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EU Launches Industry-wide Investigation of the Pharmaceutical Industry in Europe

Overview

On January 16, the European Commission ("Commission") launched a "sector inquiry" into the pharmaceutical industry by staging unprecedented "dawn raids" or unannounced inspections of the premises of several major pharmaceutical manufacturers. News reports indicate that at least nine companies have confirmed they were approached by the Commission. The Commission has stated that it believes there are signs of general problems in the competitive environment in European pharmaceutical markets. The Commission expressed particular concern that fewer new pharmaceutical products are being brought to market and that market entry of generic pharmaceuticals seems to be delayed. The Commission indicates that it plans to send out requests for further information to companies in the pharmaceutical industry and publish a final report in the spring of 2009. This investigation may then trigger specific investigations against particular companies by the Commission and/or other national competition authorities and may prompt actions in other jurisdictions.

Although the Commission has conducted sector inquiries in the past, this inquiry—and especially the use of "dawn raids"—is consistent with our observation of an emerging trend in the EU and elsewhere towards a more aggressive approach to enforcement of competition laws. (We address this and other key trends in our e-Guide on international practice.)

Legal Basis for Sector Inquiries

Sector inquiries are investigations by the Commission into a single sector of the economy when a sector does not seem to be working as well as it should. Under European Commission Regulations, the Commission may conduct an inquiry into a particular sector of the economy "where the trend of trade between Member States, the rigidity of prices or other circumstances suggest that competition may be restricted or distorted within the common market."[1]

As a result, sector inquiries are not aimed at investigating specific acts of wrongdoing by particular companies, but are considered the starting point of an investigation in order to ensure that the Commission has immediate access to relevant information that will guide any next steps. In fact, the Commission is not given any statutory basis for imposing remedies as a direct result of a sector inquiry. The Commission must initiate a separate proceeding against particular companies under either Article 81 and/or Article 82 of the European Community Treaty to impose remedies upon particular companies.

In conducting a sector inquiry, the Commission may conduct dawn raids or other inspections of company premises, take statements, and/or formally require companies to provide all necessary information.[2] If a company fails to comply with the Commission, or provides incorrect, incomplete, or misleading information, the Company may be fined up to one percent of its total annual sales.[3] There is neither a right for companies to be heard before the Commission

1 Council Regulation (EC) No. 1/2003, OJ L 1 art. 17(1) (Dec. 16, 2002), *available at* http://eurlex.europa.eu/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=32003R0001&model=guichett.

2 *Id.* at arts. 18-20.

3 *Id.* at art. 23.

reaches it conclusions nor any right for companies to comment on any findings.

Prior Inquiries

There have been a number of recent Commission sector inquiries, none of which were initiated by or utilized "dawn raids." Recent inquiries into financial services, insurance and energy industries have resulted in final reports within about 24 months of the initiation of the inquiries and have identified what the Commission felt were numerous competitive problems in those industries.[4] Some of the inquiries have resulted in significant enforcement activity against companies. For example, in the inquiry into the energy industry, the Commission explained that it would "pursue follow pursue follow up action in individual cases under the competition rules . . . and has already conducted a number of inspections in companies where these particular issues warrant investigation."[5] In fact, before the final report was published, the Commission began enforcement actions against various companies, including dawn raids of utility companies in Member States.[6] The Commission also indicated that legislative reform would be necessary to remedy the problems.

In 2007, Commissioner Neelie Kroes explained that she anticipated that the Commission would continue to conduct sector inquiries where: (a) there appear to be durable problems; (b) these problems may be due to "competition infringements"; (c) there are implications for better regulation; and (d) the industry is important for consumers and/or competitiveness.[7] She stressed the importance of following up the inquiry with proceedings against individual companies if the inquiry uncovers violations of competition law.[8]

Sector Inquiry into Pharmaceutical Industry

On January 15, 2008, the Commission issued a decision initiating a sector inquiry into the pharmaceutical industry.[9] This decision authorized an investigation "with respect to pharmaceutical suppliers of innovative and generic medicines for human consumption, consumer and professional organisations in health care, as well as authorities granting patents and marketing authorisations for drugs."[10] If the inquiry reveals "the possible existence of anticompetitive agreements or practices or abuses of a dominant position, the Commission or, where appropriate, the national competition authorities could envisage taking the appropriate measures to restore competition in the sector, including opening investigations against individual entities."[11]

For the first time, the Commission decided to begin this inquiry with a series of surprise "dawn raids" at various pharmaceutical companies. Prior inquiries were initiated by sending questionnaires to companies in the targeted industry. The Commission explained the reason for these raids is that this investigation concerned the use of "intellectual property rights, litigation and settlement agreements covering the EU," which are all highly confidential, and companies might easily withhold, conceal or destroy such information.[12] At least nine companies have confirmed that they were contacted by the Commission.

