The pharmaceutical sector and competition law in Europe

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The pharmaceutical sector has been under intense scrutiny in Europe almost since the entry into force of the Rome Treaty in 1958. In the earlier years, the predominant concerns were linked to the development of the internal market and the European Commission’s (“Commission”) desire to enable and foster parallel imports by exploiting the often significant price differences between Member States.

Accordingly, the Commission has traditionally scrutinized schemes used by pharmaceutical companies to limit parallel imports, whether this consisted in using “supply quota systems” to directly limit the quantities of medicine available for export, or in “dual pricing schemes” designed to price products differently according to the products’ destination in the European Union (“EU”).

More recently, the Commission has focused on originators’ attempts to delay or hamper the introduction of generic medicines that may compete with their products already on the market. This effort can be seen to have begun with the AstraZeneca case in 2005 and has intensified with the launch of the pharmaceutical sector inquiry in 2008. Its latest inquiries have yet to produce tangible results but unsurprisingly – and similarly to the situation in the US – the Commission now places a particular emphasis on dealing with patent settlements.

In parallel, the Commission has had to review a large number of mergers in the sector starting with the consolidation between originators and more recently – and increasingly - analyzing attempts to delay or hamper the introduction of generic medicines that may compete with their products already on the market. This effort can be seen to have begun with the AstraZeneca case in 2005 and has intensified with the launch of the pharmaceutical sector inquiry in 2008. Its latest inquiries have yet to produce tangible results but unsurprisingly – and similarly to the situation in the US – the Commission now places a particular emphasis on dealing with patent settlements.

1. The pharmaceutical sector under enhanced antitrust scrutiny

On 15 June 2005, AstraZeneca was fined by the Commission (€60 million) pursuant to Article 82 EC (now Article 102 TFEU) for having abused its dominant position by misusing public procedures and regulations in a number of EU Member States with a view to excluding generic firms and parallel traders from competing against its anti-ulcer product Losec. This infringement consisted of two types of abuses. AstraZeneca deliberately made misleading representations to a number of patent offices in the EU in an attempt to gain extended patent protection, thereby delaying the entry of cheaper generic versions. Moreover, AstraZeneca unilaterally reserved some of its marketing authorizations to delay the marketing of generic products and prevent parallel imports. The final judgment in this case is still pending with the European Court of Justice.

On 15 January 2008, the Commission launched a so-called “sector inquiry” targeting the producers – originators and generic companies – of medicine for human consumption. The inquiry was designed to collect in-depth information on the sector to better tailor its enforcement actions rather than to establish infringement by individual companies.

After having summarized its findings in two reports and two monitoring reports, the Commission has yet to provide practical guidance on its enforcement policy. While the sector inquiry has not validated many of the initial competition concerns, the Commission continues to monitor patent settlements, and in parallel has opened four individual cases under both Articles 101 and 102 TFEU. At the current stage of investigations it is difficult to predict the likely outcomes. However, it can be expected that the settlements that will come under close scrutiny are those that delay generic entry in exchange for a value transfer from a branded drug-maker to a generic rival (whether in the form of direct payments or other commercial advantages). The Commission is also likely to frown on agreements that contain restrictions beyond the exclusionary zone of the patent (i.e. which would grant protection against generic entry outside the time, product or geographic scope of the patent).

This position does not fundamentally appear to differ from the FTC’s stance against pay-for-delay settlements, but contrary to the FTC, the Commission has to operate without being able to resort to a regulatory framework such as the Hatch-Waxman Act. In any case and judging by the FTC’s struggles in court to block pay-for-delay settlements, this issue can be said to be far from settled on both sides of the Atlantic. Interestingly, while the Commission recently announced that the number of possible problematic settlements with regard to EU competition law is in decline and in the latest survey only represented a fraction of the total number of settlements (3 out of 89 for the year 2010), the FTC appeared far less optimistic (28 potential pay-for-delay deals in 2011 out of 156 final settlements).

2. Merger control in the pharmaceutical sector

The pharmaceutical sector is characterized by a continued stream of mergers and acquisitions having given rise to an established decisional practice by the Commission (in terms of market definition, closeness of substitution and remedies). The Commission has, without changing its grid of analysis, evolved with the type of transactions it has had to review and has now gained significant experience in examining concentrations involving generic companies.

When dealing with the competitive overlaps between originators and generic medicines, the Commission treats the latter as being the closest substitute to their originators’ equivalent (therefore being capable of having a direct price effect). The Commission carefully assesses the viability of the divested assets and has imposed additional safeguards (for instance, by including production facilities, R&D or sales staff in the divestiture package) to ensure that the purchaser will be able to compete effectively in the market following divestiture. In the latest decision published, the Commission required an alternative set of commitments to reflect the uncertainties regarding the suitability of the buyer. The Parties had to include a so-called crown jewel remedy (i.e. divestiture of a stand-alone business as opposed to more limited assets) which they will be obliged to implement in case they are not able to implement the initial commitment with a suitable buyer (i.e. satisfying a number of conditions to ensure the viability of the divestiture).

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