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CLIENT ADVISORY

QUOTA SCHEMES—THE NEW RULES FOR PHARMACEUTICAL COMPANIES

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THE EUROPEAN COURT RULES THAT USE OF QUOTA SCHEMES BY DOMINANT PHARMACEUTICAL COMPANIES TO LIMIT PARALLEL EXPORTS MAY CONSTITUTE AN ABUSE OF DOMINANCE.

The European Court of Justice (ECJ) has ruled that a pharmaceutical undertaking that is dominant in a national market for medicinal products and which, in order to put a stop to parallel exports, refuses to meet *ordinary* orders from wholesalers, abuses its dominant position. However, such companies remain free to refuse to supply wholesalers "with significant quantities of products that are essentially destined for parallel export."[1] This was its judgment, delivered on 16 September 2008 in Joined Cases C-468/06 to C-478/06, C-*Sot. Lélos Kai Sia EE (and Others)* v. *GlaxoSmithKline AEVE* (Greek GSK case). The ruling leaves considerable room for manoeuvre to dominant companies that should enable them to maintain workable quota schemes.

THE RISKS FACED BY DOMINANT PHARMACEUTICAL COMPANIES

The use of quota schemes by pharmaceutical companies is commonplace in those EU countries which, due to relatively low drugs prices, are normally the source of parallel exports to other Member States. Under such schemes, a manufacturer or supplier will limit supplies to each wholesaler or other intermediary to the manufacturer's or supplier's estimation of the wholesaler's domestic needs. Quota schemes, like other supply chain innovations (such as the use of exclusive wholesalers, direct-to-pharmacy, or direct-to-patient distribution) are intended to reduce the leakage of products from the quota country through parallel trade to other EU countries.

The ECJ confirmed the legality of quota schemes for non-dominant companies in the *Bayer* case in 2004.[2] The ECJ supported the finding of the Court of First Instance (CFI) that, since (a) no agreement existed between Bayer and the wholesalers, and (b) Bayer was not dominant in the relevant drug, neither Article 81 nor Article 82 applied to its conduct. Following the *Bayer* case, the adoption of lawful quota schemes has been relatively easy where the manufacturer or supplier

1 Paragraph 71 of the ECJ's judgment.
2 C-2/01 P, *Bundesverband der Arzneimittel-Importeure* v. *Bayer and Commission*.

is not dominant in the quota products. However, until the ECJ's judgment in the Greek GSK case, pharmaceutical companies continued to face uncertainty as to the risks of establishing quota schemes for dominant products—because they were clearly outside the *Bayer* safety net.

The opinion of Advocate General Ruiz-Jarabo, delivered only five months before the ECJ's judgment, urged the ECJ to rule against dominant pharmaceutical companies, a development that caused great uncertainty in the sector. That uncertainty has now been resolved to an extent by the ECJ, but the rules laid down by it are not as bright-line as anticipated.

THE FACTS BEHIND THE ECJ'S JUDGMENT

For a number of years, GlaxoSmithKline's Greek subsidiary distributed its drugs in Greece through wholesalers, including its drug *Lamictal* for epilepsy, in which it was found to be dominant. Wholesalers resold these drugs not only in Greece but also through parallel trade into Germany and the United Kingdom. In order to reduce or remove the loss of revenue caused by parallel trade, GSK briefly switched from using wholesalers to the use of a single logistics service provider to supply GSK products to the community and hospital sectors in Greece. As a result of this change in its supply chain, the wholesalers complained to the Greek competition authority that GSK's refusal to continue supplying them amounted to an abuse of its dominant position in *Lamictal*. Such a refusal lasted only a few weeks, after which GSK resumed supply to the wholesalers, but in amounts limited to their domestic needs plus a safety margin.

The Greek competition authority requested the ECJ to interpret the underlying EU law on abuse of dominance—Article 82 of the EC Treaty. This reference to the ECJ resulted in its judgment in the *Syfait* case,[3] delivered in May 2005. In that case, Advocate General Jacobs delivered an opinion to the ECJ in which he strongly supported the right of dominant pharmaceutical companies to select a distribution system designed to reduce parallel trade. According to this opinion, such a scheme would not be an abuse of dominance under Article 82. The ECJ was unable to decide the issue, however, after finding that it had no jurisdiction to rule on the matter because the Greek competition authority had no right under EU law to refer the matter to it for a ruling.

As a means of enabling the ECJ to rule in substance, the Greek wholesalers took their case to the Greek civil courts, claiming that GSK's brief refusal to supply them, and its refusal to meet their orders in full, was an abuse of GSK's dominant position in *Lamictal*. The matter was then referred again to the ECJ for an interpretive ruling, but this time by the Athens Appeal Court—which clearly did have the right to do so under EU law.

