The European Antitrust Review

2009

Published by Global Competition Review
in association with
Calavros & Partners

GCR
GLOBAL COMPETITION REVIEW

www.globalcompetitionreview.com

Pharmaceutical Companies v Parallel Trade: Another Episode To The Syfait Saga

Despina D Samara
Calavros & Partners

As we noted last year in *The European Antitrust Review 2008*, the opinion of Advocate General Jacobs on the *Syfait* case concerning a dominant pharmaceutical company's refusal to meet in full orders placed by its wholesalers on the substance was not rejected by the European Court of Justice. In the light of that opinion, in autumn of 2006, the Greek Competition Commission decided that the said pharmaceutical company had abused its dominant position only for a very short period of time and did not award a penalty. In the meantime, a question for a new preliminary ruling was referred to the European Court of Justice on the same issues by the Appeal Court of Athens and awaits discussion. Meanwhile, Advocate General Jacobs retired in 2007 and some of the judges of the court might also have done so. Indeed, the terms of about half of them will have expired by the time the case is brought before the European Court of Justice for a new ruling sometime at the end of this year. The chamber will consist of different judges and this might entail a different judgment altogether, both for the pharmaceutical companies and parallel traders in the European Union. With similar cases coming before national courts and competition authorities outside strict Greek boundaries, the question still remains whether the European Commission, national competition authorities and national courts should follow the decision of the Greek Competition Commission with the objective of achieving congruent decisions throughout the common market.

A first, negative, answer to this question came this year with the new opinion of Advocate General Colomer to the preliminary questions of the Appeal Court of Athens. The new episode concluded this year constitutes a most interesting development to the *Syfait* saga, almost one year and a half after the Greek Competition Commission delivered its long-anticipated decision on the said case. The advocate general issued his opinion on 1 April 2008, favouring a conclusion that the dominant pharmaceutical company was abusing its dominant position by refusing supplies to wholesalers intended for export. This opinion goes against not only recent European Court and national court judgments but also, and primarily, the previous opinion on the *Syfait* case given by Advocate General Jacobs in 2004.

The background of the case

By the end of 2000, 16 Greek associations of pharmacists and 41 pharmaceutical wholesalers filed a complaint before the Greek Competition Commission. They sought interim measures against GlaxoSmithKline Greece for alleged refusal to supply them with three medicines to sell to their pharmacists in order to meet national demand.

GlaxoSmithKline (GSK) responded by alleging that in 2000, certain parallel traders had increased their orders for the above products dramatically and that this had led to shortages of medicines in the Greek market. To meet high demand, the Greek subsidiary of GSK requested additional quantities from its parent company. The latter refused to procure more medicines for the Greek market, which already exported a great amount of pharmaceuticals to other European countries, placing European distributors at a competitive disadvantage. Therefore, to cope with the situation, the parent company decided to restrict its sales to GSK Greece to quantities representing recorded monthly sales of Greek pharmacists plus a small percentage sufficient under normal circumstances to secure the reserves provided by law.[1] Following this practice, GSK Greece decided to bypass the associations and sell directly to pharmacists. On their part, the pharmacists' associations claimed that the defendant company had abused its dominant position in the Greek market, in the health sectors covered by the three medicines, by adopting such measures, since the plaintiffs did not purchase more than they customarily did to cover local needs.

The Greek Competition Commission noted that a refusal from a dominant undertaking to supply wholesalers in order to restrict parallel trade could infringe article 82 of the EC Treaty. However, the Competition Commission treated GSK's conduct as justified in the circumstances. More specifically, it found that the firm suffered great economic losses due to the different prices for its product across Europe and the resulting parallel imports,[2] while consumers in the national market did not benefit at all from the operation of parallel trade. On the basis of these considerations, before ruling on the case, the Competition Commission decided to ask the ECJ if and under what circumstances a dominant pharmaceutical company was abusing its position within the meaning of article 82 of the EC Treaty, when it refused to supply wholesalers with unlimited quantities of products with a view to limiting their export activity.

The opinion of Advocate General Jacobs

The Advocate General's opinion favoured GSK's policy, concluding that a dominant undertaking's refusal to supply did not automatically constitute an abuse of its dominant position within the meaning of article 82 EC, merely because of the company's intention to limit parallel trade of its pharmaceuticals.[3]

Advocate General Jacobs argued that, even in the case that GSK's conduct was considered abusive, the refusal of the pharmaceutical company to supply could be 'objectively justified'. More specifically, Advocate General Jacobs reasoned that GSK's restriction of supply in order to limit parallel trade was capable of justification as a reasonable and proportionate measure in defence of that undertaking's commercial interests, given the characteristics of the pharmaceutical market,[4] specifically with regard to pharmaceutical pricing.[5] To reach its conclusion, the advocate general also examined many of the arguments concerning parallel trade of pharmaceutical products, including the potentially negative consequences for competition and incentives to innovate. Therefore, Advocate General Jacobs emphasised that he had reached a conclusion 'highly specific' both to the case under consideration[6] and to the pharmaceutical industry. On its part, the European Court of Justice opted for another solution: it rejected the reference for a preliminary ruling without examining the substance of the case as it ruled that the Greek Competition Commission did not "constitute a court or tribunal" within the meaning of article 234 of the EC Treaty.[7] With no answer as to the substance of the case, the Hellenic Competition Commission convened in summer of 2006.

