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# **COMPETITION & REGULATORY NEWSLETTER**

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# European Court of Justice upholds European Commission fine for Teva and Cephalon in "pay-for-delay" case

On 23 October 2025, the European Court of Justice (CJ) dismissed an appeal by pharmaceutical companies Teva and Cephalon, upholding the European Commission's decision that the parties' 2005 patent settlement agreement amounted to a restriction of competition by object under Article 101 of the Treaty on the Functioning of the European Union (TFEU). The CJ agreed with the European General Court (GC) that there was no explanation for the various transfers of value concluded in the context of the agreement between the then-competitors other than the commercial interest of the parties not to engage in competition on the merits.

## **Background**

In November 2020, the Commission announced that it had fined Teva and Cephalon a total of €60.5 million for a "pay-for-delay" arrangement that postponed for several years the market entry of Teva's generic version of modafinil, a drug for sleep disorders, after Cephalon's main patents had expired (as covered in a previous edition of this newsletter). The decision concerned a settlement agreement reached after Cephalon brought a claim alleging infringement of its patents. Under the agreement, Teva undertook not to market its generic modafinil product in the EEA before October 2012 and not to challenge Cephalon's secondary patent rights (the non-compete and non-challenge commitments). In exchange, Teva received a package of commercial benefits including the appointment as Cephalon's exclusive distributor of modafinil in the UK, as well as access to unrelated clinical data and an upfront payment of €5.5 million - allegedly for avoided litigation costs. The Commission found that these benefits represented a significant and unjustified transfer of value that had no plausible explanation other than to induce Teva to enter the restrictive non-compete and non-challenge commitments. The Commission therefore found that the settlement agreement constituted a restriction of competition by object within the meaning of Article 101 TFEU. The parties appealed to the GC, which in October 2023 dismissed the action entirely. The parties then appealed to the CJ.

### Arguments on appeal and the CJ's findings

The first ground: misapplication of Generics (UK)

The appellants' first ground of appeal alleged that the GC had misapplied the legal test from *Generics (UK)* when establishing that the settlement agreement constituted a restriction of competition by object.

• First, the appellants argued that the GC incorrectly adopted a counterfactual analysis by comparing what was actually concluded in the settlement agreement with what would have been concluded absent the non-compete and non-challenge clauses. They argued that this was an error of law because the court was applying the analysis for establishing a restriction by effect, and using it to conclude there was a restriction by object.

- Second, the appellants argued that by seeking to determine whether the parties would have concluded essentially the same commercial agreements absent the non-compete and non-challenge commitments, the GC applied a stricter legal standard than necessary and essentially reversed the burden of proof.
- Third, the appellants argued that the test applied by the GC effectively precluded the appellants from making any commercial transactions alongside the settlement agreement. They argued that the court should instead have looked at each transaction and determined whether, given the settlement context, there was a plausible commercial explanation.
- Fourth, and as a second part to the first ground of appeal, the appellants argued that the GC gave insufficient and contradictory reasons when dismissing the proposed pro-competitive effects arising from the settlement agreement, which were made clear in the Commission's 2011 *Teval Cephalon* merger decision.

The CJ rejected this ground of appeal. First, since some transfers of value in the context of a patent settlement agreement may be objectively justified - for example, as compensation for litigation costs - a by object analysis necessarily involves an assessment of those transfers, and the GC's inclusion of certain counterfactual elements in that analysis went to the question of whether the benefits transferred could be explained by anything other than an inducement not to compete. The CJ therefore held the GC had not incorrectly applied an effects analysis. Second, the CJ held that the GC had not applied the wrong legal test by considering whether, absent the restrictive clauses, the parties would have concluded the same commercial agreements, but that this was an appropriate way to analyse whether the transactions could have any explanation other than the incentive not to compete on the merits. Third, the CJ held that the test adopted by the court did not preclude concomitant transactions or impose an impossible standard: the GC had examined the transactions together with the settlement agreement as a single contractual framework and determined in that context that the transactions could not be plausibly explained other than as an inducement for Teva to agree to the restrictive clauses. The CJ rejected the second part of this first ground as in part inadmissible and in part ineffective.

