

Reports of Cases

JUDGMENT OF THE COURT (First Chamber)

27 June 2024*

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^{*} Language of the case: French.



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(Appeal – Competition – Pharmaceutical products – Market for perindopril – Article 101 TFEU – Agreements, decisions and concerted practices – Market sharing – Potential competition – Restriction of competition by object – Strategy to delay the market entry of generic versions of perindopril – Patent dispute settlement agreement – Patent licence agreement – Technology assignment and licence agreement – Article 102 TFEU – Relevant market – Abuse of dominant position)

In Case C-176/19 P,

APPEAL under Article 56 of the Statute of the Court of Justice of the European Union, brought on 22 February 2019,

European Commission, represented initially by F. Castilla Contreras, B. Mongin, J. Norris and C. Vollrath, subsequently by F. Castilla Contreras, F. Castillo de la Torre, B. Mongin, J. Norris and C. Vollrath, and lastly by F. Castilla Contreras, F. Castillo de la Torre, J. Norris and C. Vollrath, acting as Agents,

appellant,

supported by:

United Kingdom of Great Britain and Northern Ireland, represented initially by D. Guðmundsdóttir, acting as Agent, and by J. Holmes KC, subsequently by L. Baxter, D. Guðmundsdóttir, F. Shibli and J. Simpson, acting as Agents, and by J. Holmes KC, and P. Woolfe, Barrister, and lastly by S. Fuller, acting as Agent, and by J. Holmes KC, and P. Woolfe, Barrister,

intervener in the appeal,

the other parties to the proceedings being:

Servier SAS, established in Suresnes (France),

Servier Laboratories Ltd, established in Stoke Poges (United Kingdom),

Les Laboratoires Servier SAS, established in Suresnes,

represented by O. de Juvigny, J. Jourdan, T. Reymond, A. Robert, avocats, J. Killick, advocaat, and M.I.F. Utges Manley, Solicitor,

applicants at first instance,

European Federation of Pharmaceutical Industries and Associations (EFPIA), established in Geneva (Switzerland), represented by F. Carlin, Barrister, and N. Niejahr, Rechtsanwältin,

intervener at first instance,

THE COURT (First Chamber),

composed of A. Arabadjiev (Rapporteur), President of the Chamber, K. Lenaerts, President of the Court, acting as Judge of the First Chamber, P.G. Xuereb, A. Kumin and I. Ziemele, Judges,

Advocate General: J. Kokott,

Registrar: M. Longar and R. Şereş, Administrators,

having regard to the written procedure and further to the hearing on 20 and 21 October 2021,

after hearing the Opinion of the Advocate General at the sitting on 14 July 2022,

gives the following

Judgment

By its appeal, the European Commission seeks to have set aside in part the judgment of the General Court of the European Union of 12 December 2018, *Servier and Others* v *Commission* (T-691/14, 'the judgment under appeal', EU:T:2018:922), by which the General Court annulled Article 4, in so far as it found that Servier SAS and Les Laboratoires Servier SAS participated in the agreements referred to in that article, Article 6, Article 7(4)(b) and Article 7(6) of European Commission Decision C(2014) 4955 final of 9 July 2014 relating to a proceeding under Article 101 and Article 102 [TFEU] (Case AT.39612 – Perindopril (Servier)) ('the decision at issue').

I. Legal context

Paragraphs 13 to 15, 17 and 24 of the Commission Notice on the definition of relevant market for the purposes of Community competition law (OJ 1997 C 372, p. 5) are worded as follows:

'Competitive constraints

- 13. Firms are subject to three main sources or competitive constraints: demand substitutability, supply substitutability and potential competition. From an economic point of view, for the definition of the relevant market, demand substitution constitutes the most immediate and effective disciplinary force on the suppliers of a given product, in particular in relation to their pricing decisions. A firm or a group of firms cannot have a significant impact on the prevailing conditions of sale, such as prices, if its customers are in a position to switch easily to available substitute products or to suppliers located elsewhere. Basically, the exercise of market definition consists in identifying the effective alternative sources of supply for the customers of the undertakings involved, in terms both of products/services and of geographic location of suppliers.
- 14. The competitive constraints arising from supply side substitutability other [than] those described in paragraphs 20 to 23 and from potential competition are in general less immediate and in any case require an analysis of additional factors. As a result such constraints are taken into account at the assessment stage of competition analysis.

Demand substitution

15. The assessment of demand substitution entails a determination of the range of products which are viewed as substitutes by the consumer. One way of making this determination can be viewed as a speculative experiment, postulating a hypothetical small, lasting change in relative prices and evaluating the likely reactions of customers to that increase. The exercise of market definition focuses on prices for operational and practical purposes, and more precisely on demand substitution arising from small, permanent changes in relative prices. This concept can provide clear indications as to the evidence that is relevant in defining markets.

. . .

17. The question to be answered is whether the parties' customers would switch to readily available substitutes or to suppliers located elsewhere in response to a hypothetical small (in the range 5% to 10%) but permanent relative price increase in the products and areas being considered. If substitution were enough to make the price increase unprofitable because of the resulting loss of sales, additional substitutes and areas are included in the relevant market. This would be done until the set of products and geographical areas is such that small, permanent increases in relative prices would be profitable. ...

. . .

Potential competition

24. The third source of competitive constraint, potential competition, is not taken into account when defining markets, since the conditions under which potential competition will actually represent an effective competitive constraint depend on the analysis of specific factors and circumstances related to the conditions of entry. If required, this analysis is only carried out at a subsequent stage, in general once the position of the companies involved in the relevant market has already been ascertained, and when such position gives rise to concerns from a competition point of view.'

II. Background to the dispute

- The background to the dispute, as described in particular in paragraphs 1 to 73 of the judgment under appeal, may be summarised as follows.
- Servier SAS is the parent company of the Servier pharmaceutical group which includes Les Laboratoires Servier SAS and Servier Laboratories Ltd (individually or jointly, 'Servier'). Les Laboratoires Servier is specialised in the development of originator medicines, while its subsidiary Biogaran SAS is specialised in the development of generic medicines.

A. Servier's perindopril

- Servier developed perindopril, a medicinal product primarily intended for the treatment of hypertension and heart failure. That medicinal product is one of the angiotensin converting enzyme inhibitors ('the ACE medicinal products'). The 16 ACE medicinal products which existed at the material time were classified both at the third level of the Anatomical Therapeutic Chemical (ATC) classification of the World Health Organisation (WHO), which corresponds to therapeutic indications, and at the fourth level of that classification, corresponding to the mode of action, in the same group, entitled '[angiotensin converting enzyme] inhibitors, plain'. The active ingredient of perindopril takes the form of a salt. The salt used initially was erbumine.
- Patent EP0049658, relating to the active ingredient of perindopril, was filed by a company in the Servier group with the European Patent Office (EPO) on 29 September 1981. That patent was due to expire on 29 September 2001, but its protection was prolonged in a number of Member States, including the United Kingdom, until 22 June 2003. In France, protection under the patent was prolonged until 22 March 2005 and, in Italy, until 13 February 2009.

- On 16 September 1988, Servier filed a number of patents with the EPO relating to processes for the manufacture of the active ingredient of perindopril with an expiry date of 16 September 2008, namely patents EP0308339, EP0308340 ('the 340 patent'), EP0308341 and EP0309324.
- On 6 July 2001, Servier filed with the EPO patent EP1296947 ('the 947 patent'), relating to the alpha crystalline form of perindopril erbumine and the process for its manufacturing, which was granted by the EPO on 4 February 2004.
- On 6 July 2001, Servier moreover filed national patent applications in several Member States before they were parties to the Convention on the Grant of European Patents, which was signed in Munich on 5 October 1973 and entered into force on 7 October 1977. Servier filed, for example, patent applications relating to the 947 patent in Bulgaria (BG 107 532), the Czech Republic (PV 2003-357), Estonia (P200300001), Hungary (HU225340), Poland (P348492) and Slovakia (PP0149-2003). Those patents were granted on 16 May 2006 in Bulgaria, on 17 August 2006 in Hungary, on 23 January 2007 in the Czech Republic, on 23 April 2007 in Slovakia and on 24 March 2010 in Poland.

B. Krka's perindopril

From 2003, KRKA, tovarna zdravil, d.d. ('Krka'), a company established in Slovenia which manufactures generic medicines, began to develop medicinal products based on the active ingredient perindopril, composed of the alpha crystalline form of erbumine covered by the 947 patent ('Krka's perindopril'). In 2005 and 2006, it obtained a number of marketing authorisations and began to market that medicinal product in several Member States in central and eastern Europe, in particular in Hungary and Poland. During that period, it also made preparations to place the medicinal product on the market in other Member States, including France, the Netherlands and the United Kingdom

C. Disputes relating to perindopril

Between 2003 and 2009, a number of disputes were conducted between Servier and manufacturers preparing to market a generic version of perindopril.

1. The EPO decisions

- In 2004, 10 manufacturers of generic medicines, including Niche Generics Ltd ('Niche'), Krka, Lupin Ltd and Norton Healthcare Ltd, a subsidiary of Ivax Europe, which subsequently merged with Teva Pharmaceutical Industries Ltd, the ultimate parent company in the Teva group, specialising in the manufacture of generic medicines, filed opposition proceedings against the 947 patent before the EPO, seeking its revocation on grounds of lack of novelty, lack of inventive step and insufficient disclosure of the invention.
- On 27 July 2006, the Opposition Division of the EPO confirmed the validity of the 947 patent ('the EPO decision of 27 July 2006'). That decision was challenged before the EPO Technical Board of Appeal. After concluding a settlement agreement with Servier, Niche withdrew from the opposition proceedings on 9 February 2005. Krka and Lupin withdrew the proceedings before the EPO Technical Board of Appeal on 11 January 2007 and 5 February 2007, respectively.

By decision of 6 May 2009, the EPO Technical Board of Appeal annulled the EPO decision of 27 July 2006 and revoked the 947 patent. Servier's request for a revision of that decision of the Technical Board of Appeal was rejected on 19 March 2010.

2. The decisions of the national courts

- The validity of the 947 patent has been challenged before certain national courts by manufacturers of generic products, and Servier has brought actions for infringement and has applied for interim injunctions against those manufacturers. The majority of those proceedings were closed before the courts seised were able to give a final ruling on the validity of the 947 patent, as a result of settlement agreements concluded by Servier, between 2005 and 2007, with Niche, Matrix Laboratories Ltd ('Matrix'), Teva, Krka and Lupin.
- In the United Kingdom, only the dispute between Servier and Apotex Inc. gave rise to a finding, by a court, that the 947 patent was invalid. On 1 August 2006, Servier brought an action for infringement of the 947 patent before the High Court of Justice (England & Wales), Chancery Division (patents court) (United Kingdom), against Apotex, which had begun marketing a generic version of perindopril on the UK market. On 8 August 2006, Servier was granted an interim injunction against Apotex. On 6 July 2007, following a counterclaim by Apotex, that interim injunction was lifted and the 947 patent was declared invalid, thereby enabling Apotex to place a generic version of perindopril on the market in the United Kingdom. On 9 May 2008, the decision declaring the 947 patent invalid was confirmed on appeal.
- In the Netherlands, on 13 November 2007, Katwijk Farma BV, an Apotex subsidiary, brought an action before a court of that Member State seeking a declaration of invalidity of the 947 patent. Servier applied to that court for an interim injunction, which was rejected on 30 January 2008. By decision of 11 June 2008 in proceedings brought by Pharmachemie BV, a company in the Teva group, that court declared the 947 patent invalid for the Netherlands Following that decision, Servier and Katwijk Farma withdrew their claims.
- A number of disputes between Servier and Krka relating to perindopril were also brought before national courts.
- In Hungary, on 30 May 2006, Servier applied for an interim injunction preventing the marketing of Krka's perindopril, as a result of the infringement of the 947 patent. That application was rejected in September 2006.
- In the United Kingdom, on 28 July 2006, Servier brought an action for infringement of the 340 patent against Krka before the High Court of Justice (England & Wales), Chancery Division (patents court). On 2 August 2006, Servier brought an action for infringement of the 947 patent and an application for an interim injunction against Krka before that court. On 1 September 2006, Krka brought an initial counterclaim seeking the invalidation of the 947 patent, with an attached motion for summary judgment, and on 8 September 2006, a second counterclaim seeking the invalidation of the 340 patent. On 3 October 2006, that court granted Servier's application for an interim injunction and dismissed the motion for summary judgment lodged by Krka on 1 September 2006 ('the decision of the High Court of 3 October 2006'). On 1 December 2006, the proceedings were discontinued as a result of the settlement reached between the parties and that interim injunction was lifted.

D. The Krka agreements

- Servier and Krka concluded three agreements ('the Krka agreements'). On 27 October 2006, they concluded a settlement agreement ('the Krka settlement agreement') and a licence agreement, which was supplemented by an amendment on 2 November 2006 ('the Krka licence agreement' and, both those agreements together, 'the Krka settlement and licence agreements'). In addition, on 5 January 2007, Servier and Krka concluded an assignment and licence agreement ('the Krka assignment and licence agreement').
- The Krka settlement agreement covered the 947 patent and the equivalent national patents. By that agreement, in force until the expiry or the revocation of the 947 or the 340 patent, Krka undertook to withdraw any claim against the 947 patent worldwide and against the 340 patent in the United Kingdom, and not to challenge either of those two patents worldwide in the future. Moreover, Krka and its subsidiaries were not authorised to launch or to market a generic version of perindopril which would infringe the 947 patent for the duration of the validity of that patent and in the countries in which it was still valid, unless expressly authorised by Servier. Similarly, Krka could not supply to any third party a generic version of perindopril that would infringe the 947 patent, unless expressly authorised by Servier. In return, Servier was required to withdraw its actions against Krka for infringement of the 947 and 340 patents, including its pending applications for interim injunctions, worldwide.
- Pursuant to the Krka licence agreement, the duration of which corresponded to the validity of the 947 patent, Servier granted Krka an exclusive, irrevocable licence on that patent to use, manufacture, sell, offer for sale, promote and import its own products which contain the alpha crystalline form of erbumine in the Czech Republic, Latvia, Lithuania, Hungary, Poland, Slovenia and Slovakia ('Krka's core markets'). In return, Krka was required, under Article 3 of that agreement, to pay Servier 3% royalties on its net sales throughout those territories. Servier was entitled, in those States, to use the 947 patent directly or indirectly, that is to say, for one of its subsidiaries or for one third party per country.
- Pursuant to the Krka assignment and licence agreement, Krka assigned two patent applications to Servier, one concerning a process for the synthesis of perindopril (WO 2005 113500) and the other the preparation of formulations of perindopril (WO 2005 094793). The technology protected in those patent applications was used for the production of Krka's perindopril. Krka undertook not to challenge the validity of any patents granted on the basis of those applications. In return for that assignment, Servier paid Krka the sum of EUR 30 million.
- In addition, by that agreement, Servier also granted Krka a non-exclusive, irrevocable, non-assignable, royalty-free licence, with no right to sublicense (other than to its subsidiaries) on the applications or resulting patents, that licence being unrestricted in time, territory or scope of use.

III. The decision at issue

- 26 On 9 July 2014, the Commission adopted the decision at issue.
- In Articles 1 to 5 of that decision, the Commission found that Servier had infringed Article 101 TFEU by participating in the Niche, Matrix, Teva, Krka and Lupin agreements. In particular, in Article 4 of that decision, the Commission stated that the Krka agreements had constituted a

single and continuous infringement covering all the Member States of the European Union at the material time, with the exception of those constituting Krka's core markets; that the infringement had started on 27 October 2006, except in relation to Bulgaria and Romania, where it had started on 1 January 2007, Malta, where it had started on 1 March 2007, and Italy, where it had started on 13 February 2009; and that that infringement had ended on 6 May 2009, except in the case of the United Kingdom, where it ended on 6 July 2007, and the Netherlands, where it ended on 12 December 2007.

- In Article 7(1) to (5) of the decision at issue, the Commission imposed on Servier, for infringements of Article 101 TFEU, fines totalling EUR 289 727 200, including EUR 37 661 800 for its participation in the Krka agreements.
- Furthermore, in Article 6 of the decision at issue, the Commission found that Servier had infringed Article 102 TFEU by drawing up and implementing by means of technology acquisition and five settlement agreements an exclusionary strategy covering the market for perindopril and the technology market relating to the principal active ingredient of that medicinal product in France, the Netherlands, Poland and the United Kingdom.
- In Article 7(6) of the decision at issue, the Commission imposed on Servier, in respect of the infringement of Article 102 TFEU, a fine of EUR 41 270 000.

IV. The procedure before the General Court and the judgment under appeal

- By document lodged at the Registry of the General Court on 21 September 2014, Servier brought an action for annulment of the decision at issue, or, in the alternative, a reduction in the amount of the fine that had been imposed on it by that decision.
- By document lodged on 2 February 2015, the European Federation of Pharmaceutical Industries and Associations (EFPIA) sought leave to intervene in the proceedings in support of the form of order sought by Servier. That request was granted by an order of the President of the Second Chamber of the General Court of 14 October 2015.
- In its action at first instance, Servier raised 17 pleas in law in support of its claim for annulment of the decision at issue. Seven of those pleas are relevant for the purposes of the present appeal, namely the fourth, ninth and tenth grounds of appeal, relating to the infringement of Article 101 TFEU on account of that undertaking's participation in the Krka agreements, and the fourteenth to seventeenth pleas, which concern the infringement of Article 102 TFEU.
- The General Court upheld the pleas directed against the characterisation of the Krka agreements as an infringement of Article 101(1) TFEU. It found, in essence, that the Commission had not established the existence of a restriction of competition by object or of a restriction of competition by effect. Consequently, the General Court annulled Article 4 of the decision at issue, finding an infringement of Article 101 TFEU committed by Servier on account of its participation in the Krka agreements, and Article 7(4)(b) of that decision, imposing a fine on Servier in respect of that infringement.
- The General Court also upheld the pleas directed against the definition of the perindopril market and the finding that Servier had abused its dominant position on that market and the technology market relating to the active ingredient of perindopril. It held, in essence, that the definition of the

perindopril market was vitiated by errors of assessment such as to invalidate the findings in the decision at issue relating to Servier's dominant position on the relevant markets. It therefore annulled Article 6 of that decision finding an abuse of a dominant position by Servier, and Article 7(6) of that decision imposing a fine on Servier in respect of that infringement.

36 The General Court dismissed the action as to the remainder.

V. Procedure before the Court of Justice and forms of order sought

- By document lodged at the Registry of the Court of Justice on 22 February 2019, the Commission brought the present appeal.
- By document lodged at the Registry of the Court on 22 May 2019, the United Kingdom of Great Britain and Northern Ireland sought leave to intervene in the present case in support of the form of order sought by the Commission. By decision of 19 June 2019, the President of the Court of Justice granted that application.
- The Court invited the parties to submit their written observations by 4 October 2021 on the judgments of 30 January 2020, Generics (UK) and Others (C-307/18, EU:C:2020:52); of 25 March 2021, Lundbeck v Commission (C-591/16 P, EU:C:2021:243); of 25 March 2021, Sun Pharmaceutical Industries and Ranbaxy (UK) v Commission (C-586/16 P, EU:C:2021:241); of 25 March 2021, Generics (UK) v Commission (C-588/16 P, EU:C:2021:242); of 25 March 2021, Arrow Group and Arrow Generics v Commission (C-601/16 P, EU:C:2021:244); and of 25 March 2021, Xellia Pharmaceuticals and Alpharma v Commission (C-611/16 P, EU:C:2021:245). The Commission, Servier, EFPIA and the United Kingdom complied with that request within the prescribed period.
- The oral part of the procedure was closed on 14 July 2022, following the delivery of the Advocate General's Opinion. The complied with that request within the prescribed period.
- By its appeal, the Commission claims that the Court should:
 - set aside points 1 to 3 of the operative part of the judgment under appeal which annul (i) Article 4 of the decision at issue in so far as it finds that Servier participated in the Krka agreements, (ii) Article 7(4)(b) of that decision which sets the fine imposed on Servier for concluding those agreements, (iii) Article 6 of that decision which finds that Servier infringed Article 102 TFEU and (iv) Article 7(6) of that decision which sets the amount of the fine imposed on Servier in relation to that infringement;
 - set aside the judgment under appeal in so far as it declares Annexes A 286 and A 287 to the application at first instance and Annex C 29 to the reply at first instance admissible;
 - give final judgment on Servier's action for annulment of the decision at issue and dismiss Servier's application for annulment of Article 4, Article 7(4)(b), Article 6 and Article 7(6) of that decision and uphold the Commission's claim that Annexes A 286 and A 287 to the application at first instance and Annex C 29 to the reply at first instance should be declared inadmissible;
 - order Servier to bear all the costs of the present appeal.

- 42 Servier contends that the Court should
 - dismiss the appeal in its entirety, and
 - order the Commission to pay the costs.
- 43 EFPIA contends that the Court should:
 - dismiss the appeal in its entirety, and
 - order the Commission to pay the costs.
- 44 The United Kingdom requests the Court to grant the form of order sought by the Commission.

VI. The request that the oral part of the procedure be reopened

- By document lodged at the Court Registry on 21 July 2022, Servier requested that the oral part of the procedure be reopened. In support of that request, Servier relies on the need to ensure a sufficient exchange of views on key points of the factual background to the present case, while also criticising various aspects of the Advocate General's Opinion. According to Servier, such a reopening is necessary given that the forms of order sought propose that the Court should give final judgment in the dispute even though certain pleas raised at first instance involving complex factual assessments were neither examined nor, a fortiori, decided by the General Court.
- It should be borne in mind that, in accordance with Article 83 of the Rules of Procedure of the Court of Justice, the Court may at any time, after hearing the Advocate General, order the reopening of the oral part of the procedure, in particular if it considers that it lacks sufficient information or where a party has, after the close of that part of the procedure, submitted a new fact which is of such a nature as to be a decisive factor for the decision of the Court, or where the case must be decided on the basis of an argument which has not been debated between the parties.
- It should be recalled that neither the Statute of the Court of Justice of the European Union nor its Rules of Procedure make provision for parties to submit observations in response to the Advocate General's Opinion. Under the second paragraph of Article 252 TFEU, the Advocate General, acting with complete impartiality and independence, is to make, in open court, reasoned submissions on cases which require the Advocate General's involvement. The Court is not bound either by the Advocate General's conclusion or by the reasoning which led to that conclusion. Consequently, a party's disagreement with the Advocate General's Opinion, irrespective of the questions that he or she examines in his or her Opinion, cannot in itself constitute grounds justifying the reopening of the oral part of the procedure (judgment of 31 January 2023, *Puig Gordi and Others*, C-158/21, EU:C:2023:57, paragraphs 37 and 38 and the case-law cited).
- In the present case, the Court finds, having heard the Advocate General, that the elements set out by Servier do not disclose any new fact which is of such a nature as to be a decisive factor for the decision which it is called upon to deliver in the present case and that that case must not be decided on the basis of an argument which has not been debated between the parties or the interested persons. Since the Court has at its disposal, at the close of the written and oral stages of the procedure, all the elements necessary, it is therefore sufficiently informed to make a ruling on the present appeal. In any event, it should be recalled that, where the appeal is well founded and

the state of the proceedings so permits, within the meaning of Article 61 of the Statute of the Court of Justice of the European Union, the Court may itself give final judgment in the matter. In the light of the foregoing, there is no need to grant the request that the oral part of the procedure be reopened.