THE ADVOCATE GENERAL URGED THE ECJ TO FIND AGAINST GSK

On the inauspicious date of 1 April this year, Advocate General Ruiz-Jarabo presented his non-binding opinion on the questions referred to the ECJ by the Athens Appeal Court. His analysis of the national pharmaceutical markets in the EU departed radically from that of Advocate General Jacobs in the prior *Syfait* case. This was particularly surprising because the CFI had, in its judgment in the Spanish dual pricing case,[4] delivered in September 2006, already adopted an analysis broadly the same as Advocate General Jacobs' opinion. The CFI ruled that restrictions placed on pharmaceutical wholesalers that were designed to reduce parallel trade in drugs did not have an anti-competitive object under the Treaty rules on anti-competitive agreements (Article 81).

In contrast to this background, Advocate General Ruiz-Jarabo recommended the ECJ to rule that it is an abuse of dominance, contrary to Article 82 of the Treaty, for a dominant pharmaceutical undertaking to refuse to meet wholesalers' orders in full, where such refusal is made with a view to reducing the harm caused by parallel trade. Such an abuse might nevertheless be lawful, according to the Advocate General, where the pharmaceutical undertaking proves that the refusal is objectively justified—by showing that the regulation of the market compels it to behave in that manner in order to protect its legitimate business interests. However, and critically, no such proof may be based on the pricing system for drugs, the duty to supply domestic needs or the impact of parallel

3 Case C-53/03, *Syfait and Others* [2005] ECR 4609.

4 Case T-168/01, *GlaxoSmithKline Services* v. *Commission*.

trade on the incentive to innovate—the very features that were central to the analysis of Advocate General Jacobs in *Syfait*, and of the Court of First Instance in the Spanish dual pricing case.

THE ECJ RULES ON DOMINANT PHARMACEUTICAL COMPANIES

In the Greek GSK case, the ECJ relied on case law from the 1970s in holding that a dominant company may not refuse to supply a long-standing customer who abides by regular commercial practice and makes orders that are not out of the ordinary. However, a dominant company may take reasonable steps to defend its commercial interests in the face of unusual orders.

The ECJ did not consider that the particular features of the pharmaceutical sector presented any reason to depart from these principles. It acknowledged that final consumers in destination countries do not benefit from price equalisation with source countries, since parallel traders take the profit from the trade. However, the ECJ found that "parallel trade is liable to exert pressure on prices and, consequently, to create financial benefits not only for the social health insurance funds, but equally for the patients concerned, for whom the proportion of the price of medicines for which they are responsible will be lower."[5]

The ECJ also rejected the argument that the intervention by public authorities in the setting of reimbursement prices takes the issue out of the realm of competition law because pharmaceutical companies take part in price negotiations, and may thereby influence reimbursement prices. It avoided any assessment of the impact of parallel trade on R&D incentives for innovator pharmaceutical companies.

In conclusion the ECJ held that "there can be no escape from the prohibition laid down in Article 82" for an undertaking that seeks to avoid all parallel trade.[6] Having said that, the ECJ then threw a lifeline to dominant companies—by saying that (a) it was impossible to ignore the impact of State intervention on the incentives for parallel trade, and (b) Article 82 cannot mean that the only solution left to dominant pharmaceutical companies is to refrain from marketing its products in low-priced Member States.

As a result, it remains open to dominant pharmaceutical companies to take reasonable and proportionate steps to protect their own commercial interests. In practice, this means that dominant companies may refuse to honour orders that are "out of the ordinary".[7] The essential guidance of the ECJ is contained in paragraph 71 of the judgment:

> [A]lthough a pharmaceuticals company in a dominant position […] cannot be allowed to cease to honour the ordinary orders of an existing customer for the sole reason that that customer, in addition to supplying the market in [the source] Member State, exports part of the quantities ordered to [destination] Member States[…], it is none the less permissible for that company to counter in a reasonable and proportionate way the threat to its own commercial interests potentially posed by the activities of an undertaking which wishes to be supplied in the first Member State with significant quantities of products that are essentially destined for parallel export.

Ordinary orders of long-standing wholesalers must therefore be honoured. Others may be refused. Whether or not an order is "ordinary" will be assessed in the light of *both* the previous dealings between the dominant supplier and the wholesaler *and* the size of the orders in relation to the domestic requirements of the Member State concerned. In other words, if a wholesaler orders in quantities that are out of proportion to those previously sold by the same wholsealer *to meet the needs of the market in that Member State*, the dominant supplier may refuse such excess (but may not reject the order in full).

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Following the judgment of the ECJ in the Greek GSK case, it is now possible to summarise the rules for both non-dominant and dominant pharmaceutical companies that wish to introduce or maintain quota schemes.

