The application of Article 82 EC Treaty to the pharmaceutical sector – some recent EC guidance

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In recent months we have, for the first time, received guidance from the EC institutions on the application of Article 82 EC Treaty, prohibiting the abuse of a dominant position, to the pharmaceutical sector. In October 2004, Advocate General Jacobs, at the European Court of Justice (ECJ), gave his opinion in *SYFAIT v Commission*[1], a case concerning the application of Article 82 EC to unilateral restrictions of parallel trade. The opinion solely addresses the issue of abusive conduct. In June 2005, the European Commission (the Commission) adopted its first Article 82 EC decision in the sector, finding that certain behaviour by AstraZeneca had infringed Article 82 EC. The decision addresses both the issue of dominance and the issue of abusive conduct. AstraZeneca has appealed the decision to the European Court of First Instance (CFI).

SYFAIT: abuse and objective justification in relation to parallel trade

Parallel trade – the issue

The issue before the ECJ in *SYFAIT* was whether, and in what circumstances, a dominant pharmaceutical company may refuse to meet in full the orders that it receives from pharmaceutical wholesalers in order to limit parallel trade in its products.

Differences in national regimes governing pricing of pharmaceuticals and healthcare spending have led to substantial price differences between EU member states.[2] This in turn has created a significant, and growing, parallel trade activity. Wholesalers purchase in low-priced countries to sell at higher prices in the country of importation, effectively free-riding on the price differentials. Pharmaceutical manufacturers, in order to manage their inventory and production capacity, have unilaterally refused to sell or have reduced quantities made available to wholesalers. In some cases, these measures have been implemented in order to restrict parallel imports; in others, they are alleged to have the effect of restricting parallel imports.

SYFAIT – the facts

The *SYFAIT* case concerns the supply of three proprietary medicinal products, Imigran, Lamictal and Serevent, owned and manufactured by GlaxoSmithKline (GSK), to Greek pharmaceutical wholesalers and their parallel trade in these products.

Until November 2000, GSK met in full the orders that it received from the Greek wholesalers for the products concerned. A substantial proportion of these orders were then exported by the wholesalers to other EU member states, where the prices were much higher.

From early November 2000, however, GSK stopped meeting orders from pharmaceutical wholesalers and stated instead that it would supply Greek hospitals and pharmacies directly. It alleged that the export of the relevant products by wholesalers was leading to significant shortages on the Greek market. GSK subsequently reinstated supplies to wholesalers, but still refused to meet their orders in full.

It is the latter refusal that formed the subject of proceedings before the Greek Competition Commission, as a result of complaints brought by pharmaceutical wholesalers and several applications made by GSK to the Greek antitrust authority seeking clearance of its distribution policy.

SYFAIT – the questions

The Greek Competition Commission proceeded on the basis that GSK has a dominant position within the meaning of Article 82 EC on the relevant market in Greece in respect of at least one of the products at issue, Lamictal. The Greek Competition Commission was uncertain, however, whether GSK's refusal to meet in full the orders which it received from pharmaceutical wholesalers should be considered as an abuse within the meaning of that article. Hence, it referred certain questions to the ECJ for a preliminary ruling on this latter point.

In particular, the Greek Competition Commission wished to know whether the refusal constitutes a per se abuse within the meaning of Article 82 EC in circumstances where such refusal is due to GSK's intention to limit wholesalers' export activity and, thereby, the harm caused to GSK by their parallel trade. Case law confirms that a dominant undertaking is permitted to take such reasonable steps as it deems necessary to protect its legitimate commercial interests, provided its behaviour is proportionate to the threat and is not aimed at strengthening or abusing its dominant position.[3]

In addition, the Greek Competition Commission sought clarification of the criteria for determining abuse of a dominant position if the ECJ held that limitation of parallel trade does not constitute an abusive practice in every case where it is engaged in by an undertaking holding a dominant position.

Refusal to supply – the traditional case law

In general terms, a refusal to supply customers (in full) would only be abusive under EC law where the customer concerned has suffered obvious, immediate and substantial competitive disadvantage, or where it has been placed at the risk of elimination.

For example, it would be abusive for a manufacturer to stop supplying raw materials to a customer/competitor, if he thereby risks eliminating all competition on the part of that customer because the latter is dependent on the supplies concerned in order to carry out its activities downstream.[4] Similarly, withholding input that is indispensable for the activities of a customer active on a market downstream from that of the dominant undertaking (but in which a subsidiary of the latter is active), would be abusive.[5]

The ECJ has also held that a dominant undertaking cannot stop supplying a long standing customer who abides by regular commercial practice if the orders placed by that customer are in no way out of the ordinary. Such refusal to supply would be abusive to the extent that it would limit markets to the prejudice of consumers and would amount to discrimination that might in the end eliminate the customer altogether.[6]

Still, even where a refusal would prima facie be abusive, Article 82 EC applies only where the refusal is not capable of objective justification.

