Parallel Trade in Pharmaceutical Products in Europe: The European Court of Justice's Ruling in Syfaiat v. GSK

May a dominant pharmaceutical company refuse to supply in full the orders it receives from a wholesaler in an EU country in order to limit parallel trade in its products in the European Union? This was the question put to the European Court of Justice (ECJ) in the context of a preliminary reference from the Greek Competition Commission in the closely-watched case of SYFIAT v. GSK (Case C-53/03). In a disappointing judgment, the ECJ avoided answering the question by ruling that the case was inadmissible because the Greek Competition Commission did not have the power to refer a case to the ECJ as it is not a “court or tribunal” as required by the EC Treaty. By dismissing the case on jurisdictional grounds, the ECJ passed up a golden opportunity to inject much-needed certainty into the law on parallel trade in pharmaceutical products.

Background

In Greece, GlaxoSmithKline (GSK) implemented a strategy under which it limited the amounts supplied to its wholesalers so that their orders—particularly large orders placed by wholesalers engaged in export activities—were not supplied in full. The purpose of this strategy was to prevent wholesalers from buying products at the low prices prevailing in Greece and reselling them in markets with higher price levels such as the United Kingdom. Several wholesalers complained to the Greek Competition Commission, which suspended the proceeding in order to obtain clarification from the ECJ on several points of law under the so-called “preliminary reference” procedure. In essence, the Greek Competition Commission asked the ECJ whether and in what circumstances a dominant pharmaceutical company may limit supplies to its wholesalers in order to limit parallel trade in its products.

The answer to this question is of great practical significance for pharmaceutical companies because it determines to what extent a pharmaceutical company may limit supplies of products with respect to which it is dominant in order to limit parallel trade in that product. As a general rule, if a company is dominant with respect to a particular product, an attempt to limit supplies of that product is likely to constitute an infringement of Article 82. There are strong arguments, however, that this general rule should not apply to the pharmaceutical sector because of certain unique features of that sector.

Indeed, in his opinion in this case issued on 28 October 2004, Advocate General Jacobs concluded that the general rule on restrictions of supply by dominant companies should not apply to restrictions of supply put in place by pharmaceutical companies as a means of coping with parallel trade. First, the European pharmaceutical sector is subject to pervasive regulation, including price controls, which has given rise to significant price disparities among Member States. Attempts by pharmaceutical companies to restrict parallel trade are not aimed at entrenching these disparities, but are simply a legitimate reaction to them. Second, unless pharmaceutical companies are able to take steps to limit parallel trade, the adverse effect on their revenues could undermine their incentives to invest in research and development. Third, in the case of pharmaceutical products, it is the parallel trader, not the patient or purchaser of the product, that benefits from parallel trade because lower prices are not passed on by the parallel trader, but rather taken as profit.
The ECJ’s Judgment

In its judgment of 31 May 2005, the ECJ declined to address the substantive issues raised by the case, deciding instead to dismiss the case on jurisdictional grounds. Under Article 234 of the EC Treaty, only a “court or tribunal of a Member State” may refer questions to the ECJ. In reaching its conclusion that the Greek Competition Commission was not a “court or tribunal” within the meaning of Article 234, the ECJ highlighted the following features of the Competition Commission:

- The Greek Competition Commission is subject to the supervision of the Minister for Development, which implies that the Minister has the power to review the Commission’s decisions.
- There are no safeguards against the dismissal or termination of members of the Greek Competition Commission, which makes them susceptible to pressure from the government.
- The Greek Competition Commission is responsible for the secretariat, i.e. the competition officials who are in charge of fact-finding and bringing cases. This operational link between the Commission, which serves as the decision-making body, and the secretariat, which acts as a fact-finder, means that the Commission does not have the requisite degree of independence.
- National competition authorities such as the Greek Competition Commission are required to work in cooperation with the European Commission and may be relieved of their jurisdiction over a case if the European Commission decides to take jurisdiction over the case. Thus, there is no guarantee that a case started before the Greek Competition Commission will result in a judicial decision as it could wind up with the European Commission. This is inconsistent with the principle established in the case law that a body may refer a question to the ECJ only if there is a case pending before it and if the case will result in a judicial decision.