VII. The appeal

- In support of its appeal, the Commission has raised 11 grounds. By its first to sixth grounds of appeal, the Commission claims that the General Court erred in law in finding that the Krka agreements did not constitute a restriction of competition by object within the meaning of Article 101(1) TFEU. By its seventh ground of appeal, the Commission submits that the General Court erred in law in finding that the Commission had not established that those agreements constituted a restriction of competition by effect.
- The eighth and ninth grounds of appeal allege errors of law relating to the definition of the market for the medicinal product perindopril used in the decision at issue to support the existence of an infringement of Article 102 TFEU. By its tenth ground of appeal, the Commission alleges that the General Court erred in law when it held that certain documents which Servier had annexed to its application and its reply at first instance were admissible. The eleventh ground alleges errors of law in the General Court's assessment of the existence of an abuse of a dominant position on the technology market relating to the active ingredient of perindopril.

A. The first to sixth grounds of appeal, relating to the existence of a restriction of competition by object, within the meaning of Article 101(1) TFEU

- The first ground of appeal alleges infringement of Article 101(1) TFEU, in that the General Court ruled on the existence of a restriction of competition by object without ascertaining whether Krka was a potential competitor of Servier or responding to Servier's arguments in that regard, infringement of the limits of judicial review, infringement of the rules on the production of evidence, distortion of the evidence relating to the existence of potential competition between Krka and Servier, and insufficient and contradictory reasoning in the judgment under appeal.
- The second ground of appeal alleges infringement of Article 101(1) TFEU, in that the General Court applied incorrect legal criteria in order to assess the existence of a restriction of competition by object, distortion of the evidence, and insufficient and contradictory reasoning in the judgment under appeal.
- The third ground of appeal alleges infringement of Article 101(1) TFEU, in that the General Court required a market-sharing agreement to provide for 'hermetic' division between the parties in order to be caught by the prohibition laid down in that provision, a misinterpretation of Commission Regulation (EC) No 772/2004 of 27 April 2004 on the application of Article [101(3) TFEU] to categories of technology transfer agreements (OJ 2004 L 123, p. 11) and of the Commission Notice entitled 'Guidelines on the application of Article [101 TFEU] to technology transfer agreements' (OJ 2004 C 101, p. 2), and distortion of certain items of evidence.
- The fourth ground of appeal alleges infringement of Article 101(1) TFEU, in that the General Court criticised the decision at issue for finding a restriction of competition by object without analysing the intention of the parties, an infringement of the rules on the production of evidence, and an inadequate statement of reasons.

- The fifth ground of appeal alleges infringement of Article 101(1) TFEU, in that the General Court took into consideration the pro-competitive effects of the Krka licence agreement on Krka's core markets, whereas the decision at issue had not found an infringement on those markets.
- The sixth ground of appeal alleges infringement of Article 101(1) TFEU, in that the errors of law alleged in the first to fifth grounds of appeal led the General Court to refuse to recognise that the Krka assignment and licence agreement constituted a restriction of competition by object, and an inadequate statement of reasons.

1. The relevant sections of the decision at issue and the relevant paragraphs of the judgment under appeal

(a) The decision at issue

- In recitals 1670 to 1859 of the decision at issue, the Commission assessed the Krka agreements in the light of Article 101 TFEU. For the reasons set out in recitals 1670 to 1812 of that decision, it found that those agreements constituted a single and continuous infringement the object of which was to restrict competition by sharing the markets for perindopril in the European Union between those two undertakings.
- First, it is apparent from recitals 1701 to 1763 of the decision at issue that the object of the Krka settlement and licence agreements was to divide and allocate the EU markets between Servier and Krka. The licence agreement authorised Krka to continue or to start marketing a generic version of perindopril as part of a de facto duopoly with Servier in Krka's core markets. That authorisation was the quid pro quo for Krka's commitment, under the Krka settlement agreement, to refrain from competing with Servier in the other national markets in the territory of the European Union, which constitute Servier's core markets ('Servier's core markets'). The Commission therefore considered that that licence agreement represented the inducement offered by Servier for Krka to accept the restrictions agreed in the Krka settlement agreement.
- Second, the Commission found, in recitals 1764 to 1810 of the decision at issue, that the Krka assignment and licence agreement had made it possible for the parties to strengthen their competitive position, as it resulted from the Krka settlement and licence agreements, by preventing Krka from assigning its technology for the production of perindopril to other manufacturers of generic medicines which could then have used it to market generic versions of that medicinal product on Servier's core markets. Since the payment by Servier to Krka of the sum of EUR 30 million was unconnected with the income that Servier could achieve or expect from the commercial exploitation of the technology thus transferred by Krka, the payment of that sum was viewed by the Commission as a sharing of the revenues resulting from the reinforcement of market allocation between Servier and Krka.

(b) The judgment under appeal

The General Court set out, in the first place, in paragraphs 255 to 274 of the judgment under appeal, the conditions under which the insertion, into patent dispute settlement agreements, of non-challenge clauses in respect of patents and non-marketing clauses in respect of generic products is anticompetitive. According to the General Court, such an insertion is anticompetitive if it is based not on the parties' recognition of the validity of the patent and of the infringing nature of the generic products concerned, but on a significant and unjustified reverse payment made by

the patent holder to the manufacturer of generic medicines, which induces the latter to agree to those clauses. The General Court found, in paragraph 271 of the judgment under appeal, that, where they involve such an inducement, agreements of that nature must be regarded as market exclusion agreements, by which the 'stayers' are to compensate the 'goers'.

- In the second place, the General Court explained, in paragraphs 797 to 810 of the judgment under appeal, that, where a normal commercial agreement is linked to a patent dispute settlement agreement including non-marketing and non-challenge clauses, such a contractual arrangement must be regarded as anticompetitive if the value transferred by the patent holder to the manufacturer of generic medicines under the commercial agreement exceeds the value of the asset transferred by that company pursuant to that agreement. In other words, such a contractual arrangement must be regarded as anticompetitive if the normal commercial agreement linked to the settlement agreement serves, in reality, to mask a value transfer from the patent holder to the manufacturer of generic medicines, for which there is no quid pro quo other than that manufacturer's commitment not to compete.
- In the third place, the General Court ruled, in paragraphs 943 to 1032 of the judgment under appeal, on the particular situation of the linking of a settlement agreement with a licence agreement, such as the linking resulting from the Krka settlement and licence agreements. It took the view that, in such a situation, the considerations relevant to the linking of a settlement agreement with a normal commercial agreement, summarised in the preceding paragraph of the present judgment, do not apply. It is apparent from paragraphs 943 to 947 of the judgment under appeal that the linking of a settlement agreement to a licence agreement is an appropriate means of resolving the dispute, by allowing the generic company to enter the market and satisfying the wishes of both parties. Moreover, the presence, in a settlement agreement, of non-marketing and non-challenge clauses is legitimate where that agreement is based on the parties' recognition of the validity of the patent. Yet a licence agreement, which is meaningful only if the licence is actually used, is necessarily based on the parties' recognition of the validity of the patent.
- In paragraphs 948 and 952 of the judgment under appeal, the General Court considered that, in order to establish that the linking of a settlement agreement with a licence agreement in fact masks a reverse payment from the patent holder to the manufacturer of generic medicines, the Commission must demonstrate that the royalty paid to the patent holder under that licence agreement by that manufacturer is abnormally low.
- The General Court, in essence, stated in paragraphs 953 to 956 of the judgment under appeal that the abnormally low level of that royalty must be particularly clear for the purpose of characterising a settlement agreement as a restriction of competition by object, since the anticompetitive nature of the non-marketing and non-challenge clauses in that agreement is mitigated by the pro-competitive effect of the licence agreement, which would encourage the entry of the manufacturer of generic medicines on the market.
- The General Court concluded, in paragraph 963 of the judgment under appeal, that 'where there is a genuine dispute involving litigation between the parties concerned and a licence agreement that is directly connected with the settlement of that dispute, the linking of that agreement to the settlement agreement does not constitute a strong indication of the existence of a reverse payment. In such circumstances, it is therefore for the Commission to demonstrate, on the basis of other evidence, that the licence agreement does not constitute a transaction concluded at arm's length and thus masks a reverse payment'.

It was in the light of those factors that the General Court examined, in paragraphs 964 to 1031 of the judgment under appeal, the Krka settlement and licence agreements, and reached the conclusion, in paragraph 1032 of that judgment, that those agreements did not reveal 'a sufficient degree of harm to competition that the Commission could validly conclude that they constituted a restriction [of competition] by object'.

2. Admissibility of the first to sixth grounds of appeal

- 67 Servier submits that the appeal, taken as a whole and more particularly in its first to sixth grounds of appeal, is inadmissible on several grounds.
- In the first place, a large part of the Commission's arguments in the context of the first to fourth grounds of appeal is aimed at requesting the Court to carry out a new assessment of the facts.
- In that regard, it should be recalled that it is apparent from Article 256(1) TFEU and the first paragraph of Article 58 of the Statute of the Court of Justice of the European Union that an appeal is to be limited to points of law and that the General Court therefore has sole jurisdiction to find and appraise the relevant facts and to assess the evidence. The assessment of the facts and evidence does not, save where the facts or evidence are distorted, constitute a point of law, which is subject, as such, to review by the Court of Justice on appeal. Such a distortion must be obvious from the documents on the Court's file, without there being any need to carry out a new assessment of the facts and evidence (judgment of 10 July 2019, VG v Commission, C-19/18 P, EU:C:2019:578, paragraph 47 and the case-law cited).
- However, where the General Court has found or appraised the facts, the Court of Justice has jurisdiction to carry out a review, provided that the General Court has defined their legal nature and determined the legal consequences. The jurisdiction of the Court of Justice to review extends, inter alia, to the question whether the General Court has taken the right legal criteria as the basis for its appraisal of the facts (see, to that effect, judgment of 2 March 2021, *Commission* v *Italy and Others*, C-425/19 P, EU:C:2021:154, paragraph 53 and the case-law cited).
- In the present case, by its first ground of appeal, the Commission criticises the General Court, first of all, in essence, for having applied an incorrect legal standard in order to assess the legality of the reasons in the decision at issue that led to the finding of potential competition between Krka and Servier. Next, the Commission criticises the General Court for having given insufficient or contradictory reasons for the judgment under appeal, and for having distorted certain evidence. Lastly, it submits that that court infringed the rules governing the production of evidence and the scope of judicial review by failing to rule on the complaints relating to potential competition developed in the context, inter alia, of the ninth plea in the action at first instance, by failing to analyse the reasoning and all of the evidence set out in the decision at issue relating to the anticompetitive object of the Krka settlement and licence agreements, and by substituting its own assessment of the facts for the grounds of that decision, in so far as it attributed to Krka grounds explaining that undertaking's decision to pursue its litigation after the EPO decision of 27 July 2006 even though those reasons are merely alleged and are, moreover contradicted by other findings made by the General Court.

- Thus, it must be held that, by that line of argument, the Commission disputes the interpretation and application of the concept of potential competition, and alleges infringement of procedural rules and distortion of evidence. Contrary to Servier's submission, complaints of that nature fall within the jurisdiction of the Court of Justice in the context of an appeal, in accordance with the case-law cited in paragraphs 69 and 70 of the present judgment.
- By its second to fourth grounds of appeal, the Commission essentially challenges the General Court's assessment of the anticompetitive object of the Krka agreements consisting in market sharing. Such a question is clearly a point of law since it involves determining whether the General Court misinterpreted and misapplied Article 101(1) TFEU.
- By its fifth ground of appeal, the Commission submits that the General Court erred in law by taking into account the allegedly pro-competitive effects of the Krka licence agreement on Krka's core markets, when no infringement had been found by the Commission on those markets, and that such effects could not justify a restriction of competition on other markets. It must be observed that such a line of argument relates to the legal criterion applied by the General Court to assess the relevance of the pro-competitive effects which it found and that its examination therefore falls within the jurisdiction of the Court of Justice in the context of an appeal.
- By its sixth ground of appeal, the Commission complains that the General Court refused to recognise that the Krka assignment and licence agreement constituted a restriction of competition by object, on the ground that that characterisation was based on the incorrect finding that there was market sharing between Krka and Servier. Thus, the outcome of that ground of appeal depends on the outcome of the complaints put forward by the Commission in the context of its first to fifth grounds of appeal, which do in fact relate to errors of law. Consequently, the examination of the sixth ground of appeal falls within the jurisdiction of the Court of Justice in the context of an appeal.
- In the second place, Servier submits, in general terms, that the appeal merely repeats the arguments relied on by the Commission at first instance, which were rejected by the General Court, without demonstrating the existence, in the judgment under appeal, of errors of law or distortion of the facts. That is alleged to be the case as regards the Commission's arguments in support of the first ground of appeal, in particular the fourth part, and the second part of the third ground of appeal.
- It should be borne in mind that it follows from Article 256 TFEU, the first paragraph of Article 58 of the Statute of the Court of Justice of the European Union and Article 168(1)(d) and Article 169 of its Rules of Procedure that an appeal must indicate precisely the contested elements of the judgment or order which the appellant seeks to have set aside and the legal arguments specifically advanced in support of that appeal. According to the settled case-law of the Court of Justice, that requirement is not satisfied by an appeal which confines itself to reproducing the pleas in law and arguments previously submitted to the General Court. Such an appeal amounts in reality to no more than a request for re-examination of the application submitted to the General Court, which the Court of Justice does not have jurisdiction to undertake (judgment of 24 March 2022, Hermann Albers v Commission, C-656/20 P, EU:C:2022:222, paragraph 35 and the case-law cited).
- However, where an appellant challenges the interpretation or application of EU law by the General Court, the points of law examined at first instance may be discussed again in the course of an appeal. Indeed, if an appellant could not base its appeal on pleas in law and arguments

already relied on before the General Court in that way, the appeal would be deprived of part of its purpose (judgment of 24 March 2022, *Hermann Albers* v *Commission*, C-656/20 P, EU:C:2022:222, paragraph 36 and the case-law cited).

- In the present case, while it is true that the arguments put forward by the Commission in its appeal bear certain similarities to those on which it relied at first instance, the fact remains that it does not merely reiterate the arguments it has already put forward before the General Court, but specifically challenges that court's interpretation and application of EU law. It follows that Servier's line of argument based on the repetition of the Commission's arguments at first instance cannot be accepted.
- In the third place, Servier contends that the Commission's line of argument, in particular that set out in the context of the first to fifth grounds of appeal, is not sufficiently clear to be admissible.
- In that regard, it is apparent from Article 169(2) of the Rules of Procedure of the Court of Justice that the pleas in law and legal arguments raised and relied on must identify precisely those points in the grounds of the decision of the General Court which are contested (see, to that effect, judgment of 20 September 2016, *Mallis and Others v Commission and ECB*, C-105/15 P to C-109/15 P, EU:C:2016:702, paragraphs 33 and 34). That is so in the present case, since in its appeal the Commission set out in detail the contested elements of the judgment under appeal and the legal arguments in support of its claim that it should be set aside, while referring specifically to the paragraphs of the judgment under appeal which are the subject of its arguments.
- In the fourth place, Servier claims that the appeal merely cites the judgment under appeal in a piecemeal and selective manner and that it is based on a misinterpretation of that judgment's content.
- By that line of argument, Servier is in fact challenging the substantive validity of the grounds of appeal. Such a line of argument falls within the scope of the assessment of the substance of those grounds of appeal and cannot, therefore, lead to the inadmissibility of that appeal.
- Lastly, in the fifth place, Servier claims that, in so far as the Commission complains, in its first, fourth and sixth grounds of appeal, that the General Court failed to examine certain passages of the decision at issue and all the evidence cited therein, it is mistaken as to the nature of the review carried out by that court.
- However, the general nature of such a plea of inadmissibility cannot lead to the inadmissibility of the first, fourth and sixth grounds of appeal. The Court will specifically rule on the pleas of inadmissibility raised more specifically by Servier in the context of the examination of the grounds of appeal concerned.
- In the light of the foregoing considerations, the pleas of inadmissibility raised by Servier in general, in respect of the first to sixth grounds of appeal must be rejected.

3. Preliminary considerations relating to the examination of the substance of the first to sixth grounds of appeal

Before examining the merits of the grounds of appeal relating to the existence of a restriction of competition by object, it should be noted that, unlike the circumstances underlying the cases in which the Court has been called upon to rule on the legal characterisation, in the light of

Article 101 TFEU, of agreements under which a manufacturer of originator medicines compensated a manufacturer of generic medicines economically in return for the latter's refraining from entering the market, in particular the cases which gave rise to the judgments of 30 January 2020, *Generics (UK) and Others* (C-307/18, EU:C:2020:52), and of 25 March 2021, *Lundbeck v Commission* (C-591/16 P, EU:C:2021:243), and unlike the other agreements concluded by Servier that formed the subject matter of the decision at issue, the Krka settlement and licence agreements did not provide for any payment from the manufacturer of originator medicines to the manufacturer of generic medicines. On the contrary, the Krka licence agreement provided for payments from the manufacturer of generic medicines to the manufacturer of originator medicines.

- On the other hand, according to recitals 1731 to 1749 of the decision at issue, the Krka settlement and licence agreements allowed Servier to delay the entry into the market of generic medicines produced by Krka. In the territory of the European Union, it is alleged that those two undertakings divided the national markets into two spheres of influence, comprising, for each of them, their core markets, within which they could operate in the assurance, in the case of Servier, that it would not be subject to competitive pressure from Krka beyond the limits resulting from those agreements and, in the case of Krka, that it would not run the risk of being sued for infringement by Servier.
- While it is therefore clear from the evidence in the decision at issue that Servier did not make any reverse payment as such to Krka under the Krka settlement agreement, it is also clear, according to the Commission, that those undertakings divided the various national markets within the European Union geographically. It will therefore be necessary to take those circumstances into consideration in order to rule, in particular, on the second and third grounds of appeal, and to assess whether, and if so to what extent, the Commission's line of argument seeking to call into question the legal criteria on the basis of which the General Court upheld the pleas at first instance relied on by Servier to challenge the characterisation of the Krka settlement and licence agreements as a restriction of competition by object is well founded.
- In that regard, it should be recalled that Article 101(1) TFEU states that all agreements between undertakings, decisions by associations of undertakings and concerted practices which may affect trade between Member States and which have as their object or effect the prevention, restriction or distortion of competition within the internal market are incompatible with the internal market and are prohibited.
- Accordingly, if the conduct of undertakings is to be subject to the prohibition in principle laid down in Article 101(1) TFEU, that conduct must reveal the existence of coordination between them, that is to say, an agreement between undertakings, a decision by an association of undertakings or a concerted practice (see, to that effect, judgment of 30 January 2020, *Generics* (*UK*) and Others, C-307/18, EU:C:2020:52, paragraph 31 and the case-law cited).
- The latter requirement means, with respect to horizontal cooperation agreements entered into by undertakings that operate at the same level of the production or distribution chain, that the coordination involves undertakings which are in competition with each other, if not in reality, then at least potentially (judgment of 30 January 2020, *Generics (UK) and Others*, C-307/18, EU:C:2020:52, paragraph 32).

