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PRESS RELEASE

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Antitrust: Commission fines Johnson & Johnson and Novartis € 16 million for delaying market entry of generic pain-killer fentanyl

The European Commission has imposed fines of € 10 798 000 on the US pharmaceutical company Johnson & Johnson (J&J) and € 5 493 000 on Novartis of Switzerland. In July 2005, their respective Dutch subsidiaries concluded an anticompetitive agreement to delay the market entry of a cheaper generic version of the pain-killer fentanyl in the Netherlands, in breach of EU antitrust rules. Fentanyl is a pain-killer 100 times more potent than morphine. It is used notably for patients suffering from cancer.

Commission Vice-President Joaquín Almunia, in charge of competition policy, said: *"J&J paid Novartis to delay the entry of a generic pain killer. The two companies shockingly deprived patients in the Netherlands, including people suffering from cancer, from access to a cheaper version of this medicine. Today's decision should make pharmaceutical companies think twice before engaging into such anticompetitive practices, which harm both patients and taxpayers.*"

J&J initially developed Fentanyl and has commercialised it in different formats since the 1960s. In 2005, J&J's protection on the fentanyl depot patch had expired in the Netherlands and Novartis' Dutch subsidiary, Sandoz, was on the verge of launching its generic fentanyl depot patch. It had already produced the necessary packaging material.

However, in July 2005, instead of actually starting to sell the generic version, Sandoz concluded a so-called "co-promotion agreement" with Janssen-Cilag, J&J's Dutch subsidiary. The agreement provided strong incentives for Sandoz not to enter the market. Indeed, the agreed monthly payments exceeded the profits that Sandoz expected to obtain from selling its generic product, for as long as there was no generic entry. Consequently, Sandoz did not offer its product on the market. The agreement was stopped in December 2006 when a third party was about to launch a generic fentanyl patch.

The agreement therefore delayed the entry of a cheaper generic medicine for seventeen months and kept prices for fentanyl in the Netherlands artificially high - to the detriment of patients and taxpayers who finance the Dutch health system.

Why did J&J and Novartis conclude that agreement? According to internal documents Sandoz would abstain from entering the Dutch market in exchange for "*a part of [the] cake*". Instead of competing, Janssen-Cilag and Sandoz agreed on cooperation so as "*not to have a depot generic on the market and in that way to keep the high current price*". Janssen-Cilag did not consider any other existing potential partners for the so-called "co-promotion agreement" but just focused on its close competitor Sandoz. Sandoz engaged in very limited or no actual co-promotion activities.

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The Commission therefore concluded that the object of this agreement was anticompetitive and infringed Article 101 of the Treaty on the functioning of the European Union (TFEU).

Fines

The Commission based its fines on its 2006 Guidelines on fines (see IP/06/857 and MEMO/06/256). In setting the level of the fines, the Commission took into account the duration of the infringement and its gravity.

The individual fines are as follows:

	Undertaking	Fine
1.	Johnson & Johnson and Janssen-Cilag B.V., jointly and severally	€ 10 798 000
2.	Novartis AG and Sandoz B.V., jointly and severally	€ 5 493 000

Background

The Commission's competition inquiry into the pharmaceutical sector indicated a number of structural issues and problems in companies' practices that could delay the entry of cheaper medicines into the internal market. It also emphasised the importance of stronger competition law enforcement (see IP/09/1098, MEMO/09/321 and MEMO/13/56).

The Commission is actively investigating "pay-for-delay" agreements that limit generic entry in return for a value transfer by the originator company to the generic company. These may be concluded in the context of a potential patent dispute (as in the recent *Lundbeck* decision) or unrelated to any such dispute (as in the *Fentanyl* decision). In June 2013, the Commission fined the Danish company Lundbeck and several generic producers for delaying the market entry of citalopram, an antidepressant (see IP/13/563), in a first reverse payment settlement case. In 2012, the Commission also sent a Statement of Objections to Servier and several generic companies concerning the cardio-vascular medicine perindopril (see IP/12/835). In 2011, the Commission opened proceedings against Cephalon and Teva (see IP/11/511). In addition, the Commission has been monitoring patent settlements in order to identify those settlements which could be potentially problematic from an antitrust perspective (see MEMO/13/56 – IP/13/1228).

Today's decision follows the Statement of Objections sent to the parties in January 2013 (see IP/13/81 and MEMO/12/593) and the earlier opening of the formal investigation in October 2011 (see IP/11/1228).

More information on today's decision will be available on the competition website in the public case register under the case number AT.39685, once confidentiality issues will have been dealt with.

Action for damages

Any person or firm affected by anti-competitive behaviour as described in this case may bring the matter before the courts of the Member States and seek damages. The case law of the Court and Council Regulation 1/2003 both confirm that in cases before national courts a Commission decision is binding proof that the behaviour took place and was illegal. Even though the Commission has fined the companies concerned, damages may be awarded without these being reduced on account of the Commission fine.

In June 2013, the Commission has adopted a proposal for a Directive that aims at making it easier for victims of anti-competitive practices to obtain such damages (see IP/13/525 and MEMO/13/531). More information on antitrust damages actions, including a practical guide on how to quantify the harm typically caused by antitrust infringements, the public consultation and a citizens' summary, is available at:
http://ec.europa.eu/comm/competition/antitrust/actionsdamages/documents.html

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