

NEW YORK WASHINGTON PARIS BRUSSELS LONDON MOSCOW FRANKFURT COLOGNE ROME MILAN HONG KONG BEIJING

COMPETITION LAW UPDATE

Advocate General Suggests EC Competition Law Prevents A Dominant Undertaking From Reducing Customary Supplies In Order To Restrict Parallel Trade

Brussels May 20, 2008

On April 1, Advocate General Ruiz-Jarabo Colomer, rendered his opinion in Joined Cases C-468/06 to C-478/06 *Sot. Lélos Kai Sia EE (and Others) v GlaxoSmithKline AEVE* in the context of a preliminary reference to the European Court of Justice requesting clarification on the application of Article 82 EC to a dominant undertaking's reduction in customary sales to Greek wholesalers aimed at restricting parallel trade.

Advocate General Ruiz-Jarabo Colomer advised the Court to qualify the reduction as abusive, contrary to Advocate General Jacobs's opinion in Case C-53/03 *Syfait and Others* ("*Syfait*"),¹ who advised that the same conduct could be objectively justified in light of the highly regulated nature of the pharmaceutical sector.

The scope of this opinion is limited to a reduction in customary sales to wholesalers aimed at restricting parallel trade. It does not concern the question whether a dominant manufacturer must (i) sell any quantities ordered by wholesalers, even if they exceed those customarily purchased by those wholesalers;² (ii) refrain from decreasing the quantities sold to wholesalers, even if such reduction is justified on objective commercial grounds, including, for example, forecast decreased domestic demand supported by objective and reliable evidence; or (iii) supply new customers.

I. <u>BACKGROUND</u>

Having ascertained that Greek wholesalers were selling surplus amounts in Germany and in the United Kingdom, GlaxoSmithKline ("GSK"), through its subsidiary,

² The wholesalers emphasized in their submissions that the national court's question should not be interpreted as asking whether GlaxoSmithKline must supply *any* quantities ordered, even if they exceed customary orders (paras. 31-33).

¹ 2005 ECR 4609. The Court did not rule in this case because of lack of jurisdiction resulting from the fact that the entity then making the preliminary reference did not satisfy the prerequisite that it be a national court or tribunal.

[©] Cleary Gottlieb Steen & Hamilton LLP, 2008. All rights reserved.

This memorandum was prepared as a service to clients and other friends of Cleary Gottlieb to report on recent developments that may be of interest to them. The information in it is therefore general, and should not be considered or relied on as legal advice.

GSK AEVE, sought to restrict exports by first suspending supplies of the relevant products to the wholesalers, and then resuming supplies, but only in quantities sufficient to satisfy domestic demand.

A. <u>THE OPINION</u>

1. <u>The Rejection of a Per Se Approach</u>

Citing the Court's judgments in *Commercial Solvents* and in *United Brands*,³ the Advocate General considered that a dominant company refusing to supply customers in order to reserve the export market for itself abuses in principle its dominant position. Despite GSK's clear intention to restrict parallel trade, the Advocate General nevertheless advised the Court to refrain from holding that this behaviour should qualify as a *per se* abuse.⁴ The Advocate General observed that the Court has to date identified three *per se* abuses, namely the conclusion of exclusive purchasing contracts, the granting of loyalty rebates, and predatory pricing, but that, even then, the Court's more recent case law, for example with respect to rebates, allows for the possible justification of such conduct.⁵ The Advocate General referred to a number of additional factors, including the need to assess behaviour in light of the circumstances of each case, and the right of defence, to conclude that a *per se* approach would be inappropriate.

2. <u>Objective Justification</u>

The rejection of a *per se* approach led the Advocate General to consider the potential objective justifications for the conduct under scrutiny. He referred to three possible categories of justification, namely (i) market regulation, (ii) the protection of legitimate business interests; and (iii) the creation of efficiencies benefiting consumers. The Advocate General found that GSK had adduced insufficient evidence to justify its conduct.

a. <u>The nature of the relevant market</u>

In rejecting GSK's arguments that its conduct was justified in light of the characteristics of the pharmaceutical sector, Advocate General Ruiz-Jarabo Colomer pointed to the Court's holding in *Merck v. Primecrown* that distortions of competition

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 Brand v Commission [1978] ECR 207.

⁴ Advocate General Jacobs took a similar position in *Syfait*.

⁵ Case C-95/04P British Airways v. Commission [2007] ECR I-2331.

flowing from price and reimbursement regulation cannot restrict the fundamental objective of ensuring the free movement of goods between Member States,⁶ adding that manufacturers in any event benefit from a margin of negotiation with national authorities concerning price and reimbursement levels.