- In addition, it is necessary to demonstrate, in accordance with the very wording of that provision, either that that conduct has as its object the prevention, restriction or distortion of competition, or that that conduct has such an effect (judgment of 21 December 2023, *European Superleague Company*, C-333/21, EU:C:2023:1011, paragraph 158). It follows that that provision, as interpreted by the Court, makes a clear distinction between the concept of restriction by object and the concept of restriction by effect, each of those concepts being subject to different rules with regard to what must be proved (judgment of 30 January 2020, *Generics (UK) and Others*, C-307/18, EU:C:2020:52, paragraph 63).
- Accordingly, as regards practices characterised as restrictions of competition by object, there is no need to investigate their effects nor a fortiori to demonstrate their effects on competition, in so far as experience shows that such behaviour leads to falls in production and price increases, resulting in poor allocation of resources to the detriment, in particular, of consumers (see, to that effect, judgments of 19 March 2015, *Dole Food and Dole Fresh Fruit Europe v Commission*, C-286/13 P, EU:C:2015:184, paragraph 115, and of 21 December 2023, *European Superleague Company*, C-333/21, EU:C:2023:1011, paragraph 159).
- On the other hand, where the anticompetitive object of an agreement, a decision by an association of undertakings or a concerted practice is not established, it is necessary to examine its effects in order to prove that competition has in fact been prevented or restricted or distorted to an appreciable extent (see, to that effect, judgment of 26 November 2015, *Maxima Latvija*, C-345/14, EU:C:2015:784, paragraph 17).
- That distinction arises from the fact that certain forms of collusion between undertakings can be regarded, by their very nature, as being injurious to the proper functioning of normal competition (judgments of 20 November 2008, *Beef Industry Development Society and Barry Brothers*, C-209/07, EU:C:2008:643, paragraph 17, and of 14 March 2013, *Allianz Hungária Biztosító and Others*, C-32/11, EU:C:2013:160, paragraph 35). The concept of restriction of competition by object must be interpreted strictly and can be applied only to certain agreements between undertakings which reveal, in themselves and having regard to the content of their provisions, their objectives, and the economic and legal context of which they form part, a sufficient degree of harm to competition for the view to be taken that it is not necessary to assess their effects (see, to that effect, judgments of 26 November 2015, *Maxima Latvija*, C-345/14, EU:C:2015:784, point 20, and of 21 December 2023, *European Superleague Company*, C-333/21, EU:C:2023:1011, paragraphs 161 and 162 and the case-law cited).
- The Court has already held that market-sharing agreements constitute particularly serious breaches of the competition rules (see, to that effect, judgments of 11 July 2013, *Gosselin Group* v *Commission*, C-429/11 P, EU:C:2013:463, paragraph 50; of 5 December 2013, *Solvay Solexis* v *Commission*, C-449/11 P, EU:C:2013:802, paragraph 82; and of 4 September 2014, *YKK and Others* v *Commission*, C-408/12 P, EU:C:2014:2153, paragraph 26). The Court has moreover held that agreements of that nature have, in themselves, an object restrictive of competition and fall within a category of agreements expressly prohibited by Article 101(1) TFEU, and that such an object cannot be justified by an analysis of the economic context of the anticompetitive conduct concerned (judgment of 19 December 2013, *Siemens and Others* v *Commission*, C-239/11 P, C-489/11 P and C-498/11 P, EU:C:2013:866, paragraph 218).
- As regards such categories of agreements, it is thus only if Article 101(3) TFEU applies and all of the conditions provided for in that provision are observed that they may be granted the benefit of an exemption from the prohibition laid down in Article 101(1) TFEU (see, to that effect,

- judgments of 20 November 2008, *Beef Industry Development Society and Barry Brothers*, C-209/07, EU:C:2008:643, paragraph 21, and of 21 December 2023, *European Superleague Company*, C-333/21, EU:C:2023:1011, paragraph 187).
- The implementation of the principles set out above with regard to collusive practices in the form of horizontal cooperation agreements between undertakings, such as the Krka agreements, involves determining, at an initial stage, whether those practices may be characterised as a restriction of competition by undertakings which are in competition with each other, even if only potentially. If that is the case, it is necessary to ascertain, at a second stage, whether, in the light of their economic characteristics, those practices fall within the characterisation of a restriction of competition by object.
- As regards the first stage of that analysis, the Court has already held that, in the specific context of the opening of the market for a medicinal product to the manufacturers of generic medicines, it is necessary to determine, in order to assess whether one of those manufacturers, although absent from a market, is a potential competitor of a manufacturer of originator medicines present in that market, whether there are real and concrete possibilities of the former moving into that market and competing with the latter (see, to that effect, judgment of 30 January 2020, *Generics (UK) and Others*, C-307/18, EU:C:2020:52, paragraph 36 and the case-law cited).
- Thus, it is necessary to assess, first, whether, at the time when those agreements were concluded, the manufacturer of generic medicines had taken sufficient preparatory steps to enable it to enter the market concerned within such a period of time as would impose competitive pressure on the manufacturer of originator medicines. Such steps permit the conclusion that a manufacturer of generic medicines has a firm intention and an inherent ability to enter the market of a medicine containing an active ingredient that is in the public domain, even when there are process patents held by the manufacturer of originator medicines. Second, it must be determined that the market entry of such a manufacturer of generic medicines does not meet barriers to entry that are insurmountable (see, to that effect, judgment of 30 January 2020, *Generics (UK) and Others*, C-307/18, EU:C:2020:52, paragraphs 43 to 45).
- The Court has already held that any patents protecting an originator medicine or one of its manufacturing processes are indisputably part of the economic and legal context characterising the relationships of competition between the holders of those patents and the manufacturers of generic medicines. However, the assessment of the rights conferred by a patent must not consist in a review of the strength of the patent or of the probability of a dispute between the patent holder and a manufacturer of generic medicines concluding with a finding that the patent is valid and has been infringed. That assessment must rather concern the question whether, notwithstanding the existence of that patent, the manufacturer of generic medicines has real and concrete possibilities of entering the market at the relevant time (judgment of 30 January 2020, *Generics (UK) and Others*, C-307/18, EU:C:2020:52, paragraph 50).
- Furthermore, a finding of potential competition between a manufacturer of generic medicines and a manufacturer of originator medicines can be confirmed by additional factors, such as the conclusion of an agreement between them when the manufacturer of generic medicines was not present on the market concerned, or the existence of transfers of value to that manufacturer in exchange for the postponement of its market entry (see, to that effect, judgment of 30 January 2020, *Generics (UK) and Others*, C-307/18, EU:C:2020:52, paragraphs 54 to 56).

- 104 At a second stage of that analysis, in order to determine whether a delay in the market entry of generic medicines, as the result of a patent dispute settlement agreement, in exchange for transfers of value by the manufacturer of originator medicines to the manufacturer of those generic medicines must be regarded as a collusive practice constituting a restriction of competition by object, it is necessary to examine first of all whether those transfers of value may be fully justified by the need to compensate for the costs of or disruption caused by that dispute, such as the expenses and fees of the latter manufacturer's advisers, or by the need to provide remuneration for the actual and proven supply of goods or services by the manufacturer of generic medicines to the manufacturer of the originator medicine. If that is not the case, it must be ascertained whether those transfers of value can have no explanation other than the commercial interest of those manufacturers of medicinal products not to engage in competition on the merits. For the purposes of that analysis, it is necessary, in each individual case, to assess whether the net gain from the transfers of value was sufficiently large to actually act as an incentive to the manufacturer of generic medicines to refrain from entering the market concerned and, therefore, not to compete on the merits with the manufacturer of originator medicines, without it being necessary for that net gain necessarily to be greater than the profits which the manufacturer of generic medicines would have made if it had been successful in the patent proceedings (see, to that effect, judgment of 30 January 2020, Generics (UK) and Others, C-307/18, EU:C:2020:52, paragraphs 84 to 94).
- In that regard, it must be borne in mind that challenges to the validity and scope of a patent are part of normal competition in the sectors where there exist exclusive rights in relation to technology, so that settlement agreements whereby a manufacturer of generic medicines that is seeking to enter a market recognises, at least temporarily, the validity of a patent held by a manufacturer of originator medicines and gives an undertaking, as a result, not to challenge that patent nor indeed to enter that market are liable to restrict competition (see, to that effect, judgment of 30 January 2020, *Generics (UK) and Others*, C-307/18, EU:C:2020:52, paragraph 81 and the case-law cited).
- In the light of the foregoing, the General Court was required to apply the criteria set out in paragraphs 104 and 105 of the present judgment in order to rule on those of Servier's arguments, invoked in particular in the context of the ninth plea at first instance, that relate to the existence of a restriction of competition by object and thus to determine whether the Commission was entitled, in the decision at issue, to find the existence of such a restriction.
- Thus, once the existence of the elements relating to potential competition, which are the subject of the first ground of appeal, had been established, the General Court needed, at that second stage, to ascertain whether the Krka settlement and licence agreements constituted a market-sharing agreement which restricted competition by object within the meaning of Article 101(1) TFEU, a category of agreements expressly prohibited by that provision. The General Court was required to examine, in that context, the objectives of those agreements and the economic link which existed between them, according to the decision at issue, and, more specifically, whether the transfer of value by Servier to Krka by means of the Krka licence agreement was sufficiently significant to induce Krka to share markets with Servier, by refraining, even if only temporarily, from entering Servier's core markets in return for the assurance that it would be able to market its generic version of perindopril on its own core markets without incurring the risk that it would be the subject of patent infringement actions brought by Servier.

Furthermore, the General Court had to take into account the intentions of the undertakings involved, in order to ascertain whether, in the light of the factors referred to in the preceding paragraph, those intentions bore out its analysis of the objective aims that those undertakings were seeking to achieve from a competition standpoint, bearing in mind nevertheless that, in accordance with the case-law of the Court of Justice, the fact that those undertakings acted without having an intention to prevent, restrict or distort competition and the fact that they pursued certain legitimate objectives are not decisive for the purposes of the application of Article 101(1) TFEU (judgment of 21 December 2023, *European Superleague Company*, C 333/21, EU:C:2023:1011, paragraph 167 and the case-law cited).

4. The first ground of appeal

(a) The relevance of the first ground of appeal

(1) Arguments of the parties

os Servier submits that the first ground of appeal, according to which the General Court erred in law in finding that Krka was not a source of competitive pressure on Servier at the time of the Krka agreements, is ineffective. The fact that the General Court did not rule on potential competition cannot call into question the General Court's findings relating to the absence of a restriction of competition by object. Demonstrating potential competition is not a sufficient condition for such a characterisation. Servier adds that, since the General Court considered that the Commission had incorrectly adopted that characterisation on grounds unrelated to Krka's status as a potential competitor, it was not necessary to examine that status, as is, moreover, apparent from paragraph 1234 of the judgment under appeal.

110 According to the Commission, the first ground of appeal is ineffective.

(2) Findings of the Court

- It follows from the case-law of the Court of Justice that a ground of appeal directed against the reasoning of a judgment under appeal which has no effect on its operative part is ineffective and must therefore be rejected (judgment of 27 April 2023, *Fondazione Cassa di Risparmio di Pesaro and Others* v *Commission*, C-549/21 P, EU:C:2023:340, paragraph 80 and the case-law cited).
- Moreover, it is open to the General Court, after setting out the grounds on which a plea for annulment must be declared well founded, to consider, for reasons of procedural economy, that it is not necessary to respond to all the arguments put forward in support of that plea, provided that those grounds are sufficient to justify the operative part of the judgment under appeal (see, to that effect, judgment of 16 February 2012, *Council and Commission* v *Interpipe Niko Tube and Interpipe NTRP*, C-191/09 P and C-200/09 P, EU:C:2012:78, paragraph 111).
- In the present case, point 1 of the operative part of the judgment under appeal, in which the General Court annulled Article 4 of the decision at issue, which had found an infringement of Article 101 TFEU as a result of the Krka agreements, is based (i) on the grounds set out in paragraphs 943 to 1060 of the judgment under appeal, by which the General Court held that the Commission had erred in finding that those agreements constituted a restriction of competition by object, and (ii) on the grounds set out in paragraphs 1061 to 1232 of that judgment, by which

the General Court held that the Commission had erred in finding that there was a restriction of competition by effect. Thus, after finding, in essence, in paragraph 1233 of that judgment that the Commission had not established that Servier, in concluding the Krka agreements, had infringed Article 101 TFEU, the General Court held, in paragraph 1234 of that judgment, that it was appropriate to annul Article 4 of the decision at issue, 'without there being any need to examine the other complaints relied on by [Servier] in the present plea or the plea relating to the status of Krka as a potential competitor'.

- 114 Contrary to what Servier claims, that assessment by the General Court does not mean that the Commission's first ground of appeal is directed against grounds of the judgment under appeal which have no effect on its operative part. That ground of appeal seeks to call into question the grounds of that judgment relating to the characterisation of the Krka agreements as a restriction of competition by object, grounds which led the General Court to annul Article 4 of the decision at issue. By that ground of appeal, the Commission submits, in essence, that the General Court, in its analysis of the characterisation of the Krka agreements in the light of the concept of a restriction of competition by object, took into consideration Krka's alleged recognition of the validity of the 947 patent, on the basis, inter alia, of an incorrect legal test, of an incomplete or even selective assessment of the evidence set out in the decision at issue and of the distortion of some of that evidence. The Commission submits, in particular, that the General Court could not take a view on Krka's recognition of the validity of the 947 patent without examining the evidence referred to in the decision at issue in order to demonstrate that Krka was a potential competitor of Servier. According to that institution, that evidence shows that Krka, which had both a firm intention and an inherent ability to enter the perindopril market, concluded the Krka settlement agreement not because it was convinced of the validity of that patent, but because the Krka licence agreement had induced it to conclude an agreement with Servier on the geographic allocation of the national markets, with each refraining from competing freely also on the other's core markets.
- It should be noted in that regard that the General Court found, first of all, in paragraph 970 of the judgment under appeal, that there were, at the time the Krka settlement and licence agreements were concluded, 'consistent indications capable of leading the parties to believe that the 947 patent was valid'; and then, in paragraph 971 of that judgment, that the EPO decision of 27 July 2006 confirming the validity of the 947 patent had therefore been 'one of the driving factors leading to the settlement and licence agreements'. It inferred, lastly, in paragraph 972 of that judgment that 'the linking of those two agreements was justified and therefore [did] not constitute a strong indication of ... a reverse payment from Servier to Krka giving rise to the licence agreement'.
- Similarly, the General Court considered, in paragraph 1026 of the judgment under appeal, that the fact that Krka had continued to challenge Servier's patents and to market its product even though the validity of the 947 patent had been upheld by the EPO Opposition Division was not a decisive factor for the purpose of establishing the existence of a restriction of competition by object, since the fact that Krka continued to exert competitive pressure on Servier can be explained by Krka's desire, despite the expected litigation risks, to strengthen its position in the negotiations that it was likely to have with Servier with a view to reaching a settlement.
- That reasoning only makes sense if it is considered that the General Court necessarily held that, after the EPO had confirmed the validity of the 947 patent, Krka's perindopril, composed of the alpha crystalline form of erbumine protected by that patent, could no longer compete with Servier's perindopril, thus putting an end to any potential competition between those

undertakings. On that view, the Krka settlement agreement, by which that undertaking refrained from entering Servier's markets, merely reflects the rights arising from that patent and cannot therefore be perceived as the real consideration for Servier's grant of a licence to that patent on Krka's core markets. Indeed, the General Court expressly stated in paragraph 1234 of the judgment under appeal that it was appropriate to annul Article 4 of the decision at issue 'without there being any need to examine ... the plea relating to the status of Krka as a potential competitor'. However, it is apparent from the grounds which led to the annulment of that decision that the General Court did in fact examine certain complaints falling within the scope of that plea and a number of recitals of that decision which relate to the issue of potential competition between Krka and Servier.

- Indeed, it is apparent from the assessments made, inter alia, in paragraphs 943 to 1032 and 1140 to 1233 of the judgment under appeal that the General Court relied decisively on Krka's alleged recognition of the validity of the 947 patent following the EPO decision of 27 July 2006 and that of the High Court of 3 October 2006, as regards the characterisation of the Krka agreements as both a restriction of competition by object and a restriction of competition by effect. Since the General Court considered that the possibility of Krka's entering Servier's core markets in order to compete with Servier depended essentially on whether, at the date of the Krka agreements, Krka recognised the validity of the 947 patent, and Krka's status as a potential competitor to Servier resulting from the possibility of Krka's entering those markets, it must be held that there is a close link between that alleged recognition and Krka's status as a potential competitor to Servier.
- In those circumstances, contrary to Servier's assertion, the fact that the General Court, after upholding Servier's line of argument relating to the existence of an infringement of Article 101(1) TFEU, stated in paragraph 1234 of the judgment under appeal that there was no need to adjudicate on 'the plea relating to the status of Krka as a potential competitor' does not therefore mean that the Commission's first ground of appeal is directed against grounds which have no effect on the operative part of that judgment, since it follows, inter alia, from paragraphs 967, 968 and 970 to 972 of that judgment that the General Court necessarily examined certain complaints put forward by Servier at first instance relating to potential competition.
- 120 It follows that the first ground of appeal is effective.

(b) The first to third parts

(1) Arguments of the parties

By the first part of its first ground of appeal, the Commission criticises paragraph 1026 of the judgment under appeal. In its view, the General Court did not apply the correct test when it appears to have considered that Krka had ceased to be a potential competitor following the EPO decision of 27 July 2006 and because it no longer had an incentive to enter the market. In that regard, it is necessary to determine whether, in the absence of agreements, there would have been real and concrete possibilities of entering the market and competing with established undertakings. Moreover, the General Court substituted its own assessment for that of the Commission by holding that Krka continued to exert competitive pressure on Servier after that EPO decision only in order to strengthen its position in negotiations with that undertaking, but did not explain why, in its view, Krka would not have been in a position to enter the market in the absence of the agreements at issue.

- By the second part of its first ground of appeal, the Commission criticises paragraphs 970 and 1028 of the judgment under appeal. The General Court held, in essence, that the Commission had not succeeded in proving that the Krka settlement agreement had been concluded by that undertaking for reasons other than the fact that the EPO decision of 27 July 2006 had convinced it of the validity of the 947 patent. However, the General Court failed to examine the evidence and the reasoning to the contrary set out in recitals 1686 to 1690 of the decision at issue. According to the Commission, the General Court thus infringed the rules on the production of evidence and the scope of the review of legality which it is required to carry out under Article 263 TFEU with regard to Commission decisions relating to proceedings applying Articles 101 and 102 TFEU.
- By the third part of its first ground of appeal, the Commission alleges a contradiction between paragraph 361 and paragraph 970 of the judgment under appeal. Paragraph 361 states that the EPO decision of 27 July 2006 was not in itself sufficient to prevent potential competition from taking place, whereas, according to paragraph 970, that EPO decision had convinced Krka that the 947 patent was valid, thus prompting it to reach a settlement with Servier.
- Servier submits, first of all, that the first part is based on a misreading of the judgment under appeal, since the General Court did not rule out Krka's status as a potential competitor. The General Court did not substitute its assessment for that of the Commission, but rejected the relevance of Krka's continuation of the disputes after the EPO decision of 27 July 2006. Next, Servier submits that the second part is inadmissible because the Commission asks the Court to re-examine the facts in the light of the evidence referred to in the decision at issue, in particular in recitals 1680 to 1700 thereof. Lastly, it claims that the third part is unfounded.

(2) Findings of the Court

- As a preliminary point, it is necessary to reject Servier's claim that the Commission's line of argument put forward in the first three parts of the first ground of appeal is based on a misreading of the judgment under appeal. As is apparent from paragraphs 114 to 119 of the present judgment, by holding, inter alia, in paragraph 970 of the judgment under appeal that, at the time the Krka settlement and licence agreements were concluded, there were consistent indications capable of leading Servier and Krka to believe that the 947 patent was valid, the General Court inferred from those indications that competition between those undertakings on the national markets within the European Union was now precluded and that there was therefore no potential competition between them.
- It is appropriate to deal first with the third part of the first ground of appeal, since it relates to an alleged failure to state reasons in the judgment under appeal. Although there is a certain tension between, on the one hand, paragraphs 970 and 1154 of the judgment under appeal and, on the other, paragraph 361 of that judgment, the latter paragraph is worded in cautious terms which cannot be regarded as directly contradicting those two other paragraphs. In that paragraph 361, the General Court stated that the fact that the EPO decision of 27 July 2006 declared the 947 patent valid was not 'in itself' sufficient to prevent potential competition from taking place. That finding is not incompatible with the finding which follows, as has been held in paragraph 125 of the present judgment, from paragraph 970 of the judgment under appeal, according to which the General Court considered that Servier and Krka were not potential competitors before the conclusion of the Krka agreements, in the light, in particular, of the 'consistent indications' leading those undertakings to believe that the 947 patent was valid.

- As regards the admissibility of the second part of the first ground of appeal, it should be borne in mind that, on appeal, complaints based on findings of fact and on the assessment of those facts in the contested decision are admissible on appeal where it is claimed that the General Court has made findings which the documents in the file show to be substantially incorrect or that it has distorted the clear sense of the evidence before it (judgment of 18 January 2007, *PKK and KNK* v *Council*, C-229/05 P, EU:C:2007:32, paragraph 35).
- That distortion must be obvious from the documents in the Court's file, without there being any need to carry out a new appraisal of the facts and the evidence (judgment of 28 January 2021, *Qualcomm and Qualcomm Europe v Commission*, C-466/19 P, EU:C:2021:76, paragraph 43). Although such a distortion may consist in an interpretation of a document that is at odds with its content, that must be manifestly clear from the file and the General Court must have manifestly exceeded the limits of a reasonable assessment of the evidence. In that regard, it is not sufficient to show that a document could be interpreted in a different way from that adopted by the General Court (judgment of 17 October 2019, *Alcogroup and Alcodis* v *Commission*, C-403/18 P, EU:C:2019:870, paragraph 64 and the case-law cited).
- Contrary to what Servier claims, the Commission, by the second part of its first ground of appeal, does not seek to obtain a fresh assessment of the evidence, which would not fall within the jurisdiction of the Court of Justice in appeal proceedings. By its line of argument, the Commission alleges, in essence, an error in the application of Article 101(1) TFEU, in that the General Court failed, in the context of the review of the legality of the decision at issue, to take into consideration all the relevant factors for the purpose of determining whether the Commission was entitled to consider that the Krka agreements could be characterised as a restriction of competition, even if only potential. The Commission is therefore challenging an error of law, which falls within the jurisdiction of the Court of Justice in the context of an appeal.
- As regards the first and second parts of the first ground of appeal, on the substance, the General Court was required to apply the criteria set out in paragraphs 100 to 103 of the present judgment in order to rule on those of the arguments put forward by Servier, in particular, in the context of the ninth plea at first instance, that relate to potential competition and thus to determine whether the Commission had been entitled, in the decision at issue, to conclude that Krka was a potential competitor of Servier at the time the Krka agreements were concluded.
- In view of the characteristics of the infringement of Article 101 TFEU found in the decision at issue, the General Court therefore had to examine whether those agreements had been concluded between undertakings in a potential competitive relationship and could be characterised as a restriction of competition. To that end, that court was required to ascertain whether the Commission had been right to consider that, on the date those agreements were concluded, there were real concrete possibilities for Krka to enter the relevant market and compete with Servier, in view of sufficient preparatory steps and the absence of insurmountable barriers to that entry, it being possible to confirm the finding of potential competition, where appropriate, by additional factors, such as the existence of a transfer of value to Krka in exchange for the postponement of its market entry.
- Admittedly, where the validity of a patent protecting an originator medicinal product or one of its manufacturing processes has been definitively established before all the courts before which that question has been brought, it would hardly be conceivable that other aspects of the economic and legal context characterising objectively the competitive relationships between the holder of those patents and a manufacturer of generic medicines could justify the conclusion that there is still a

potential competitive relationship between them. However, where disputes between them on the question of the validity of the patent in question are still pending, it is for the administrative authority or the competent court to examine all the relevant elements before reaching the conclusion that that holder and that manufacturer are not potential competitors, as is apparent from the case-law referred to in paragraph 102 of the present judgment.

