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A legal update from Dechert's Antitrust Group

European Court of Justice Rules that Dominant Pharmaceutical Companies Cannot Refuse to Meet Ordinary Orders By Wholesalers in Order to Prevent Parallel Imports

Key Points for Clients to Consider

- A recent European Court of Justice ruling in a dispute between a GlaxsoSmithKline subsidiary and Greek pharmaceutical wholesalers fails to reinforce recent judicial trends recognizing the specificity of the pharmaceutical sector.
- There are no sector-specific circumstances unique to the pharmaceutical industry that would override general EU competition rules.
- However, dominant pharmaceutical companies are not required to supply beyond "ordinary" quantities to meet demands for parallel export.
- The concept of "ordinary" will be assessed at the national level with specific reference to demand in the wholesaler's European member state and the previous commercial relationship with the wholesaler concerned.
- Litigation in this field will continue, with the potential for diverging decisions from member state courts.

On September 16, 2008, the European Court of Justice (ECJ) delivered its preliminary ruling for the Athens Court of Appeal in relation to a dominant pharmaceutical company's ability to limit the supply of wholesale orders.[1] The ECJ failed to reinforce recent rulings favoring pharmaceutical companies in their efforts to prevent parallel trade, holding that pharmaceutical companies in a dominant position cannot refuse to supply wholesalers in an attempt to inhibit parallel trade among the different EU member states. The decision does recognize the right of pharmaceutical companies to protect their commercial interests by not supplying orders that are "out of the ordinary" in relation to demand in the originating member state and the previous business relations between the manufacturer and the exporting wholesaler in that member state.

The Nature of the EU Pharmaceutical Industry

The issue of parallel exports in the EU pharmaceutical sector derives from a conflict between the principle of free trade across the member states and the existence of country-specific price regulations in the industry. The existence of multiple price control regimes in the EU pharmaceutical sector enables wholesalers to buy drugs at a low cost in certain countries and earn a profit by exporting them at a higher price into another member state.

The pharmaceutical industry has been trying to curb this practice of parallel trading for a number of years through various measures. Strategies have included restricting supply through export bans, quota systems and outright refusals to supply. In addition, companies have engaged in direct distribution systems to bypass wholesalers or have set a higher price for products that are resold into another member state. These tactics, however, have landed some pharmaceutical companies before the courts to answer competition law infringement charges.

[1] *Sot. Lelos kai Sia EE et.al. v. GlaxoSmithKline*, Joined Cases C-468/06 to C-478/06, September 16, 2008

GlaxoSmithKline (GSK) is the most recent company to have found itself defending its supply quota measures.

Background of the Case

Citing a shortage of medicine, GSK's Greek subsidiary initially ceased supplying Greek wholesalers in November 2000 in preference for a direct distribution system. In February 2001, GSK resumed fulfilling orders to Greek wholesalers, but in limited quantities in order to restrict parallel exports to other member states. The Greek wholesalers complained before the Greek Competition Authority and the Athens courts. Both the Greek Competition Authority and the Athens Court of Appeal asked the ECJ to rule on the issue of whether a dominant company's refusal to supply in order to inhibit parallel export is a breach of Article 82 of the Treaty Establishing the European Community.

Laying the Boundaries in Parallel Exports: The ECJ Judgment

The ECJ held that it is an abuse of dominance to refuse to supply ordinary orders from wholesalers in order to stop parallel exports without objective justification.

The decision thus stays within established competition principles in relation to Article 82. It has, in fact, reiterated prior case law on (i) a refusal to supply constituting an abuse of dominance, and (ii) the right of a dominant company to protect its commercial interests, notwithstanding the special circumstances of the pharmaceutical industry. In *United Brands*, the ECJ stated that a dominant company "*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*", however, it can "*take such reasonable steps as it deems appropriate to protect its [commercial] interests.*"[2]

In line with this existing case law, the ECJ held that while refusing to supply parallel exporters is an abuse of dominance, pharmaceutical companies are able to take reasonable and proportionate measures to protect their commercial interests. Companies are not required to supply significant quantities of products that are beyond ordinary requirements and essentially destined for parallel export. The ECJ, however, stopped short of defining "ordinary" and left the matter to the national court which should consider:

- The size of the orders in relation to the requirements of the market in the wholesalers' member states; and
- The previous business relations between the dominant pharmaceutical company and the wholesalers concerned.

New Battleground: What is ''Ordinary''?

The judgment is likely to encourage innovative tactics by both parallel traders attempting to increase orders in low-price member states and pharmaceutical companies intending to limit supplies there to what is needed for internal consumption. Both sides will have to rely on the concept of "ordinary" in support of their respective positions. The judgment gives only general guidance on the concept, and substantial room is available for the parties to argue how it should be applied.

Wholesalers, keeping in mind the importance of past orders and business relations, may now try to increase their supplies slowly but incrementally in an attempt to boost order history. Pharmaceutical companies, on the other hand, will likely find themselves trying to combat such tactics by limiting the amount of the increase to keep pace with demand in the national market. Pharmaceutical companies are likely to keep in mind the importance of past business relations and keep an even closer eye on wholesalers who have previously engaged in parallel exporting.

It remains to be seen though whether a manufacturer has to deal with new wholesalers who are likely to export, or has to support new export activities by wholesalers who do not currently export. Member states such as France have in the past required that manufacturers supply new entrants in the wholesale market.

No News to Non-Dominant Players

This ECJ judgment is only relevant to pharmaceutical companies holding a dominant position in relation to the products at stake. For non-dominant players, the *Bayer/Adalat* precedent[3]

[2] Case 27/76 *United Brands and United Brands Continental BV v. Commission*, February 14, 1978, paras 182 and 189.

[3] Joined Cases C-2/01 P and C-3/01 P, *Bundesverband der Arzneimittel-Importeure eV and Commission v. Bayer AG*, January 6, 2004

remains valid. This allows non-dominant pharmaceutical companies to limit quantities supplied to wholesalers in order to avoid parallel exporting, provided that such limitation is a unilateral action of the supplier and not based on any agreement with the wholesalers.

Reaction of the European Commission

The European Commission has traditionally been in favor of parallel trading. The Commission views restrictions in supply as unacceptable and inconsistent with the fundamental EU principle of market integration. The ECJ judgment was welcomed by the Commission, which has independently launched its own pharmaceutical sector inquiry at the beginning of this year to evaluate possible concerns about competition in the industry, unrelated to parallel exporting.

To be Continued at the National Level

Although pharmaceutical companies cannot escape the confines of competition law in a very specialized sector, they may still be in a position to defend their interests and prevent "excessive" parallel exports. The battle will continue at the national level, where the parties will attempt to rely on the yet broadly defined concept of "ordinary" in support of their position.

Practice group contacts

If you have questions regarding the information in this legal update, please contact the Dechert attorney with whom you regularly work, or any of the attorneys listed. Visit us at www.dechert.com/antitrust.

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