

Antitrust & Competition

Competition Authorities

Prescription before Diagnosis? The European Commission's Sector Inquiry into the Pharmaceutical Industry

Contributed by:

David Cardwell, Hogan & Hartson LLP

On 16 January, 2008, the European Commission announced that it had opened a sector inquiry into competition in the pharmaceuticals industry. The Commission began this inquiry by conducting dawn raids at the premises of a number of innovative and generic pharmaceutical companies with significant commercial activities in Europe. The Commission has made it clear that it has a particular interest in patent dispute settlements and the creation of artificial barriers to entry through the misuse of patent rights. One of the chief concerns of the Commission is to identify whether the alleged lack of generic entry in the European Union could be caused by some distortions to the competition rules.

Background and Mechanics

The Commission stated that it had launched the sector inquiry in response to indications that competition in pharmaceutical markets in Europe may not be functioning properly. In June 2005, the Commission fined the Anglo-Swedish pharmaceutical company AstraZeneca €60 million for alleged misuse of the patent system and marketing of pharmaceuticals allegedly to delay market entry for generic competitors to one of its drugs.¹ In launching its sector inquiry in January 2008, the Commission made reference to this case as being one of the factors that indicated to it that there may be elements in the pharmaceuticals sector that it would like to investigate further.²

The Commission expressed concerns that fewer new drugs were being brought to market and the entry of generic drugs appeared to be delayed. According to the Commission's figures, between 1995 and 1999, an average of forty novel molecular entities were launched per year compared to only twenty-eight per year between 2000 and 2004.

Explaining the rationale for the enquiry, EU Competition Commissioner Neelie Kroes remarked that "if innovative products are not being produced, and cheaper generic alternatives to existing products are in some cases being delayed, then we need to find out why and, if necessary, take action."³

Having launched its investigation in January, the Commission stated that it had decided to carry out dawn raids in order to ensure that it had immediate access to relevant information.

For the Commission, dawn raids were appropriate to ensure that highly confidential information relating to intellectual property rights, litigation and settlement agreements would not be withheld, concealed or destroyed following the announcement of the sector inquiry.

The Commission has a wide range of investigative tools to gather information from companies and trade associations, including requests for information sent to individual companies, the power to take statements, conduct inspections, and to request national competition authorities to conduct inspections for it. Importantly, the Commission has the authority to impose sanctions for non-compliance, including potentially hefty fines.

Issues

The Commission's inquiry focuses on specific areas of concern, namely: whether agreements between certain companies, such as settlements in patent disputes, may infringe European Community competition law on anticompetitive agreements; whether companies may have created artificial barriers to entry through the misuse of patent rights, vexatious litigation or other means and whether such practices may infringe EC competition law.

A second round of information requests issued by the Commission in April 2008 seemed to focus more closely on patent litigation and dispute settlements over a seven-year period (2000–2007). The Commission has requested from the companies involved detailed information on the number of patents filed, the stage of Research and Development (R&D) at which such patents are submitted to the European Patent Office (EPO) as well as the circumstances and conditions of patent litigation and settlement between these companies and generics.

On an analysis of the Commission's agenda in this inquiry, it would appear that it is focusing on whether certain patterns of conduct could be used as a strategy to delay the entry of generics on to the market, including tactics such as vexatious litigation, or unduly restrictive conditions that could be imposed in the context of settlements or licensing and distribution agreements between patent holders and generics manufacturers. As regards settlements, the Commission seems to be focusing on compensations that could be offered to generics as a way to settle, probably to assess whether such compensations could amount to a retribution to stay out of the market. As far as licensing and distribution agreements are concerned, the Commission is investigating whether certain provisions such as non-compete or exclusivity could act as barriers to entry.

Industry Reaction

The inquiry has been the subject of rigorous criticism from the pharmaceutical industry. The European Federation of Pharmaceutical Industries and Associations (EFPIA), a representative group of companies and thirty-two national

pharmaceuticals associations, has warned against the long-term consequences of what they consider to be an excessive intervention in the patent policy of pharmaceutical companies, which it considers could result in the weakening of protection of IP rights in the pharmaceuticals sector. The EFPIA, on behalf of pharmaceutical companies, links any such weakening to the potential for subsequent deterrence effects on innovation in the industry.