### The second ground: restriction by effect

Having upheld the GC's restriction by object ruling, the CJ held that it was unnecessary to examine the appellants' arguments alleging errors of law in the GC's effects analysis, given that these are alternative conditions for establishing breaches of Article 101 TFEU.

#### Conclusion

The appellants' argument on the counterfactual is reminiscent of a decades-long back-and-forth by the European Courts into the distinction between restrictions by object and effect. The ruling confirms the middle ground established in previous case law: consistent with the CJ's judgment in *Lundbeck*, it is indeed not necessary to examine the counterfactual to determine whether conduct is a restriction by object. However, consistent with Advocate General Bobek in *Budapest Bank*, this does not preclude a high-level assessment of the legal or factual circumstances to determine whether the specific provisions in question are anti-competitive as a matter of fact. Whilst this "reality check" may in isolation appear akin to a by effect analysis of alternative hypotheticals, properly construed it is a contextual assessment of the commercial incentive for the transfers of value and does not engage a full effects analysis of the alternative hypothetical.

The judgment confirms that whilst associated or concurrent commercial deals will not in themselves cause a settlement agreement to fall foul of the competition rules, any such transfers of value must be objectively justified. Practically, parties should assume that any commercial arrangements entered into at a similar time as a patent settlement agreement will be scrutinised together as a whole with the agreement. The judgment therefore also provides a reminder of the importance for businesses of ensuring that in such cases the commercial rationale for entering such transactions is clearly and contemporaneously documented.

#### OTHER DEVELOPMENTS

#### **MERGER CONTROL**

### CMA consults on draft revised merger remedies guidance

On 16 October 2025, the Competition and Markets Authority (CMA) published its draft revised merger remedies guidance and launched a consultation seeking views on the proposed changes. This follows the CMA's review of its approach to remedies in merger cases launched in May this year (as reported in a previous edition of this newsletter) and forms part of its ongoing programme to improve the pace, predictability, proportionality and process of the UK merger control regime (the '4Ps').

In a press release, the CMA described the new draft guidance as a "comprehensive refresh [that] seeks to ensure merger remedies are effective, provide greater certainty for businesses and allow more deals to be cleared".

Among the more notable revisions to the current guidance are changes to the approach to behavioural remedies, signalling a more flexible approach by the CMA. In particular, the draft guidance moves away from the position that behavioural remedies can generally only be appropriate in a very narrow set of circumstances, and removes the presumption against behavioural remedies being accepted at Phase 1, so aligning the guidance with recent practice. Although the draft guidance retains the distinction between structural and behavioural remedies and states that "a structural remedy is more likely to be effective in resolving the SLC and its adverse effects than a behavioural remedy", also positive is the new acknowledgment that some remedies might fall "within a spectrum of the two classifications". In terms of complex divestiture remedies, the draft guidance makes clear that the CMA's preferred approach remains the divestment of existing standalone businesses rather than carveouts, but does provide guidance on assessing the effectiveness of carve-out remedies.

The draft guidance now also includes "remedies to secure merger-specific rivalry-enhancing efficiencies" as a category of enabling behavioural remedies, building on the approach adopted in Vodafone/Three, and provides additional detail on the CMA's approach to assessing relevant customer benefits (RCBs), with the stated aim, according to the CMA's press release, of ensuring "pro-growth deals that enhance competition and benefit UK consumers can proceed wherever possible". In addition, the draft guidance contains updates on certain procedural matters, building on the CMA's ongoing efforts to enhance transparency and engagement with businesses. According to its press release, the CMA anticipates these procedural changes "should allow more deals to be cleared with remedies, and at an earlier stage".

The consultation is open until 13 November, after which the CMA will review responses and publish the final guidance.

# Japan's FTC launches new online platform to collect information on below-threshold mergers

On 15 October 2025, the Japan Fair Trade Commission (JFTC) introduced an online submission platform allowing companies and individuals to anonymously provide information on mergers that may affect domestic competition in Japan, even if the transactions fall below the formal notification thresholds.

Under the existing framework, companies are required to notify transactions where certain domestic thresholds are met - for share acquisitions, notification is required where the acquirer's turnover in Japan exceeds ¥20 billion (approximately £100 million), the target's turnover in Japan exceeds ¥5 billion (approximately £25 million) and the acquirer will hold more than 20% or 50% of the shares post-transaction.

