European Commission - Press release

Antitrust: Commission sends Statement of Objections to Teva over misuse of the patent system and disparagement of rival multiple sclerosis medicine

Brussels, 10 October 2022

The European Commission has informed Teva of its preliminary view that the company has breached EU antitrust rules by engaging in practices intended to delay competition to its blockbuster medicine, Copaxone. These consisted in artificially extending patent protection of Copaxone and by systematically spreading misleading information about a competing product with a view to hinder its market entry and uptake.

Executive Vice-President Margrethe **Vestager**, in charge of competition policy, said: *"Until today, there is not yet a treatment for the chronic illness of multiple sclerosis. So innovative medicines can make a major difference to patients' quality of life. Effective protection of intellectual property is key to this scientific progress. Our concern is that Teva may have misused the patent system to shield itself from competition. It may have spread misleading information to discredit its closest competitor, to the detriment of patients and public health systems across the EU."*

Teva is a global pharmaceutical company headquartered in Israel and operating through several subsidiaries in the European Economic Area. Teva's blockbuster medicine, **Copaxone**, is widely used for the treatment of multiple sclerosis and contains the active pharmaceutical ingredient glatiramer acetate over which Teva held a basic patent until 2015.

Statement of Objections on Teva's abusive practices

The Commission preliminarily finds that Teva abused its dominant position in the markets for glatiramer acetate in Belgium, Czechia, Germany, Italy, the Netherlands, Poland and Spain.

The Commission is concerned that Teva engaged in two types of abusive conduct, with an overall objective of artificially prolonging the exclusivity of Copaxone by hindering the market entry and uptake of competing glatiramer acetate medicines.

In particular, the Commission preliminarily found that since February 2015 until today Teva:

- **Misused patent procedures:** after the original, basic patent expired, Teva artificially extended glatiramer acetate's basic patent protection by filing and withdrawing secondary patent applications, thereby forcing its competitors to file new lengthy legal challenges each time. This scheme is sometimes referred to as the "divisionals game". This is because the strategy implies filing so-called "divisional patents" which are patents derived from an earlier secondary patent and whose subject matter is already contained in the earlier patent. This artificially prolongs legal uncertainty to the benefit of the patent holder, and can effectively block or delay entry of generic or generic-like medicines.
- Implemented a systematic **disparagement campaign** targeting healthcare professionals and casting doubts about the safety and efficacy of a competing glatiramer acetate medicine and its therapeutic equivalence with Copaxone.

If the Commission's preliminary views were confirmed, Teva's behaviour would infringe Article 102 of the Treaty on the Functioning of the European Union (`TFEU'), which prohibits the abuse of a dominant position. If confirmed, Teva's behaviour would not only harm competitors and patients, but also inflate public health spending on certain multiple sclerosis treatments, which for Copaxone alone amounts to up to €500 million per year in the EU.

The sending of a Statement of Objections does not prejudge the outcome of the investigation.

Background

The Commission carried out unannounced inspections at the premises of several Teva subsidiaries in October 2019. On 4 March 2021, the Commission initiated proceedings against Teva Pharmaceutical Industries Limited and Teva Pharmaceuticals Europe BV.

The Commission regularly receives complaints about misuse of patents as well as about disparagement campaigns. On 20 June 2022, the Commission opened a formal investigation into possible anticompetitive disparagement by Vifor Pharma.

Article 102 of the TFEU prohibits the abuse of a dominant position. The implementation of these provisions is defined in the Antitrust Regulation (Council Regulation No 1/2003), which can also be applied by the national competition authorities.

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.

If the Commission concludes, after the company has exercised its rights of defence, that there is sufficient evidence of an infringement, it can adopt a decision prohibiting the conduct and imposing a fine of up to 10% of the company's annual worldwide turnover.

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 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.

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