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QUICK LINKS

European Court of Justice hands down judgment in Servier, siding with Commission in 'pay for delay' appeals

On 27 June 2024, the European Court of Justice (CJ) delivered its latest judgments in a long-running saga relating to so-called 'pay for delay' agreements. The judgments largely affirm the European Commission's 2014 decision to fine Les Laboratoires Servier and several generic pharmaceutical manufacturers for entering into patent settlement agreements relating to the blood pressure medication perindopril. The Commission had found that these agreements were intended to delay the entry of generic versions of the medication into the market.

Background

The Servier group developed and marketed perindopril, a prescription medicine used for treating high blood pressure and certain heart conditions. While the perindopril compound patent expired over the course of the 2000s, in 2004, Servier acquired a new patent over the manufacturing process of the active ingredient. Several generic drug companies contested the validity of this patent. Servier consequently entered into settlement agreements whereby the generic companies agreed to stop challenging the validity of the patent and to refrain from entering the perindopril market in exchange for compensation ('reverse payments') from Servier.

In 2014, the European Commission found that these agreements amounted to illegal 'pay for delay' agreements under Article 101 TFEU. In addition, the Commission found Servier guilty of abusing a dominant position in the markets for perindopril in France, the Netherlands, Poland and the UK (a Member State at the time). Accordingly, the Commission imposed fines of €330m on Servier and of around €97m collectively on the generic manufacturers party to the agreements.

Appeals to the General Court

In 2018, the European General Court (GC) partially overturned the Commission's 2014 decision. The GC agreed with the Commission's finding that the agreements Servier made with Niche, Unichem, Matrix (now Mylan), Teva, and Lupin constituted infringements of competition by object in that they amounted to market exclusion agreements. However, it annulled the Commission's decision on two points: the allegation of abuse of a dominant position by Servier and the agreements Servier made with Krka.

- *Abuse of dominance allegations*: Rather than construing the relevant product market for perindopril as one which encompassed other drugs in the ACE inhibitor class, the Commission had defined the market by reference to a single molecule within this class (namely, perindopril). The GC found that the Commission had attached too much weight to evidence showing the price of perindopril had remained stable in the face of other

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ACE inhibitor products dramatically decreasing in price. Adopting instead a wider market definition based on non-price factors of competition (such as the functional characteristics of the drugs), the GC determined that Servier did not enjoy a dominant position, and accordingly annulled the Commission's abuse of dominant position infringement decision.

- *The agreements with Krka*: Servier and generics manufacturer Krka had entered into various agreements, including a settlement agreement and a separate licensing agreement under which Servier licenced perindopril to Krka in several markets. The GC rejected the Commission's assessment of the settlement and licence agreements as constituting infringements of Article 101 TFEU. It considered that the Commission was required to establish, first, that there was a sufficiently direct link between those two agreements for their association to be justified and, second, that, in the absence of such a link, it was for the Commission to prove that the licence agreement had not been concluded at arm's length, but masked a reverse payment from Servier to Krka intended to delay Krka's entry into Servier's core markets. The GC also did not consider that the agreement amounted to a restriction of competition by effect. Therefore, the GC annulled the Commission's infringement decision in respect of Servier's agreements with Krka.

The GC accordingly reduced Servier's fine by €103m to €228m, overturned the €10m fine imposed on Krka, and upheld the fines imposed on Niche, Unichem, Matrix (now Mylan), Teva, and Lupin.

The CJ rulings

Ruling on nine appeals lodged by the parties and the Commission against the GC's judgment, the CJ largely upheld the Commission's original 2014 decision.

- The CJ dismissed the appeals of Niche, Unichem, Matrix, Teva and Biogaran (a Servier subsidiary), thus confirming the GC's judgment and original Commission decision that the agreements entered into by these parties were anti-competitive infringements by object.
- As regards Servier's abuse of dominance infringement, the CJ disagreed with the GC's emphasis on non-price competitive pressures for the purpose of defining the relevant market. The CJ noted that, irrespective of the specific characteristics of the pharmaceutical sector, *"the economic substitutability between medicinal products must be assessed in the light of the shifts in sales between medicinal products intended for the same therapeutic indication, brought about by the changes in the relative prices of those medicinal products*". The CJ overturned the GC's annulment and referred the decision back to the GC to determine the appropriate fine.
- The CJ also overturned the GC's judgment in respect of Servier's agreements with Krka. It found that the GC had disregarded the very nature of the infringement of Article 101 TFEU attributed to Servier and Krka - an infringement which was not limited to a patent dispute settlement agreement in return for reverse payment but "*pursued the broader objective of sharing markets between those undertakings*". Whether or not the Krka licence agreement was in line with normal market conditions was therefore not decisive. The CJ also affirmed that, given the 'by object' nature of the infringement: (i) an analysis of the existence of pro-competitive effects was unwarranted in this context, in an apparent departure from previous case law on 'pay for delay' agreements;[1] and (ii) the fact that the companies may have acted without having an intention to prevent, restrict or distort competition and the fact that they may have pursued certain legitimate objectives was not decisive.[2]
- A third assignment and licence agreement between Servier and Krka had not been addressed by the GC in its judgment. The CJ therefore referred the assessment of that third agreement back to the GC.

