Case C-2/24 P

Teva Pharmaceutical Industries Ltd and Cephalon Inc.
v
European Commission

Judgment of the Court (Fourth Chamber) of 23 October 2025

(Appeal – Competition – Article 101 TFEU – Agreements, decisions and concerted practices – Modafinil market – Patent settlement agreement between two pharmaceutical companies for the purpose of delaying a generic version of modafinil being brought to the market – Decision finding an infringement of Article 101 TFEU – Criteria for assessment – Restriction by object)

1. *Agreements, decisions and concerted practices – Adverse effect on competition – Amicable agreement on patents – Agreement concluded between an originator company and a generic undertaking – Agreement containing non-compete clauses and clauses prohibiting patent challenges in favour of the originator company – Consideration consisting in transfers of value – Characterisation as a restriction by object – Criteria – Degree of harm of the agreements to competition in the market concerned – Assessment of the inducive effect of the transfers of value on the decision of the generic manufacturer not to enter the market – Assessment carried out on the basis of a hypothetical scenario – Whether permissible*
(Art. 101(1) TFEU)

(see paragraphs 61-79)

2. *Agreements, decisions and concerted practices – Adverse effect on competition – Amicable agreement on patents – Agreement concluded between an originator company and a generic undertaking – Agreement containing non-compete clauses and clauses prohibiting patent challenges in favour of the originator company – Consideration consisting in transfers of value – Characterisation as a restriction by object – Criteria – Degree of harm of the agreements to competition in the market concerned – Assessment of the inducive effect of the transfers of value on the decision of the generic manufacturer not to enter the market – Burden of proof*
(Art. 101(1) TFEU)

(see paragraphs 82-94)

3. *Agreements, decisions and concerted practices – Adverse effect on competition – Criteria for assessment – Anticompetitive object – Sufficient*
(Art. 101(1) TFEU)

(see paragraph 122)

Résumé

In dismissing the appeal brought by two manufacturers of medicinal products against the judgment of the General Court of 18 October 2023, (1) the Court of Justice clarifies the criteria governing the making of a finding of a restriction of competition within the meaning of Article 101 TFEU in the context of patent dispute settlement agreements concluded by pharmaceutical companies.

In 1993, Cephalon, a United States biopharmaceutical company, obtained exclusive rights to the active pharmaceutical ingredient (‘API’) modafinil, marketed for the treatment of certain sleep disorders in a number of countries in the European Economic Area (EEA).

Cephalon’s various national compound patents for modafinil in the EEA expired at the latest in 2003, but Cephalon was still using particle size secondary patents and other modafinil-related patents expiring in 2015.

In 2002, Cephalon initiated patent infringement proceedings in the United States against Teva Pharmaceutical Industries Ltd ('Teva') and three other generic companies, seeking to prevent them from marketing their version of the originator product in the United States. Once Teva launched its generic product in the United Kingdom in June 2005, Cephalon also initiated patent court proceedings in that country, against which Teva brought a counterclaim for revocation.

At the end of 2005, Cephalon and Teva concluded a settlement agreement putting an immediate end to their modafinil litigation in the United States and in the United Kingdom ('the settlement agreement'). Pursuant to that agreement, Teva committed not to enter the market independently and not to compete with Cephalon in the modafinil market ('the non-compete clause') and not to challenge Cephalon's modafinil patent rights ('the non-challenge clause') (together, 'the restrictive clauses').

The settlement agreement also provided for a package of commercial transactions relating to, inter alia, the grant of a licence from Teva to Cephalon in respect of its intellectual property rights for modafinil, the supply of the modafinil API by Teva to Cephalon and the distribution by Teva of Cephalon's products in the United Kingdom. The payments and royalties envisaged under the various transactions involved significant transfers of value to Teva. Moreover, the settlement agreement granted to Teva a non-exclusive licence to launch its generic modafinil product, including in the EEA, from 2012 at the latest.