- However, instead of applying the criteria set out in paragraphs 100 to 103, 131 and 132 of the present judgment in order to carry out the necessary verifications to determine whether Krka was a potential competitor of Servier, as it was required to do, the General Court merely stated, in essence, in particular in paragraphs 970, 1026 and 1028 of the judgment under appeal, that those two undertakings were convinced that the 947 patent was valid and, without specific reasons or supporting evidence, that Krka's conduct consisting in maintaining competitive pressure on Servier could be explained by Krka's desire to strengthen its position in the negotiations that it was likely to have with Servier with a view to reaching a settlement accompanied by a licence agreement, the obtaining of such a licence having become the commercial solution preferred by Krka on the perindopril market.
- It follows that the first part of the first ground of appeal is well founded. The General Court was mistaken as to the legal relevance of the patent situation found to exist on the markets in question, as well as of the parties' intentions, and erred in law in the application of Article 101(1) TFEU by assessing the concept of potential competition according to incorrect criteria.
- As regards the second part of the first ground of appeal, it was for the General Court, in accordance with what was held in paragraph 132 of the present judgment and in the light of the case-law cited in paragraph 102 thereof, to take into account all the relevant factors on the basis of which the Commission considered, in the decision at issue, that Krka and Servier were in a potential competitive relationship. By limiting, in essence, its analysis of the relationship between those two undertakings, on the date of conclusion of the Krka settlement and licence agreements, to the patent situation alone and, in particular, to the perception that Krka may have had of the validity of the 947 patent, as well as to the parties' intentions, in the light more particularly of the EPO decision of 27 July 2006 and of that of the High Court of 3 October 2006, the General Court infringed that obligation.
- Not only did the General Court err in law as regards the review which it is required to conduct of Commission decisions relating to proceedings under Articles 101 and 102 TFEU, but it also infringed its obligation under Article 36 of the Statute of the Court of Justice of the European Union, applicable to the General Court by virtue of the first paragraph of Article 53 thereof, to state the reasons on which its judgments are based. having failed to set out, in paragraph 970 of the judgment under appeal, the reasons on which it relied in order to find implicitly, in that paragraph, that Servier and Krka were no longer potential competitors, even though the evidence set out, inter alia, in recitals 1686 to 1690 of the decision at issue was aimed at demonstrating the contrary. The fact that the General Court did not expressly state that it had ruled out the existence of potential competition between Krka and Servier is not such as to call into question that finding relating to a failure to state reasons. It cannot be accepted that the General Court may, by failing to set out an essential step in its own reasoning, dispense with its obligation to state the reasons on which its judgments are based and thus prevent the Court of Justice from being in a position to exercise its power of review on appeal.
- 137 It follows that the first and second parts of the first ground of appeal must be upheld. By contrast, the third part of the first ground of appeal must be rejected.

(c) The fourth and sixth parts

(1) Arguments of the parties

- By the fourth part of its first ground of appeal, the Commission complains that, in paragraphs 967, 968 and 970 of the judgment under appeal, the General Court distorted the evidence cited therein relating to the EPO decision of 27 July 2006 and the decision of the High Court of 3 October 2006.
- By the sixth part of that ground of appeal, the Commission submits, first of all, that the General Court distorted the evidence referred to in paragraphs 968, 1017 and 1024 of the judgment under appeal, from which it is apparent, according to that court, that those decisions had substantially altered the context in which the Krka settlement and licence agreements were concluded, in particular as regards the perception that Krka and Servier could have of the validity of the 947 patent.
- Those distortions vitiate the validity of the General Court's findings (i) in paragraphs 970, 1025 and 1028 of that judgment as regards Krka's recognition of the validity of the 947 patent and (ii) in paragraph 999 of that judgment, as to the fact that that recognition explained why Krka, rather than embarking on an 'at risk' entry into the markets of all the Member States, preferred to restrict itself to its core markets, covered by the Krka licence agreement. The Commission submits, next, that those assessments are contradicted by the evidence referred to in recitals 1687, 1693 and 1826 of the decision at issue, which the General Court failed to examine. Lastly, it claims that the reasoning of the judgment under appeal is insufficient and contradictory.
- According to Servier, first of all, the complaint of distortion should be rejected since the Commission has not identified any distorted evidence. Next, since that complaint is in fact directed only at the decision of the High Court of 3 October 2006, it is ineffective. Thus, even if it were to be considered that the injunctions had not altered Krka's perception of the validity of the 947 patent, that would not call into question the fact that the EPO decision of 27 July 2006 had altered it.
- Lastly, the Commission's line of argument is unfounded. The General Court took account of the fact that Krka had maintained its challenges after the EPO decision of 27 July 2006 confirming the validity of the 947 patent, but considered, in its absolute discretion, that that did not call into question the finding that Krka had settled because of the perception that it had acquired of the validity of that patent. As to the remainder, the Commission's line of argument is based on a misreading of the judgment under appeal. Far from having based its decision on contradictory grounds, the General Court noted that several indications might have led Krka to believe that the 947 patent was valid, which induced it to settle. The General Court held that both that fact and the absence of a reverse payment contributed to precluding a finding of a restriction of competition by object, without, however, ruling out Krka's status as a potential competitor.
- As regards the decision of the High Court of 3 October 2006, Servier argues that the temporary nature of an injunction does not contradict the General Court's factual assessment that that injunction contributed to altering the context in which the Krka settlement and licence agreements were concluded. Moreover, those injunctions did indeed alter the context of the agreements.

(2) Findings of the Court

- It should be noted at the outset that, notwithstanding the fact that the first two parts of the first ground of appeal have been upheld, with the consequence that the finding that the General Court's reasoning in relation to potential competition was vitiated by errors of law, it is still useful to examine the other parts of that ground of appeal in order to establish whether, irrespective of the fact that the General Court failed to apply the requisite legal criteria and failed to take into account all the relevant evidence, its interpretation of the evidence which it actually examined is vitiated by illegality and, in particular, by a possible distortion of that evidence, as the Commission claims.
- In paragraph 965 of the judgment under appeal, the General Court examined whether there were genuine disputes between Servier and Krka and whether the Krka licence agreement appeared to have a sufficiently direct connection with the settlement of those disputes to justify linking it to the Krka settlement agreement. In paragraphs 967 and 968 of that judgment, the General Court noted the existence of disputes between Servier and Krka which had given rise (i) to the EPO decision of 27 July 2006 and (ii) to the decision of the High Court of 3 October 2006. In paragraph 970 of that judgment, the General Court stated that there were, at the time the Krka settlement and licence agreements were concluded, 'consistent indications capable of leading the parties to believe that the 947 patent was valid' and referred, in that regard, to paragraphs 967 and 968 of that judgment.
- In order to assess whether the General Court distorted the decision of the High Court of 3 October 2006 and the EPO decision of 27 July 2006, the review carried out by the Court of Justice is limited to verifying that the General Court did not manifestly exceed the limits of a reasonable assessment of that evidence. The task of the Court of Justice is not to assess independently whether the Commission discharged its burden of proof in order to show the existence of a restriction of competition by object, but to determine whether, in finding that that was not the case, the General Court construed that evidence in a manner manifestly at odds with its wording (see, by analogy, judgment of 10 February 2011, *Activision Blizzard Germany* v *Commission*, C-260/09 P, EU:C:2011:62, paragraph 57).
- 147 The Commission's complaints alleging distortion must be examined in the light of those considerations.
 - (i) The decision of the High Court of 3 October 2006
- Paragraph 968 of the judgment under appeal is worded as follows:
 - '... On 1 September 2006, Krka had brought a counterclaim for annulment of the 947 patent and, on 8 September 2006, a separate counterclaim for annulment of the 340 patent. On 3 October 2006, the High Court of Justice (England & Wales), Chancery Division (Patents Court), granted Servier's application for an interim injunction and denied the motion brought by Krka on 1 September 2006. On 1 December 2006, the ongoing proceedings were discontinued as a result of the settlement reached between the parties and the interim injunction was lifted.'
- It follows from the wording of that paragraph 968 that the General Court, by referring to the denial of 'the motion brought by Krka on 1 September 2006' was referring to the rejection by the decision of the High Court of 3 October 2006 of Krka's counterclaim.

- However, that decision, which is set out in Annex A.174 to Servier's application at first instance, first, states that Servier's application for an interim injunction was granted and, second, dismisses not Krka's counterclaim but the application that that counterclaim, seeking the invalidation of the 947 patent, be granted by means of a motion for summary judgment.
- It follows that, in paragraph 968 of the judgment under appeal, the General Court distorted the clear and precise terms of the decision of the High Court of 3 October 2006, even though it faithfully referred to that decision in paragraphs 23 and 1196 of that judgment.
- On the basis of that distortion, the General Court, first of all, stated, in paragraph 970 of the judgment under appeal, that 'there were, at the time the [Krka] settlement and licence agreements were concluded, consistent indications capable of leading the parties to believe that the 947 patent was valid' and, next, in paragraph 1017 of that judgment, that the two events consisting of the EPO decision of 27 July 2006 and the decision of the High Court of 3 October 2006 'substantially altered the context in which the agreements were concluded, in particular as regards the perception that Krka, as well as Servier, could have of the validity of the 947 patent'. Lastly, on the basis of that latter finding, the General Court held, in paragraph 1024 of that judgment, that the occurrence of those two events 'considerably limits' the relevance of a Servier document relating to its strategy towards Krka. Furthermore, in paragraph 999 of that judgment, the General Court stated that Krka had settled with Servier not in return for the earnings obtained from the Krka licence agreement, but because Krka 'recognised the validity of the 947 patent', which was the 'decisive factor' in that regard.
- The decision of the High Court of 3 October 2006, given its provisional nature and the preliminary procedure at the end of which it was adopted, in no way prejudged the substantive outcome of the dispute, as the General Court moreover noted, in essence, in paragraphs 367 and 368 of the judgment under appeal. The national court merely found, in reality, in accordance with the criteria for granting summary judgment, that Krka's counterclaim was not manifestly well founded, yet pointed out in that regard, in paragraph 70 of that decision, that there was 'no doubt that Krka has shown that there is a serious issue to be tried that the sale of [Servier's perindopril] tablets before the priority date deprives the [947] patent of novelty', also stating, however, that it was not 'persuaded that Servier [has] no real prospects of defending [the 947] patent against that attack'.
- By thus distorting the clear and precise terms of the decision of the High Court of 3 October 2006, the General Court vitiated paragraphs 968, 970, 999, 1017 and 1024 of the judgment under appeal with illegality.
 - (ii) The EPO decision of 27 July 2006
- Paragraph 967 of the judgment under appeal is worded as follows:

'In 2004, 10 generic companies, including Krka, had filed opposition proceedings against the 947 patent before the EPO, seeking the revocation of that patent in its entirety on grounds of lack of novelty, lack of inventive step and insufficient disclosure of the invention. On 27 July 2006, the EPO Opposition Division confirmed the validity of that patent following minor amendments to Servier's original claims. Seven companies then brought an appeal against the EPO decision of 27 July 2006. Krka withdrew from the opposition proceedings on 11 January 2007, pursuant to the settlement agreement concluded with Servier.'

- The General Court thus gave an accurate account of the content of the EPO decision of 27 July 2006.
- However, it must be noted that the statement, in paragraph 970 of the judgment under appeal, that 'there were, at the time the [Krka] settlement and licence agreements were concluded, consistent indications capable of leading the parties to believe that the 947 patent was valid' is based, at least in part, on the distortion of the decision of the High Court of 3 October 2006, on which the General Court also relied in paragraphs 1017 and 1024 of that judgment.
- Furthermore, that statement by the General Court disregards several other items of evidence referred to in the decision at issue, which, according to the Commission, prove that, although the EPO decision of 27 July 2006 constituted a setback for Krka, that undertaking was far from having resigned itself to recognising the validity of the 947 patent. The decision at issue mentions, inter alia, in recitals 1687 to 1689 that Krka, which had appealed against that EPO decision, also continued the challenge to the 947 patent by bringing, on 1 September 2006, in the United Kingdom, a counterclaim against Servier seeking a declaration of invalidity of that patent. The decision of the High Court of 3 October 2006 emphasises that Krka had a 'powerful base' for attacking the 947 patent. The decision at issue also mentions statements by Krka's employees in response to that decision, which contradict any sense of resignation with regard to the EPO decision of 27 July 2006 as well as the fact that Krka obtained, in September 2006, the dismissal of the action for infringement of the 947 patent brought by Servier in Hungary and continued to market its generic version of perindopril on the market of that Member State.
- It was on the basis of that material that, in recital 1690, the decision at issue made the following finding as regards Krka's position following the EPO decision of 27 July 2006:
 - 'Krka's assessment of the patent situation was certainly influenced by the Opposition Decision, and the grant of the interim injunctions against Krka and Apotex in the UK. Yet, the above strongly suggests that, from an *ex ante* perspective, nothing precluded a real concrete possibility for Krka to invalidate the 947 patent in full trial.'
- It is therefore clear, on reading that material, that the decision at issue, examined as a whole, set out to demonstrate, on the basis of a body of consistent evidence, that Krka had not resigned itself to recognising the validity of the 947 patent following the EPO decision of 27 July 2006, despite the doubts to which that decision could have given rise as regards the chances of obtaining the revocation of that patent. In paragraph 970 of the judgment under appeal, the General Court stated, without giving adequate reasons, since it did not examine all the evidence relied on in that regard in the decision at issue, that 'there were, at the time the settlement and licence agreements were concluded, consistent indications capable of leading the parties to believe that the 947 patent was valid'. Thus, as the Advocate General observed in point 105 of her Opinion, the General Court not only failed to take into consideration the matters referred to in paragraphs 158 and 159 of the present judgment, but also failed to explain the reasons for that omission, whereas the existence of an infringement of the competition rules can only be correctly determined if the evidence upon which the decision at issue is based is considered, not in isolation, but as a whole, account being taken of the specific features of the market of the products in question (judgment of 14 July 1972, Imperial Chemical Industries v Commission, 48/69, EU:C:1972:70, paragraph 68).

- In so doing, the General Court distorted the meaning and scope of the decision at issue in so far as it relates to the effects of the EPO decision of 27 July 2006 on Krka's recognition of the validity of the 947 patent (see, by analogy, judgment of 11 September 2003, *Belgium v Commission*, C-197/99 P, EU:C:2003:444, paragraphs 66 and 67). In addition, it infringed its obligation under Article 36 of the Statute of the Court of Justice of the European Union, applicable to the General Court by virtue of the first paragraph of Article 53 of that Statute, to state the reasons on which its judgments are based, since it failed to set out, in paragraph 970 of the judgment under appeal, the grounds on which it relied in a manner sufficient to enable the persons concerned to be apprised of those grounds and the Court of Justice to have the evidence available to it to exercise its power of review on appeal (see, to that effect, judgment of 25 November 2020, *Commission v GEA Group*, C-823/18 P, EU:C:2020:955, paragraph 42 and the case-law cited).
- Therefore, in addition to the distortion of the decision of the High Court of 3 October 2006 established in paragraph 154 of the present judgment, paragraph 970 of the judgment under appeal is based on a distortion of the decision at issue and is vitiated by a failure to state reasons.
- In the light of the foregoing, the fourth and sixth parts of the first ground of appeal must be upheld.

(d) The fifth part

(1) Arguments of the parties

- By the fifth part of its first ground of appeal, the Commission criticises the General Court for having considered, in paragraph 1000 of the judgment under appeal, that the fact that Krka estimated the opportunity cost of not reaching a settlement with Servier at EUR 10 million over a period of three years was an indication of Krka's recognition of the validity of the 947 patent. First, that estimate was provided during the investigation, with the result that it could not be used retroactively as evidence of Krka's perception at the time of the conclusion of the Krka settlement and licence agreements. Second, Krka's expected profits were one of the reasons why the Krka licence agreement constituted an inducement to reach a settlement. Third, there was no evidence on the basis of which to assert, as the General Court did in paragraph 1000 of that judgment, that it was unlikely that Krka would decide to make an 'at risk' entry to its core markets, which were covered by the Krka licence agreement. On the contrary, recital 1675 of the decision at issue referred to serious evidence of such an intention on the part of Krka.
- According to Servier, that part is inadmissible, since the Commission does not allege any distortion.

(2) Findings of the Court

- It should be noted that, by the fifth part of its first ground of appeal, the Commission does not allege any distortion but is seeking to have the evidence reassessed, which does not fall within the jurisdiction of the Court of Justice in appeal proceedings.
- 167 The fifth part of the first ground of appeal must therefore be rejected as inadmissible.

(e) Conclusion on the first ground of appeal

In the light of all the foregoing considerations, the third and fifth parts of the first ground of appeal must be rejected and the first, second, fourth and sixth parts of that ground must be upheld.

5. The second ground of appeal

(a) The second part

(1) Arguments of the parties

- By the second part of its second ground of appeal, the Commission complains that the General Court held, in paragraphs 963 and 965 to 972 of the judgment under appeal, that, where there is a genuine dispute relating to a patent, the linking of a settlement agreement with a licence agreement does not constitute a strong indication of reverse payment. That formalistic approach is contrary to the case-law, in particular the judgment of 4 October 2011, *Football Association Premier League and Others* (C-403/08 and C-429/08, EU:C:2011:631, paragraph 136), which requires, in order to identify a restriction of competition by object, account to be taken of the content, objective and economic and legal context of the agreements at issue.
- Servier submits, as a preliminary point, that the Commission does not challenge the legal criteria set out in paragraphs 943 to 963 of the judgment under appeal, relating to the analysis of a patent dispute settlement agreement coupled with a licence for that patent, but the application of those principles and the findings of fact made by the General Court in paragraphs 964 to 1032 of that judgment.
- Servier submits that the second part of the second ground of appeal lacks clarity and is manifestly unfounded. Contrary to the Commission's assertion, the ground set out in paragraph 972 of the judgment under appeal is not based solely on the form of the agreements in question, but also on an analysis of their context, described in paragraphs 967, 968, 970 and 971 of that judgment. Furthermore, the General Court also rejected the Commission's argument that the object of the agreement was to share markets.

(2) Findings of the Court

- Since the second part of the second ground of appeal relates to the criteria in the light of which the General Court had to assess the existence of a restriction of competition by object, it is appropriate to examine it first.
- It should be noted that, by the second part of the second ground of appeal, the Commission challenges the legal criteria set out in paragraph 963 of the judgment under appeal and calls into question the assessment carried out on the basis of those criteria in paragraphs 965 to 972 of that judgment, maintaining, inter alia, that that assessment is based 'solely on the form of the agreements at issue' and 'has no basis in the case-law'. It is thus apparent from the very wording of that second part of the second ground of appeal that that part includes a criticism of the legal criteria set out in paragraphs 943 to 963 of that judgment. Servier's preliminary argument is therefore based on a misreading of the appeal.

- As regards the Commission's criticisms of paragraph 963 of the judgment under appeal, it should be borne in mind that, in that paragraph, the General Court held that, where there is a genuine dispute relating to a patent and a licence agreement directly connected with the settlement of that dispute, an agreement settling that dispute, containing competition-restricting clauses such as non-challenge and non-marketing clauses, linked to a licence agreement concerning that patent, can be characterised as a restriction of competition by object only if the Commission can demonstrate that that licence agreement does not constitute a transaction concluded at arm's length and thus masks a reverse payment.
- Although the infringement of Article 101 TFEU found by the decision at issue consisted in Servier and Krka dividing the markets into two areas, only one of which falls within the scope of that infringement, the General Court stated, in essence, in paragraphs 963 to 965 of the judgment under appeal, that it would confine itself to examining whether the Krka licence agreement could be justified by the Krka settlement agreement or whether, on the contrary, that licence agreement actually masked a reverse payment inducing Krka to agree to the non-marketing and non-challenge clauses provided for in that settlement agreement. That reasoning disregards (i) the fact that the Krka licence agreement concerns markets which do not fall within the scope of the infringement of Article 101 TFEU and (ii) the nature of that infringement, consisting not in a simple patent dispute settlement agreement in return for a reverse payment, but of a market-sharing agreement.
- Thus, paragraphs 963 to 965 of the judgment under appeal lay down criteria for assessing the existence of a restriction of competition by object which are incompatible with those referred to in paragraphs 99 to 105 of the present judgment and which are based on a misinterpretation of Article 101(1) TFEU. It must be stated that the differences between those legal criteria applied by the General Court and those referred to in paragraphs 99 to 105 of the present judgment are not merely semantic but lead to substantially different results.
- In addition, it must be borne in mind that, in paragraph 972 of the judgment under appeal, the General Court held that 'having regard to the scope of the terms of the [Krka settlement and licence agreements] and the context in which those agreements were signed, it must be held that the linking of those two agreements was justified and therefore does not constitute a strong indication of the existence of a reverse payment from Servier to Krka giving rise to the licence agreement', while referring the reader to paragraph 948 of that judgment.
- It is true that the fact that undertakings conclude a patent dispute settlement agreement linked to a licence agreement concerning that patent does not, in itself, constitute conduct restricting competition. Nevertheless, such agreements may, depending on both their content and their economic context, serve as an instrument for influencing the commercial conduct of the undertakings in question so as to restrict or distort competition on the market on which they carry on business (see, by analogy, judgment of 17 November 1987, *British American Tobacco and Reynolds Industries* v *Commission*, 142/84 and 156/84, EU:C:1987:490, paragraph 37).
- In order to be caught by the prohibition laid down in Article 101(1) TFEU, a collusive practice must fulfil certain conditions depending not on the legal nature of that practice or on the legal instruments intended to implement it, but on its relationship with competition. Since the application of that provision is based on an assessment of the economic impacts of the practice in question, that provision cannot be interpreted as establishing any kind of prejudgment with regard to a category of agreements determined by their legal nature, since every agreement must be assessed in the light of its specific content and economic context and, in particular, in the light

of the situation on the market concerned (see, to that effect, judgments of 30 June 1966, *LTM*, 56/65, EU:C:1966:38, p. 248, and of 17 November 1987, *British American Tobacco and Reynolds Industries* v *Commission*, 142/84 and 156/84, EU:C:1987:490, paragraph 40). As the Advocate General stated, in particular, in point 127 of her Opinion, the effectiveness of EU competition law would be seriously jeopardised if the parties to anticompetitive agreements could evade the application of Article 101 TFEU simply by giving such agreements particular forms.

