European Commission - Press release

Antitrust: Commission opens formal investigation into possible anticompetitive conduct of Teva in relation to a blockbuster multiple sclerosis medicine

Brussels, 4 March 2021

The European Commission has opened a formal antitrust investigation to assess whether the pharmaceutical company Teva has illegally delayed the market entry and uptake of medicines that compete with its blockbuster multiple sclerosis drug Copaxone. The Commission will investigate whether Teva has abused a dominant market position in breach of EU antitrust rules.

Executive Vice-President Margrethe **Vestager**, in charge of competition policy, said: *"Multiple sclerosis is a chronic illness affecting the daily lives of more than half a million Europeans requiring life-long treatment. Despite great efforts of the scientific community, humanity has not yet found a treatment for this disease, which remains incurable. It is therefore paramount to preserve healthy competition in the market for available drugs that aim at slowing down the disease and improving patients' quality of life. It is also important that companies compete to innovate so that new and affordable treatments can emerge. Today, we have decided to launch an in-depth investigation into whether Teva may have abusively blocked or delayed the market entry of competitors to its blockbuster drug Copaxone, to the detriment of patients and health systems".*

Copaxone, Teva's best selling drug, is widely used for the treatment of relapsing forms of multiple sclerosis and contains the active pharmaceutical ingredient glatiramer acetate.

In 2015, Teva's basic patent covering glatiramer acetate expired. The Commission will investigate whether, following the patent expiry, Teva may have artificially extended the market exclusivity of Copaxone by strategically filing and withdrawing divisional patents, repeatedly delaying entry of its generic competitor who was obliged to file a new legal challenge each time. Divisional patents originate from a broader "parent" patent and may cover significantly overlapping inventions, sometimes allowing the patentee to multiply the patent barriers that a generic competitor needs to overcome to enter the market.

In addition, the Commission will also examine whether Teva may have pursued a communication campaign to unduly hinder the use of competing glatiramer acetate products. The Commission has indications that Teva's campaign, primarily directed at healthcare institutions and professionals, may have targeted competing products to create a false perception of health risks associated with their use, even following the approval of these medicines by competent public health authorities.

If proven, Teva's behaviour may amount to an abuse of dominant position and infringe Article 102 of the Treaty on the Functioning of the European Union (TFEU) and Article 54 of the European Economic Area (EEA) Agreement.

This is the Commission's first formal investigation into potential abuses relating to the misuse of patent procedures and exclusionary disparagement of competing products in the pharmaceutical industry.

The Commission will now carry out its in-depth investigation as a matter of priority. The opening of formal proceedings does not prejudge the outcome of the investigation.

Background

Teva is a global pharmaceutical company headquartered in Israel and operating from several subsidiaries in the EEA.

The Commission carried out unannounced inspections at the premises of a number of Teva subsidiaries in the EEA in October 2019, followed by continued inspections at the Commission's premises in Brussels in January 2020.

Market players have repeatedly pointed at alleged misuses of patent procedures and alleged exclusionary disparagement as important barriers to the entry of generic or biosimilar medicines.

Article 102 of the Treaty of the Functioning of the EU prohibits the abuse of dominant market positions. The implementation of these provisions is defined in the EU's Antitrust Regulation (Council Regulation No 1/2003), which is also applied by national competition authorities.

Article 11(6) of the Antitrust Regulation provides that the opening of proceedings by the Commission relieves the competition authorities of the Member States of their competence to also apply EU competition rules to the practices concerned. Article 16(1) further provides that national courts must avoid adopting decisions which would conflict with a decision contemplated by the Commission in proceedings it has initiated.

The Commission has informed Teva and the competition authorities of the Member States that it has opened proceedings in this case.

There is no legal deadline for bringing an antitrust investigation to an end. The duration of an antitrust investigation depends on a number of factors, including the complexity of the case, the extent to which the companies concerned cooperate with the Commission and the exercise of the rights of defence.

More information on this investigation will be available on the Commission's competition website, in the public case register under the case number AT.40588.

IP/21/1022

Press contacts:

Arianna PODESTA (+32 2 298 70 24)
Maria TSONI (+32 2 299 05 26)

General public inquiries: Europe Direct by phone 00 800 67 89 10 11 or by email