Finding that the settlement agreement infringed the prohibition on agreements, decisions and concerted practices laid down in Article 101 TFEU and Article 53 of the EEA Agreement, the Commission imposed fines on Cephalon and Teva amounting to EUR 30 480 000 and EUR 30 000 000, respectively. (2)

On 5 February 2021, the parties found to have committed an infringement brought an action before the General Court seeking, primarily, the annulment of that decision and, in the alternative, the cancellation or reduction of the amount of the fines.

By the judgment under appeal, the General Court dismissed that action and held, in particular, that the Commission had not erred in classifying the settlement agreement as a 'restriction of competition by object' as referred to in Article 101(1) TFEU.

Cephalon and Teva then brought an appeal against that judgment before the Court of Justice.

Findings of the Court

In support of their appeal, the appellants submit, inter alia, that the General Court erroneously applied the legal test resulting from the judgment in *Generics (UK)* (3) in order to establish that there was a restriction of competition by object in the context of a settlement agreement.

Under that test, settlement agreements must be classified as restrictions of competition by object where it is plain from examining them that the transfers of value made by the manufacturer of the originator medicine to the manufacturer of the generic medicine can ultimately have as their sole explanation the commercial interest of those operators not to engage in competition on the merits.

Applying that principle to the present case, the General Court considered that, in order to determine whether each of the commercial transactions found in the settlement agreement had as its sole plausible explanation the objective of incentivising Teva to accept the restrictive clauses and thereby, to refrain from competing with Cephalon on the merits, or whether those transactions would in any event have been concluded under normal market conditions, it was necessary to analyse whether the commercial transactions contained in that agreement would actually have been concluded or whether they would have been concluded on the same terms absent the restrictive clauses. In order to do so, the Commission had to compare what had actually happened with what would have happened absent the restrictive clauses.

From that perspective, the Court of Justice analyses, first of all, whether, as the appellants maintained, the test confirmed by the General Court amounts, in reality, to a counterfactual analysis which is part of an assessment of the agreements as a restriction by effect.

In that regard, the Court of Justice finds that the General Court undertook a detailed analysis and an overall assessment of the settlement agreement, following which it concluded that the transfer of value made by Cephalon to Teva by means of commercial transactions constituted consideration for the inclusion of restrictive clauses in the settlement agreement and, therefore, for Teva's commitment to refrain from entering the generic medicinal products market independently.

For the purposes of that analysis, the General Court intended to establish, based on a hypothetical scenario, whether the commercial transactions between the appellants departed from normal market conditions by focusing, in particular, on the objectives and the economic and legal context of those transactions at the time the settlement agreement was concluded, in order to determine the incentive effect of the transfers of value provided for by that agreement.

The Court of Justice notes that there is nothing to prevent the counterfactual elements from being taken into account by the General Court in order to make a finding of a restriction of competition by object. However, the taking into account of a hypothetical situation cannot be conflated with the so-called 'counterfactual' method, as made clear by the General Court in the judgment under appeal.

Unlike the so-called 'counterfactual' method, which consists of comparing the situation of the agreement concerned with the situation which would exist in its absence, in order to assess whether an agreement between undertakings has anticompetitive effects, the General Court's analysis sought to determine whether those clauses constituted an incentive for Teva to refrain from competing with Cephalon on the merits in order to determine the objective seriousness of the practice concerned, and did not seek to assess whether the settlement agreement had anticompetitive effects.

Therefore, contrary to the appellants' assertions, the test confirmed by the General Court does not require an assessment, for each commercial transaction, of whether it would actually have been concluded, or whether it would have been concluded on the same terms, absent the settlement agreement taken as a whole. On the contrary, that test is intended to establish, in accordance with the case-law, whether the transfers of value cannot have any explanation other than the commercial interest of both the operators concerned not to engage in competition on the merits.

In addition, the General Court's assessment necessarily had to be based on an analysis of the commercial transactions and the settlement agreement together where those transactions and that agreement formed part of the same contractual framework.

In order to determine whether an agreement may be characterised as a restriction of competition by object, it is essential, in particular because of the close links between the non-challenge, non-marketing and exclusive supply clauses of a settlement agreement, not to analyse each of the restrictive clauses separately, but to assess whether that agreement, taken as a whole, reveals a degree of economic harm to the proper functioning of competition in the market concerned which justifies such a characterisation.