The decision of the Greek Competition Commission

The Competition Commission reached Decision No. 318/V/2006 in autumn 2006. After taking into account all the information collected regarding the specific cases and the opinions of the involved parties, it concluded that GSK: abused its dominant position under the meaning of article 2 of Law 703/77 for the period November 2000 to February 2001, did not infringe article 2 of Law 703/77 following February 2001, and did not infringe article 82 EC.

On that basis, the Competition Commission, while balancing the short duration of the infringement and because, due to the short duration, no consequences on the Hellenic market were proved, recommended that GSK omit any anti-competitive conduct like that followed between November 2000 and February 2001 in the future. If the infringement were to be repeated, the Committee threatened a fine equal to 3 per cent of GSK's gross revenues of the year prior to the infringement.

The questions of the Appeal Court of Athens

In the meantime, before the Greek civil courts, Sot Lelos and the other wholesalers maintained that GSK's interruption of supplies, as well as its practice of trading through a subsidiary wholesaler, amounted to anti-competitive conduct and abuse of a dominant position. On that basis, the three-member Appeal Court of Athens sought anew a preliminary ruling on a number of questions concerning competition law and the abuse of dominance, as well as parallel exports of medicinal products from Greece to other member states.

More specifically, the Court referred the following questions to the European Court of Justice:

(1) Does refusal of a dominant undertaking to meet in full the orders placed to it by pharmaceutical wholesalers, owing to its intention to limit their export activity and, thus, the damage caused to it by parallel trade, constitute per se abuse within the meaning of article 82 EC? Does it have any bearing on the answer to the above question that profits from parallel trade are rendered especially lucrative for wholesalers owing to governmental intervention in setting up prices in a different manner in the member states of the European Union, namely because the pharmaceutical market is characterised by a high degree of government intervention where pure conditions of competition do not work in practice? Finally, is it legally correct for national courts to apply Community rules of competition in the same manner, on the one hand, in markets that function competitively, and, on the other hand, in markets where competition is distorted by government interventions?

(2) Provided that the court finds that restriction of parallel trade, on the above-mentioned grounds does not constitute an abusive practice in every case, how is then abuse to be examined in the case of conduct of a dominant undertaking? More specifically:

(a) is the criterion of surpassing the rate of regular domestic consumption and/or that of the damage suffered by the dominant undertaking in relation to its turnover and its profits to be treated as a suitable one? In the event of an affirmative answer, how is the level of the above-mentioned rate and/or the damage to be determined, the last one as a percentage of the company's turnover and profits, above which a conduct is rendered abusive?

(b) is it more suitable to assess both parties' interests and, in case of an affirmative answer, which interests should be compared? More specifically:

(i) shall the answer be influenced by the fact that the final consumer bears little economic profit from the operation of parallel trade?

(ii) shall, and to what extent, account be taken of the interests of social security systems in buying cheaper medicines?

(iii) what other criteria and approaches shall be considered appropriate in this respect?

The opinion of Advocate General Colomer

Four years after the opinion of Advocate General Jacobs in the Syfait case, Advocate General Colomer was called to provide his opinion on the same issues once more.[8] Like Advocate General Jacobs in 2004, Advocate General Colomer in 2008 found that there was no per se abuse of a dominant position. On this basis, the advocate general accepted that, in theory, it is therefore possible for an undertaking to provide objective justification for its conduct in refusing to meet in full the orders of wholesalers of pharmaceutical products, with a view to reducing the harm caused to it by parallel trade, without such conduct constituting an abuse within article 82 EC. For such objective justification to apply, however, regulation of the market should compel the dominant undertaking to behave in that manner in order to protect its legitimate business interests.

Unlike Advocate General Jacobs, Advocate General Colomer concluded that the particular circumstances of the pharmaceutical market in Europe, even though there is no complete harmonisation reached as yet, do not merit such objective justification and found that GSK's conduct was breaching article 82 EC.

More specifically, Advocate General Colomer employed the following reasoning in his opinion.

