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Commentary
Sector inquiry into the pharmaceutical sector

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Introduction

More than 8 months ago (on 15 January 2008) the European Commission ("Commission") launched a sector inquiry into the pharmaceutical sector relating to the introduction of innovative and generic medicines for human consumption onto the market. The Commission believes that there are some indications of commercial practices by pharmaceutical undertakings intended to restrict competition in the pharmaceutical sector in the EU. In particular, the Commission stated that less innovative medicines reach the market and that in some cases the entry of cheaper generic medicines seems to be delayed. "Market monitoring suggests that these developments result from anti-competitive practices", said Competition Commissioner Neelie Kroes. With the inquiry the Commission intends to take a closer look at the commercial practices between pharmaceutical companies, particularly at patent disputes, vexatious litigation and settlement agreements, presumably creating artificial barriers for novel and generic medicines.

What is a sector inquiry?

The Commission is entitled to open sector inquiries relating to business sectors that do not seem to function as well as they should, e.g. when the trend of trade, price developments or other facts indicate that competition in a particular sector might be distorted. The data acquired then serves as a basis for further investigations in particular cases against undertakings suspected of infringing the competition law regulations. The variety of tools to carry out a sector inquiry ranges from simple information requests to undertakings and trade associations to unannounced inspections (dawn raids).

Inquiry's procedure

The starting signal for the inquiry into the pharmaceutical sector apparently was the AstraZeneca case in 2005 in which the Anglo-Swedish pharmaceutical company was accused of misusing the patent system and the procedures for marketing pharmaceuticals to block or delay market entry for generic competitors to its ulcer treatment Losec. The investigation resulted in a EUR 60 million fine which has been appealed by AstraZeneca.

In contrast to sector inquiries launched before, the Commission started the inquiry into the pharmaceutical sector with dawn raids of a number of innovative and generic pharmaceutical undertakings in Europe. Following the inspections the Commission sent out detailed, 42-pages strong questionnaires to approximately 100 undertakings as well as to other actors participating in the market, such as medical organisations, associations of doctors, pharmacies and governmental pharmaceutical price agencies. The Commission announced that it will publish an interim report on 28 November 2008 giving the market participants the opportunity to comment on the preliminary results of the inquiry. The final report can be expected in spring 2009. Depending on the inquiry's results, the Commission or the

national competition authorities may take appropriate measures regarding the most serious competition concerns.

Competition law aspects

The inquiry raises a number of questions from the competition law point of view.

First, it has to be noticed that (the duration of) any patent protection in the pharmaceutical sector constitutes a typical area of conflict between the intellectual property rights of the pharmaceutical undertakings and the interest of the producers of generic medicines in entering the market. A pharmaceutical patent grants to its holder a temporary protection from generic competition as a compensation for its efforts and significant investments into the development of the novel medicine. Taking into consideration the regular duration of a pharmaceutical patent of 20 years and the fact, that under certain circumstances the patent protection can be further extended, it becomes clear that the competition on the pharmaceutical sector can be inhibited in line with competition law provisions for a quite long period of time. However, the legal boundaries of the lawful distortion of competition are, for instance, crossed when an undertaking having a dominant market position extends its patent rights by manipulative or misleading practices, as the Commission was alleging in the AstraZeneca proceeding.

Second, the questionnaires sent by the Commission bear themselves a number of risks for the undertakings participating in the inquiry. Any failure to cooperate with the Commission in a proper way can result in a separate fine. Hence, the undertakings should treat the questionnaires carefully and should ensure that the information is provided in an accurate manner.

Furthermore, one should bear in mind that in their response to the questionnaires companies might reveal information concerning (unintended) anti-competitive behaviour. For instance, a company might unveil imprudent corporate communications which negligently were not considered to be anti-competitive or which were not approved by the legal department. In this case the companies could face a separate investigation resulting in a fine of up to 10% of the overall turnover. For this reason especially undertakings with a significant market power should assess the impact of the questionnaires quite carefully.

Finally, from experience with previous sector investigations it can be taken that the sector inquiry will inevitably lead to a period of legal and commercial uncertainty. Even though the Commission stated that innovation in the pharmaceutical sector is driven by patents and other intellectual property rights and that the inquiry will be conducted under consideration of these existing rights, i.e. the Commission is not willing to challenge the existing intellectual property law system, the final results of the inquiry will be published at the earliest in spring 2009. Until then the undertakings will not have the certainty that their commercial practices are in line with the competition law regulations as interpreted by the Commission.

Outlook

From the present point of view it is hard to predict which results the inquiry will have and which conclusions the Commission will draw from its findings. If in the course of the inquiry the Commission determines that undertakings have infringed the competition law regulations, it may impose severe fines on the undertakings involved. It might also recommend structural changes to the way the pharmaceutical industry is functioning, as it was the case after the inquiry into the energy sector.

In any case, due to the vital importance of the pharmaceutical sector for the public, the eagerness to produce novel medicines must not be hindered. The rigorous enforcement of the competition law regulations is certainly an appropriate tool towards affordable medicines. However, pharmaceutical manufacturers should not be discouraged from further investments into innovative drugs!