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PRESS RELEASE

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Antitrust: Commission sends Statement of Objections to J&J and Novartis on delayed entry of generic pain-killer

The European Commission has informed the pharmaceutical companies Johnson & Johnson (J&J, of the USA) and Novartis (of Switzerland) of its objections regarding an agreement concluded between their respective Dutch subsidiaries on fentanyl, a strong pain-killer. The Commission takes the preliminary view that the agreement delayed the market entry of a cheaper generic medicine in the Netherlands, in breach of EU antitrust rules. The sending of a Statement of Objections does not prejudice the final outcome of the investigation.

"If our preliminary conclusions are confirmed, the Dutch subsidiaries of Johnson & Johnson and Novartis entered into a so-called 'co-promotion' agreement to avoid competing against each other, depriving users of fentanyl in the Netherlands from access to a cheaper pain killer. The Commission is determined to fight undue delays in the market entry of generic medicines so that European citizens have access to affordable healthcare. It is also important to make sure that pharmaceutical companies do not free ride our welfare state and health insurance systems, especially in this period of constraints on public spending", said Joaquín Almunia, Commission Vice President in charge of competition policy.

Janssen-Cilag, the J&J subsidiary supplying the pain-killer fentanyl in the Netherlands, concluded a so-called "co-promotion agreement" with its close generic competitor Sandoz, a Novartis subsidiary, in July 2005. At the time there were no regulatory barriers to develop and market generic versions of the fentanyl patches and therefore for Sandoz to enter the Dutch market. The agreement foresaw monthly payments from Janssen-Cilag to Sandoz for as long as no generic product was launched in the Dutch market. Consequently, Sandoz abstained from entering the market with generic fentanyl patches for the duration of the agreement from July 2005 until December 2006. This may have delayed the entry of a cheaper generic medicine for seventeen months and kept prices for fentanyl in the Netherlands artificially high.

This investigation involving major pharmaceutical companies is a further step in the Commission's fight against undue delay to generic entry, following its sector enquiry (see [MEMO/13/56](#)). In the Statement of Objections, the Commission takes the preliminary view that the agreement concluded between these companies infringes EU antitrust rules that prohibit anti-competitive business practices (Article 101 of the Treaty on the Functioning of the European Union – TFEU).

Background on the investigation

Fentanyl is a pain-killer stronger than morphine. It is typically used to treat patients with severe pain.

The Commission opened an investigation on its own initiative in October 2011 (see [IP/11/1228](#)).

The Statement of Objections is addressed to Johnson & Johnson, its subsidiary Janssen-Cilag B.V., Novartis and its subsidiary Sandoz B.V.

A Statement of Objections is a formal step in Commission investigations into suspected violations of EU antitrust rules. The Commission informs the parties concerned in writing of the objections raised against them and the companies can examine the documents in the Commission's investigation file, reply in writing and request an oral hearing to present their comments on the case before representatives of the Commission and national competition authorities.

If, after the parties have exercised their rights of defence, the Commission concludes that there is sufficient evidence of an infringement, it can issue a decision prohibiting the conduct and impose a fine of up to 10% of a company's annual worldwide turnover.

More information is available under the case number AT.39685 in the Commission's public [case registry](#) on the [competition website](#). New decisions on competition policy are listed in the electronic newsletter [Competition weekly news summary](#).

Background on antitrust enforcement in the pharmaceutical sector

The Commission's competition inquiry into the pharmaceutical sector issued in 2009 indicated a number of structural issues and problems in companies' practices that potentially led to distortions of competition and delays to the entry of new, innovative and cheaper generic medicines into the EU market (see [IP/09/1098](#) and [MEMO/09/321](#)). It emphasised, in particular, that so-called "originator" drug companies may be paying to delay the entry on to the market of generic medicines.

Following the statements of objections sent in the Lundbeck (see [IP/12/834](#)) and Servier (see [IP/12/835](#)) cases, and in line with the Commission's overall enforcement action in the sector (see [MEMO/13/56](#)), today's Statement of Objections is an additional step in addressing the competition issues highlighted in the final report of the sector inquiry.

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