- In addition to the fact that, in the present case, the Krka settlement and licence agreements relate to separate markets and that the markets covered by the Krka licence agreement do not fall within the scope of the infringement of Article 101 TFEU, it must be pointed out that, while the conclusion by the holder of a patent of a settlement agreement with a manufacturer of generic medicines accused of patent infringement does constitute an expression of the intellectual property right of that holder, which permits that holder, inter alia, to oppose any infringement, the fact remains that that patent does not permit its holder to enter into contracts that are contrary to Article 101 TFEU (see, to that effect, judgment of 30 January 2020, *Generics (UK) and Others*, C-307/18, EU:C:2020:52, paragraph 97).
- Moreover, classification as a restriction of competition by object does not depend either on the form of the contracts or other legal instruments intended to implement such a collusive practice or on the subjective perception that the parties may have of the outcome of the dispute between them as to the validity of a patent.
- Furthermore, as recalled in paragraph 108 of the present judgment, the fact that undertakings the conduct of which could be characterised as a restriction of competition by object acted without having an intention to prevent, restrict or distort competition and the fact that they pursued certain legitimate objectives are not decisive for the purposes of the application of Article 101(1) TFEU (see, to that effect, judgment of 21 December 2023, *European Superleague Company*, C-333/21, EU:C:2023:1011, paragraph 167 and the case-law cited). Only the assessment of the degree of economic harm of that practice to the proper functioning of competition in the market concerned is relevant. That assessment must be based on objective considerations, where necessary as a result of a detailed analysis of that practice, its objectives and the economic and legal context of which it forms part (see, to that effect, judgments of 30 January 2020, *Generics (UK) and Others*, C-307/18, EU:C:2020:52, paragraphs 84 and 85, and of 25 March 2021, *Lundbeck v Commission*, C-591/16 P, EU:C:2021:243, paragraph 131).
- That is why, in order to determine whether a collusive practice may be classified as a restriction of competition by object, it is necessary to examine its content, its origin and its legal and economic context, in particular the specific characteristics of the market in which its effects will actually occur. The fact that the terms of an agreement intended to implement that practice do not reveal an anticompetitive object is not, in itself, decisive (see, to that effect, judgments of 8 November 1983, *IAZ International Belgium and Others* v *Commission*, 96/82 to 102/82, 104/82, 105/82, 108/82 and 110/82, EU:C:1983:310, paragraphs 23 to 25, and of 28 March 1984, *Compagnie royale asturienne des mines and Rheinzink* v *Commission*, 29/83 and 30/83, EU:C:1984:130, paragraph 26).
- Instead of carrying out such an assessment of the collusive practice implemented by means of the Krka settlement and licence agreements in the light of its specific content and its economic impacts, the General Court, in paragraphs 943 to 963 of the judgment under appeal, developed criteria to identify, in a general and abstract manner, the conditions under which a combination of a patent dispute settlement agreement and a licence agreement relating to that patent may, in

view of the legal characteristics of those agreements alone, be classified as a restriction of competition by object within the meaning of Article 101(1) TFEU. Applying those criteria to the Krka settlement and licence agreements, the General Court focused its analysis on the form and legal characteristics of those agreements, rather than examining their actual relationship with competition. It thus disregarded the principles governing the application and interpretation of Article 101(1) TFEU referred to in paragraphs 179 and 183 of the present judgment and vitiated paragraphs 943 to 972 of the judgment under appeal with illegality.

185 Accordingly, the second part of the second ground of appeal must be upheld.

(b) The first, third and fourth parts

(1) Arguments of the parties

- 86 By the first part of its second ground of appeal, the Commission complains that the General Court's reasoning is contradictory. In paragraph 1029 of the judgment under appeal, the General Court recognised that the Krka licence agreement was a condition for that undertaking to agree to the non-marketing and non-challenge clauses, which, as the General Court pointed out in paragraph 273 of that judgment, are 'inherently restrictive'. However, it refused to infer from this that that licence agreement induced Krka to settle the disputes relating to the 947 patent, by relying on two erroneous grounds, namely, (i) the parties' perception of the validity of that patent and (ii) the fact that that licence agreement was concluded at arm's length. The General Court, in relying on the fiction of a settlement based on the merits of the 947 patent and of a licence for that patent concluded at arm's length, therefore did not, for the purposes of the legal characterisation of those agreements as a restriction of competition by object, attach sufficient importance to the objective pursued by those agreements. The General Court also overlooked statements by which Krka acknowledged that it had 'sacrificed' its entry into Servier's core markets in order to be able to remain on its seven core markets.
- By the third part, the Commission criticises the grounds set out in paragraphs 806, 963, 975 to 984 and 1029 of the judgment under appeal, by which the General Court considered that the Krka licence agreement had been concluded at arm's length. That consideration is, in its view, irrelevant, since the decisive factor is that the Krka settlement and licence agreements were based not on each party's assessment of the validity of the 947 patent, but on their common objective of sharing the markets, at the expense of consumers, by means of the Krka agreements, taken as a whole.
- By the fourth part, the Commission complains that, in paragraphs 806 and 977 to 982 of the judgment under appeal, the General Court limited its analysis of the inducive nature of the Krka licence agreement to the question whether the royalty rate provided for in that agreement was abnormally low. The General Court should have analysed that agreement, together with the Krka settlement agreement, and examined the effect of those agreements on the parties' incentives to compete with each other and the profit estimated at over EUR 25 million which Servier forewent by concluding that licence agreement.
- Servier contends that the first part of the second ground of appeal is unfounded, since the contradictory nature of the grounds criticised by the Commission has not been established. It adds that the General Court analysed the Krka settlement and licence agreements as a whole and

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reached the factual conclusion that it was the strength of the 947 patent that persuaded Krka to settle. The Commission's line of argument is based on the incorrect premiss that Krka could have entered Servier's core markets whereas the validity of that patent prevented it from doing so.

- 190 The third part seeks to call into question findings of fact and is therefore inadmissible.
- The fourth part is manifestly unfounded, since the General Court took into account the patent context, the link between the Krka settlement agreement and the Krka licence agreement, and the value attributed by Krka to that licence. The profit which Servier forewent by granting a licence to Krka is not one of the relevant legal criteria. That foregone profit is inherent in any settlement and the calculation of the profit allegedly sacrificed by Servier is incorrect.
- In EFPIA's view, the ancillary restraints doctrine should have led the General Court to find that Article 101(1) TFEU did not apply, having regard to the legitimate objective pursued by the Krka settlement agreement and the objective necessity of its clauses. In any event, the General Court was right to conclude that the linking of a licence and a settlement agreement does not constitute a restriction of competition by object.

(2) Findings of the Court

- It should be noted at the outset that the third part of the second ground of appeal is admissible because, by its line of argument, the Commission calls into question not factual findings but the criterion applied by the General Court for the purposes of assessing the inducement for Krka to settle the disputes relating to the 947 patent by the settlement agreement.
- By the first, third and fourth parts of the second ground of appeal, which it is appropriate to examine together, the Commission essentially criticises the General Court for having held that the Krka licence agreement had not induced that undertaking to conclude the Krka settlement agreement. The Commission claims that the General Court relied on a limited and reductive analysis of the content, objectives and economic context of the infringement resulting from those agreements.
- As regards the first part of the second ground of appeal, it should be noted that, as the Commission claims, paragraph 1029 of the judgment under appeal is contradictory. Indeed, it is stated in that paragraph that the conclusion of the Krka licence agreement was the 'condition' or, in other words, the inducement offered to Krka for it to agree to the non-marketing and non-challenge clauses contained in the Krka settlement agreement. It follows that, irrespective of whether the level of the royalty provided for by that licence agreement was appropriate in the light of the market conditions, it was the access to its core markets without risk of infringement which motivated Krka to refrain from selling its perindopril on Servier's core markets. Therefore, the General Court could not, without contradicting itself, assert, in that paragraph, that the Commission had not established that the royalty rate 'was not chosen on the basis of commercial considerations, but rather in order to induce Krka to accept [those] clauses'.
- In the light of the characteristics of the infringement found by the Commission which are recalled in paragraphs 57 and 58 of the present judgment, the General Court needed, in order to rule on the part of Servier's arguments put forward in the context of the ninth plea at first instance relating to the existence of a restriction of competition by object, to apply the criteria recalled in paragraphs 94, 96 to 99, 104, 105 and 107 of the present judgment to the unlawful practice

resulting from the Krka settlement and licence agreements. It was incumbent on the General Court to assess the degree of economic harm of that practice, by carrying out a detailed analysis of its characteristics, its objectives and the economic and legal context of which it forms part.

- As has been noted in paragraph 174 of the present judgment, the General Court found, in essence, in paragraph 963 of the judgment under appeal, that, where there is a genuine dispute, the linking of a licence agreement to an agreement settling that dispute does not constitute a strong indication of the existence of a reverse payment, and that it is for the Commission to 'demonstrate ... that the licence agreement does not constitute a transaction concluded at arm's length', with the effect that that institution could not find the existence of a restriction of competition by object in the present case.
- It follows that, by focusing its analysis on the Krka licence agreement, whereas it should have examined the infringement found by the Commission, taken as a whole, as resulting from the combination of that agreement and the Krka settlement agreement, the General Court erred in law in the interpretation and application of Article 101 TFEU. That error led the General Court to restrict the scope of its analysis of the characterisation of a restriction of competition by object to the question whether the Commission had succeeded in establishing that the royalty rate provided for in the Krka licence agreement was abnormally low.
- As the Advocate General noted in point 168 of her Opinion, by merely finding, for the reasons set out in paragraphs 973 to 984 of the judgment under appeal, that the Commission had not established that Servier had granted Krka a licence at an abnormally low price, the General Court ignored the essential elements of the infringement referred to in paragraphs 57 and 58 of the present judgment and failed to examine, in the light of the parties' reciprocal commitments and incentives, whether the Krka licence agreement might have induced that undertaking to refrain from competing with Servier.
- It follows that, by relying on the fact that the royalty rate provided for by the Krka licence agreement was not abnormally low without analysing in the light of the economic and legal context which gave rise to a sharing of markets resulting from that agreement in conjunction with the Krka settlement agreement whether the transfer of value resulting from the fact that the Krka licence agreement allowed that undertaking to market its products on its core markets without risk of infringement was sufficiently large to actually induce Krka not to enter Servier's core markets, the General Court erred in law in the interpretation and application of Article 101(1) TFEU and vitiated the lawfulness of the grounds set out in paragraphs 963, 973 to 984 and 1029 of the judgment under appeal.
- The first, third and fourth parts of the second ground of appeal must therefore be upheld.

(c) The fifth to eighth parts

(1) Arguments of the parties

By the fifth part of its second ground of appeal, the Commission submits that the grounds set out in paragraphs 975 to 984 of the judgment under appeal are based on the distortion of several items of evidence. First, contrary to what is stated in paragraph 978 of that judgment, the Commission did not consider that the royalty rate provided for in the Krka licence agreement was much lower than Servier's operating profit, but that the loss suffered by Servier constituted a net transfer of

value to Krka. Second, in paragraph 979 of that judgment, the General Court distorted the fact that that royalty represented a small proportion of Krka's profits from the markets covered by that licence agreement. Third, contrary to what is stated in paragraph 981 of that judgment, the fact that the licence granted to Krka is not exclusive does not prevent it from constituting a sufficient inducement, since it offered that undertaking, on its core markets, the prospect of constituting a de facto duopoly with Servier.

- By the sixth part, the Commission criticises the General Court for having held, in paragraphs 994 to 998 of the judgment under appeal, that it would be paradoxical to consider that the broader the terms of a patent licence, the greater the incentive to conclude a settlement agreement containing competition-restricting clauses, and the easier it would be to characterise those agreements as a restriction of competition by object. That assertion is based on a misreading of the decision at issue, from which it is apparent that the Krka licence agreement served to induce that undertaking to refrain from entering Servier's core markets, which were not covered by the Krka licence agreement.
- By the seventh part, the Commission criticises paragraph 997 of the judgment under appeal in so far as it states that the decision at issue obliges the patent holder to grant a licence over the entire territory covered by a settlement agreement. The decision at issue does not lay down such an obligation.
- 205 By the eighth part, the Commission criticises the General Court for having held, in paragraph 998 of the judgment under appeal, that, in order for an agreement to be regarded as an 'inducement' for a party, that agreement must compensate that party for the loss resulting from the clauses prohibiting it from entering certain markets. That assessment, first, is contrary to the case-law, which merely requires that a transfer of value be sufficiently high to induce a manufacturer of generic medicines to refrain from entering the market and, second, distorts the evidence referred to in footnote 2348 to the decision at issue, on the basis of which the Commission considered that the profits that Krka expected to make on its core markets as a result of the Krka licence agreement were sufficiently high to persuade it to refrain from entering Servier's core markets.
- 206 According to Servier, no distortion alleged in the fifth part is well founded.
- Servier submits that the sixth part is ineffective, since it relates to a ground included in the judgment under appeal for the sake of completeness. It is in any event unfounded, since the General Court applied the case-law according to which only agreements which are sufficiently harmful to competition must be characterised as a restriction of competition by object.
- The seventh part is also directed against a ground included in the judgment under appeal for the sake of completeness and is therefore ineffective. Furthermore, in so far as it seeks to prescribe certain forms of licence, the Commission's line of argument is incompatible with the discretion enjoyed both by the proprietor of an intellectual property right to grant a licence to a third party and by the parties to a dispute to settle it in good faith.
- According to Servier, the eighth part is based on a distortion of paragraph 998 of the judgment under appeal. The General Court did not rule out the inducive nature of an asymmetrical licence on the ground that it does not offset the lost profits, but rightly held that an undertaking which does not recognise the validity of a patent is rationally led to demand, in return for its decision not to enter a market, compensation covering at least the certain loss of expected profits. Contrary to what the Commission claims, the General Court took the view that, having been

concluded at arm's length, the Krka licence agreement could not be regarded as a reverse payment, the decisive factor which led Krka to accept the clauses of the settlement agreement being the validity of the 947 patent.

(2) Findings of the Court

- By the fifth part of its second ground of appeal, the Commission submits that the General Court distorted several items of evidence in its assessments made, in paragraphs 975 to 984 of the judgment under appeal, on the level at which the royalty rate of the Krka licence agreement was set, in order to determine whether that agreement could have induced that undertaking to refrain from entering Servier's core markets. The Court of Justice has already held, in paragraphs 198 to 200 of the present judgment, that that reasoning of the General Court is based on the application of a legally incorrect test, relating to the question whether the Krka licence agreement had been concluded at arm's length. Since paragraphs 975 to 984 of the judgment under appeal are vitiated by illegality as a result of that error of law, it is not necessary to rule on that fifth part.
- By the sixth to eighth parts of its second ground of appeal, the Commission criticises the assessments made in paragraphs 992 to 998 of the judgment under appeal, by which the General Court rejected the Commission's reasoning that the Krka licence agreement constituted an inducement to postpone its entry into Servier's core markets, on the ground, in essence, that the scope of the non-marketing and non-challenge clauses set out in the Krka settlement agreement was broader than that of the Krka licence agreement. Those findings of the General Court are based on the premiss that a licence agreement concluded at arm's length automatically satisfies the test laid down by the General Court in paragraph 963 of that judgment and cannot therefore constitute an inducement to conclude a dispute settlement agreement relating to that patent containing competition-restricting clauses. Since that test is legally incorrect, the assessments made in paragraphs 994 to 998 of that judgment are based on a premiss which is itself incorrect and are therefore vitiated by illegality. It follows that the plea of inadmissibility raised by Servier must be rejected and the sixth to eighth parts of that ground of appeal upheld.
- 212 In the light of the foregoing, the second ground of appeal must be upheld.

6. The third ground of appeal

(a) The first part

(1) Arguments of the parties

By the first part of its third ground of appeal, the Commission criticises paragraph 1006 of the judgment under appeal, in which the General Court held that a market-sharing agreement presupposes a 'hermetic' division of the markets between the parties. That assessment is contrary to Article 101(1)(c) TFEU, which, as is apparent from the judgment of 27 July 2005, *Brasserie nationale and Others* v *Commission* (T-49/02 to T-51/02, EU:T:2005:298, paragraph 156), does not impose any condition of that nature for classification as a market-sharing agreement or, as follows, in particular, from the judgment of 20 January 2016, *Toshiba Corporation* v *Commission* (C-373/14 P, EU:C:2016:26, paragraph 28), for classification of that type of agreement as a restriction of competition by object.

According to Servier, that line of argument is based on a misreading of the judgment under appeal. The General Court did not require a 'hermetic' division of the markets, but observed that no market had been reserved to Krka. The judgments of the Court of Justice and of the General Court relied on by the Commission are irrelevant, since the Krka settlement and licence agreements were aimed not at allocating customers or preventing the market entry of foreign competitors, but were based on the recognition of the 947 patent.

(2) Findings of the Court

- After concluding, in essence, in paragraph 985 of the judgment under appeal, that the Commission could not characterise the Krka settlement and licence agreements as a restriction of competition by object, the General Court held that that conclusion could not be called into question by any of the other factors relied on in the decision at issue. Thus, for the reasons set out in paragraphs 1003 to 1014 of that judgment, the General Court held that the Commission was not justified in finding that those agreements constituted market sharing between Servier and Krka. In particular, in paragraph 1005 of that judgment, it found that Servier was not excluded from Krka's core markets. In paragraph 1006 of that judgment, the General Court inferred from that finding that 'there was no part of the market which, under the agreements, was reserved for Krka' and that, therefore, it could not 'be concluded that there was market sharing in the sense of a hermetic division between the parties to the agreement[s] of that part of the internal market'.
- However, as the Advocate General observed in points 182 to 194 of her Opinion, the fact that an agreement which shares markets is not 'hermetic' by no means precludes its being characterised as a restriction of competition by object. Article 101(1)(c) TFEU expressly prohibits agreements which share markets. It follows from the case-law referred to in paragraph 97 of the present judgment that horizontal cooperation agreements between undertakings concerning the sharing of markets are, in view of their particularly serious nature, characterised as restrictive of competition by object.
- In that regard, Article 101(1) (c) TFEU does not contain any specific condition providing that the prohibition which it lays down is to be limited solely to agreements which establish a 'hermetic' division between those markets, by means, for example, of provisions reserving access to some of those markets to one of those undertakings, to the exclusion of the other, or prohibiting exports from one market to another. Thus, in the absence of any specific provision in that regard, there is no need to distinguish between market-sharing agreements on the basis of a condition which Article 101(1) TFEU does not lay down and which no consideration relating to the purpose or general scheme of that provision makes it possible to envisage.
- Moreover, the General Court's interpretation would amount to allowing agreements consisting in sharing markets to avoid being characterised as restrictions of competition by object, in particular by reserving certain markets to one undertaking in exchange for the grant by that undertaking of a patent licence to another undertaking operating at the same level of the production or distribution chain, thus allowing the second undertaking to enter other markets without risk of infringement, which would reduce the full effectiveness of the prohibition laid down in Article 101(1)(c) TFEU and would seriously undermine the implementation of EU competition law, given the clearly anticompetitive nature of such agreements.

- Accordingly, in holding, in paragraph 1006 of the judgment under appeal, that, since the Krka settlement and licence agreements had not reserved a part of the market for Krka, 'it therefore cannot be concluded that there was market sharing in the sense of a hermetic division between the parties to [those agreements] of [a] part of the internal market', the General Court relied on a misinterpretation of Article 101(1) TFEU and vitiated paragraph 1006 of that judgment with illegality.
- 220 Consequently, the first part of the third ground of appeal must be upheld.

(b) The second part

(1) Arguments of the parties

- By the second part of its third ground of appeal, the Commission criticises paragraph 1012 of the judgment under appeal, according to which a contractual framework based on the parties' recognition of the validity of the patent concerned cannot be characterised as a market exclusion agreement. The General Court distorted the clear sense of the evidence of the parties' perception of the validity of the 947 patent. Even if the Krka settlement agreement was based on that recognition, that agreement could not escape the prohibition laid down in Article 101(1) TFEU, since the object of that agreement was to divide the market.
- According to Servier, the complaint of distortion must be rejected because the Commission failed to identify any error in the analysis of the evidence. The General Court, without disregarding the case-law relied on by the Commission, observed that the Krka settlement and licence agreements were based on the parties' recognition of the validity of the 947 patent.

(2) Findings of the Court

- In paragraph 1012 of the judgment under appeal, the General Court held that, 'since it has not been shown that there was an inducement ..., the non-marketing and non-challenge clauses must be regarded as arising from a legitimate patent dispute settlement agreement which is linked to a licence agreement' and that 'such a contractual framework, based on the recognition of the validity of the patent, cannot, therefore, be characterised as a market exclusion agreement'.
- It must be stated, in accordance with what has been held in paragraphs 102 and 132 of the present judgment, that, although the recognition of the validity of a patent which is the subject of a dispute between two parties may constitute a relevant factor in assessing whether, on the same market, the restrictions of competition brought about by a settlement agreement in that dispute may be mitigated or even offset by the conclusion, between those parties, of an agreement licensing that patent, that recognition is not, in itself, a decisive, or even relevant, factor in determining whether a collusive practice such as that attributed, by the decision at issue, to Servier and Krka, consisting in market sharing by means of a patent dispute settlement agreement which concerns, in particular, markets covered by the geographic scope of the infringement, and of a licence agreement for that patent relating to markets which are not covered by it, may be characterised as a restriction of competition by object.
- It follows from the considerations set out in paragraphs 102, 132, 178 to 184 and 224 of the present judgment that, by relying (i) on Krka's recognition of the 947 patent even though that factor is not, in itself, decisive and (ii) on the content and form of the Krka settlement and licence

agreements rather than on the specific analysis of their harmfulness to competition in the light of the context of which they form part, in order to invalidate the characterisation of those agreements as a restriction of competition by object, the General Court erred in law.

Furthermore, it is true that a patent dispute settlement agreement and a licence agreement for that patent may be concluded, with a legitimate aim and entirely lawfully, on the basis of the parties' recognition of the validity of that patent, in the absence of any other circumstance constituting an infringement of Article 101 TFEU. However, the fact that such agreements pursue a legitimate objective is not such as to exclude them from the application of Article 101 TFEU if it is established that they also have the aim of sharing markets or restricting competition in other ways (see, to that effect, judgments of 30 January 1985, *BAT Cigaretten-Fabriken* v *Commission*, 35/83, EU:C:1985:32, paragraph 33, and of 11 September 2014, *CB* v *Commission*, C-67/13 P, EU:C:2014:2204, paragraph 70).

227 Therefore, the second part of the third ground of appeal must be upheld.

(c) The third part

(1) Arguments of the parties

By the third part of its third ground of appeal, the Commission submits that, in paragraphs 987 and 988 of the judgment under appeal, the General Court distorted the terms of the Krka licence agreement. The General Court stated that the possible establishment of a de facto duopoly in the seven Member States covered by that agreement – Krka's core markets – was not the result of the terms of that agreement, but of subsequent choices made individually by Servier and Krka. That assertion is contradicted by Article 2(2) of that agreement, according to which Servier undertook not to authorise a third operator to use the 947 patent on those seven national markets.

Servier disputes that the Krka licence agreement established a de facto duopoly. Under that agreement, Servier could grant an additional licence to a third-party operator. Moreover, since the Commission did not dispute the existence of a certain degree of competition between Servier and Krka, found in paragraph 991 of the judgment under appeal, that argument is ineffective.