In ruling that the reference from the Greek Competition Commission was inadmissible, the ECJ ignored the Advocate General’s advice on this issue. In what he admitted was a close case, Advocate General Jacobs erred in favor of finding that the Competition Commission constituted a court or tribunal. In doing so, he specifically took into account the sea change in the EU competition landscape brought about by the decentralization of competition enforcement under Regulation 1/2003. With the increase in cases in which EU competition law is applied at the national level that inevitably will result from this decentralization, he reasoned that a system that allows references to be made at the earliest possible stage and by a specialized body that is well qualified to identify issues ripe for interpretation by the ECJ would clearly be desirable in terms of judicial economy and promoting uniformity in the law.

What is the Impact of the ECJ’s Ruling on Pharmaceutical Companies?

The ECJ’s dismissal of the case on jurisdictional grounds leaves pharmaceutical companies in a state of legal limbo. Without a ruling from the ECJ, there is no clear answer to the question of whether a pharmaceutical company may restrict supplies of a product with respect to which it is dominant. While the Advocate General’s opinion suggests that such a restriction is permissible because of certain unique features of the European pharmaceutical sector, his opinion is not binding. Thus, a national court, a national competition authority, or the European Commission could well decide that a restriction of supplies by a dominant pharmaceutical firm constitutes an abuse under Article 82.

While the Advocate General’s opinion is not binding, it is a source of persuasive law and will undoubtedly be given serious consideration by any competition authority or court considering the
issue. More specifically, the existence of an Advocate General's opinion stating in clear terms that a limitation of supplies by a pharmaceutical company with respect to which it is dominant does not constitute an infringement of Article 82 would seem significant in at least two respects:

• First, a national court confronted with the question would think twice before reaching a different conclusion. In fact, if the question were to reach a national court, it is likely that the national court would ask the ECJ for guidance pursuant to a preliminary reference before ruling on the issue.

• Second, if the issue were to reach the ECJ again, an Advocate General's opinion in favor of the pharmaceutical industry means, at the very least, that the industry's arguments must be taken seriously. Of course, in the event of a reference, there would be a new Advocate General's opinion and there is no guarantee that either this opinion or the ECJ's judgment would agree with Advocate General Jacobs's opinion. Nevertheless, the industry is clearly better off with AG Jacobs's opinion on the books than without.

It is unlikely that the ECJ will provide guidance on the issue anytime in the near future. The ECJ may get a second bite at the apple in SYFIAT v. GSK. If the Greek Competition Commission rules against GSK and GSK decides to appeal the decision to the Greek courts, the Greek court could well seek guidance from the ECJ. Another case that will offer the Community Courts an opportunity to address many of the issues raised by SYFIAT v. GSK is the Spanish dual pricing case, which also involves GSK, and which is currently pending before the European Court of First Instance (Case T-168/01). Under the dual-pricing system at issue in that case, GSK charged higher prices for products that are exported in comparison with the prices charged for products sold on the Spanish market. GSK has raised many of the same arguments in the Spanish dual-pricing case that it raised in SYFIAT v. GSK. It is unlikely that definitive guidance will be forthcoming anytime soon because it is safe to assume that, whichever way the CFI rules, the losing party will appeal the judgment to the ECJ. Pending clarification from the Community Courts, pharmaceutical companies that restrict supplies of products with respect to which they are dominant will continue to do so at their peril.

The ECJ's judgment is available at http://www.curia.eu.int/jurisp/cgi-bin/form.pl?lang=en&lango=de&Submit=Suchen&dorequire=alldocs&numaff=C-53/03&datefs=&datefe=&nomusuel=&domaine=&mots=&resmax=100.

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