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Advocate General's Opinions in Cases C-176/19 P  $\mid$  Commission v Servier and Others and C-201/19 P  $\mid$  Servier and Others v Commission

Marketing of perindopril: Advocate General Kokott proposes that the Court of Justice should rule that all agreements concluded by the Servier group with generic pharmaceutical companies constituted restrictions of competition by object and that it should set aside the General Court's findings regarding the agreements between Servier and Krka, on the one hand, and the definition of the relevant market for the purposes of applying Article 102 TFEU, on the other

The present cases follow on from the cases *Generics (UK) and Others* <sup>1</sup> and *Lundbeck* v *Commission*, <sup>2</sup> in which the Court set out the criteria for determining whether an agreement in settlement of a dispute between the holder of a pharmaceutical patent and a manufacturer of generic medicinal products is contrary to EU competition law.

The Servier group, whose parent company, Servier SAS, is established in France, developed perindopril, a medicinal product used in cardiovascular medicine and intended primarily for the treatment of hypertension and heart failure. The perindopril compound patent, filed with the European Patent Office (EPO) in 1981, expired in various EU Member States over the course of the 2000s. New patents relating to perindopril and its manufacturing processes were filed by Servier, in particular the 947 patent, filed before the EPO in 2001 and granted in 2004.

Following disputes in which the validity of that patent was challenged, Servier entered into separate settlement agreements with several generic companies, namely Niche/Unichem (Niche's parent company), Matrix (now Mylan Laboratories), Teva, Krka and Lupin, by which each of those companies undertook, inter alia, to refrain from entering the market with generic perindopril considered to be in infringement of Servier's patents and from challenging those patents. Those agreements, in essence, ensured that generic companies wishing to enter the market with generic versions of perindopril undertook to defer market entry in return for transfers of value by Servier.

On 9 July 2014, the Commission adopted a decision in which it found that the contested agreements constituted restrictions of competition by object and by effect. The Commission also found that Servier had

<sup>&</sup>lt;sup>1</sup> Judgment of 30 January 2020, Generics (UK) and Others, C-307/18 (see Press Releases Nos 5/20 and 8/20).

<sup>&</sup>lt;sup>2</sup> Judgments of 25 March 2021, Lundbeck v Commission, <u>C-591/16 P</u>, Sun Pharmaceutical Industries and Ranbaxy (UK) v Commission, <u>C-586/16 P</u>, Generics (UK) v Commission, <u>C-588/16 P</u>, Arrow Group and Arrow Generics v Commission, <u>C-601/16 P</u>, Xellia Pharmaceuticals and Alpharma v Commission, <u>C-611/16 P</u>, and Merck v Commission, <u>C-614/16 P</u> (see Press Releases Nos <u>66/20</u> and <u>49/21</u>).

implemented, inter alia through those agreements, an exclusionary strategy which amounted to an abuse of a dominant position and imposed fines on the companies concerned.

In a judgment of 12 December 2018 (hereinafter 'the judgment under appeal'), <sup>3</sup> the General Court of the European Union annulled in part the Commission's decision, finding, inter alia, that Servier had not committed an infringement through the agreements with Krka and that the Commission had erroneously defined the relevant market for the purposes of applying Article 102 TFEU as being limited solely to originator and generic versions of perindopril. By contrast, the General Court confirmed, in the judgment under appeal, that the agreements concluded by Servier with Niche/Unichem, Matrix, Teva and Lupin constituted, by virtue of their object, restrictions of competition.

Servier brought an appeal against the judgment under appeal in so far as it upheld the classification of the agreements concluded with Niche/Unichem, Matrix, Teva and Lupin as restrictions of competition by object (Case C-201/19 P), while the Commission brought an appeal against the judgment under appeal in so far as it annulled in part the Commission's decision regarding the classification of the agreements between Servier and Krka as restriction of competition by object and by effect and regarding the definition of the relevant market for the purposes of applying Article 102 TFEU (Case C-176/19 P).