5 Paragraph 56 of the ECJ's judgment.
6 Paragraph 66 of the ECJ's judgment.
7 Paragraph 70 of the ECJ's judgment.

All Pharmaceutical Manufacturers or Suppliers

All pharmaceutical manufacturers or suppliers—whether dominant or not in the quota products—should carefully observe the principles established in the *Bayer* case, and developed in practice thereafter.[8]

- ensure that internal documents properly reflect the true purpose of the scheme (i.e., the need to restrict the volume of products to that sufficient to satisfy home demand, without any threat to penalise wholesalers for exporting);
- do not use any monitoring undertaken (e.g., for pharmacovigilance purposes)—to adjust the quota of exporting wholesalers;
- calculate quotas carefully and objectively, based on the estimated domestic market share of each wholesaler, using the most accurate and recent data; apply the quotas ex ante and apply them systematically to avoid discriminating between wholesalers who are thought to be exporters and those thought not to be;
- impose quotas unilaterally and not by agreement with wholesalers; this is important in order to avoid an agreement arising under Article 81;
- put standard operating procedures in place in order to prevent customer-facing staff from establishing oral agreements with wholesalers in relation to their quota;
- include a reasonable safety margin in the quotas in addition to the estimated current domestic needs of each wholesaler; this is important to correct for any under-estimation that might result in product shortages at retail, and to provide wholesalers with the ability to compete against each other for market share; where the total domestic demand is rising, or where the market shares of wholesalers are more volatile, the safety margin should be correspondingly larger;
- review the quotas at least annually, and preferably more frequently, in order to ensure that they remain accurate and appropriate; review any complaint made by a wholesaler that its quota is insufficient, but in doing so, avoid the danger of "agreeing" a new quota;
- because quota schemes will not entirely eliminate parallel exports, establish emergency supply systems to enable patients to receive medicines in a timely manner where shortfalls arise; this may be done in a number of ways (e.g., by direct-to-pharmacy supply or through providing consignment stock to one or more wholesalers, who are appointed as logistics service providers for the express purpose of emergency supply).

Dominant Pharmaceutical Manufacturers or Suppliers

Dominant companies should observe all of the above points, and in addition:

- do not refuse to supply existing wholesalers as a means of removing the possibility for parallel export from the relevant national market;
- do not refuse to supply a wholesaler with an order that is consistent with its previous orders and is necessary to meet its domestic sales;
- where a wholesaler requests an order that is disproportionate to its prior orders and is not required to meet its domestic sales, you may refuse to meet it in full, but do not refuse to meet the "ordinary" portion of the order;

WHEN IS A PHARMACEUTICAL COMPANY DOMINANT?

In determining whether a pharmaceutical company is dominant, the European Commission starts by considering the market share of the company in the relevant market. In selecting a market for the drug in question, it will first consider a putative market made up of all the drugs in the same category, measured at the third level of the Anatomic Therapeutic Chemical Classification (ATC3). However, this is only a starting point in its definition because the relevant market is one that contains drugs that may be substituted by prescribers and users for the drug in question, taking account of their suitability for the clinical indication, the patient population, the method of delivery, the stage of illness for which the drug is suitable,

8 The principles are set out by the CFI in Case T - 41/96, *Bayer AG v Commission*, and confirmed by the ECJ in Case C-2/01 P, *Bundesverband der Arzneimittel-Importeure* v. *Bayer and Commission*.

etc. This may not be the same as the ATC3—which may contain drugs that are not close substitutes, and may exclude drugs that are.

In order to define a relevant pharmaceutical market for the purposes of assessing dominance, it is therefore necessary to:

- identify substitute drugs, taking account of what choices a physician may make when prescribing drugs (e.g., on the basis of efficacy and safety, suitability for the relevant patient population, whether a first-line or second-line medication, method of delivery, side effects and contra-indications, scope of authorisation, etc.);
- consider IMS volume and share data for the relevant drug and all possible competitor drugs at a country level; there is no clear threshold for dominance, but a share of 40-50% or more may give rise to a presumption of dominance;
- consider whether the drug, or competitor drugs, will lose patent or other exclusivity in the short term;
- consider whether any pipeline products (yours or others') that are close to marketing will likely supersede the relevant drug because of increased efficacy or safety, etc.

This approach has been developed mainly in the context of pharmaceutical mergers. More guidance on the correct approach in assessing dominance will be available when the CFI issues a judgment in relation to the appeal against the Commission's decision in *AstraZeneca*.[9]

CONCLUSIONS

The additional requirements imposed on dominant pharmaceutical companies as a result of this judgment do not radically affect the way in which quota schemes should be designed, maintained and communicated to wholesalers. The essential elements are to ensure that domestic needs are carefully assessed and that they are applied objectively and in a non-discriminatory fashion. Dominant companies remain free to protect their legitimate interests through refusing to supply excessive orders that are intended for export.

9 Commission Decision 15 June 2005, AstraZeneca.

We hope that you find this brief summary helpful. If you would like more information on the issues raised in this client advisory, please feel free to contact:

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