**Meeting Competition** 



Newsletter, 7 November 2025

# The Teva Copaxone Decision: Drawing the Line Between Pharma, IP Rights and Antitrust Law

A focused look at how the European Commission's EUR 462.6 million Teva decision reshapes the concept of competition on the merits in pharma antitrust enforcement

On 31 October 2024, the European Commission ("Commission") added a new chapter to its antitrust enforcement in the pharmaceutical sector. With its decision in Teva Copaxone (Case AT.40588), published in April 2025, the Commission built on its precedents in AstraZeneca1, Servier2, and Vifor<sup>3</sup> (among others), delivering a clear message: IP-based and communication strategies by originator pharma companies are not immune from antitrust scrutiny. It imposed a fine of EUR 462.6 million on Teva for a dual abuse of dominance under Article 102 TFEU, involving misuse of the European patent system and systematic disparagement campaign.

Yet, the decision also raises questions. The Commission focused narrowly on two specific elements of Teva's conduct, deliberately avoiding others common in pharmaceutical lifecycle management, such as product switching or interventions in regulatory procedures.

#### The context

Teva's blockbuster medicine Copaxone (glatiramer acetate, "GA") is used to treat relapsing-remitting multiple sclerosis. After the original composition patent expired in 2015, Teva sought to preserve market exclusivity. According to the Commission, it pursued an exclusionary strategy to delay entry and hinder the entry of a generic alternative developed by Synthon.<sup>4</sup>

Teva's conduct was multifaceted, with the Commission focusing on two key elements: the use of divisional patents to prolong legal uncertainty and a disparagement campaign against Synthon GA. According to the

Commission, the two actions were components of one single and continuous infringement.

### Abuse No. 1: The divisionals game

The first abuse concerned Teva's manipulation of European Patent Office (EPO) rules on divisional patents. Divisionals are secondary patent applications derived from a "parent" patent. While it shares the same filing date and disclosure, divisional patents allow new claims on different aspects of the invention. When used properly, divisionals serve to clarify innovation. Misused, they can create a dense web of overlapping rights with an option to prolong exclusivity if used and dropped strategically.

In 2005, Teva filed patents covering a new manufacturing process and, in 2010, a new dosage regime (40mg instead of 20mg). Over the following eight years, Teva filed a series of divisional patent applications. According to the Commission, these divisionals repeated previously disclosed content and created multiple generations of nearly identical claims, with little or no novel contribution.

In its material assessment, the Commission identified two legs of Teva's abusive "divisionals game" (i) the staggered filing of patents that largely overlapped in content and (ii) the obstruction of the legal review of these patents. The Commission's assessment focuses on the second leg. Here, the Commission found that Teva had abusively "gamed" the patent system. After enforcing the patents via interim injunctions against generic competitors, Teva "strategically withdrew them, to avoid a formal invalidity ruling, which would have set a precedent threating other divisional patents to fall like dominos".

<sup>&</sup>lt;sup>1</sup> European Commission, decision of 15 June 2005, case AT.37507; appealed to the General Court, decision of 1 July 2010, T-321/05; and CJEU, decision of 6 December 2021, C-457/10 P.

<sup>&</sup>lt;sup>2</sup> European Commission, decision of 9 July 2014, case AT.39612; appealed to the General Court, decision of 12 December 2018, T-691/14; and CJEU, decision of 27 June 2024, C-176/19 P.

 $<sup>^{3}</sup>$  European Commission, decision of 22 July 2024, case AT.40577.

<sup>&</sup>lt;sup>4</sup> European Commission, decision of 31 October 2024, case AT.40588, para. 3.

<sup>&</sup>lt;sup>5</sup> European Commission, decision of 31 October 2024, case AT.40588, para. 1066.

<sup>&</sup>lt;sup>6</sup> European Commission, press release of 31 October 2024, available at:

This tactic deprived competitors of definitive legal outcomes and avoided damaging precedents.<sup>7</sup> The Commission found that Teva thereby prolonged uncertainty and deterred market entry of generics.<sup>8</sup> In the Commission's eyes, that was no longer competition on the merits but an abuse of Teva's dominant position under antitrust law.