(2) Findings of the Court

In paragraph 987 of the judgment under appeal, the General Court held that, even if the Krka licence agreement allowed the implementation of an 'advantageous duopoly' between Servier and Krka, 'that duopoly did not result from the agreement itself, but from the choices made by Servier and Krka after that agreement, namely, Servier's choice not to grant a licence to another generic company or to sell its own generic version of perindopril at a low price ... and Krka's choice not to adopt an aggressive pricing policy'.

In that regard, it should be noted that Article 2 of the Krka licence agreement, which is referred to in paragraph 46 of the judgment under appeal and which is set out in Annex A.176 to Servier's application at first instance, is worded as follows:

'SERVIER hereby grants to KRKA the exclusive, irrevocable [licence] on the 947 patent and KRKA hereby accepts from SERVIER such licence to use, manufacture, sell, offer for sale, promote and

import KRKA Products which contain crystalline form alpha of perindopril tertbutylamine salt in the Territory during the term of this Agreement.

Notwithstanding the above, SERVIER shall be entitled directly or through one of its Affiliates or through solely one third party per country, to use the 947 patent to do any of the above stated operations in the Territory.

KRKA is not allowed to grant [sublicenses], other than to KRKA's affiliates, without a prior written consent of SERVIER.'

It is thus apparent from those clear and precise terms that Servier granted Krka, on an exclusive and irrevocable basis, the licence to the 947 patent, subject to Servier's right to use that patent 'directly or through one of its Affiliates or through solely one third party per country'. Although the existence of that reservation may help to explain the cautious language used by the Commission, which merely referred, inter alia in recitals 1728, 1734 and 1742 of the decision at issue, to a 'de facto' duopoly on Krka's core markets, the fact remains that the wording of that reservation, read in the light of the exclusive and irrevocable nature of the licence granted to Krka, cannot be interpreted as allowing Servier to grant a licence to that patent to another manufacturer of generic medicines which, while acting independently of Servier, could compete with Krka. Thus, by stating, in paragraph 987 of the judgment under appeal, that a duopoly between Servier and Krka resulted not from the provisions of the Krka licence agreement but from the subsequent choice made by Servier 'not to grant a licence to another generic company', the General Court interpreted that agreement in a manner incompatible with its wording. By distorting the sense of that agreement, the General Court vitiated paragraph 987 of that judgment with illegality.

233 In those circumstances, the third part of the third ground of appeal must be upheld.

(d) The fourth part

(1) Arguments of the parties

By the fourth part of its third ground of appeal, the Commission submits that the General Court erred in law in finding, in paragraphs 989 and 990 of the judgment under appeal, that the decision at issue could not rely on the establishment of a duopoly between Servier and Krka in order to find the existence of a restriction of competition by object without analysing the potential effects of the Krka settlement and licence agreements. In the Commission's view, the object of those agreements was to change appreciably the structure of Servier's core markets by granting Krka a licence in return for the latter's undertaking not to enter those markets. Consequently, the examination of their effects was not necessary and was undertaken in the decision at issue only for the sake of completeness.

Servier contends that that line of argument is based on a misreading of the judgment under appeal.

(2) Findings of the Court

- It should be borne in mind that, as follows from the case-law cited in paragraph 96 of the present judgment, the concept of restriction of competition by object can be applied only to certain agreements between undertakings which reveal a sufficient degree of harm to competition that it may be found that there is no need to examine their effects.
- In order to determine whether an agreement between undertakings reveals such a degree of harm, regard must be had to the content of its provisions, its objectives and the economic and legal context of which it forms a part. When determining that context, it is also necessary to take into consideration the nature of the goods or services affected, as well as the real conditions of the functioning and structure of the market or markets in question (judgment of 11 September 2014, *CB* v *Commission*, C-67/13 P, EU:C:2014:2204, paragraph 53).
- However, as has been recalled in paragraphs 93 and 94 of the present judgment, and as the Commission rightly points out, as regards practices classified as restrictions of competition by object, there is no need to investigate or, a fortiori, to demonstrate their effects on competition. Experience shows that certain behaviour is in itself likely to have negative consequences on markets (see, to that effect, judgments of 11 September 2014, *CB* v *Commission*, C-67/13 P, EU:C:2014:2204, paragraph 51, and of 21 December 2023, *European Superleague Company*, C-333/21, EU:C:2023:1011, paragraph 162). In addition, it is apparent from the case-law referred to in paragraph 97 of the present judgment that agreements which aim to share markets have, in themselves, an object restrictive of competition and fall within a category of agreements expressly prohibited by Article 101(1) TFEU, and that that prohibition cannot be called into question by an analysis of the economic context of the anticompetitive conduct concerned.
- Therefore, as the General Court itself noted in paragraphs 221 and 989 of the judgment under appeal, it is apparent from the case-law of the Court of Justice referred to in paragraphs 236 to 238 of the present judgment that establishing the existence of a restriction of competition by object cannot, under the guise, inter alia, of the examination of the economic and legal context of the agreement at issue, lead to the assessment of the effects of that agreement, since otherwise the distinction between a restriction of competition by object and by effect laid down in Article 101(1) TFEU would lose its effectiveness. The General Court also held in paragraph 989 of that judgment, which refers to the case-law cited in paragraph 304 of that judgment, that the Commission and the Courts of the European Union cannot, when examining whether an agreement restricts competition by object and, in particular, in assessing the economic and legal context of that agreement, completely ignore its potential effects. In paragraph 990 of that judgment, it therefore stated that 'the alleged potential effects in question, that is to say, the duopoly alleged by the Commission, are based on hypothetical circumstances which were therefore not objectively foreseeable at the time of the conclusion of the agreement'.
- It must be stated that paragraph 989 of the judgment under appeal is vitiated by an internal contradiction, since it indicates both that the effects of a restriction of competition by object do not have to be assessed in order to establish the existence of that restriction and that such effects cannot be ignored when examining the restrictive object of an agreement. Those two statements are incompatible.
- Moreover, paragraphs 304 and 989 of the judgment under appeal contain an error of law in so far as the General Court observed that the Commission and the Courts of the European Union cannot, when examining whether an agreement restricts competition by object, completely

ignore its potential effects. That observation, which is not based on any judgment of the Court of Justice, directly contradicts the case-law referred to in paragraphs 236 to 238 of the present judgment, according to which, as regards practices characterised as restrictions of competition by object, there is no need to investigate nor a fortiori to demonstrate their effects on competition.

- That incorrect assessment confuses, moreover, the exercise of ascertaining whether conduct is capable, by its very nature, of systematically harming competition by reason of its particular characteristics and whether it therefore reveals a sufficient degree of harm to competition in order to be characterised as a restriction of competition by object, with that of analysing the actual or potential effects of specific conduct in a particular case, which is relevant solely for the assessment of the existence of a possible restriction of competition by effect.
- In order to determine whether conduct presents such a degree of harm, it is not necessary to examine, nor, a fortiori, to prove, the effects of that conduct on competition, be they actual or potential, or negative or positive (see, to that effect, judgment of 21 December 2023, *European Superleague Company*, C-333/21, EU:C:2023:1011, paragraphs 159, 162 and 166 and the case-law cited).
- In the light of the case-law referred to in paragraphs 236 to 238 and 243 of the present judgment, which precludes the effects of an agreement or a practice from being taken into account, the General Court erred in law, in paragraph 990 of the judgment under appeal, by introducing, in its reasoning relating to the restriction of competition by object found in the decision at issue and based on the fact that the Krka settlement and licence agreements gave rise to a sharing of geographic markets in the European Union, considerations relating to the allegedly hypothetical nature of the potential effects of those agreements, considerations which it was not for the Commission to take into account in that regard.
- The fourth part of the third ground of appeal must therefore be upheld.

(e) The fifth part

(1) Arguments of the parties

- By the fifth part of its third ground of appeal, the Commission criticises the General Court for having, in paragraph 1023 of the judgment under appeal, rejected Lupin's statement referred to in recital 1730 of the decision at issue, according to which it 'would seem the rationale for this settlement from Servier's view is that it protects the core markets where high level substitution and/or [international non-proprietary name] prescribing is prevalent', on the ground that that statement does not prove Servier's intention to adopt market sharing or market exclusion agreements with Krka. According to the Commission, that statement was not intended to prove Servier's intention, but to corroborate a subsequent statement by Krka, which demonstrated that the Krka settlement and licence agreements had made a form of market sharing possible, thereby helping to establish the anticompetitive object of those agreements.
- 247 Servier submits that this fifth part is inadmissible because it seeks to call into question the General Court's assessment of the evidence.

(2) Findings of the Court

- It should be recalled that it is apparent from Article 256(1) TFEU and the first paragraph of Article 58 of the Statute of the Court of Justice of the European Union that an appeal is limited to points of law and that the General Court therefore has sole jurisdiction to find and appraise the relevant facts and to assess the evidence. The assessment of the facts and evidence does not, save where the facts and evidence are distorted, constitute a point of law which is subject, as such, to review by the Court of Justice on appeal (judgment of 16 February 2023, *Commission* v *Italy*, C-623/20 P, EU:C:2023:97, paragraph 116 and the case-law cited).
- In the present case, it must be held that the Commission does not allege distortion, with the result that the fifth part of the third ground of appeal is inadmissible.

(f) Sixth part

(1) Arguments of the parties

- By the sixth part of its third ground of appeal, the Commission submits that, in paragraphs 248, 958 and 965 of the judgment under appeal, the General Court misinterpreted Regulation No 772/2004 and the Guidelines on the application of [Article 101 TFEU] to technology transfer agreements, referred to in paragraph 53 of the present judgment.
- Servier disputes any error of law committed by the General Court in the application of the concept of restriction of competition by object.

(2) Findings of the Court

- It should be noted that paragraph 248 of the judgment under appeal, which confines itself, in essence, to setting out and commenting on certain paragraphs of the guidelines referred to in paragraph 250 of the present judgment, forms part of the preliminary considerations which led the General Court to state, in paragraph 252 of the judgment under appeal, that 'a balance must be struck between, on the one hand, the need to allow undertakings to make settlements, the increased use of which is beneficial for society and, on the other hand, the need to prevent the risk of misuse of settlement agreements, contrary to competition law, leading to entirely invalid patents being maintained and, especially in the medicinal products sector, an unjustified financial burden for public budgets'. Since such preliminary considerations, by reason of their general nature, have no bearing on the operative part of that judgment, the complaint directed against paragraph 248 of that judgment is therefore ineffective. In addition, it follows from the considerations set out in paragraphs 179 to 184 of the present judgment, in response to the second part of the second ground of appeal, that paragraphs 943 to 972 of the judgment under appeal are vitiated by illegality. Accordingly, it is not necessary to respond to the complaints calling into question paragraphs 958 and 965 of the judgment under appeal.
- 253 Since the first to fourth parts and the sixth part of the third ground of appeal are well founded, the third ground of appeal must be upheld.

7. The fourth ground of appeal

By its fourth ground of appeal, the Commission challenges the findings made by the General Court in relation to the intention of the parties to the Krka agreements. That ground has four parts.

(a) The first part

(1) Arguments of the parties

By the first part of its fourth ground of appeal, the Commission criticises the General Court for having held, in paragraph 1015 of the judgment under appeal, that the decision at issue had failed to demonstrate that Servier or Krka had intended to conclude anticompetitive agreements. Such proof is not required, since the infringement attributed to those undertakings is a restriction of competition by object. Even if those undertakings did not have the intention of restricting competition, that circumstance has no bearing on the fact that the Krka agreements revealed, in Servier's core markets, a sufficient degree of harm to competition to justify their characterisation as a restriction of competition by object.

Servier contends that, since proof of the parties' intention is not required for characterisation of a restriction as a restriction of competition by object, the fourth ground of appeal is, as a whole, directed against a ground included in the judgment under appeal purely for the sake of completeness and, on that basis, ineffective.

(2) Findings of the Court

After holding, in essence, in paragraph 985 of the judgment under appeal, that the Commission could not characterise the Krka settlement and licence agreements as a restriction of competition by object, the General Court held that that assessment could not be called into question by the other factors relied on in the decision at issue. Among those factors, paragraph 1015 of that judgment states that 'the Commission failed to demonstrate that Servier or Krka had intended to conclude a market sharing or market exclusion agreement, that Servier had intended to induce Krka not to compete or that Krka had intended to agree, in exchange for an inducive benefit, not to exert competitive pressure on Servier'. For the reasons set out in paragraphs 1016 to 1024 of that judgment, the General Court then rejected certain evidence relating to the intentions of the parties to the Krka agreements and referred to by the decision at issue, and found, in paragraph 1025 of that judgment, that, in any event, the Commission had not been able to produce a body of relevant and consistent evidence capable of calling into question the conclusion which it had reached in paragraph 985 of the judgment under appeal.

In that regard, it should be recalled that, as noted in paragraphs 108 and 182 of the present judgment, the fact that undertakings the conduct of which could be characterised as a restriction of competition by object acted without having an intention to prevent, restrict or distort competition and the fact that they pursued certain legitimate objectives are not decisive for the purposes of the application of Article 101(1) TFEU (see, to that effect, judgment of 21 December 2023, *European Superleague Company*, C-333/21, EU:C:2023:1011, paragraph 167 and the case-law cited). Although evidence of the intentions of the parties to an agreement can, in certain cases, contribute to establishing the objective aims that that agreement is intended to achieve from a competition standpoint, it is clear from the case-law recalled in the present

paragraph that, when it criticised the Commission for failing to demonstrate, in essence, that either Servier or Krka intended to restrict competition between them, whereas no such demonstration was required in order to establish the existence of a restriction of competition by object, the General Court erred in law and vitiated paragraph 251 of the judgment under appeal with illegality.

259 The first part of the fourth ground of appeal must therefore be upheld.

(b) The second part

(1) Arguments of the parties

- By the second part of its fourth ground of appeal, the Commission submits that the General Court, in ruling in paragraphs 1016 to 1024 of the judgment under appeal on Servier's and Krka's intention to share the markets, erred in its interpretation of the principles governing the analysis of the evidence. It puts forward four complaints in that respect.
- First, as regards the recognition by Servier and Krka of the validity of the 947 patent, the General Court confined itself, in paragraphs 1017 to 1024 of that judgment, to examining certain documents referred to in the decision at issue, whereas it was required to ascertain whether all the documentary evidence, analysed as a whole, made it possible to establish an infringement according to the standard of proof required. The General Court thus failed to take into consideration the documents referred to in recitals 873, 874 and 1759 of the decision at issue.
- Second, as regards the importance attached, in paragraph 1016 of that judgment, to the content of the Krka settlement and licence agreements, the General Court, in essence, followed an erroneous line of reasoning, of an 'a contrario' nature, and misinterpreted the case-law arising from the judgment of 7 January 2004, Aalborg Portland and Others v Commission (C-204/00 P, C-205/00 P, C-211/00 P, C-213/00 P, C-217/00 P and C-219/00 P, EU:C:2004:6, paragraph 57), concerning the inferences that may be drawn from indicia where the parties have not kept documentary evidence of the content of their agreement. The General Court inferred from this that the fact that the content of an agreement is available qualifies the relevance of the other documentary evidence. In the absence of that error of law, the General Court would have had to take into account an email from Krka of 29 September 2005 identifying the anticompetitive strategy pursued together with Lupin's statement, which is referred to in recitals 1730 and 1748 of the decision at issue, corroborating the existence of that strategy.
- Third, in paragraph 1016 of the judgment under appeal, the General Court erred in law by holding, in a general and abstract manner, that documents contemporaneous with agreements 'cannot easily call into question a finding based on the actual content of the agreements'. There is no such hierarchy in the production of evidence. The General Court failed to have regard to the essential function of evidence, which is to establish convincingly the merits of an argument and erred in law by failing to verify the credibility of all the evidence referred to in recitals 1758 to 1760 of the decision at issue.
- Fourth, the Commission submits that paragraph 1019 of the judgment under appeal is insufficiently reasoned. In particular, that judgment fails to explain why the evidence referred to in recitals 1758 to 1760 of the decision at issue, read in conjunction with recitals 1687 to 1690 of that decision, was not sufficient to establish that Krka did not recognise the validity of the 947 patent.

Servier submits that the General Court explained the reasons why Krka's continuation of the legal proceedings did not call into question the fact that Krka recognised the validity of the 947 patent without failing to fulfil its obligation to analyse all relevant evidence or its duty to state reasons. As regards the second and third complaints, Servier notes that, since the Krka agreements were made public, the General Court's distinction between those agreements and secret cartels was relevant.

(2) Findings of the Court

- Since the Commission has put forward, in the context of its first complaint, arguments which overlap with those relied on in the fourth part of its fourth ground of appeal, it is appropriate to examine all of those arguments in the context of the assessment of that fourth part.
- As regards the fourth complaint, alleging a failure to state reasons, it should be borne in mind that, according to the settled case-law of the Court of Justice, the statement of the reasons on which a judgment is based must clearly and unequivocally disclose the General Court's reasoning in such a way as to enable the persons concerned to ascertain the reasons for the decision taken and the Court of Justice to exercise its power of review (judgment of 9 March 2023, *Les Mousquetaires and ITM Entreprises* v *Commission*, C-682/20 P, EU:C:2023:170, paragraph 40 and the case-law cited).
- In paragraph 1019 of the judgment under appeal, the General Court rejected the evidence referred to in recitals 849 to 854 and 1758 to 1760 of the decision at issue, on the ground that it was too 'fragmentary or ambiguous' to cast doubt on the General Court's finding that Krka had ultimately recognised the validity of the 947 patent. Although that reasoning is laconic, it is nevertheless sufficient for the purpose of understanding, in the light of paragraph 1016 of that judgment, the reasons why the General Court thus disregarded that evidence. Since the fourth complaint is unfounded, it must be rejected.
- As regards the second and third complaints, which it is appropriate to examine together, the Commission submits, in essence, that paragraph 1016 of the judgment under appeal is vitiated by an error of law in that the General Court held that documents contemporaneous with agreements cannot easily call into question a finding based on the actual content of the agreements.
- In paragraph 1016 of the judgment under appeal, the General Court correctly recalled, referring to the judgment of 25 January 2007, *Sumitomo Metal Industries and Nippon Steel* v *Commission* (C-403/04 P and C-405/04 P, EU:C:2007:52, paragraph 51), that, even if the Commission discovers evidence explicitly showing unlawful contact between traders, it will normally be only fragmentary and sparse, so that it is often necessary to reconstitute certain details by deduction. However, the General Court considered, in paragraph 1016, that the Krka settlement and licence agreements were 'genuine contracts which, moreover, were well publicised (recital 915 of the [decision at issue])', that, 'since the Commission could easily obtain the full content of the agreements at issue, the applicability of the case-law which has just been cited is less evident' and that, 'thus, inferences drawn from partial extracts of emails or other documents purporting to establish the intentions of the parties cannot easily call into question a finding based on the actual content of the agreements, that is to say, on the legally binding relationship which the parties have decided to establish between themselves'.

- In that regard, it must be borne in mind that, in EU law, the prevailing principle is that evidence may be freely adduced and that the only criterion for the purpose of assessing the evidence adduced is its credibility (judgments of 25 January 2007, *Dalmine v Commission*, C-407/04 P, EU:C:2007:53, paragraphs 49 and 63, and of 27 April 2017, *FSL and Others v Commission*, C-469/15 P, EU:C:2017:308, paragraph 38).
- In order to satisfy the burden of proof incumbent on it, the Commission must gather sufficiently serious, precise and consistent evidence to support the firm conviction that the alleged infringement took place (see, to that effect, judgments of 28 March 1984, *Compagnie royale asturienne des mines and Rheinzink* v *Commission*, 29/83 and 30/83, EU:C:1984:130, paragraph 20, and of 25 January 2007, *Sumitomo Metal Industries and Nippon Steel* v *Commission*, C-403/04 P and C-405/04 P, EU:C:2007:52, paragraphs 42 and 45).
- However, it is not necessary for every item of evidence produced by the Commission to satisfy those criteria in relation to every aspect of the infringement. It is sufficient if the body of evidence relied on by the institution, viewed as a whole, meets that requirement (see, to that effect, judgments of 15 October 2002, *Limburgse Vinyl Maatschappij and Others* v *Commission*, C-238/99 P, C-244/99 P, C-245/99 P, C-247/99 P, C-250/99 P to C-252/99 P and C-254/99 P, EU:C:2002:582, paragraphs 513 to 523, and of 14 May 2020, *NKT Verwaltungs and NKT* v *Commission*, C-607/18 P, EU:C:2020:385, paragraph 180).
- As the Advocate General observed in points 97 and 220 of her Opinion, those principles relating to the production of evidence apply not only where the Commission must infer the actual existence of a collusive practice from fragmentary and sparse evidence, but also where the content of agreements intended to implement that practice was available to the Commission. In such a situation, the actual content of those agreements does not necessarily make it possible to determine whether those agreements form part of an anticompetitive practice or, a fortiori, whether that practice reveals a sufficient degree of harm in order to be characterised as a restriction of competition by object.
- As has already been stated, in paragraph 183 of the present judgment, in response to the second part of the second ground of appeal, the fact that the terms of agreements intended to implement a collusive practice do not reveal an anticompetitive object is not, in itself, decisive. That is why it is necessary to take into account not only the content of those agreements, but also their objectives and the economic and legal context of which they form part (see, to that effect, judgments of 26 November 2015, *Maxima Latvija*, C-345/14, EU:C:2015:784, paragraph 20, and of 23 January 2018, *F. Hoffmann-La Roche and Others*, C-179/16, EU:C:2018:25, paragraphs 78 and 79). In that regard, although the parties' intention is not a necessary factor in determining whether an agreement between undertakings is restrictive, there is nothing to prevent the competition authorities, the national courts or the Courts of the European Union from taking that factor into account (judgment of 11 September 2014, *CB* v *Commission*, C-67/13 P, EU:C:2014:2204, paragraph 54 and the case-law cited), in particular in order to understand the true object of that agreement in the light of the context in which it was concluded, as held in paragraph 258 of the present judgment.
- Therefore, first, the General Court infringed the principle that evidence may be freely adduced in EU law by holding, in paragraph 1016 of the judgment under appeal, that there is a distinction in law, as regards the taking into account of fragmentary and sparse evidence in order to establish the existence of an infringement, between situations in which the content of anticompetitive agreements is available to the Commission and those in which that content is not available to it.

Second, the General Court erred in law by observing, in paragraph 1016, that 'inferences drawn from partial extracts of emails or other documents purporting to establish the intentions of the parties cannot easily call into question a finding based on the actual content of the agreements, that is to say, on the legally binding relationship which the parties have decided to establish between themselves'. In so doing, the General Court vitiated its assessments set out in paragraphs 1016 to 1025 of that judgment with illegality.

