify Conduct Otherwise Deemed Abusive

GSK AEVE argued that State intervention in the pharmaceuticals sector "*prevent[ed] the manufacturers of medicines from developing their activities in normal competitive conditions*" (para. 41). The ECJ rejects this argument on the following grounds:

- State regulation leaves some room to the law of supply and demand (para. 62);

- Manufacturers participate in price negotiations with the authorities (para. 63).

The ECJ thus holds, first, that restrictions to parallel trade of pharmaceuticals are liable to impede competition; second, that the fact that national price regulations may generate incentives for parallel trade in pharmaceuticals does not as a general matter justify measures to curb parallel trade.

3. Rejecting Orders That Are "Out Of The Ordinary" May Be Legitimate

The ECJ nevertheless recognizes that State intervention "*is one of the factors liable to create opportunities for parallel trade*", as a result of which a dominant company should be allowed "*to take steps that are reasonable and in proportion to the need to protect its own commercial interests*" (paras. 67-69). In particular, it may be legitimate to refuse to supply wholesalers involved in parallel exports where their orders are "*out of the ordinary*", by reference to (i) "*the previous business relations between the*

pharmaceutical company and the wholesalers concerned"; and (ii) "*the requirements of the [national market] concerned*" (paras. 70 and 73).

The ECJ indicates that orders could be considered "out of the ordinary" if they involve "*quantities which are out of all proportion to those previously sold by the same wholesalers to meet the needs of the market in [the Member State concerned]*" (para. 76).[4] It is for national courts to decide on a case-by-case basis whether specific orders are "ordinary" (and must be satisfied by an undertaking in a dominant position) or "out of the ordinary" (and can be rejected by an undertaking in a dominant position).

4. Open Questions

Although the judgment provides important guidance with regard to refusal to supply cases in the pharmaceutical industry, it leaves open a number of questions that may be relevant for determining the extent of supply obligations of dominant companies.

- First, the judgment leaves doubt as to what degree of impact on inter- and/or intra-brand competition is required to qualify a refusal to supply as being abusive. At para. 34, the ECJ appears to cite *United Brands* and *Commercial Solvents* for the proposition that the elimination of a single trading party may be sufficient to justify a duty to supply. At para. 35, however, it refers to the "*elimination of effective competition*" from parallel traders, suggesting that a broader effect in the market is required. Indeed, in *Commercial Solvents*, the elimination of the dominant company's trading party in practice resulted in the elimination of all effective competition in the downstream market. In the present case, the ECJ appears to have assumed that a restriction of parallel trade would result in the elimination of all effective competition in the country of import, since the judgment takes the view that, until the expiration of a product's patent protection, parallel trade is "*the only form of competition which can be envisaged*" (para. 64). This is, however, not always the case. It is well established that IP rights do not necessarily shield a company from competition.[5] In the case of patented pharmaceuticals, competition can arise from products incorporating different active ingredients that are indicated for the same

[4] The Greek and French versions of the judgment use a slightly different wording, which is closer to "out of proportion" than "out of all proportion"; our reading of the Greek and French versions would suggest a lower standard for the assessment of the "out of the ordinary" character of an order.

[5] Case 40/70 *Sirena* [1979] ECR 3169. See also the recent judgment of the U.S. Supreme Court in Illinois Tool Works Inc. v. Independent Ink, Inc., 126 S. Ct. 1281 (2006).

treatment.[6] It is not clear from the judgment whether in such circumstances a restriction of parallel trade – or an elimination of effective intra-brand competition – would be sufficient to treat a refusal to supply as an abuse, given that wholesalers may have substitutes available and the refusal would thus not eliminate them as (inter-brand) competitors.

- Second, the judgment does not address the terms under which a dominant company is supposed to provide the relevant supplies. In particular, it does not indicate whether a company must price supplies intended for export at the same price as local sales that aresubject to national price regulation. The issue of destination-based pricing in the pharmaceutical industry is currently on appeal before the ECJ in *GlaxoSmithKline (Spain)*. Although that case concerns the application of Article 81 EC, its outcome may also shed some light on whether a dominant company is required to apply regulated prices to supplies that are not intended for local consumption.

- Third, the ECJ declined to address the issue of the "*causal link*" between the losses sustained by pharmaceutical companies as a result of parallel trade and their ability to invest in research and development.[7] Interestingly, while the ECJ endorses the wholesalers' argument that parallel trade in pharmaceuticals may generate social security savings, it left the question about the relationship between parallel trade and R&D capability open (paras. 47 and 70).

- Fourth, the judgment does not discuss the determination of dominance in the pharmaceuticals sector, which is left for national courts or competition authorities to decide on a case-by-case basis. Some national authorities have in the past suggested that pharmaceutical products are "must haves" for wholesalers and that therefore all pharmaceutical products should be considered as conferring "dominance" in supplier-wholesaler relations. Such an approach, however, does not find support in Commission case law and does not appear to have been applied by the Greek authorities in the present case, since only one out of the three products at issue was treated as dominant (para. 24).

[6] For this reason, the Commission typically takes the group of medicines that are included in the same WHO ATC 3 level as the starting point for market definition in the pharmaceutical sector.

[7] This was considered to be a relevant factor in the opinion of Advocate General Jacobs in Syfait.

