European Commission - Press release

Antitrust: Commission sends Statement of Objections to Teva on 'pay for delay' pharma agreement

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The European Commission has informed pharmaceutical company Teva of its preliminary view that an agreement concluded with Cephalon was in breach of EU antitrust rules. Under the agreement, Teva committed not to market a cheaper generic version of Cephalon's drug for sleep disorders, modafinil.

Margrethe **Vestager**, Commissioner in charge of competition policy, said: "*Market entry and competition by generic drugs is an essential element to improve the affordability of healthcare. In this case, our preliminary finding is that Teva and Cephalon broke EU antitrust rules by agreeing on Cephalon paying Teva to keep its cheaper generic version of Cephalon's sleep disorder drug modafinil out of the market. It's now up to the companies to respond to our concerns.*"

Modafinil was a blockbuster drug used to treat sleep disorders. Cephalon owned the patents for the drug and its manufacture. After certain Cephalon patents on the modafinil compound expired in the European Economic Area (EEA), Teva entered the UK market for a short period of time with a cheaper generic product.

Following a lawsuit concerning an alleged infringement of Cephalon's processing patents on modafinil, the companies settled their litigation in the UK and the US with a world-wide agreement. As part of this agreement Teva undertook not to sell its generic modafinil products in the EEA until October 2012. In exchange, Teva received a substantial transfer of value from Cephalon through a series of cash payments and various other agreements.

The Commission's preliminary view is that the transferred value served as a significant pay-for-delay inducement for Teva not to compete with Cephalon's modafinil worldwide, including in the European Economic Area. The Statement of Objections alleges that the patent settlement agreement between Cephalon and Teva may have caused substantial harm to EU patients and health service budgets. This is because they may have delayed the entry of a cheaper generic medicine, leading to higher prices for modafinil.

This behaviour, if confirmed, would infringe Article 101 of the Treaty on the Functioning of the European Union (TFEU) that prohibits restrictive business practices.

In October 2011, Cephalon became a subsidiary of Teva. The Statement of Objections issued today is addressed to Teva Pharmaceutical Industries Ltd. and its subsidiary Cephalon Inc. The sending of a Statement of Objections does not prejudge the outcome of the investigation.

Background

The Commission opened formal antitrust proceedings in April 2011.

The 2005 agreement between Teva and Cephalon was also subject to antitrust proceedings in the US (where the majority of modafinil sales were recorded over the same period). In particular, the Federal Trade Commission(FTC) filed an antitrust action against Cephalon in 2008. In May 2015, the FTC and Teva (parent company of Cephalon) reached a settlement ending the antitrust litigation.

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. The companies can then examine the documents on 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.

There is no legal deadline for the Commission to complete antitrust inquiries into anticompetitive conduct. The duration of an antitrust investigation depends on a number of factors, including the complexity of the case, the extent to which the undertaking concerned cooperates with the Commission and the exercise of the rights of defence.

The Statement of Objections follows the Commission decisions concerning the "pay-for-delay" agreements addressed to Lundbeck (2013), Johnson & Johnson (2013), Servier (2014) and a number of generic companies. On 8 September 2016, the General Court upheld the Commission decision

appealed by Lundbeck and others (see MEMO/16/2994). The proceedings concerning the decision appealed by Servier and others are still pending.

The Commission's competition inquiry of 2009 into the pharmaceutical sector indicated a number of structural issues and problems in companies' practices that potentially lead to distortions of competition and delays to entry of new, innovative and cheaper generic medicines into the EU market (see IP/09/1098 and MEMO/09/321). In the final report, the Commission made a number of recommendations to address these problems, and emphasised stronger competition law enforcement with regard to patent settlemeånts. Since the inquiry, the Commission has monitored patent settlement agreements in the pharmaceutical sector on an annual basis.

More information on this investigation is available on the Commission's competitionwebsite, in the public case register under the reference 39686.

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