Where these thresholds are not met, parties have the option of consulting the JFTC voluntarily and the authority also retains the power to "call in" and review transactions that it believes might substantially restrain competition. In practice, however, this power has been exercised sparingly: in 2024, the JFTC completed reviews of only seven non-notifiable cases (including both voluntary consultations and ex-officio reviews) compared to the 437 formal notifications it received.

With the launch of this new platform, businesses and individuals can now submit information anonymously to the JFTC on a range of transactions (including mergers, joint ventures and minority investments) regardless of whether they meet any specific threshold. While this development is intended to encourage stakeholder engagement and make it easier to provide feedback on transactions, it also creates greater uncertainty for transaction parties by increasing the scope for below-threshold transactions to be "called in", for non-competition considerations to be flagged to the JFTC and for third parties, including competitors, to seek to abuse the system and obstruct deals. Consequently, notifying parties may need to consider, even for transactions that do not meet the thresholds, early stakeholder outreach to minimise the likelihood of negative feedback being raised through the new system.

This move by the JFTC aligns with a broader trend across Asia to look at transactions that do not meet traditional merger control thresholds. For example, in China, the State Administration for Market Regulation (SAMR) has already demonstrated its willingness to exercise call-in powers to investigate below-threshold mergers, as illustrated in the *Qualcomm-Autotalks* deal discussed in the last newsletter.

#### **ANTITRUST**

# Advocate General Medina finds seizure of business emails does not breach EU Charter of Fundamental Rights

On 23 October 2025, AG Medina issued her supplementary Opinion that Articles 7 and 8 of the EU Charter of Fundamental Rights (the Charter) do not prevent the seizure of business emails during competition investigations, provided there is a strict legal framework and robust safeguards in place, in particular ex post judicial review.

This follows AG Medina's first Opinion of 20 June 2024 in the joined cases of *Imagens Médicas Integradas and Others*, in which the AG concluded that the search and seizure of business emails by a national competition authority in the course of an inspection at the premises of an undertaking carried out as part of an Article 101 or 102 antitrust investigation, without prior judicial authorisation, does not infringe the right to respect for private life under Article 7 of the Charter.

The supplementary Opinion was requested by the CJ following its ruling in *Landeck* on 4 October 2024, in which the CJ held that competent enforcement authorities should have the possibility to access personal data on a mobile phone in <u>criminal</u> investigations, provided prior judicial approval is obtained, except in duly justified urgent cases. AG Medina was therefore asked to consider whether *Landeck* applies by analogy to competition dawn raids involving the seizure of employee emails, on which she gave her first opinion.

AG Medina concluded that Landeck does not govern the competition investigations at issue, since the situation is not comparable. She noted that seizures by competition authorities concern business information concerning legal persons, not individuals, who are, in principle, only affected in an "ancillary manner". She also drew the distinction between a mobile phone and a corporate mailbox. In considering the scope of both Article 7 and Article 8 (the right to protection of personal data) under the Charter, AG Medina considered that unlike mobile phones and other personal devices which are capable of giving "full and uncontrolled access" to a unified repository of highly sensitive personal data, business emails typically do not allow "very precise" conclusions about an individual's private life. She further considered that the public-interest objective of detecting anticompetitive practices justifies the seizure of business emails, as there is no equally effective, less intrusive alternative. AG Medina therefore concluded that the interference with the rights under Article 7 and Article 8 in the context of seizures of employees' emails during a competition investigation is distinguishable from the criminal law context in Landeck. She also made clear that as regards the interference with the fundamental right to the protection of personal data created by the inspection activities in question, the principle of proportionality is complied with provided that certain procedural safeguards are ensured. Those safeguards are in addition to the obligations incumbent on national competition authorities under the GDPR and to subsequent judicial review both during and at the end of the investigation procedure.

AG Medina further concluded that the two circumstances where prior authorisation would still be required in the competition context are: first, in the case of seizures of emails containing personal data carried out at a person's

private home; and second, where seized emails containing personal data will be used to establish a natural person's criminal liability under national law for anti-competitive conduct.

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