The second and third complaints of the second part of the fourth ground of appeal must therefore be upheld.

(c) The third part

(1) Arguments of the parties

- 278 By the third part of its fourth ground of appeal, the Commission submits that, for the reasons set out in the sixth part of its first ground of appeal, paragraphs 1017 and 1024 of the judgment under appeal are vitiated by an error of law.
- According to Servier, that third part must be rejected for the same reasons as those allegedly justifying the rejection of the sixth part of the first ground of appeal.
 - (2) Findings of the Court
- Since the sixth part of the first ground of appeal has been upheld in paragraph 163 of the present judgment, it is not necessary to rule separately on the third part of the fourth ground of appeal.

(d) The fourth part

(1) Arguments of the parties

- By the fourth part of its fourth ground of appeal, the Commission criticises the General Court for having, in paragraphs 999, 1000, 1010 and 1026 of the judgment under appeal, infringed the principles requiring it to carry out a full and impartial analysis of all the evidence. The General Court 'preferred' subjective evidence that postdates the conclusion of the Krka settlement and licence agreements to the contemporaneous evidence referred to in paragraphs 1015 to 1024 of that judgment, whereas the contemporaneous evidence would have enabled it to ascertain whether Krka actually recognised the validity of the 947 patent. Even though that undertaking claimed that the EPO decision of 27 July 2006 had led it to believe that the 947 patent was valid, such a claim could not stand up to a full and impartial assessment of all the evidence. The General Court erred in law by failing to review all the evidence referred to in Section 5.5 of the decision at issue.
- According to Servier, the fourth part of the fourth ground of appeal is based on a misreading of the judgment under appeal. The General Court analysed both the evidence subsequent to, and the evidence contemporaneous with, the Krka settlement and licence agreements. In any event, the contemporaneous evidence lacked probative value, since it predated the EPO decision of 27 July 2006. Furthermore, the Commission cannot complain that the General Court failed to review all the evidence referred to in Section 5.5 of the decision at issue. In particular, that

complaint is inadmissible, since the Commission does not clearly indicate which specific evidence, in its view, the General Court should have examined in that section, which comprises 55 pages. In Servier's view, it is not for the General Court to review the decision at issue beyond the evidence which the Commission put forward during the litigation stage, or for the Court of Justice to substitute its own assessment for that of the General Court.

(2) Findings of the Court

- By the first complaint of the second part of the fourth ground of appeal, and by the fourth part of that ground of appeal, the Commission submits, in essence, that the General Court erred in law in ruling on the existence of a restriction of competition by object on the basis of an incomplete and selective assessment of the evidence of Krka's recognition of the validity of the 947 patent and of the intentions of the parties to the Krka agreements.
- In that regard, it has been held in paragraphs 160 to 162 of the present judgment that, by failing to take into consideration the matters referred to in paragraphs 158 and 159 of the present judgment relating to Krka's perception of the validity of the 947 patent and by failing to explain the reasons for that omission, whereas the existence of an infringement of the competition rules can only be correctly determined if the evidence upon which the decision at issue is based is considered as a whole, the General Court distorted the decision at issue and vitiated the judgment under appeal with a failure to state reasons. In those circumstances, the first complaint of the second part and the fourth part of the fourth ground of appeal must be upheld.
- In the light of the foregoing considerations, the first part, the first to third complaints of the second part and the fourth part of the fourth ground of appeal must be upheld.

8. The fifth ground of appeal

(a) Arguments of the parties

- By its fifth ground of appeal, the Commission criticises paragraphs 1007 to 1009 and 1031 of the judgment under appeal, by which the General Court took into account the positive effects of the Krka licence agreement in Krka's core markets. The General Court made three errors. First of all, since no infringement was found on those markets, the alleged positive effects do not justify the restriction of competition on the other markets. Next, the General Court misconstrued the judgment of 13 July 1966, *Consten and Grundig* v *Commission* (56/64 and 58/64, EU:C:1966:41), according to which, in essence, an exclusive distribution agreement which establishes absolute territorial protection constitutes a restriction of competition by object. Lastly, the General Court misconstrued the settled case-law according to which the weighing up of the positive and negative effects of an agreement on competition can be carried out only in the context of Article 101(3) TFEU.
- Servier disputes that line of argument. It disputes any analogy with the case that gave rise to the judgment of 13 July 1966, Consten and Grundig v Commission (56/64 and 58/64, EU:C:1966:41), which did not concern the settlement of a patent dispute. The Krka agreements do not offer absolute territorial protection. Servier remained free to sell on Krka's core markets, whereas Krka remained free to develop a non-infringing product in the rest of the European Union. The assertion that potential competition was eliminated on those markets is incorrect since the Krka settlement agreement only prohibited Krka from infringing the 947 patent, the validity of which

had just been confirmed. According to Servier, Krka was moreover actively working to develop a non-infringing form of perindopril. In any event, the General Court was able, in Servier's view, to take into account, in paragraphs 304 and 996 of the judgment under appeal, the pro-competitive effects of the Krka licence agreement, as contextual factors, in order to rebut the finding of a restriction of competition by object.

(b) Findings of the Court

- It should be borne in mind that, as the Court of Justice has held, in order to determine whether conduct reveals the degree of harm required in order to constitute a restriction of competition by object within the meaning of Article 101(1) TFEU, it is not necessary to examine, nor, a fortiori, to prove, the effects of that conduct on competition, be they actual or potential, or negative or positive (judgment of 21 December 2023, *European Superleague Company*, C-333/21, EU:C:2023:1011, paragraphs 159 and 166 and the case-law cited). It follows that any positive or pro-competitive effects of conduct cannot be taken into account in order to determine whether it should be characterised as a restriction of competition by object under Article 101(1) TFEU, including in the context of any examination of whether the conduct at issue reveals the degree of harm required in order to be characterised as such.
- In any event, as noted in paragraph 175 of the present judgment, the Krka licence agreement concerns markets which do not fall within the geographic scope of the infringement of Article 101 TFEU. In those circumstances, any pro-competitive effects that that agreement might have on those markets, even if they exist, would be irrelevant, from a logical standpoint, for the purpose of determining the existence of the infringement found in the present case on Servier's core markets.
- Therefore, by relying, in paragraph 1031 of the judgment under appeal, as well as in paragraph 1032 thereof which draws conclusions from it, on the pro-competitive effects that it had found to exist on Krka's core markets, in paragraphs 1007 to 1009 of that judgment, the General Court erred in its interpretation and application of Article 101(1) TFEU and vitiated all of those paragraphs with illegality.
- The fifth ground of appeal must therefore be upheld.

9. Interim conclusion on the first to fifth grounds of appeal

- By the judgment under appeal, the General Court held, in essence, that, in order to characterise the Krka settlement and licence agreements as a restriction of competition by object, 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 Krka 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.
- As is apparent from paragraphs 133 to 135 and 179 to 184 of the present judgment, the General Court 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. It also disregarded the geographic scope of that infringement which did not extend to Krka's core markets.

- That error of law led the General Court, as is apparent from paragraphs 178 to 184 of the present judgment, to verify the characterisation of the unlawful practice attributed to Servier and Krka as a restriction of competition by object by analysing the form and legal characteristics of the agreements intended to implement that practice rather than by having regard to the economic impacts of that practice. It is in the light of those incorrect criteria that the General Court attached decisive importance to Krka's recognition of the validity of the 947 patent and to the question whether the royalty rate of the Krka licence agreement was in line with normal market conditions, whereas, as is apparent from paragraphs 196 to 200 and 223 to 226 of the present judgment, those factors were not, in themselves, decisive.
- Furthermore, when, on the basis of those errors of law, the General Court examined whether the conclusion of the Krka settlement and licence agreements was justified by the fact that Krka, having suffered two legal setbacks, was no longer convinced of the invalidity of the 947 patent, the General Court, as is apparent from paragraphs 145 to 162 of the present judgment, distorted the clear and precise meaning of one of those judicial decisions and, as regards the other, distorted the decision at issue and infringed its obligation to state reasons.
- In addition, in order to support the conclusion vitiated by the errors of law just summarised that the Commission could not characterise the Krka settlement and licence agreements as a restriction of competition by object, the General Court disputed seven factors which, according to the decision at issue, demonstrated that the Krka licence agreement was the quid pro quo for that undertaking's commitment not to compete with Servier on its core markets.
- First, the General Court disputed, in paragraphs 987 to 991 of the judgment under appeal, the prospect of the establishment of a de facto duopoly between Servier and Krka on Krka's core markets, on the ground that that duopoly was the result not of the Krka licence agreement, but of subsequent choices made by the parties to that agreement. However, that finding is based solely on an examination of the content of the clauses of that agreement, regardless of its economic context, and on a distortion of the wording of one of those clauses, as is apparent from paragraphs 178 to 184 and 230 to 232 of the present judgment.
- Second, the General Court rejected, in paragraphs 992 to 999 of the judgment under appeal, the possibility that the Krka licence agreement could have constituted the quid pro quo for the Krka settlement agreement, on the ground that it was Krka's recognition of the validity of the 947 patent that was the decisive factor in its decision to settle. However, that assessment is based (i) on the error of law found in paragraphs 223 to 226 of the present judgment as regards the decisive nature of that recognition and (ii) on the distortions and failure to state reasons found in paragraphs 145 to 162 and paragraphs 283 to 285 of the present judgment.
- Third, the General Court stated, in paragraphs 1000 to 1002 of the judgment under appeal, that Krka's assessment of the opportunity cost of the Krka settlement agreement did not establish that the Krka licence agreement was the quid pro quo for the Krka settlement agreement, but rather confirmed that Krka recognised the validity of the 947 patent. However, that latter circumstance is not, in itself, decisive, as is apparent from paragraphs 223 to 226 of the present judgment.

- Fourth, the General Court considered, in paragraphs 1003 to 1014 of the judgment under appeal, first of all, that, in the absence of markets reserved for Krka, the Commission had not proved the existence of a 'hermetic' division of the markets, next, that the licence had had a pro-competitive effect on Krka's core markets, and, lastly, that no part of the market had been unlawfully reserved for Servier. However, it is apparent from paragraphs 216 to 219, 225 and 226 of the present judgment that those assessments are based (i) on a formalistic analysis of the Krka settlement and licence agreements rather than on the specific analysis of their harmfulness to competition and (ii) on an error of interpretation of Article 101(1) TFEU, since the prohibition of agreements aimed at partitioning markets is not applicable only to agreements that effect a 'hermetic' division between those markets.
- Fifth, the General Court held, in paragraphs 1015 to 1025 of the judgment under appeal, that the Commission had failed to demonstrate that Servier and Krka intended to conclude a market-sharing agreement. However, in addition to the fact, as held in paragraph 258 of the present judgment, that the Commission was not required to demonstrate that either Servier or Krka intended to restrict competition between them, it is apparent from paragraphs 145 to 162 and 269 to 276 of the present judgment that that finding is based on a distortion of the decision at issue and of the decision of the High Court of 3 October 2006, on an infringement of the obligation to state reasons for judgments and on an incorrect application of the principles relating to the production of evidence.
- Sixth, the General Court held, in paragraphs 1026 to 1028 of the judgment under appeal, that the fact that Krka continued to challenge Servier's patents after the EPO decision of 27 July 2006 did not mean that that decision did not have a decisive impact on Krka's perception of the validity of the 947 patent and that Krka continued to exert competitive pressure on Servier. According to the General Court, that continuation of litigation could be explained by Krka's desire to strengthen its position in the negotiations with Servier and by its belief that it would run only a limited risk of being the subject of actions for infringement. However, it is apparent from paragraphs 130 to 137 and 145 to 162 of the present judgment that that finding of the General Court is based on the incorrect premiss that Krka's recognition of the validity of the 947 patent was decisive, a premiss which is itself based on the distortion not only of an item of evidence but also of the decision at issue as such and on a failure to state reasons in the judgment under appeal.
- Seventh, the General Court reiterated, in paragraphs 1029 to 1031 of the judgment under appeal, its position that (i) the Krka licence agreement was based on that undertaking's recognition of the validity of the 947 patent and (ii) the Commission had not established that that agreement had not been concluded at arm's length. However, it is apparent from paragraphs 90 to 104, 131 to 134 and 196 to 200 of the present judgment that those considerations are based on the application of criteria which are wrong in law.
- In the light of all the foregoing and having regard to the breadth, nature and scope of the errors of law made by the General Court identified in the analysis of the first to fifth grounds of appeal, it must be held that those errors affect the entirety of the reasoning set out in paragraphs 943 to 1032 of the judgment under appeal relating to the characterisation of the Krka settlement and licence agreements as a restriction of competition by object.

10. The sixth ground of appeal

(a) Arguments of the parties

By its sixth ground of appeal, the Commission complains that the General Court refused, for the reasons set out in paragraphs 1041 to 1060 of the judgment under appeal, to recognise that the Krka assignment and licence agreement constituted a restriction of competition by object, on the ground that that characterisation was based on the incorrect finding that there was market sharing between Krka and Servier. Since that assessment is based on an incorrect premiss, it cannot be allowed to stand. The Commission submits moreover that the General Court did not provide an adequate statement of reasons for that assessment.

According to Servier, this ground of appeal is based on the premiss of the validity of the first to fifth grounds of appeal, which it disputes.

(b) Findings of the Court

In paragraphs 1053, 1054 and 1059 of the judgment under appeal, the General Court noted that, in the decision at issue, the Commission had characterised the Krka assignment and licence agreement as a restriction of competition by object by relying on the finding of the existence of a market-sharing agreement as a result of the Krka settlement and licence agreements. That finding having been invalidated by the General Court, the latter considered that it was also necessary, for that reason alone, to reject the characterisation of the Krka assignment and licence agreement as a restriction of competition by object.

However, it follows from the examination of the first to fifth grounds of appeal that the General Court's reasoning – set out in paragraphs 943 to 1032 of the judgment under appeal – relating to the characterisation of the Krka settlement and licence agreements is, in its entirety, vitiated by illegality. Since the premiss of the reasoning by which the General Court rejected the characterisation of the Krka assignment and licence agreement as a restriction of competition by object is thus vitiated, the sixth ground of appeal must be upheld.

B. The seventh ground of appeal, relating to the existence of a restriction of competition by effect within the meaning of Article 101(1) TFEU

1. The relevant sections of the decision at issue and the relevant paragraphs of the judgment under appeal

(a) The decision at issue

In recitals 1214 to 1218 of the decision at issue, the Commission stated that, in order to assess the anticompetitive effects of an agreement, account should be taken of the actual circumstances in which those effects are produced, in the light not only of current competition, but also of potential competition. In recitals 1219 and 1220 of that decision, the Commission stated that that assessment should be carried out on the basis of the facts at the time that agreement was concluded, while taking into account how it was actually implemented.

- In recitals 1221 to 1227 of the decision at issue, the Commission stated that the effects of an agreement must be compared with what would have happened in the absence of that agreement, in particular as regards potential competition. According to recitals 1228 to 1243 of that decision, the main competitive constraint exercised on the perindopril market resulted from the entry into that market of generic versions of that medicinal product, without which Servier could maintain its prices at a level above the competitive price. The settlement agreements concluded by that undertaking with manufacturers of generic medicines therefore directly produced anticompetitive effects. In recitals 1244 to 1269 of that decision, the Commission stated that, after the conclusion of settlement agreements with Niche, Matrix, Teva, Krka and Lupin, only two manufacturers of generic medicines Apotex and Sandoz constituted a significant threat of entry to Servier's core markets, which shows that, faced with a small number of potential competitors, the elimination of a single one is sufficient to significantly reduce the likelihood of such entry.
- As regards, more specifically, the characterisation of the Krka agreements as a restriction of competition by effect on the markets in France, the Netherlands and the United Kingdom, which were the only ones relied on for the purposes of establishing that infringement, it is apparent from recitals 1813 to 1850 of the decision at issue that Krka was a potential competitor of Servier on those markets and had real and concrete possibilities of entering those markets within a short period. Krka had initiated litigation in the United Kingdom and was preparing to enter those markets. By inducing that undertaking to abandon that plan, the Krka agreements had the effect of eliminating a source of potential competition.
- In addition, those agreements significantly reduced the risk of entry of other manufacturers of generic medicines to which Krka could have supplied perindopril products. On the basis of those factors, the Commission found that those agreements had the effect of appreciably restricting potential competition, noting in that regard, in recital 1850 of that decision, that those agreements 'appreciably increased the likelihood that Servier's market exclusivity would remain uncontested for a longer period of time and that consumers would forego a significant reduction of prices that would ensue from timely and effective generic entry'.

(b) The judgment under appeal

- For the reasons set out in paragraphs 1075 to 1234 of the judgment under appeal, the General Court upheld the tenth plea at first instance, by which Servier disputed the characterisation of the Krka agreements as a restriction of competition by effect on the three geographic markets concerned.
- In the first place, after recalling, in paragraphs 1078 to 1104 of that judgment, the grounds which led the Commission to adopt that characterisation, the General Court held, in paragraphs 1107 to 1139 of that judgment, that the case-law relating to the taking into account of the potential effects of an agreement, in particular that resulting from the judgments of 21 January 1999, *Bagnasco and Others* (C-215/96 and C-216/96, EU:C:1999:12, paragraph 34), of 23 November 2006, *Asnef-Equifax and Administración del Estado* (C-238/05, EU:C:2006:734, paragraph 50), of 28 February 2013, *Ordem dos Técnicos Oficiais de Contas* (C-1/12, EU:C:2013:127, paragraph 71), and of 26 November 2015, *Maxima Latvija* (C-345/14, EU:C:2015:784, paragraph 30), is inapplicable where that agreement has already been implemented. According to the General Court, the Commission cannot find a restriction of competition by effect solely on the basis of a limitation, or even the elimination, of a source of

potential competition. Proof of such effects requires account to be taken, for the sake of practicality, of all the relevant factual developments, including those subsequent to the conclusion of the agreement concerned.

- In the second place, the General Court found, in paragraphs 1140 to 1217 of the judgment under appeal, that the Commission, by relying solely on an impediment to potential competition and on hypothetical considerations, erred in characterising the Krka settlement agreement and the Krka assignment and licence agreement as restrictive of competition by effect.
- First of all, for the reasons set out in paragraphs 1142 to 1187 of that judgment, the General Court held that the Commission had not demonstrated that, in the absence of the non-marketing clause provided for in the Krka settlement agreement, Krka would probably have entered the markets in France, the Netherlands and the United Kingdom. According to that judgment, the Commission failed to take into account the fact that Krka recognised the validity of the 947 patent and failed to demonstrate that, in the absence of that agreement, competition would probably have been more open, since it had not specified the probable effects of such a situation on prices, production or innovation.
- Next, the General Court held, in paragraphs 1188 to 1213 of that judgment, that the Commission had not established that, in the absence of the non-challenge clause provided for in the Krka settlement agreement, it was probable, or even plausible, that the continuation of the litigation relating to the 947 patent would have allowed a faster or more complete invalidation of the patent. According to the General Court, the Commission therefore failed to demonstrate that that clause had the effect of restricting competition.
- Lastly, the General Court noted, in paragraphs 1214 and 1215 of that judgment, that the Commission had not demonstrated that the Krka assignment and licence agreement had the effect of restricting competition, since that agreement did not provide for any exclusionary measure similar to a non-marketing clause.
- In the third place, after upholding, in paragraphs 1216 and 1217 of the judgment under appeal, the plea alleging the absence of anticompetitive effects of the Krka agreements, the General Court examined 'whether the Commission [had], in addition, vitiated [the decision at issue] by errors of law'. In that regard, it found, in paragraphs 1219 to 1232 of that judgment, that, by failing to take into account the course of events observable at the date of the decision at issue and by analysing competition in the absence of the Krka agreements on the basis of hypothetical considerations, the Commission had unjustifiably limited its examination of the effects on competition of those agreements, both in the light of the case-law relating to the taking into account of potential effects on competition and of the case-law relating to the elimination of potential competition. In the General Court's view, such an incomplete examination is contrary to the distinction established in Article 101(1) TFEU between restrictions of competition by object and restrictions of competition by effect.

2. Arguments of the parties

320 The seventh ground of appeal comprises seven parts.

- By the first part, the Commission criticises the General Court for having held, in paragraphs 1128, 1178, 1179 and 1227 to 1231 of the judgment under appeal, that the effect of restricting potential competition, although an actual effect, was not sufficient for a finding of a restriction of competition by effect.
- By the second part, the Commission submits that, in paragraphs 1107 to 1128 and 1225 of the judgment under appeal, the General Court erred in its interpretation and application of Article 101(1) TFEU in finding that taking potential effects into account was not sufficient to establish the effects of an agreement which had already been implemented.
- By the third part, the Commission criticises paragraphs 399, 1160, 1165, 1168, 1169, 1173, 1174, 1178, 1204, 1206, 1207, 1209, 1221 and 1223 of the judgment under appeal. It complains that the General Court held that it was required to demonstrate that Krka would probably have entered the perindopril market in France, the Netherlands and the United Kingdom in the absence of the Krka agreements, in particular by speculating on the outcome of the disputes relating to the 947 patent.
- By the fourth part, the Commission, supported by the United Kingdom, criticises paragraphs 1089 to 1092, 1130 to 1133, 1151, 1170, 1181, 1210 and 1219 of the judgment under appeal. In particular, the General Court required, in paragraph 1130 of that judgment, that the Commission take into account factual developments subsequent to the conclusion of the agreements. However, an agreement must be analysed at the date on which it was concluded, on the basis of the likely developments that would have occurred on the market in the absence of that agreement.
- By the fifth part, the Commission submits that the General Court, in paragraphs 1148 to 1151 and 1154 of the judgment under appeal, distorted the decision at issue in stating that that decision had not taken into account the effects of the 947 patent and Krka's recognition of the validity of that patent.
- By the sixth part, the Commission complains that the General Court substituted its own assessment of the facts for the findings in the decision at issue, thereby exceeding the limits of the review of lawfulness. The General Court, in paragraphs 1162 to 1170 of the judgment under appeal, thus held (i) that Krka's decision to continue to challenge the 947 patent, after the EPO decision of 27 July 2006, was a mere ploy intended to strengthen its position in its negotiations with Servier, whereas that assessment is not based on any contemporaneous evidence and (ii) that Krka would probably not have entered Servier's core markets.
- By the seventh part, the Commission takes issue with paragraphs 1198 to 1207 of the judgment under appeal. The General Court wrongly placed on the Commission the burden of demonstrating that Krka's continuance of the legal proceedings relating to the patents would have made it possible to invalidate the 947 patent more quickly or more fully.
- As regards the first part, Servier disputes that the elimination of a source of potential competition is sufficient to establish the existence of negative effects on competition. In that regard, Servier and EFPIA submit that the General Court examined competition in the actual context in which it would have occurred in the absence of the Krka settlement agreement.
- As regards the second part, Servier submits that the distinction between agreements according to whether or not they have been implemented is well founded. In order to compare the competitive structure brought about by agreements already implemented with that which would have existed

without them, it is necessary to take account of facts subsequent to the conclusion of those agreements. That distinction, which, according to EFPIA, is not novel, is consistent with point 29 of the Commission Notice entitled 'Guidelines on the applicability of Article [101 TFEU] to horizontal cooperation agreements' (OJ 2001 C 3, p. 2). The second part is therefore unfounded.