It is apparent, therefore, that the situations in which a dominant undertaking may be forced to continue supplying existing customers

are strictly limited in traditional Article 82 EC case law.

To our knowledge, no case had applied the cases discussed above to refusals to supply specifically aimed at limiting parallel trade until the opinion of Advocate General Jacobs in *SYFAIT*.

Refusal to supply and parallel trade

To start with, both the advocate general and the Commission, as intervening party, recognised that a refusal to supply (in full) with a view to restricting parallel trade does not amount to a per se infringement. However, the Commission argued that the intention to limit parallel trade should be one of the circumstances that would 'ordinarily' render a refusal to supply abusive. Advocate General Jacobs considered the Commission's view 'plausible', to the extent that "such conduct is normally aimed at removing a source of competition from the dominant undertaking on the market in the Member State of import". He added that "even assuming that a sufficient effect on competition could not in all cases be shown, an additional argument can be made in support of such a conclusion on the basis of the market-partitioning object of the conduct at issue".

However, the advocate general concluded that "in the present case, [...] the partitioning of the market is not the primary intent, but rather an inevitable consequence, given the characteristics of the market, of the attempt by GSK to protect what it sees as its legitimate commercial interests [...]." In any event, EC case law provides dominant undertakings the possibility of demonstrating an objective justification for their conduct, even if it is prima facie an abuse. In the present case, the advocate general found that, given the characteristics of the sector, a refusal to supply by a dominant pharmaceutical company in order to limit parallel trade was capable of justification "as a reasonable and proportionate measure in defence of that undertaking's commercial interests".

(Note that on the latter two points the opinion differs from the position taken by the Commission that such refusal (i) is prima facie abusive and (ii) is capable of justification only in very limited circumstances.)

More specifically, the advocate general considered a refusal to supply capable of justification where the price differential giving rise to parallel trade is the result of state intervention in the EU member state of export to fix the price there at a level lower than that which prevails elsewhere in the Community, taking into account:

- the pervasive and diverse state intervention in the pricing of pharmaceutical products;
- obligations upon pharmaceutical undertakings and wholesalers to ensure the availability of adequate stocks of products in any given country;
- the potentially negative consequences of parallel trade for competition, the common market, and incentives to innovate, given the characteristics of the pharmaceutical industry; and
- the fact that end-users of pharmaceutical products may not in all cases benefit from parallel trade and that public authorities in the EU member states, as the main purchasers of such products, cannot be assumed to benefit from lower prices, given that they are themselves responsible for fixing prices within their territories.

Hence, as long as the above conditions are fulfilled on the facts, a refusal to supply (in full) would in principle be justifiable as a matter of Article 82 EC.

Two caveats should be added, though. Firstly, similar circumstances to those put forward by Advocate General Jacobs as objective justification were advanced by GlaxoWellcome in its dual-pricing case[7], albeit in an Article 81(3) EC context (seeking to justify an alleged restriction of competition). They were rejected by the Commission.

In particular, at issue in that case are:

- the potentially negative consequences of parallel trade for incentives to innovate;
- the disruptive effect of parallel trade on distribution systems and the potential for under-supply or late introduction of innovative products in low-priced countries;
- consumers do not benefit from parallel trade;
- pharmaceutical companies should not bear the brunt of differences in health policy between EU member states.

The GlaxoWellcome dual-pricing case is currently on appeal before the CFI and we may, therefore, soon receive further guidance on these elements.

Secondly, in a final, rather cryptic, remark, the advocate general noted that his analysis "does not preclude the possibility that a restriction of supply by a dominant pharmaceutical undertaking might fall foul of the Court's established case law on refusal to supply if it had negative consequences for competition arising other than as a consequence of its restriction of parallel trade". This suggests that the justification for a refusal to supply that restricts parallel trade cannot necessarily be applied to other types of refusal, or indeed other types of abuse.

SYFAIT – the outcome

In accordance with ECJ procedure, the advocate general's opinion preceded the decision of the ECJ, but was not binding on it. The ECJ, however, ultimately declared the application by the Greek Competition Commission inadmissible because it is not a "court or tribunal of a member state" within the meaning of its case law.[8] Only courts and tribunals may refer questions to the ECJ for preliminary ruling. Hence, the ECJ threw out the case on procedural grounds. The issues of substance, therefore, remain unsettled as a matter of EC law.

