Statement by Executive Vice-President Margrethe Vestager on the Commission decision to fine Teva and Cephalon €60.5 million for delaying entry of cheaper generic medicine

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Today, the Commission has fined the pharmaceutical companies Teva and Cephalon a total of 60 million euros. They agreed to delay the market entry of Teva's cheaper generic version of Cephalon's sleeping disorder medicine, modafinil. Such agreements are called "pay-for-delay" agreements. They stand in the way of competition and are illegal under EU antitrust rules.

Pharmaceutical companies bring innovation, which requires large investments into research and development to find new medicines and treatments. And we, as society and citizens benefit enormously from such innovations. Pharmaceutical companies that innovate contribute significantly to overcoming some of the most serious diseases, for example, bringing potentially life-saving vaccines to citizens.

To encourage and reward this innovation, our patent systems give the companies that develop new medicines – so-called originators – exclusive rights for a certain period of time. Patents offer a temporary protection from competition in order to allow innovators to recoup the cost of discovering and developing new medicines. This is also important because research is not always successful but the costs of research still need to be incurred.

But, patent protection is temporary. Once the time to recoup is over, then other companies can enter the market with their generic products. With competition, medicines become more affordable. And we know that generic entry in pharmaceutical markets can lead to very significant drops in prices, sometimes by up to 90%. This is good for patients, and it is good for health budgets.

A pay-for-delay arrangement disturbs this normal cycle. When originators buy-off potential generic entrants to delay the moment when competition starts and cheaper medicines become available, they interfere with the fine balance between the protection of intellectual property rights and the benefits of competition.

Pay-for-delay arrangements serve both the originator and generic entrants well: the originator enjoys extended supra-competitive profits and the generic company gets the money and other benefits. But it means that patients and health budgets lose out because they have to pay higher prices.

The Commission's investigation

Today's decision found that a patent settlement between Cephalon and its generic challenger Teva was exactly this type of "pay-for-delay" agreement which is illegal under EU antitrust rules.

The agreement concerned modafinil, a medicine used to treat sleeping disorders and associated in particular with narcolepsy, a neurological illness.

Cephalon's main patents on modafinil had expired at the time of the agreement. But Cephalon still held secondary patents relating to how its modafinil-based medicine was composed. Cephalon hoped that those patents would allow it to keep out generic competition for some time longer – but it feared they were weak and not sufficient to stop generic companies from entering the market and launching their own product.

This is what happened in June 2005, when Teva introduced its generic modafinil product in the UK at half the price. Cephalon responded with an infringement lawsuit alleging a breach of its patents. Shortly after, the two companies agreed to settle the dispute. This is not an issue as such. But as part of the settlement, Teva received a package of commercial side-deals and cash payments, and in return Teva committed not to compete against Cephalon and not to challenge its patents.

Our investigation showed that the only reason Teva agreed to settle and not compete was that

Cephalon offered to share the extra profits it would make by delaying entry. Our investigation also showed that Cephalon offered the cash payments and side-deals to induce Teva into the settlement agreement. In this way, Cephalon replaced the risk of competition and litigation with the certainty of additional profits. Teva replaced the risk of competition and litigation with the certainty of the value transfers it received from Cephalon.

To reach our conclusion, we analysed a large amount of internal documents and other evidence from the time of the settlement agreement. This evidence showed how negotiations took place and how the package of transactions was the price to pay Teva to stay out of the market.

To give a few examples: Cephalon gave Teva a lucrative supply contract earning Teva at least 5 million Euros in profits, although at the time Cephalon could fully cover its needs without these additional supplies. Cephalon also paid a significant amount for a licence to Teva's own secondary patents, developed to pave the way to Teva's generic entry. And yet, our investigation shows that Cephalon did not see a need for that licence, nor did Cephalon ever use this license.

For several years, this agreement eliminated Teva as a competitor and allowed Cephalon to continue charging high prices even though the main modafinil patent had long expired. In the words of Cephalon, this arrangement secured it "*6 more years of patent protection (…) that no one expected*". In the absence of the pay-for-delay settlement agreement, Teva could have entered the market earlier and pushed down the prices for modafinil to the benefit of patients and healt budget. This means that for years patients, national health systems and taxpayers lost out on lower prices, and maybe also on innovation.

The infringement lasted from the time the settlement agreement was signed in 2005 until Teva acquired Cephalon in 2011.

The importance of today's decision

Today's decision is the fourth "pay-for-delay" decision that the Commission adopts. It is nonetheless significant because of the form taken by the payments. In previous cases, generic entry was delayed by means of simple cash payments. In the present case, the mechanism was much more sophisticated, relying on some cash payments and a package of seemingly standard commercial deals. So our decision gives a clear signal that the form of the payment does not matter. What matters is that value is being transferred from a patent holder to a potential generic entrant with the aim to delay entry. Our decision therefore provides a clear signal to pharmaceutical companies that delaying generic entry is not tolerated under the EU competition rules. And obviously we will remain vigilant.

In many cases, people's lives and well-being are dependent on medicines, so keeping medicines affordable is of the utmost importance. All patients and health systems deserve that pharmaceutical markets work well. Cephalon's product was an important drug for patients suffering from narcolepsy. Even if the majority of sales occurred in the US, the European market for modafinil represented about 50 million Euros a year or 5% of global sales. But that does not change the fact that our decision shows that EU competition enforcement has an important role to play also in the Commission's wider efforts to make medicines accessible and affordable for patients and health budgets – and this holds for any medicine, blockbuster or not.

Competition law enforcement complements the Commission's efforts in this respect. Yesterday the Commission launched its Pharmaceutical Strategy. In this strategy, access to innovative and affordable medicines is a clear target for the Commission. This is what we aim at. The Strategy also stresses that the entry of cheaper generic and biosimilar medicines plays a big role in the affordability of medicines and in achieving savings for health systems.

The Commission also launched its "Intellectual Property Action Plan" to address a number of the challenges of intellectual property protection.

Conclusions

To conclude, this decision today gives a clear message – Intellectual property rights in pharmaceutical markets are crucial to provide the right incentives to innovate. They can however not be misused to delay in an articial way entry in a market. We remain determined to enforce competition rules so that patients and health systems and authorities in Member States can take full advantage of a pharmaceutical industry that is innovative and that produces affordable and accessible medicines.

Thank you

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