In today's Opinion in Case C-176/19 P, Commission v Servier and Others, Advocate General Juliane Kokott proposes that the Court should declare that the General Court erred in law in holding that the agreements concluded by Servier with Krka did not constitute a restriction of competition by object and by effect. According to Advocate General Kokott, the General Court erred in law when it took the view that those agreements, comprising, inter alia, a settlement agreement and a licensing agreement, were based on the recognition of the validity of the 947 patent by Krka and not on a reverse payment by Servier in favour of Krka. Advocate General Kokott concludes, on the contrary, that the Commission acted correctly in law in taking the view that those agreements constituted a restriction of competition by object, inter alia, because the licence constituted a transfer of significant value by Servier in favour of Krka which, in substance, had no consideration from Krka other than the latter's commitment not to compete with Servier on EU markets not covered by the licensing agreement. Furthermore, the Advocate General considers that the General Court wrongly found that those agreements had no anti-competitive effects, as the Commission had established to the requisite legal standard that they had the effect of eliminating Krka as a potential competitor of Servier. Finally, the Advocate General is of the opinion that the General Court erred in law and vitiated its judgment by failing to state reasons when it annulled the Commission's findings relating to the definition of the relevant market for the purposes of applying Article 102 TFEU.

Advocate General Kokott therefore proposes, first, that the Court should set aside the judgment under appeal in so far as it found that the agreements concluded between Servier and Krka did not constitute a restriction of competition by object and by effect, dispose of the case in regard to that point and reject the pleas raised at first instance with respect to that point. Second, she proposes that the Court should set aside the judgment under appeal in so far as the General Court held that the Commission had erroneously defined the relevant market for the purposes of applying Article 102 TFEU, and that it should refer the case back to the General Court for it to rule again on the pleas raised at first instance relating to Article 102 TFEU.

Furthermore, in today's Opinion in Case C-201/19 P, the Advocate General proposes that the Court should uphold the General Court's finding that the agreements concluded by Servier with Niche/Unichem, Matrix, Teva and Lupin constituted, by virtue of their object, restrictions of competition. According to the Advocate General, the General Court's analysis of those agreements is consistent with the case-law of the Court of Justice,

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<sup>&</sup>lt;sup>3</sup> Judgment of 12 December 2008, Servier and Others v Commission, <u>T-691/14</u>; see also judgments of 12 December 2018, Biogaran v Commission, <u>T-677/14</u>, Teva UK and Others v Commission, <u>T-679/14</u>, Lupin v Commission, <u>T-680/14</u>, Mylan Laboratories and Mylan v Commission, <u>T-682/14</u>, Krka v Commission, <u>T-684/14</u>, Niche Generics v Commission, <u>T-701/14</u>, and Unichem Laboratories v Commission, <u>T-705/14</u> (see Press Release No <u>194/18</u>).

according to which it is necessary to assess whether the net gain arising from the transfers of value by the manufacturer of originator medicines in favour of the manufacturer of generic medicines can be justified by the existence of any consideration on the part of the generic company. <sup>4</sup> It follows that, in this case, the General Court correctly held that the payments received by the generic companies were not justified by consideration other than the agreement not to compete with the patent holder, Servier.

**NOTE:** The Advocate General's Opinion is not binding on the Court of Justice. It is the role of the Advocates General to propose to the Court, in complete independence, a legal solution to the cases for which they are responsible. The Judges of the Court are now beginning their deliberations in this case. Judgment will be given at a later date.

**NOTE:** An appeal, on a point or points of law only, may be brought before the Court of Justice against a judgment or order of the General Court. In principle, the appeal does not have suspensive effect. If the appeal is admissible and well founded, the Court of Justice sets aside the judgment of the General Court. Where the state of the proceedings so permits, the Court of Justice may itself give final judgment in the case. Otherwise, it refers the case back to the General Court, which is bound by the decision given by the Court of Justice on the appeal.

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The full texts of the Opinions ( $\underline{\text{C-}176/19 P}$  and  $\underline{\text{C-}201/19 P}$ ) are published on the CURIA website on the day of delivery.

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<sup>&</sup>lt;sup>4</sup> See above, footnotes 1 and 2.