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EU scrutiny of the pharmaceutical sector since the European Commission's sector inquiry

Introduction

On 8 July 2009, the European Commission (the "**Commission**") published the final report on its pharmaceutical sector inquiry. This confirmed its provisional findings that the market is not functioning as well as it could, in part due to shortcomings in the regulatory framework but in part due to company practices such as the use of defensive patent strategies that focus on excluding competitors, actions aimed at delaying generic market entry (such as interventions in marketing authorisation processes) and settlement agreements that have a potentially anti-competitive effect. As a result, the Commission stated its intention to intensify its scrutiny of the pharmaceutical sector under competition law.

Please click here for further details.

Monitoring of patent settlements

12 January 2010: Commission launches monitoring of patent settlements concluded between pharmaceutical companies

On 12 January 2010, the Commission announced that it had it addressed requests for information to certain pharmaceutical companies, asking them to submit copies of their patent settlement agreements concluded in the period from 1 July 2008 to 31 December 2009 and relating to the EU/EEA. The Commission is in particular looking at patent settlements where an originator company pays a "reverse payment" to a generic competitor in return for delayed market entry of a generic drug.

Please click here for further details.

6 July 2011: Commission publishes second report on monitoring of patent settlements

On 6 July 2011, the Commission published its second report on the monitoring of patent settlements, covering patent settlement agreements concluded in the EEA in 2010. The Commission stated that the number of "potentially problematic" settlements from an antitrust perspective had decreased to 3% of the settlements reported (compared to 10% of agreements examined during the first monitoring period from July 2008 to

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December 2009, and 22% in the period covered by the sector inquiry). However, the Commission did note that it would remain vigilant that companies' behaviour respected antitrust law and did not delay the entry of cheaper pharmaceuticals, stating that it would repeat the monitoring exercise in 2012.

Please click here for further details.

Commission investigations

Chronic obstructive pulmonary disease drugs (Boehringer-Ingelheim)

6 July 2011: Commission closes antitrust investigation into Boehringer's COPD drug marketing

On 6 July 2011, the Commission closed its investigation into the alleged "misuse of the patent system in order to exclude potential competition in the area of chronic obstructive pulmonary disease (COPD) drugs" by German drugs group Boehringer. At the time, Boehringer was the leader in the COPD market, which includes drugs to treat bronchitis and emphysema, with its inhaled line of treatments. The decision to close the investigation followed Boehringer agreeing to remove the alleged blocking positions, lifting the obstacles to the launch of competing products.

Please click here and here for further details.

Cardio-vascular drugs (Les Laboratoires Servier)

8 July 2009: Commission opens formal proceedings against Les Laboratoires Servier and a number of generic pharmaceutical companies

On 8 July 2009, the same day that it published its pharmaceutical sector inquiry final report, the Commission announced that it had opened a formal investigation into Les Laboratoires Servier for suspected breaches of Articles 101 (restrictive business practices) and 102 (abuse of a dominant position) of the Treaty on the Functioning of the European Union ("**TFEU**"). The proceedings concern both unilateral behaviour by Servier, and agreements between Servier and a number of generic companies, which may have the object or effect of hindering the entry of generic versions of the cardio-vascular medicine perindopril into markets in the EEA.

The Commission subsequently announced on 27 January 2012 that it had closed its separate investigation into Servier for suspected provision of misleading and incorrect information to the Commission's pharmaceuticals sector inquiry.

Please click here and here for further details.

Generic drugs in France

6 October 2009: Commission confirms surprise inspections in the pharmaceutical sector

On 6 October 2009, the Commission announced that its officials had started surprise inspections at the premises of certain companies active in the

pharmaceutical industry. The Commission had reason to believe that Articles 101 and 102 of the TFEU may have been infringed. The companies involved are reported to be Mylan, Novartis, Ranbaxy, Ratiopharm, Sandoz, Sanofi-Aventis and Teva and the investigation reportedly concerns delays in the launch of generic drugs in France.

Please click here for further details.

Anti-depressant drugs (Lundbeck)

7 January 2010: Commission opens formal proceedings against pharmaceutical company Lundbeck

On 7 January 2010, the Commission announced that it had opened a formal investigation into potential breaches of Articles 101 and 102 of the TFEU by the pharmaceutical company Lundbeck. The Commission intends to investigate unilateral behaviour and agreements entered into by Lundbeck which may hinder the entry of generic versions of the anti-depressant drug citalopram into markets in the EEA. The decision to open formal proceedings follows surprise inspections by Commission officials in December 2009, at the premises of certain companies active in the pharmaceutical industry.

Please click here for further details.

Heartburn drugs (AstraZeneca)

6 July 2011: Commission closes antitrust investigation into AstraZeneca and Nycomed

On 6 July 2011, the Commission closed its antitrust investigation into AstraZeneca and Nycomed. On 3 December 2010, the Commission announced that its officials had carried out unannounced inspections at the premises of a number of companies active in the pharmaceutical industry. AstraZeneca reportedly confirmed that the Commission had visited it as part of an investigation concerning a heartburn drug called esomeprazole (Nexium) in Europe.

Please click here and here for further details.

Sleeping disorder drugs (Cephalon and Teva)

28 April 2011: Commission opens formal investigation against pharmaceutical companies Cephalon and Teva

On 28 April 2011, the Commission announced that it has opened a formal antitrust investigation to assess whether a patent settlement agreement between US-based pharmaceutical company Cephalon and Israel-based generic drugs firm Teva may have had the object or effect of hindering the entry of generic modafinil (brand name Provigil), used for the treatment of certain types of sleeping disorder, in the EEA.

Cephalon has subsequently been acquired by Teva, and the merger cleared by the Commission under the EU Merger Regulation, subject to divesting Cephalon's generic pipeline Modafinil product.

Please click here and here for further details.

Pain killer drugs (Johnson & Johnson and Novartis)

21 October 2011: Commission opens proceedings against Johnson & Johnson and Novartis

On 21 October 2011, the Commission announced that it has opened proceedings in respect of potential breaches of Article 101 of the TFEU by Johnson & Johnson and Novartis. The Commission intends to investigate agreements entered into between the parties' Dutch entities which may hinder the entry onto the market of generic versions of Fentanyl (a strong pain killer) in the Netherlands.

Please click here for further details.

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