European Commission imposes Fines of € 16 000 000 on Johnson & Johnson and Novartis for delaying Market Entry of generic Pain-Killer Fentanyl

On 10 December 2013, the European Commission 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 Article 101 of the Treaty on the functioning of the European Union (TFEU).

Further to the Lundbeck decision in June 2013, this is the second time that the Commission sanctions “pay-for-delay” agreements in the pharmaceutical sector. However, the Lundbeck case involved so-called “patent settlement agreements”, in contrast to the Fentanyl decision which does not relate in any way to potential intellectual property matters.

Fentanyl is a pain-killer 100 times more potent than morphine, used notably for patients suffering from cancer. 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.

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. Moreover, 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.

The Commission based the fines on its 2006 Guidelines on fines. In setting the level of the fines, the Commission took into account the duration of the infringement and its gravity.

More information on the case is available on the competition website in the Commission’s public case register under case number 39685 Fentanyl.