That is all the more so where, as in the present case, the objective of that analysis consists of identifying whether the transfers of value had an incentive effect and of determining whether the insertion of the restrictive clauses in the settlement agreement represented the consideration for the transfers of value made by Cephalon through the commercial transactions covered by the settlement agreement.

If it is found that, absent the restrictive clauses contained in the settlement agreement, the parties would not have concluded the commercial transactions provided for by that agreement, it may be inferred that those transactions cannot have any explanation other than the restriction of competition agreed therein.

Next, the Court of Justice examines whether the General Court did not err in holding that the Commission was required to ascertain whether the commercial transactions covered by the settlement agreement would also have been concluded, on equally favourable terms, absent the restrictive clauses.

In that regard, it is for the Commission to demonstrate that, in the relevant context, the restrictive clauses concluded in the context of the settlement agreement gave rise to an agreement which restricts competition by object and therefore to demonstrate that it is plain from the examination of that agreement that the transfers of value provided for therein cannot have any explanation other than the

commercial interest of both the holder of the patent at issue and the party allegedly infringing the patent not to engage in competition on the merits.

Since the appellants maintained at first instance that the commercial transactions in the settlement agreement had a plausible explanation other than to act only as consideration for the restrictive clauses, the General Court ascertained whether, for each of the commercial transactions provided for in that agreement, the Commission had made an error of assessment in concluding that the purpose of those transactions was to serve as a transfer of value from Cephalon to Teva in consideration for Teva's commitment not to enter the markets for generic medicines independently and not to compete with Cephalon in relation to modafinil.

Following a detailed analysis of the decision at issue and of each commercial transaction provided for in the agreement, the General Court found that the Commission had applied the appropriate legal test by establishing that each of the commercial transactions provided for in the settlement agreement had had no other purpose than to increase the level of the overall value transfer made to Teva under that agreement with a view to inducing it to agree to the restrictive clauses.

Therefore, according to the Court of Justice, the General Court did not make an error of law in holding that the Commission had duly proven, as required by the judgment in *Generics (UK)*, that the transfers of value conducted in the context of the commercial transactions provided for in the settlement agreement could have no explanation other than the commercial interest of Teva and Cephalon not to engage in competition on the merits.

Lastly, the Court of Justice rejects the appellants' argument that the test established by the General Court is impossible to meet in practice in that it necessarily precludes the conclusion of commercial transactions concomitantly with a settlement agreement.

In that regard, the Court of Justice states, in the first place, that, contrary to the appellants' assertions, the overall assessment carried out by the General Court did not relate to whether the appellants would have concluded a given commercial transaction independently of the settlement agreement, but sought to determine whether the commercial transactions contained in the settlement agreement could have any explanation other than the commercial interest of the appellants not to engage in competition on the merits.

In the second place, it is also not apparent from the judgment under appeal that the General Court excluded the conclusion of commercial transactions concomitantly with a settlement agreement. On the contrary, the General Court recognised that possibility by examining all the commercial transactions concluded between the parties in the context of the settlement of their disputes.

Consequently, the relevant question, in the present case, to establish a restriction of competition by object is whether the commercial transactions concluded in the context of a settlement agreement can be explained in a plausible manner, in the sense that their aim must not be to restrict or distort competition on the market by inducing a potential competitor not to enter the market in exchange for a transfer of value not justified by the need to compensate for the costs or disruption caused by the litigation between the parties to that agreement.

Since none of the grounds of appeal has been upheld, the Court dismisses the appeal in its entirety.

---

1 Judgment of 18 October 2023, *Teva Pharmaceutical Industries and Cephalon* v *Commission* (T-74/21, 'the judgment under appeal', EU:T:2023:651).

---

2 Commission Decision C(2020) 8153 final of 26 November 2020 relating to a proceeding under Article 101 [TFEU] and Article 53 of the EEA Agreement (Case AT.39686 – CEPHALON).

---

3 Judgment of 30 January 2020, *Generics (UK) and Others* (C-307/18, EU:C:2020:52).