[1] See CJ judgment in Case C-307/18, *Generics (UK) Ltd and others v Competition and Markets Authority*.

[2] The CJ referred to its judgment in Case-333/21, *European Superleague Company SL v FIFA and UEFA*, as to which see our previous client briefing.

- Finally, the CJ reduced Servier's fine relating to its agreement with Lupin, from €37m to €34m, on account of errors in the calculation of the duration of the infringement.

Conclusion

With the Servier saga progressively drawing to a close, the CJ's judgments provide welcome clarity on the extent to which patent settlement agreements may be analysed as 'by object' infringements of Article 101 TFEU and the circumstances in which an effects analysis will not be required of the Commission. The judgments provide an indication from the CJ that market definition should be heavily influenced by economic substitutability.

Pharmaceuticals continue to be a sector under heightened scrutiny in the EU, with the Commission pursuing investigations on abuse of dominance grounds for competitor disparagement and recently building up its portfolio of cartel cases in the sector.

OTHER DEVELOPMENTS

MERGER CONTROL

European Commission conditionally clears proposed acquisition of stake in ITA Airways by Lufthansa

On 3 June 2024, the Commission announced that, following an in-depth Phase 2 investigation, it has conditionally cleared the proposed acquisition of joint control of ITA Airways by Deutsche Lufthansa AG and the Italian Ministry of Economy and Finance (MEF).

ITA is a full-service carrier operating a hub-and-spoke network with its principal hubs in Rome and Milan. Lufthansa is a global full-service carrier operating a hub-and-spoke network with its principal hubs in Frankfurt, Munich, Zurich, Vienna and Brussels. The MEF is currently the sole shareholder in ITA.

The transaction was notified to the Commission on 30 November 2023 and, on 23 January 2024, the Commission commenced an in-depth investigation into the proposed acquisition. As a result of its market investigation, the Commission raised three key concerns: first, the transaction would reduce competition on a number of short-haul routes between Italy and central European countries through non-stop and one-stop flights; second, the transaction would reduce competition on a limited number of long-haul routes between Italy and the US and Canada; and third, the transaction would create or strengthen ITA's dominant position at the Milan-Linate airport.

To address the Commission's concerns, Lufthansa and the MEF submitted a remedy package consisting of three key commitments: Lufthansa and the MEF commit to making available to one or two rival airlines the necessary assets to enable them to start operating non-stop flights between Rome or Milan and certain airports in Central Europe, ensuring to grant one of those rival airlines access to ITA's domestic network to offer indirect connections. In addition, the merged company committed to enter into interlining agreements and slot swaps with rivals to improve the latter's competitiveness on the long-haul routes of concern. Finally, Lufthansa and the MEF committed to divest certain slots at Milan-Linate to the remedy takers for the short-haul routes. Lufthansa and the MEF can only implement the transaction following the Commission's approval of suitable remedy takers for each of the three sets of commitments.

The Commission is satisfied that the remedy package "*fully addresses [the] competition concerns by ensuring that a sufficient level of competitive pressure remains on all relevant routes*". Therefore, the Commission has cleared the acquisition, subject to full compliance with the commitments.

ANTITRUST

European Court of Justice rules in MOL that 'economic unit' concept does not apply to claimants in antitrust damages claims

On 4 July 2024, in a reference for a preliminary ruling, the CJ ruled on the application of the 'economic unit' concept to claimants in antitrust damages claims. The CJ held that a parent company cannot bring an action for damages resulting from anti-competitive conduct of another company, in the country where that parent company has its registered office, where the harm is suffered solely by its subsidiaries in other EU Member States. This is irrespective of whether that parent company and its subsidiaries form part of the same economic unit.