Dominance and abuse – the AstraZeneca case

In June 2005, the Commission imposed a €60 million fine on AstraZeneca for misusing national patent systems and national procedures for marketing pharmaceuticals to block or delay market entry for generic competitors to its ulcer drug Losec.[9] The Decision has not yet been published but the Commission briefly describes its findings in its press release.

The alleged abuses

In the first finding of abuse, the Commission concludes that AstraZeneca misled several national patent offices and as a result gained extended patent protection for Losec through so-called supplementary protection certificates. The second finding of abuse concerns AstraZeneca's deregistering of the marketing authorisations for Losec capsules in Denmark, Norway and Sweden, and replacing them with authorisations for Losec tablets. At the time, so the Commission maintains, generics could only be marketed and parallel importers could only obtain import licences if there were an existing reference marketing authorisation for the original corresponding product. The Commission considered the deregistration abusive because it was intended to block or delay entry by generic firms and parallel traders.

It is conceivable that the Commission will also in the future focus its attention on alleged attempts to block or delay generic entry, as the US antitrust authorities have been doing for a number of years—albeit against the background of a fundamentally different regulatory framework. Yet, due to the particular facts of the case and the changes in legislation brought about since then, we are unlikely to see more cases involving abuses similar to those at issue in *AstraZeneca*.

The issue of dominance

More critically, *AstraZeneca* represents the first time that the Commission has analysed market definition and dominance in the pharmaceutical sector outside the merger control context. It will also be the first occasion for one of the European Courts to consider these matters.

The most widely-used tool for the Commission to assess demand-side substitution when defining markets is the so-called 'small but significant non-transitory increase in price', or SSNIP test. The SSNIP test examines whether a hypothetical small but permanent price increase in the products concerned (typically in the range of 5 to 10 per cent) would lead to a loss of sales of such magnitude that the price increase would be unprofitable for the manufacturer. If so, additional substitutes are included in the relevant market.

In a recent study, the European Federation of Pharmaceutical Industries and Associations (EFPIA) explains that the application of the SSNIP test is difficult, if not impossible, in the pharmaceutical sector, given national regulation of prices and reimbursement levels. Both consumers and prescribing doctors tend to be price-insensitive, and manufacturers will typically be constrained, directly or indirectly, by national price regulation. As a result, the basic assumptions underlying the SSNIP test regarding the ability of an undertaking to maximise profits by increasing price cannot be applied. Instead, the emphasis is more likely to be on non-price factors.[10] This seems, moreover, to be confirmed by the Commission's practice in relation to merger control, where the SSNIP test is not normally used.

To date, therapeutic substitution has been the most widely used market definition starting point, both at EC (merger control) and at national level. Medicines will typically be grouped according to their therapeutic properties by reference to the so-called anatomical therapeutic chemical (ATC) classification—in particular, level 3 of the classification (ATC-3), which groups medicines in terms of their therapeutic indications.

It is difficult to comment on the Commission's findings of dominance without the text of the decision. The EFPIA study analyses in great detail why traditional concepts of dominance may not be applicable to the pharmaceutical sector. It points in particular to the buyer power of EU member states' health authorities as the sole purchasers of medicine and the constraints imposed on manufacturers through regulations designed to contain healthcare costs.

On both issues, therefore it will be interesting to see how the CFI assesses the Commission's analysis.

Notes

1 Case C-53/03, *Syfait and others v GlaxoSmithKline AEVE*, opinion of Advocate General Jacobs, 28 October 2004.
2 Joined cases C-2/01 p and C-3/07P, *Bundesverband der Arzneimittel Importeure and Commission v Bayer AG*, judgment of 6 January 2004.
3 Case 27/76, *United Brands v Commission*.
4 eg Joined cases 6/73 and 7/73, Commercial Solvents v Commission
5 eg Case 311/84, *CBEM v CTL and IPB* ('Télémarketing').
6 eg Case 27/76, *United Brands v Commission*.
7 Case IV/36.957.
8 Case C-53/03, *SYFAIT and others v GlaxoSmithKline AEVE*, judgment of 31 May 2005.
9 IP/05/737, 15 June 2005.
10 EFPIA, *Article 82 EC: Can it be applied to control sales by pharmaceutical manufacturers to wholesalers?*, November 2004.