Antitrust: Commission fines Teva and Cephalon €60.5 million for delaying entry of cheaper generic medicine

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The European Commission has fined the pharmaceutical companies **Teva** and **Cephalon** €60.5 million for agreeing to delay for several years the market entry of a cheaper generic version of Cephalon's drug for sleep disorders, modafinil, after Cephalon's main patents had expired. The agreement was concluded well before Cephalon became a subsidiary of Teva. The agreement violated EU antitrust rules and caused substantial harm to EU patients and healthcare systems by keeping prices high for modafinil.

Executive Vice-President Margrethe **Vestager**, in charge of competition policy, said: *"It is illegal if pharmaceutical companies agree to buy-off competition and keep cheaper medicines out of the market. Even when their agreements are in the form of patent settlements or other seemingly normal commercial transactions. Teva's and Cephalon's pay-for-delay agreement harmed patients and national health systems, depriving them of more affordable medicines."*

Modafinil is a medicine used for the treatment of excessive daytime sleepiness associated in particular with narcolepsy. It was Cephalon's best-selling product under the brand name "Provigil" and for years accounted for more than 40% of Cephalon's worldwide turnover. While the main patents protecting modafinil had expired in Europe by 2005, Cephalon still held some secondary patents related to the pharmaceutical composition of modafinil, which aimed at securing additional patent protection.

Today's decision concerns a patent settlement agreement whereby Cephalon induced Teva not to enter the market with a cheaper version of modafinil, in exchange for a package of commercial side-deals that were beneficial to Teva and some cash payments. Teva held its own patents relating to modafinil's production process, was ready to enter the modafinil market with its own generic version, and it had even started selling its generic in the UK. Then, it agreed with Cephalon to stop its market entry and not to challenge Cephalon's patents.

The Commission investigation has found that for several years, this "pay-for-delay" agreement eliminated Teva as a competitor and allowed Cephalon to continue charging high prices even if the main modafinil patent had long expired.

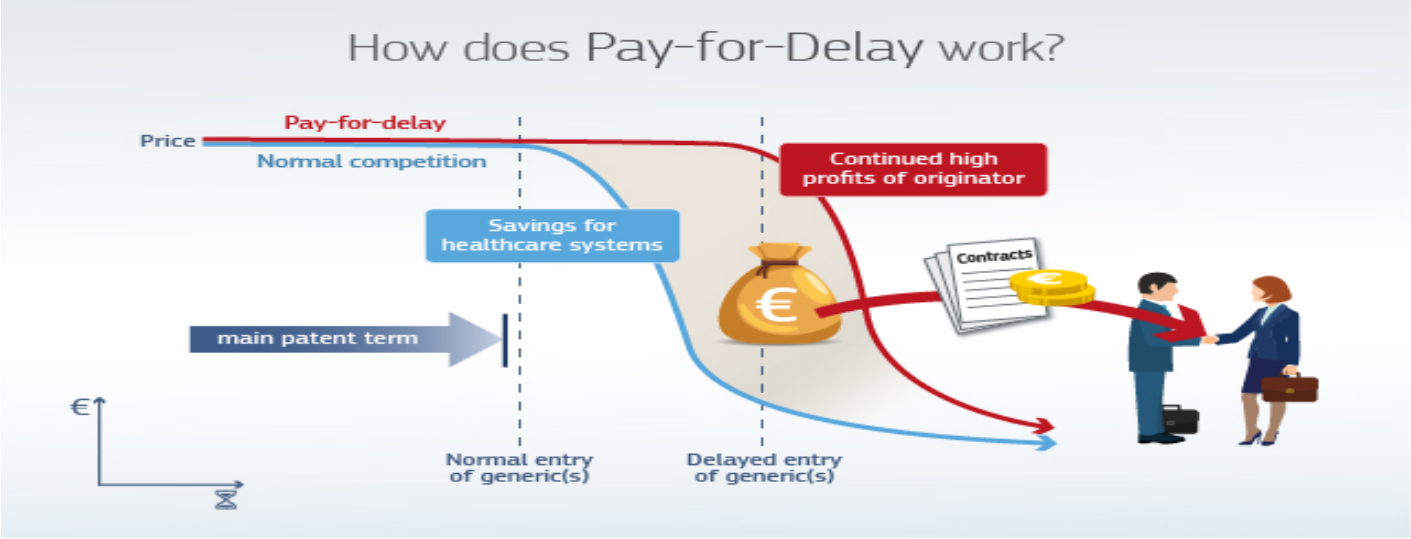
While generally patent settlements can be legitimate, we believe that the settlement agreement between Teva and Cephalon was not. Teva committed to stay out of the modafinil markets, not because it was convinced of the strength of Cephalon's patents, but because of the substantial value transferred to it by Cephalon. The value transfer was mainly embedded in a number of commercial side-deals, which Teva would not have achieved without committing to staying out of the market.