This ruling was made in the context of a dispute between MOL and Mercedes Benz Group. MOL is a Hungarian undertaking with controlling interests in a number of subsidiaries in different EU Member States. MOL brought a claim for damages against Mercedes following the Commission's 2016 trucks decision. As a result of MOL's subsidiaries having directly purchased/leased trucks from Mercedes during the period of the infringement, MOL brought a claim against Mercedes in Hungary (the place of MOL's registered office) alleging that it suffered harm equivalent to the overpayment that its subsidiaries, in other Member States, had unduly made as a result of the anti-competitive conduct identified by the Commission.

MOL sought to rely on the international jurisdiction of the Hungarian courts under article 7(2) of EU Regulation No 1215/2012 (the Recast Brussels Regulation) which states that a person domiciled in a Member State may be sued in another Member State "*in matters relating to tort, delict or quasi-delict, in the courts for the place where the harmful event occurred or may occur*". MOL argued that its registered office in Hungary, as the centre of the economic and financial interests of the group that it forms with its subsidiaries, was the place where the harmful event occurred.

On appeal, the case eventually reached the Hungarian Supreme Court, which referred to the CJ the question of the interpretation of Article 7(2) of the Recast Brussels Regulation in an antitrust context.

MOL argued that, although it did not directly purchase the trucks at issue, nor did it therefore suffer any direct damage as a result of the anti-competitive conduct, the concept of "*place where the damage occurred*" must be interpreted in the light of the concept of 'economic unit' used in competition law for the purposes of determining liability for an infringement of competition law. According to MOL, the concept of economic unit should not be given a different meaning depending on whether the undertaking concerned is the claimant or the defendant in the dispute.

The CJ rejected this approach and concluded that no support for MOL's interpretation could be found in previous case law. Moreover, that interpretation would be contrary to "*the objectives of proximity and predictability of the rules governing jurisdiction, and of consistency between the forum and the applicable law*". The CJ further concluded that the courts of the Member State(s) in which the affected market is located are best placed to examine actions for damages (i.e. in this case, where the trucks were leased/purchased by MOL's subsidiaries). The CJ also considered that an operator engaging in anti-competitive practices may reasonably expect to be sued before the courts of the place in which those practices have distorted the rules of fair competition.

ACCC opens consultation on its guide on sustainability collaborations and Australian competition law

The Australian Competition and Consumer Commission (ACCC) has launched a public consultation on its draft guide on sustainability collaborations and Australian competition law. The consultation will be open until 26 July 2024.

In recognition of the growing trend of businesses discussing or agreeing to conduct or practices aimed at mitigating the adverse impact that economic activities have on the environment, the ACCC's draft guide seeks to assist businesses by highlighting when such collaborations are likely or unlikely to be problematic from a competition law perspective. The ACCC notes that sustainability collaborations are less likely to be problematic where:

- the businesses are not competitors in terms of selling/buying goods or services;
- the businesses are making decisions independently, rather than in consultation, coordination, or cooperation with competitors;
- the businesses are free to innovate, buy from or sell to whom they choose; and/or
- it does not involve the sharing of commercially sensitive information, particularly on price.

To reduce the risk of enforcement action by the ACCC or complaints from third parties, businesses may consider approaching the ACCC for an informal discussion on whether there are any potential areas of concern, and/or whether obtaining the ACCC's pre-collaboration authorisation is the most suitable process. The ACCC may grant authorisation where it is satisfied that the sustainability collaboration is likely to result in a net public benefit (i.e. the likely public benefit from the proposed collaboration is likely to outweigh the likely public detriment). The 'net public benefit' may include sustainability objectives such as diverting waste from landfill, increasing generation of renewable energy from waste and decreasing greenhouse gas emissions. Notwithstanding authorisation, businesses should take care to ensure that any sharing of commercially sensitive information during the collaboration is only to the extent reasonably necessary to achieve the environmental benefit.

Australia follows Japan and Singapore as countries in the APAC region with published guidance on the application of competition law to sustainability-related projects. In February 2024, Japan's Fair Trade Commission allowed five petrochemical companies to collaborate on a carbon-neutral initiative. The ACCC's draft guide serves as a helpful reminder not to see competition law as a barrier to collective action in industries with genuine sustainability goals and challenges. However, businesses are also warned not to disguise anti-competitive conduct in the name of sustainability.

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