The imperfect nature of the pharmaceutical market

Contrary to Advocate General Jacobs's argument in 2004 that the imperfect nature of the pharmaceutical market and its specificities could justify GSK's behaviour, Advocate General Colomer found that pricing of pharmaceuticals, even though state-regulated, is not free from manufacturers' influence, and takes account of demand up to a certain extent, although neither of these factors could justify ceasing to supply pharmaceutical wholesalers.

The objective justification of an undertaking's legitimate business interests

Contrary to Advocate General Jacobs's opinion, Advocate General Colomer came to the following conclusions:

- he rejected the proposition that the loss of income due to parallel trading would directly impact upon the level of research and development in the pharmaceutical industry; and
- suggested that dominant undertakings might be able to show that potentially abusive conduct is economically efficient.

The intention of the dominant undertaking:

Advocate General Colomer emphasised that the pharmaceutical company's intention to reduce the volume of parallel trade of its products constituted an essential part of the examination of a dominant company's abusive behaviour.

On this basis, Advocate General Colomer concluded that GSK did not provide enough evidence to demonstrate its conduct resulted in economic efficiency, and proposed that the European Court of Justice finds that GSK's refusal to meet in full the orders placed by its wholesalers was unjustified and disproportionate to its said objective, thus committing an abuse of its dominant position. However, even though the advocate general denied that GSK had put forward sufficient evidence to demonstrate economic efficiencies to justify its refusal in this particular case, he took the view that it is

possible that an undertaking could provide objective justification for such conduct by showing that the regulation of the pharmaceuticals market compels it to take such action to protect its legitimate business interests. Nevertheless, by eliminating from the pharmaceutical companies' armoury the arguments of an imperfect market in pharmaceutical pricing conditions (because the system allows for an element of negotiation by pharmaceutical companies with national price control authorities) and the impact of parallel trade on pharmaceutical companies' profits as a disincentive to research and innovation, the advocate general in essence upset what seemed to be calm waters between pharmaceutical companies and parallel traders.

With the ongoing parallel trade debate showing little sign of abating, most probably the end of this year will bring long-awaited developments regarding EC legislation on combating counterfeits and the European Court of Justice ruling in the case *Sot Lelos v GSK*. Even though the European Court of Justice is not bound to follow the opinion of Advocate General Colomer when it adopts its full judgment in a few months' time, it will be more than interesting to see how the court is going to avoid answering the same questions posed by the preliminary ruling in a different manner. Such a prospect could weight heavily on the decisions to be reached by all concerned Greek courts, namely the Appeal Court of Athens and the Administrative Appeal Court of Athens (which has suspended judgment on the validity of the decision of the Competition Commission in light of the awaited decision of the European Court of Justice) and, even more crucially, upon the balance to be achieved between pharmaceutical producers and parallel trades in the very near future four years after the opinion of Advocate General Jacobs.

***

The legal profession under scrutiny by the Competition Commission

Following a complaint filed by a 'disappointed' lawyer, the General Management for Competition, after closely examining the terms and conditions under which lawyers attend to civil and administrative procedures, submitted its proposal to the Greek Competition Commission. According to the proposal, the General Management for Competition argued that the operation of the legal occupation is restricted in practice geographically and this violates free competition, to the extent that a lawyer is permitted to present only before the courts and tribunals of the prefecture of the Bar Association he or she is a member of. Specifically with regards to signing contracts, the Greek bar associations employ similar restriction mechanisms forbidding lawyers from other associations from attending and signing contracts 'out of their seat'. In this way, the above-mentioned legal restraints compartmentalise the Greek market, as in effect a citizen, especially in relation to his or her representation before the civil and administrative courts, if he or she chooses a lawyer from another bar, will be obliged to pay for legal expenses twice in order to have the said lawyer legalised by another colleague from the local bar association. In contrast, representation for the signing of a contract by a lawyer out of his or her seat is in all cases unfeasible.

Although the above restrictions constitute the effect of specific legislative measures adopted by the Greek state, the General Management for Competition proposed to the Competition Committee not to apply these provisions, based on the relevant case law of the European Court of Justice according to which a national competition authority has a duty not to apply national laws that violate Community competition law. It is noted that the proposition of the General Management of Competition is not binding upon the Committee, which will decide after evaluating the arguments of all parties concerned. The case was discussed on 17 April 2008 and a decision is expected by the end of 2008.

***

Calavros & Partners

19, Vrana str.
Athens 115 25
Greece
Tel: +30 210 36 98 700 (50 lines)
Fax: +30 210 36 98 750
calavros@calavros.com

Despina D Samara

www.calavros.com

Calavros & Partners enjoys a widely established reputation due to its commitment always to provide top quality legal services. Our firm's overall approach is to combine excellence in results, taking extra care to keep close, personal contact with clients throughout the handling of every case. Our goal remains to provide practical solutions that meet clients' requirements cost-effectively.

