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European Commission Raids Pharmaceutical Companies to Start Sector Inquiry

January 2008

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On January 16, 2008, the European Commission launched a sector inquiry into the pharmaceuticals industry by carrying out a series of unannounced inspections of innovative and generic pharmaceutical companies. The targeted companies include both European and U.S. pharmaceutical companies with significant operations in Europe. The inquiry is likely to implicate important and controversial issues regarding the intersection of competition and intellectual property law, including the legality of patent litigation settlement agreements and conduct relating to the procurement and enforcement of intellectual property rights.

The sector inquiry is generally designed to provide the Commission with insight into commercial practices within the pharmaceutical industry; however, it was launched in response to the Commission's concern that competition in the European pharmaceutical sector may not be working as it should. Specifically, the Commission noted that there has been a significant decrease in novel and generic medicines for human consumption entering the European pharmaceutical market in recent years.

The sector inquiry also follows two recent and significant enforcement actions by the Commission against firms in the pharmaceutical sector. In 2005, the Commission fined *AstraZeneca* €60 million for providing misleading representations to patent offices in the EU, and thereby restricting the entry of generic medicines to the market. Last year, the Commission also started proceedings against *Boehringer* for alleged misuse of the patent system to exclude competition in the area of chronic obstructive pulmonary disease drugs.

The Commission's sector inquiry will focus on similar business practices; indeed the Commission's announcement indicated it would examine whether the investigated parties' exercise of patents and agreements between competitors, such as terms for litigation settlement agreements, are compatible with the EC Treaty's rules on restrictive business practices. In addition, the inquiry will examine potential abuses of dominant position by market actors, including possible misuse of patent application procedures or frivolous lawsuits to prevent or deter launches of generic alternatives.

Enforcement actions in the United States on patent settlement agreements have proven controversial and even resulted in policy disagreements among the two U.S. antitrust agencies (*i.e.*, the Department of Justice and the Federal Trade Commission) about the proper application of the antitrust laws. In addition, antitrust claims in the U.S. based on frivolous litigation or misuse of the patenting process generally must satisfy a high standard of proof. Thus, if the Commission's sector inquiry results in any enforcement actions, they are likely to generate significant debate.

Finally, this sector inquiry is also notable because it is the first in which the Commission commenced the inquiry with dawn raids. (The Commission has in recent years carried out sector inquiries in the telecommunications, energy and financial services sectors, but all of these were initiated by sending out questionnaires to the targeted companies.) According to the Commission, the motivation to secure information in this manner stemmed from the fact that the information sought is usually considered by companies to be highly confidential and "may also be easily withheld, concealed or destroyed."

The Commission also recently used dawn raids in a merger investigation to investigate whether parties had integrated their business operations prior to obtaining clearance under the EU's merger control regulations. It remains to be seen whether the Commission will continue to expand the use of dawn raids in non-cartel investigations; however, firms should ensure that their employees and in-house legal department are prepared for such an event.

The first results of the pharmaceutical sector inquiry are expected to be published in an interim report by the Commission this autumn and a final report due in the spring of 2009. Any subsequent competition law enforcement actions by the Commission (or EU member state competition authorities) against individual companies would be launched outside the framework of the sector inquiry.