Presumably, the pharmaceutical industry satisfied the conditions described above which were outlined by Commissioner Kroes for warranting a sector inquiry. According to the Commission, they specifically have indications that competition in European pharmaceutical markets "may be restricted or distorted." The Commission noted indications of anticompetitive practices by pharmaceutical companies including patenting or the

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4 For more details, see European Commission Web page at http://ec.europa.eu/comm/competition/antitrust/sector_inquiries.html.

5 *See* European Commission, Press Release IP/07/26, Commission Energy Sector Inquiry Confirms Serious Competition Problems (Jan. 10, 2007), *available at* http://europa.eu/rapid/pressReleasesAction.do?reference=IP/07/26&format=HTML&aged=0&language=EN&guiLanguage=en.

6 *See* Neelie Kroes, European Competition Commissioner, SPEECH/07/4, Introductory Remarks on Final Report of Energy Sector Competition Inquiry (Jan. 10, 2007), *available at* http://europa.eu/rapid/pressReleasesAction.do?reference=SPEECH/07/4&format=HTML&aged=0&language=EN&guiLanguage=en; and Neelie Kroes, European Competition Commissioner, SPEECH 06/541, The Need for a Renewed European Energy Policy (Sept. 28, 2006), *available at* http://europa.eu/rapid/pressReleasesAction.do?reference=SPEECH/06/541&format=HTML&aged=0&language=EN&guiLanguage=en.

7 *See* Neelie Kroes, European Competition Commissioner, SPEECH/07/186, Fact Based Competition Policy—The Contribution of Sector Inquiries to Better Regulation, Priority Setting and Detection, 13th International Conference on Competition and the 14th European Competition Day (Mar. 26, 2007), *available at* http://europa.eu/rapid/pressReleasesAction.do?reference=SPEECH/07/186&format=HTML&aged=0&language=EN&guiLanguage=en.

8 *See id.*

9 *See* European Commission Decision, Case No. COMP/D2/39.514 (Jan. 14, 2008), *available at* http://ec.europa.eu/comm/competition/sectors/pharmaceuticals/inquiry/decision_en.pdf.

10 *Id.*

11 *Id.*

12 *See* European Commission, Antitrust – Sector Inquiry into Pharmaceuticals — Frequently Asked Questions (Jan. 16, 2008), *available at* http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/08/20&format=HTML&aged=0&language=EN&guiLanguage=en.

exercise of patents that may serve to block innovation, vexatious litigation, and collusive agreements. Specifically, the Commission pointed to a decline in the number of new medicines reaching the market from an average of 40 per year from 1995-1999 to 28 per year from 2000-2004; and a delay in the entry of generic medicines into the market.[13] The Commission also pointed to: (a) the recent decision fining AstraZeneca for trying to exclude generic firms from competing against its anti-ulcer product by providing misleading information to national patent offices and by selectively deregistering market authorizations; and (b) the ongoing proceedings against Boehringer for misusing the patent system to exclude potential competition.[14]

In particular, the Commission said that this sector inquiry will examine:

- whether agreements between pharmaceutical companies across the sector, such as settlements in patent disputes, may infringe EC Treaty Article 81, which governs restrictive business practices; and

- whether companies may have created artificial barriers to entry (for example, through the misuse of patent rights or vexatious litigation) that may infringe EC Treaty Article 82, which prohibits abuse of a dominant market position.

Many of these issues have been the subject of investigation and litigation in the United States particularly in light of the Hatch-Waxman regulatory structure. In Europe, where the regulatory structure is quite different, the issues may present themselves differently.

Commissioner Kroes explained that this sector inquiry—like other sector inquiries—was "not based on specific evidence of wrongdoing" and emphasized that the "[i]nspections are just the starting point of a broad inquiry."[15] However, Kroes went on to say, "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."[16]

The sector inquiry is expected to produce an interim report in the fall of 2008 and a final report in the spring of 2009. The inquiry's findings will allow the Commission and/or other national competition authorities to focus any future action on the most serious competition concerns, and to identify remedies to resolve the specific competition problems in individual cases.

Conclusion

Pharmaceutical companies that operate in Europe should be prepared for significant investigatory activity during the upcoming years even if they have not yet been contacted by the Commission. It is also important to note, as discussed in our *2008 Trends Report*, that there has been increasing coordination between competition agencies in different jurisdictions and that there is the possibility that any investigation could spill over into other jurisdictions. Companies also should be concerned about possible class actions or other private lawsuits which may follow any adverse findings, another important trend discussed in the *2008 Trends Report*.

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13 *Id.*

14 *See id.*

15 Neelie Kroes, European Competition Commissioner, SPEECH/08/18, Commission Launches Sector Inquiry into Pharmaceuticals, Introductory Remarks at Press Conference (Jan. 16, 2008), *available at* http://europa.eu/rapid/pressReleasesAction.do?reference=SPEECH/08/18&format=HTML&aged=0&language=EN&guiLanguage=en.

16 *Id.*

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