Calavros & Partners has abroad commercial practice and is distinguished for servicing multinational private and public sector companies as well as Greek companies seeking to expand their business abroad.

Our advising of national and international pharmaceutical companies during recent years has given us the opportunity to deepen our knowledge and experience of the complex Greek and European Union legal framework regarding pharmaceutical products, their development, protection and circulation, as well as their pricing and reimbursement by national health insurance systems.

Calavros & Partners is the exclusive legal counsel of Novartis Hellas Aebe, the Greek subsidiary of the Novartis group.

Furthermore, Calavros & Partners acts as the external legal counsel of Glaxo Smith Kline Aebe, in a number of significant legal matters related to free and unfair competition law (eg, the leading case brought before the Greek Competition Commission with regard to quota systems and their impact on parallel trade), as well as in the judicial proceedings related to product liability matters and administrative law issues.

The office consults the Piraeus Port Authority (OLP AE) with regard to a complaint brought before the Greek Competition Commission for potential infringement of articles 1 and 2 of law 703/77, as it is in effect, and articles 81 and 82 EC.

In addition, Professor Constantin Calavros is appointed as special legal adviser to the Association of Greek Pharmaceutical Companies – SFEE.

Calavros & Partners Law Firm, now comprising 30 members, including lawyers, trainee lawyers, information technology system operators, accountants and supporting administrative and secretarial personnel, is among the largest law firms in Greece.

The Commission's 'uncompromised' composition under suspicion

Since its foundation in 1977, the very composition of the Greek Competition Commission has been contested. More specifically, this July, an official demand was submitted to the Greek government by a private company, asking for the expulsion of the representation of the Greek Industrialists Association (SEV) from the Greek Competition Commission based on the conflict of interests principle. This is not the first move against SEV. Since last year, the Stop Cartel Organisation has already submitted to the Greek government a proposal to withdraw the participation of the Greek Industrialists Association from the Greek Competition Commission, based similarly on the principle of conflict of interests. Under both proposals, it is considered controversial that a member of the Competition Commission that decides upon the complaints of cartels and monopolies, constitutes, at the same time, the party that is under scrutiny for possible violations of competition laws.

Even though there has been no formal answer of any kind to the complaint by the Greek government as yet, any such developments damage an already problematic image for the Greek Competition Commission and the protection of competition in the Greek market, especially when taking into account a rather long period of stagnation that the Commission faced between 2006 and 2007, owing to internal problems.

Notes

1 Hellenic Republic, Hellenic National Drug Organisation, Ensuring adequate supply of pharmaceutical products in the Greek market, (Circular). Athens, 27 November 2001.

2 In this part, the ruling of the Competition Commission seemed to follow the rationale of the European Commission in the 'ADALAT' case even if examined under article 82 EC.

3 Opinion of Advocate General Jacobs in *Syfait and others v GlaxoSmithKline AEVE*, Case C-53/03 [2004] E.C.R. I-00000, paragraph 53, 69.

4 The advocate general considered the following factors: the pervasive regulation of price (paragraphs 77-79) and distribution in the sector (paragraphs 80-82); the likely impact of unmoderated parallel trade upon pharmaceutical undertakings in the light of the economics of the sector (paragraphs 89-95); the effect of such trade upon consumers and purchasers of pharmaceutical products (paragraphs 96-99).

5 Ibid, paragraph 71.

6 The advocate general considered that conduct by a dominant pharmaceutical undertaking, which more clearly and directly partitioned the common market, would not be open to a similar line of defence (paragraph 103).

7 *Synetairismos Farmakopoion Aitolias & Akarnanias (Syfait) and others v GlaxoSmithKline AEVE*, Case C-53/03 [2005] ECR I-00000.

8 Joined Cases C-468/06 to C-478/06, *Sot. Lelos kai Sia EE v GlaxoSmithKline AEBEE* [2008] ECR II- 00000.

About the Authors

Despina D Samara
Calavros and Partners Law Firm

Dr Despina Samara joined the EU and competition law department of Calavros and Partners Law Firm in 2006. She specialises in European and Greek competition law and IP rights, with particular expertise in the pharmaceuticals and maritime transport sectors. As a competition lawyer she frequently advises corporate clients on all legal aspects of their day-to-day operations, and regularly represents clients before the National Competition Commission and national courts.

Despina was admitted as a solicitor in 2002. She holds a Law degree from the Aristotle University of Thessaloniki, a Masters degree in Commercial and Corporate Law, and a PhD from King's College University, London. She has also completed a stage in the industrial property unit of the Directorate General of Internal Market, European Commission. ■