Concerning GSK's second argument relating to the statutory obligation to maintain a sufficient stock of product to cover domestic patient needs, the Advocate General observed that wholesalers are subject to the same obligation and that domestic patient needs can normally be reliably forecast. As a result, he failed to see a nexus between this statutory obligation and any reduction in quantities sold to wholesalers in order to restrict parallel trade.

b. <u>The legitimate business interests defence</u>

The Advocate General then considered whether GSK's behaviour could be justified by the need to protect its legitimate business interests, namely, as sustained by GSK, the need to preserve revenue to finance R&D activities, given the 12 to 13-year delay between obtaining a patent for an active ingredient and the commercialization of the corresponding product. The Advocate General was not persuaded that any nexus exists between the need to restrict parallel trade and the need to preserve revenue to finance R&D activities. He suggested that GSK could also have mitigated its losses by not establishing commercial relations with wholesalers in Greece when it began selling there, and that GSK's conduct appeared designed more to wrest back profits from the wholesalers using R&D as a pretext. The Advocate General's opinion on this point is nevertheless somewhat unclear.

c. <u>The economic efficiency defence</u>

The third possible objective justification, namely the so-called "efficiency defence", relates to the conduct's efficiencies benefiting consumers. Advocate General Ruiz-Jarabo Colomer took the view that GSK had failed to demonstrate any efficiencies because it emphasized only the negative effects of parallel trade, without mentioning any positive effect flowing from its limitation of supplies to wholesalers. However, he explored this point only very briefly.

⁶ In Joined Cases C-267/95 and C-268/95 Merck and Beecham [1996] ECR I-6285 para.47 the Court stated that "[a]s to that, although the imposition of price controls is indeed a factor which may, in certain conditions, distort competition between Member States, that circumstance cannot justify a derogation from the principle of free movement of goods".

B. <u>CONSEQUENCES</u>

During a number of years, pharmaceutical companies felt that the highly regulated nature of the pharmaceutical sector meant that EC competition law should not prohibit restrictions on parallel trade: differences in national price and reimbursement levels and other national state regulations should not be corrected by applying EC competition law without restriction to practices designed to protect legitimate business interests.

Advocate General Jacobs's opinion in *Syfait* confirmed this view, finding that GSK's conduct could be objectively justified as a reasonable and proportionate measure in defence of its commercial interests on the grounds that "[s]uch a restriction does not protect price disparities which are of the undertaking's own making, nor does it directly impede trade, which is rather blocked by public service obligations imposed by the Member States. To require the undertaking to supply all export orders placed with it would in many cases impose a disproportionate burden given the moral and legal obligations on it to maintain supplies in all Member States. Given the specific economic characteristics of the pharmaceutical industry, a requirement to supply would not necessarily promote either free movement or competition, and might harm the incentive for pharmaceutical undertakings to innovate. Moreover, it cannot be assumed that parallel trade would in fact benefit either the ultimate consumers of pharmaceutical products'.

The opinion of Advocate General Ruiz-Jarabo Colomer brings the clock back to 1996, when the Court held in *Merck v. Primecrown* that the EC Treaty's rules apply to the pharmaceuticals sector, regardless of how significantly it is regulated. In short, the Member States are responsible for addressing any unfair or illogical consequences flowing from the different national pharmaceutical regulations. The Court should not be expected to do so by suspending the full application of EC competition law

Secondly, the facts of the case are strictly limited to a reduction of customary sales designed to stop parallel trade. This case does not concern the question whether a dominant manufacturer must sell any quantities ordered by wholesalers, even if they exceed those customarily purchased by those wholesalers. Sufficient principles exist under EC competition law to reject any such obligation. As a result, a dominant manufacturer may continue to set a maximum amount it is prepared to sell to any wholesaler during any reference period. In addition, the opinion would not prevent a dominant manufacturer from decreasing the quantities sold to any wholesaler, if such reduction is justified on objective commercial grounds, including, for example, forecast decreased domestic demand supported by objective and reliable evidence. Finally, the opinion clearly does not require dominant undertakings to begin selling to new customers.

II. <u>CONCLUSION</u>

The opinion's scope is limited, but still a reminder that the authorities' "benign neglect" during the last few years of practices restricting parallel trade may not be grounded in the case law of the Court. Furthermore, the opinion may well signal an end to the regulatory holiday enjoyed by companies concerning any of their practices designed to have or having the effect of restricting parallel trade. The opinion is not binding on the Court. The final judgment is expected before the end of the year.

* * * *

For additional information, please do not hesitate to contact Stephan Barthelmess, Maurits Dolmans, Francisco-Enrique González-Díaz, Nicholas Levy, James Modrall, Till Müller-Ibold, Robbert Snelders, Romano Subiotto, Dirk Vandermeersch or Antoine Winckler of the Firm's Brussels office (+32 2 287 2000); Mario Siragusa and Giuseppe Scassellati-Sforzolini in Rome (+39 06 69 52 21), Dirk Schroeder and 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

Office Locations

Cleary Gottlieb

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

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

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