III. STATUS OF EC COMPETITION CASE-LAW CONCERNING PARALLEL TRADE IN PHARMACEUTICALS

The *GSK AEVE* judgment is the latest in a series of judgments concerning measures taken by pharmaceutical companies faced with parallel trade in their products. Whereas *GSK AEVE* addresses the relationships between a dominant pharmaceutical company and its wholesalers under Article 82 EC, other cases have focused on the application of Article 81 EC to relationships between non-dominant pharmaceutical companies and their wholesalers.

In *Bayer (Adalat)* (2000), the Court of First Instance ("CFI") found that a non-dominant pharmaceutical company's unilateral limitation of supplies did not constitute an agreement, and was therefore not prohibited under Article 81 EC.[8]

In *GlaxoSmithKline (Spain)* (2006), the CFI annulled a Commission decision finding that GSK violated Article 81 EC by operating a dual pricing system under which it applied the price set by Spanish regulation to supplies intended for the Spanish market, while pricing supplies destined for exportation at a higher level.[9] Although the CFI confirmed that GSK's dual pricing system infringed Article 81(1) EC, the CFI found that the Commission had not properly examined GSK's arguments for exemption under Article 81(3) EC. The CFI in particular criticized the Commission for failing to properly examine arguments concerning the impact of parallel trade on research and development, an issue that the ECJ expressly left open in *GSK AEVE*. The CFI ruling in *GlaxoSmithKline (Spain)* was appealed and (as noted above) is now pending before the ECJ.[10]

IV. CONCLUSION

Although the ECJ adopts a somewhat nuanced position on the obligation of dominant companies to supply parallel traders, the judgment may signal an end to the "regulatory holiday" enjoyed by pharmaceutical companies over the last few years with regard to practices that are designed to limit parallel trade. Parallel traders are likely to test the limits of the duty to supply established by this judgment, and the Commission, following a period of "benign neglect", may well show a renewed interest in this area. In a press release welcoming the judgment, the Commission indicated that it understood the judgment to confirm "*the Commission's antitrust policy, namely that the protection of parallel trade in the pharmaceutical sector is within the scope of EC competition law*".

[8] Case T-41/96. The CFI's ruling was upheld by the ECJ in 2004.

[9] Case T-168/01.

[10] Cases C-501/P, C-519/06 and C-515/06.

Since the judgment leaves a number of open questions, it is not excluded that further litigation will arise in this area, including on issues such as (i) the precise delineation between ordinary and extraordinary orders; (ii) the relevance of inter-brand competition from alternative products; (iii) the appropriate terms of supply; (iv) the relevance of any impact on R&D costs; and (v) the definition of dominance in the pharmaceutical industry.

* * *

For additional information, please do not hesitate to contact Stephan Barthelmess, Brian Byrne, Christopher Cook, Maurits Dolmans, Francisco-Enrique González-Diaz, Nicholas Levy, James Modrall, Till Müller-Ibold, Robbert Snelders, Romano Subiotto, John Temple Lang, Dirk Vandermeersch, or Antoine Winckler of the Firm's Brussels office (+32 2 287 2000); Mario Siragusa or Giuseppe Scassellati-Sforzolini in Rome (+39 06 69 52 21); Dirk Schroeder or Romina Polley in Cologne (+49 221 800 400); François Brunet in Paris (+33 1 40 74 68 00); or Shaun Goodman in London (+44 20 7614 2200).

CLEARY GOTTLIEB STEEN & HAMILTON LLP

BRUSSELS
Rue de la Loi 57
1040 Brussels, Belgium
32 2 287 2000
32 2 231 1661 Fax

NEW YORK
One Liberty Plaza
New York, NY 10006-1470
1 212 225 2000
1 212 225 3999 Fax

WASHINGTON
2000 Pennsylvania Avenue, NW
Washington, DC 20006-1801
1 202 974 1500
1 202 974 1999 Fax

PARIS
12, rue de Tilsitt
75008 Paris, France
33 1 40 74 68 00
33 1 40 74 68 88 Fax

LONDON
City Place House
55 Basinghall Street
London EC2V 5EH, England
44 20 7614 2200
44 20 7600 1698 Fax

MOSCOW
Cleary Gottlieb Steen & Hamilton LLP
CGS&H Limited Liability Company
Paveletskaya Square 2/3
Moscow, Russia 115054
7 495 660 8500
7 495 660 8505 Fax

FRANKFURT
Main Tower
Neue Mainzer Strasse 52
60311 Frankfurt am Main, Germany
49 69 97103 0
49 69 97103 199 Fax

COLOGNE
Theodor-Heuss-Ring 9
50668 Cologne, Germany
49 221 80040 0
49 221 80040 199 Fax

ROME
Piazza di Spagna 15
00187 Rome, Italy
39 06 69 52 21
39 06 69 20 06 65 Fax

MILAN
Via San Paolo 7
20121 Milan, Italy
39 02 72 60 81
39 02 86 98 44 40 Fax

HONG KONG
Bank of China Tower
One Garden Road
Hong Kong
852 2521 4122
852 2845 9026 Fax

BEIJING
Twin Towers – West
12 B Jianguomen Wai Da Jie
Chaoyang District
Beijing 100022, China
86 10 5920 1000
86 10 5879 3902 Fax