#### Abuse No. 2: Disparagement campaign

Teva's second infringement was more public-facing. Following Synthon's application for marketing authorization, Teva launched a concerted campaign to cast doubt on the safety, efficacy, and therapeutic equivalence of Synthon GA - despite the product having been approved by national competent authorities across the EU.

According to the Commission, Teva disseminated objectively misleading messages to healthcare professionals, payers (i.e. entities responsible for financing or reimbursing the costs of medicines), and pharmacists. Among other things, Teva: (i) emphasized minor compositional differences between Copaxone and Synthon GA, (ii) referenced adverse events linked to unrelated GA variants, and (iii) undermined the findings of a study, which formed the scientific basis for the regulatory approval of Synthon GA.

The Commission found that this communication materially influenced prescribing behavior and reimbursement decisions in several Member States.<sup>9</sup> The messages lacked objective justification and were considered capable of restricting competition.

In the Commission's view, this campaign crossed the line from legitimate communication to anticompetitive conduct. It was seen as departing from competition on the merits and reinforcing Teva's dominant position unlawfully.

## The concept of competition on the merits post-Teva

So what qualifies as competition on the merits and when is the line crossed to an abuse of dominance? The concept of competition on the merits in the pharma-IP-antitrust world distinguishes between legitimate regulatory and commercial conduct, including aggressive patenting, from practices that result in a restriction of competition absent an objective justification. Like in previous decisions, the Commission does not provide an abstract definition of competition on the merits but rather

considers the anticompetitive outcome absent any objective justification as decisive.

In Teva, the Commission underlines that conduct may breach antitrust law even if compliant with patent/IP rules. Once more, the Commission extensively relied on internal company documents for its decision highlighting the strategic scheme to prevent or delay market access of competitors.

#### ... And what does the decision not say

Interestingly, the Commission does not provide an assessment as regards other facets of Teva's broader strategy, in particular:

- Teva's efforts to switch patients to the 40mg dosage (product hopping);
- Its regulatory interventions and objections during Synthon's MA procedure;
- Litigation in national courts aimed at slowing generic launch.

While acknowledging these elements as part of a broader lifecycle management strategy, the Commission did not take a decision regarding their legality. This should not be regarded as an endorsement. In fact, some of these strategies were addressed by the Commission as potentially abusive in the Commission's Pharma Sector Inquiry already back in 2009.<sup>10</sup>

#### Outlook

The Teva Copaxone decision once more shows the Commission's focus on abuses of dominance in the pharmaceutical sector. The Commission's enforcement priority was lately demonstrated in September, when it conducted dawn raids at the premises of a pharmaceutical company in relation to possible exclusionary practices that, according to the Commission, may constitute anticompetitive disparagement. This enforcement trend culminated most recently, on 23 October 2025, when the ECJ upheld the Commission's decision fining Teva and Cephalon for an anticompetitive pay-fordelay agreement.

For companies navigating the pharma-IP/regulatory-antitrust intersection, one of the key takeaways is that permissible behavior under regulatory or patent law is not necessarily lawful under antitrust law. It requires a careful assessment also of internal documents not to cross the line to unlawful behavior.

The story doesn't end here. We'll be watching what comes next.

https://ec.europa.eu/commission/presscorner/detail/en/ip\_24\_5581.

<sup>&</sup>lt;sup>7</sup> European Commission, decision of 31 October 2024, case AT.40588, paras. 1146 et seqq.

<sup>&</sup>lt;sup>8</sup> European Commission, decision of 31 October 2024, case AT.40588, paras. 1067 et seqq.

<sup>&</sup>lt;sup>9</sup> European Commission, decision of 31 October 2024, case AT.40588, paras. 1536 et seqq.

<sup>&</sup>lt;sup>10</sup> European Commission, Pharmaceutical Sector Inquiry, Final Report of 8 July 2009, available at: https://competitionpolicy.ec.europa.eu/system/files/2022-

<sup>05/</sup>pharmaceutical\_sector\_inquiry\_staff\_working\_paper\_p art1.pdf.







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