This echoes a line of argumentation that has been developed recently by the pharmaceutical companies, according to which the pharmaceutical industry is a special sector where R&D investments are both of great importance and where the commercial risks linked to bringing a product on to the market are particularly high. This may explain why undermining IP protection could be particularly dangerous for the pharmaceutical industry. Protection of strong product development competencies in tandem with effective and innovative research have emerged as one of the key themes running through the arguments in favour of the way in which the pharmaceuticals sector operates.

One further criticism levelled at the Commission by industry players is that the inquiry is not seeking to establish whether the alleged delay of new molecules could be caused by factors other than anticompetitive practices. The pharmaceutical industry points to the role played by the different regulatory and pricing regimes in the Member States. By apparently placing the blame for the slow market entry of generics at the foot of pharmaceutical companies alone, there is perhaps a strengthening perception that the Commission may have based its inquiry on the wrong premise, or at least approached the launch of its inquiry from the wrong angle.

Next Steps

Having issued requests for further information both to the companies who were the subject of inspections and to other companies active in the sector, the Commission will publish an interim report and hold a stakeholder event on 28 November 2008. Companies will be invited to submit their views on the report and to possibly submit comments at an oral hearing. The Commission will then publish a final report, currently scheduled for Spring 2009 – although this timetable is perhaps ambitious. It is only after the publication of this final report that players in the pharmaceutical inquiry will know exactly what direction the Commission will be taking over the course of the next few years in its enforcement of EC competition law in the pharmaceuticals sector.

What is clear, therefore, is that companies will have some clarification on the direction of the Commission's thinking in the near future. Patent litigation, settlements and the payment of compensation to generic manufacturers, as well as licensing terms and exclusivity are all important issues in the pharmaceutical sphere. Once the Commission presents its initial findings, innovative and generic companies will

have an opportunity to present their views on these issues and voice their responses to the Commission's initial conclusions, whatever they might be.

David Cardwell is an associate in the Brussels office of Hogan & Hartson LLP. He is a UK qualified lawyer specialising in EU competition law. E-mail: dcardwell@hhlaw.com Tel: +32 2 505 0920

¹ See Case COMP/37.507 Generics/Astra Zeneca. Astra AB; Commission fines AstraZeneca €60 million for misusing patent system to delay market entry of competing generic drugs – European Commission Press Release, IP/05/737 of 15 June 2005.

² Antitrust sector inquiry into pharmaceuticals – frequently asked questions – European Commission, Press Release MEMO/08/20 of 16 January 2008.

³ Antitrust: Commission launches sector inquiry into pharmaceuticals with unannounced inspections – European Commission Press Release, IP/08/49 of 16 January 2008.

Legislative and Regulatory Developments

Commission Authorises Infrastructure Aid for German Airport

Commission authorises aid for infrastructure at Leipzig Halle Airport; prohibits certain guarantees in favour of DHL – European Commission Press Release, IP/08/1191 of 23 July 2008; Commission Decision of 23 July 2008, C 48/2006 Germany DHL and Leipzig/Halle Airport, Non Confidential Version of 23 July 2008 (published in German)

On 20 April 2004, the European Commission approved a grant of €70.8 million for a new air logistics hub operated by DHL Airways GmbH (DHL), a subsidiary of Deutsche Post, to be established at Leipzig/Halle airport in Germany. Under the 1998 Multisectoral Framework Rules,¹ the approved grant corresponds to the maximum regional aid intensity of twenty-eight percent of DHL's investment cost. In January 2006, DHL began building its logistics centre, while in December 2005, Leipzig/Halle airport began building a new southern runway – in addition to the existing northern runway – at an investment cost of €350 million.

DHL's move from Brussels to Leipzig/Halle airport, which is publicly owned, is subject to three measures in respect of which the European Commission published its final decision on 23 July 2008.

The Capital Contribution

Contrary to past practice, the European Courts now accept that the operation of airports is an economic activity.² Although the business plan submitted by Germany failed to show that the new runway would earn enough revenue to meet its incremental costs, the Commission concluded that public capital contributions amounting to €350 million do not constitute State aid within the meaning of Article 87(1) EC Treaty since they fall within the airport's public service remit.