Harm caused by pay-for-delay agreements

The delay in Teva's entry, the most advanced generic competitor at the time of the settlement agreement, meant that Cephalon did not face competition from cheaper medicines. Without the "pay-for-delay" settlement agreement, Teva could have entered the market earlier and could have, in turn, pushed down prices for modafinil.

Generic entry brings price competition to markets that can lead to price drops of up to 90%. When Teva entered the UK market for a short period in 2005, it indeed offered a 50% lower price than the price of Cephalon's Provigil.

The graphic below illustrates the negative impact of pay-for-delay settlement agreements for patients and healthcare systems. Delayed generic entry prevents consumers and health systems from benefitting from significantly lower prices earlier. With pay-for-delay settlement agreements, companies share the extra profits generated by the lack of competition.



Pay-for-delay agreements can also have a detrimental effect on innovation. Competition from generics stimulates pharmaceutical companies to focus their efforts on developing new drugs rather than on maximising income streams from their old drugs by artificially preserving market exclusivity.

Fines

The fines were set on the basis of the Commission's 2006 Guidelines on fines (see press release and MEMO). Regarding the level of the fines, the Commission took into account, in particular, the duration of the infringement and its gravity.

As in other "pay-for-delay" cases, the general fines methodology does not work for generic companies, as they, by virtue of the restrictive agreement, do not realise any sales with the affected product. The Commission, therefore, imposed a fixed amount fine to Teva that is slightly below the fine for Cephalon.

The fines imposed by the Commission on Teva and Cephalon are €30 million and €30.5 million, respectively, amounting in total to €60.5 million.

The infringement lasted, for almost all EU Member States and EEA countries, from December 2005 to October 2011, when Teva acquired Cephalon and they became part of the same group.

Fines imposed on companies found in breach of EU antitrust rules are paid into the general EU budget. This money is not earmarked for particular expenses, but Member States' contributions to the EU budget for the following year are reduced accordingly. The fines therefore help to finance the EU and reduce the burden for taxpayers.

Background to the settlement agreement

To defend itself against Teva's launch of modafinil in the UK, Cephalon brought legal actions alleging an infringement of its secondary modafinil patents, although it had doubts as to the strength of these patents. Teva also believed that Cephalon had a weak patent position.

Nonetheless, in 2005 the two companies concluded the patent settlement agreement. In exchange, Teva received certain cash payments and secured a package of commercial side-deals. These included a distribution agreement, the acquisition of a licence on certain Teva modafinil patents by Cephalon, purchases of raw materials from Teva, and granting by Cephalon of access to clinical data that were highly valuable to Teva for a different medicine. Our investigation found that none of these transactions would have been concluded in the absence of the patent settlement agreement, either not at all or at least not at the terms that the companies agreed to.

By virtue of the settlement agreement, as of October 2012, Teva could have started selling generic modafinil on the basis of a licence granted by Cephalon, in exchange for significant royalty payments to Cephalon.

Teva's limited entry under the licence eventually did not happen, as, in October 2011, Teva acquired Cephalon.

General background

The pay-for-delay agreement between Teva and Cephalon infringed Article 101 of the Treaty on the Functioning of the European Union (TFEU), which prohibits agreements between companies that prevent, restrict or distort competition within the EU's internal market.

The Commission opened formal antitrust proceedings in April 2011 and sent a Statement of Objections to Teva in July 2017.

Today's decision completes the cycle of pay-for-delay investigations launched with the Commission's 2009 sector inquiry into the pharmaceutical sector.

To date, the Commission has fined companies in three other investigations – one concerning perindopril, a cardiovascular medicine, one concerning citalopram, an anti-depressant, and one concerning fentanyl, a painkiller.

Evidence from these cases shows that prices dropped up to 90% further to generic entry. The Commission's 2019 Pharma Report has found that, in general, average prices for a medicine tend to decrease by more than 50% after generic entry.

The recently adopted 'Intellectual Property Action Plan' promotes the need for effective intellectual property protection to stimulate competitiveness. The 'Pharmaceutical Strategy for Europe' further stresses the importance of accessible, innovative and affordable medicines for EU citizens, to which competition significantly contributes.

More information on the investigation will be available on the Commission's competition website, in the public case register under the reference AT.39686.

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.

The Antitrust Damages Directive, which Member States had to transpose into their legal systems by 27 December 2016, makes it easier for victims of anti-competitive practices to obtain damages. 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 here.

Whistleblower tool

The Commission has set up a tool to make it easier for individuals to alert it about anti-competitive behaviour while maintaining their anonymity. The tool protects whistleblowers' anonymity through a specifically-designed encrypted messaging system that allows two way communications. The tool is accessible via this link.

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Related documents

Pay for Delay graph_en.pdf