- As regards the third part, in the view of Servier and EFPIA, the General Court did not require it to be demonstrated that Krka was likely to enter the market, but merely invalidated an element of the reasoning set out in the decision at issue. In any event, such a requirement does not oblige the Commission to speculate on the outcome of a patent dispute, since an 'at risk' entry to Servier's core markets meant, by definition, that Krka did not await the outcome of that dispute to make such an entry. The counterfactual analysis must be based not on mere speculation, but on tangible evidence. Furthermore, the fact that Article 101 TFEU protects competition as such does not relieve the Commission of its obligation to demonstrate actual effects on competition.
- As regards the fourth part, the Commission's line of argument relating to the taking into account, in the judgment under appeal, of effects subsequent to the date of conclusion of the Krka agreements is directed against a factual assessment by the General Court. According to Servier, that line of argument must be declared inadmissible.
- As to the substance, Servier complains that the Commission's line of argument is contradictory. While criticising the taking into account of events subsequent to the Krka agreements, the Commission nevertheless states that it took such events into account, on the ground that they were reasonably foreseeable.
- Servier contests any error of law in the comparison between the situation resulting from the Krka agreements and that resulting from the counterfactual scenario. The taking into account of the likely developments concerns the counterfactual scenario. In the decision at issue, the Commission relied exclusively on hypothetical considerations in order to characterise the situation brought about by those agreements.
- Servier and EFPIA submit that the fifth part of the plea, alleging distortion, is inadmissible, since the Commission merely referred to numerous recitals of the decision at issue.
- According to Servier and EFPIA, the sixth part is inadmissible, since the Commission is criticising a factual assessment made by the General Court. Furthermore, the Commission's line of argument lacks clarity and does not identify precisely the error of law allegedly committed by the General Court, merely repeating that the decision at issue was well founded. That part of the ground of appeal is, moreover, ineffective, since it cannot lead to the judgment under appeal being set aside. That part is, in any event, unfounded, since the decision at issue does not rule out the possibility that Krka may have acted for tactical reasons. The limits of judicial review cannot be found to have been exceeded.
- The seventh part is based on a misreading of the judgment under appeal. The Commission confuses the analysis of the situation brought about by the Krka agreements and the analysis of the counterfactual situation. The invalidation of the 947 patent obtained by Apotex is not a counterfactual hypothesis, but a fact. It was for the Commission to set out a probable counterfactual situation that was more competitive than the situation brought about by the Krka agreements.

3. Findings of the Court

- By its seventh ground of appeal, the Commission essentially criticises the General Court for having considered that the decision at issue had not established that the Krka agreements had had the effect of restricting potential competition, since that institution had failed to prove that, in the absence of those agreements, Krka would probably have entered Servier's core markets.
- As the Advocate General noted in point 292 of her Opinion, an agreement between undertakings may fall within the scope of Article 101(1) TFEU, not only on account of its object, but also because of its effects on competition, including where those effects affect potential competition exerted by one or more undertakings which, although absent from the relevant market, have the ability to enter it, and thereby affect the conduct of undertakings already present on that market. The burden of proving such effects on potential competition is borne by the Commission.
- According to the settled case-law of the Court of Justice, recalled by the General Court in paragraph 1076 of the judgment under appeal, in order to assess the existence of anticompetitive effects caused by an agreement between undertakings, it is necessary to compare the competitive situation resulting from that agreement and the situation that would exist in its absence (see, to that effect, judgments of 30 June 1966, *LTM*, 56/65, EU:C:1966:38, p. 250; of 11 September 2014, *MasterCard and Others* v *Commission*, C-382/12 P, EU:C:2014:2201, paragraph 161; and of 18 November 2021, *Visma Enterprise*, C-306/20, EU:C:2021:935, paragraph 74).
- The purpose of that 'counterfactual' method is to identify, in the context of the application of Article 101(1) TFEU, the existence of a causal link between, on the one hand, an agreement between undertakings and, on the other, the structure or functioning of competition on the market within which that agreement produces its effects. That method thus makes it possible to ensure that characterisation as a restriction of competition by effect is reserved for agreements displaying not a mere correlation to a deterioration in the competitive situation of that market, but for those agreements that are the cause of that deterioration.
- The *raison d'être* of the counterfactual method is that any attempt to identify such a relationship of cause and effect runs up against the fact that it is impossible, in practice, to observe the state of the market at the same time with and without the agreement concerned, as those two states are, by definition, mutually exclusive. It is therefore necessary to compare the observable situation, namely that resulting from that agreement, with the situation which would have arisen had that agreement not been adopted. That method therefore requires an observable situation to be compared with a scenario which, by definition, is hypothetical, in the sense that it has not materialised. When appraising the effects of an agreement between undertakings in the light of Article 101 TFEU, it is necessary to take into consideration the actual context in which that agreement is situated, in particular the economic and legal context in which the undertakings concerned operate, the nature of the goods or services affected, as well as the real conditions of the functioning and the structure of the market or markets in question. It follows that the counterfactual scenario, envisaged on the basis of the absence of that agreement, must be realistic and credible (see, to that effect, judgment of 30 January 2020, *Generics (UK) and Others*, C-307/18, EU:C:2020:52, paragraphs 115 to 120).
- It is therefore essential, for the correct application of the counterfactual method, to ensure that the comparison made is based on sound and verifiable grounds, as regards both the observed situation that resulting from the agreement between undertakings and the counterfactual scenario. In order to achieve that, the time reference point for making such a comparison must

be the same for the situation observed and for the counterfactual scenario, since the anticompetitive nature of an act must be evaluated at the time when it was committed (see, to that effect, judgment of 6 December 2012, *AstraZeneca* v *Commission*, C-457/10 P, EU:C:2012:770, paragraph 110).

- It follows that, as the Advocate General observed in point 318 of her Opinion, in so far as the counterfactual scenario is intended to give a realistic picture of the market situation as it would have occurred in the absence of the agreement that was concluded, that scenario cannot be based on events subsequent to the date of conclusion of that agreement precisely because, on that date, those events had not occurred and, in the circumstances of the present case, could not occur in the future due to the existence of the Krka agreements.
- Unlike the counterfactual scenario, the situation observed is that corresponding to the competitive conditions which exist at the time of conclusion of the agreement and which result from it. That situation is real and it is therefore not necessary to rely on realistic assumptions in order to assess it. Accordingly, for the purposes of establishing an infringement of Article 101 TFEU, events subsequent to the conclusion of that agreement may be taken into account in order to assess that situation. However, in accordance with the case-law referred to in paragraph 342 of the present judgment, such events are relevant only in so far as they help to determine the competitive conditions obtaining at the time when that infringement was committed, as they result directly from the existence of that agreement.
- In the present case, in paragraphs 1078 to 1103 of the judgment under appeal, the General Court analysed the approach taken by the Commission in the decision at issue in order to characterise the patent dispute settlement agreements between Servier and the manufacturers of generic medicines referred to in that decision, and emphasised the hypothetical nature of that approach. It moreover held, in paragraphs 1107 to 1139 of that judgment, that the case-law according to which an agreement between undertakings may be characterised as a restriction of competition by effect by reason of its potential effects ceases to be applicable once the agreement has been implemented.
- As the actual effects of such an agreement on competition can be observed in the light of events subsequent to its conclusion, the General Court held, in paragraphs 1122 and 1123 of that judgment, that it would be paradoxical to allow the Commission to prove the existence of anticompetitive effects by merely carrying out a counterfactual analysis solely on the basis of the potential effects of an agreement, when (i) the Commission has observable evidence as to the actual effects of that agreement and (ii) it is only where there is a restriction of competition by object that the burden, which falls on the Commission, to prove the anticompetitive effects may be diminished.
- In so doing, the General Court misconstrued, in three main respects, the characteristics of the counterfactual method inherent in the assessment of a restriction of competition by effect, for the purposes of applying Article 101 TFEU.
- In the first place, the General Court held that the assessment of the anticompetitive effects of the Krka settlement agreement was based on a hypothetical approach and an incomplete examination of those effects, since the Commission had not included in the counterfactual scenario the actual course of events subsequent to that agreement. However, that reasoning of the General Court disregards the fact that, as recalled in paragraphs 341 to 343 of the present judgment, identifying the anticompetitive effects of an agreement requires recourse to a counterfactual scenario which,

by definition, is hypothetical, in the sense that it has not materialised, and which therefore cannot be based on matters subsequent to the conclusion of that agreement. It follows that the General Court erred in law in the interpretation and application of Article 101(1) TFEU and vitiated by illegality the grounds set out in paragraphs 1078 to 1103, 1089, 1090, 1102, 1151, 1170, 1181, 1203, 1210, 1219 to 1223 and 1227 of the judgment under appeal.

- In the second place, by holding, in paragraphs 1107 to 1139 of the judgment under appeal, that the case-law according to which an agreement between undertakings may be characterised as a restriction of competition by effect by reason of its potential effects ceases to be applicable once that agreement has been implemented, on the ground that the actual effects of that agreement on competition can be observed, the General Court based its reasoning on an imperfect understanding of the *raison d'être*, object and functioning of the counterfactual method, which are recalled in paragraphs 340 to 344 of the present judgment.
- It is true that, in the case of an agreement the implementation of which has changed the number or conduct of undertakings already present within the same market, the application of the counterfactual method may, from a practical point of view and depending on the factual circumstances, amount to a comparison between, on the one hand, the state of competition between those undertakings before the conclusion of that agreement and, on the other, the coordination between those undertakings brought about by the implementation of that agreement, which may be evidenced, where applicable, by events subsequent to its conclusion.
- However, where an agreement leads not to a change but, on the contrary, to keeping unchanged the number or the conduct of competing undertakings already present within that market by postponing or delaying the entry of a new competitor to that market, a mere comparison between the situations found to exist on that market before and after the implementation of that agreement would be insufficient to support the conclusion that there has been no anticompetitive effect. In such a situation, the anticompetitive effect arises from the certain disappearance, as a result of that agreement, of a source of competition which, at the time that agreement is concluded, remains potential, in so far as it is exerted by an undertaking which, although not yet present on the market concerned, is nevertheless capable of affecting the conduct of the undertakings already present on that market because of the credible threat of its entry to that market.
- Moreover, as the Advocate General observed in point 326 of her Opinion, the distinction drawn by the General Court in paragraphs 1107 to 1139 of the judgment under appeal, for the purposes of characterising agreements concluded by undertakings as a restriction of competition by effect fails to have regard to the settled case-law of the Court of Justice, according to which restrictive effects on competition may be both actual and potential, but must be sufficiently appreciable (see, to that effect, judgments of 9 July 1969, *Völk*, 5/69, EU:C:1969:35, paragraph 5/7, and of 23 November 2006, *Asnef-Equifax and Administración del Estado*, C-238/05, EU:C:2006:734, paragraph 50), and would amount to a reduction in the full effectiveness of the prohibition laid down in Article 101(1) TFEU.
- In the third place, as noted in paragraph 340 of the present judgment, the counterfactual method is not intended to predict what a party's conduct would have been if it had not concluded an agreement with its competitor or competitors, but to highlight a causal relationship between that agreement and a deterioration in the competitive situation on the market, on the basis of a counterfactual scenario which, although hypothetical, must nevertheless be realistic and credible. In that regard, the Court has already had occasion to state, in the context of a patent dispute

settlement agreement in return for reverse payment, that the sole purpose of the counterfactual scenario is to establish the realistic possibilities with respect to the conduct of the manufacturer of generic medicines in the absence of that agreement. While that counterfactual scenario cannot be unaffected by the chances of success of that manufacturer in the patent proceedings or again in relation to the probability of conclusion of a less restrictive agreement, those factors constitute, however, only one of the factors among many to be taken into consideration. Consequently, it is not for the entity bearing the burden of proving the existence of appreciable potential or real effects on competition, when it establishes the counterfactual scenario, to make a definitive finding in relation to the chances of success of the manufacturer of generic medicines in the patent dispute or to the probability of the conclusion of a less restrictive agreement (see, to that effect, judgment of 30 January 2020, *Generics (UK) and Others*, C-307/18, EU:C:2020:52, paragraphs 119 to 121).

- 354 It follows from those factors that the Commission is required to prove that the counterfactual scenario used in a decision finding the existence of a restriction of competition by effect is realistic and credible.
- scenario used by the Commission met those criteria. In so far as the restriction of competition found in the decision at issue consisted in the certain and deliberate elimination of the source of potential competition exercised by Krka in respect of Servier by means of its perindopril composed of the alpha crystalline form of erbumine protected by the 947 patent, analysis of the counterfactual scenario amounted, in essence, to analysing whether that potential competition existed, since the elimination of such competition, if established, is by definition a sufficiently appreciable effect on competition for the purpose of the case-law recalled in paragraph 352 of the present judgment. Thus, in order to determine whether the Krka agreements, by prohibiting Krka from entering the markets in France, the Netherlands and the United Kingdom, had a proven effect on potential competition, it was necessary to ascertain, in accordance with the case-law referred to in paragraph 101 and with what has been held in paragraph 351 of the present judgment, whether Krka had a real and concrete possibility of entering those markets within a period of time capable of putting competitive pressure on Servier, with the result that the threat of such an entry could be regarded as realistic and credible.
- By holding, in paragraphs 1142 to 1168 of the judgment under appeal, that the Commission had not proved that, in the absence of the non-marketing clause provided for in the Krka settlement agreement, Krka would probably have entered the markets in France, the Netherlands and the United Kingdom and, in paragraphs 1188 to 1213 of that judgment, that the Commission had not proved that, in the absence of the non-challenge clause provided for in that agreement, the continuation of the litigation challenging the validity of the 947 patent would, to use the words of paragraph 1203 of that judgment, 'probably, or even plausibly, have allowed a faster or more complete invalidation of the patent', the General Court erred in its interpretation and application of Article 101(1) TFEU and paragraphs 1147 to 1168 and 1188 to 1213 of the judgment under appeal were as a result vitiated with illegality.
- The errors of law thus identified vitiate with illegality the entirety of the General Court's reasoning relating to the characterisation of the Krka agreements as a restriction of competition by effect set out in paragraphs 1075 to 1234 of the judgment under appeal.

In the light of the foregoing, the seventh ground of appeal must be upheld, without its being necessary to rule separately on each of the parts of that ground of appeal, and in particular on the fifth part, alleging distortion of the decision at issue, and on the sixth part, alleging that the General Court substituted its own assessment for that of the Commission.

C. The eighth to eleventh grounds of appeal, relating to the infringement of Article 102 TFEU

The eighth and ninth grounds of appeal allege errors of law in the assessment of the importance attached, for the purposes of determining the relevant product market, to the price and therapeutic substitutability of perindopril. The tenth ground of appeal alleges that certain documents annexed by Servier to its pleadings at first instance are inadmissible. The eleventh ground of appeal alleges errors of law concerning the definition of the technology market relating to the active ingredient of perindopril.

1. The relevant sections of the decision at issue and the relevant paragraphs of the judgment under appeal

(a) The decision at issue

- For the purposes of applying Article 102 TFEU, the Commission, first of all, defined, in the decision at issue, the relevant market as being the perindopril market, on the basis of observations made between 2000 and 2009, in France, the Netherlands, Poland and the United Kingdom, relying essentially on two factors.
- On the one hand, it considered, in recitals 2445 to 2457 of that decision, that, of the 16 ACE medicinal products sharing the same mode of action and having similar therapeutic indications and side effects, perindopril had certain special characteristics highlighted by Servier in its efforts to promote it with doctors, in order to pursue a policy of differentiation from other ACE inhibitors.
- On the other hand, it noted, in recitals 2460 to 2495, 2528 and 2546 of that decision, that the sharp fall in the prices of other ACE medicinal products following the arrival of generic versions had not led to a decrease in the prices of perindopril and Servier's promotional expenditure, which had remained stable throughout the period under consideration, or to a decrease in the volumes sold of perindopril, which had constantly increased. That fall in prices did not therefore result in a transfer of demand for perindopril to those other ACE medicinal products. The Commission inferred from this that, in the absence of any significant competitive constraint from the other ACE medicinal products during that period, Servier was therefore in a position to behave, to an appreciable extent, independently of the manufacturers of those medicinal products. According to the Commission, that situation contrasted with the situation resulting from the arrival on the market of generic versions of perindopril, which led to average price reductions of that medicinal product of 27% in France, 81% in the Netherlands, 17% in Poland and 90% in the United Kingdom.

- Next, the Commission found, in recitals 2561 to 2600 of the decision at issue, that Servier held a dominant position on the perindopril market in France, the Netherlands, Poland and the United Kingdom. The Commission moreover found, in recitals 2601 to 2758 of that decision, that Servier also held a dominant position on the technology market relating to the active ingredient of that medicinal product.
- Lastly, the Commission considered, in recitals 2759 to 2998 of that decision, that Servier's single and continuous strategy aimed at delaying the market entry of generic versions of perindopril by combining, inter alia, the acquisition of technology relating to that medicinal product's active ingredient with patent settlement agreements in return for reverse payment constituted a single and continuous infringement of Article 102 TFEU.

(b) The judgment under appeal

- The General Court held, in paragraphs 1367 to 1592 of the judgment under appeal, that the Commission had wrongly limited the definition of the relevant product market to perindopril alone, to the exclusion of other ACE inhibitor medicinal products.
- After rejecting, first of all, a first complaint by Servier, alleging failure to take into account the overall economic context, the General Court then upheld a complaint alleging an error of assessment of the substitutability of other ACE inhibitor medicinal products for perindopril. In that regard, the General Court held, in paragraphs 1418 to 1482 of the judgment under appeal, that the Commission had erred in finding that there were therapeutic differences between perindopril and other ACE inhibitor medicinal products, in paragraphs 1483 to 1513 of that judgment, that the Commission had not established that the inertia and loyalty of prescribers towards perindopril contributed to limiting the competitive pressure exerted by the other ACE inhibitor medicinal products, in paragraphs 1514 to 1540 of that judgment, that the Commission had underestimated the propensity of patients treated with perindopril to switch medicinal products and, in paragraphs 1541 to 1566 of that judgment, that the Commission had not taken into consideration the importance of Servier's promotional efforts.
- Lastly, the General Court upheld, for the reasons set out in paragraphs 1567 to 1585 of the judgment under appeal, Servier's complaint that the Commission had attached excessive importance to prices when determining the relevant market. It held, in paragraph 1586 of that judgment, that there was no longer any need to adjudicate on Servier's complaint alleging methodological errors affecting the Commission's econometric analysis.
- The General Court invalidated, in paragraphs 1595 to 1608 and 1611 to 1622 of that judgment, the Commission's findings relating to the existence of a dominant position on the perindopril market and on the technology market relating to the active ingredient of that medicinal product. In the absence of a correct definition of the relevant product market, the General Court, for the reasons set out in paragraphs 1625 to 1632 of that judgment, overturned the findings made in the decision at issue concerning the abuse of a dominant position attributed to Servier.
- In the light of those factors, the General Court annulled Article 6 and Article 7(6) of the decision at issue.

2. The eighth ground of appeal

(a) Arguments of the parties

- By its eighth ground of appeal, the Commission criticises the General Court for holding that the decision at issue had attached excessive importance to prices in the definition of the relevant product market. This ground of appeal consists of six parts.
- By the first, third and fifth parts of its eighth ground of appeal, the Commission essentially criticises the assessments made by the General Court, in paragraphs 1380 to 1405 and 1567 to 1586 of the judgment under appeal, on the definition of the relevant market.
- The Commission submits, first of all, that, in paragraphs 1567 to 1586 of that judgment, the General Court, for the purposes of that definition, downplayed the importance to be attached to the price of perindopril and favoured considerations relating to the quality of that medicinal product. The General Court failed to take account of the fact that the prices of perindopril remained stable and that the sales volumes of perindopril increased while the prices of other ACE inhibitor medicinal products fell sharply (between 28% and 90% in Poland, 47% and 58% in France, 88% and 90% in the United Kingdom and 94% and 97% in the Netherlands), following the arrival of generic versions of those medicinal products. The General Court relied on a distinction between qualitative constraints and 'price' constraints, which is artificial, abstract, contrary to the method established to define the relevant market and to the findings in the judgment of 6 December 2012, *AstraZeneca* v *Commission* (C-457/10 P, EU:C:2012:770).
- The Commission submits, next, that the General Court overestimated the importance of the role of prescribing doctors in assessing the characteristics of demand for perindopril. First, the General Court wrongly held, in paragraphs 1393 to 1395 of the judgment under appeal, that demand was solely determined by those prescribers, without taking into account other relevant factors. Second, according to the Commission, the fact that prescribers are not price-sensitive gives more freedom to Servier, which does not have to adjust its prices in order to persuade those doctors to prescribe its perindopril. By focusing on constraints on prescribers rather than those imposed on Servier, the General Court misapplied the concept of the relevant market.
- Lastly, the Commission claims that the General Court, in paragraphs 1385, 1395, 1397, 1401, 1404, 1576 to 1579 and 1584 of the judgment under appeal, disregarded the importance of competition exerted by generic versions of perindopril. After establishing that importance, the General Court should have found that the other ACE inhibitor medicinal products did not exert any constraint over perindopril. It is artificial to consider, as the General Court did in paragraph 1392 of that judgment, that the competitive constraint exerted by generic medicines can be taken into account only after they have actually entered the market.
- By the second, fourth and sixth parts of its eighth ground of appeal, the Commission submits, in essence, that the reasoning in paragraphs 1392 and 1567 to 1586 of the judgment under appeal is insufficient or contradictory.
- 376 Servier submits that the reasoning in the judgment under appeal is sufficient and free of contradictions.

- As regards the substance, Servier and EFPIA maintain, first of all, that the General Court did not err in law in attributing a lower value to the importance of the price factor than the Commission. In the pharmaceutical sector, therapeutic aspects mitigate competitive price pressure. The General Court did not disregard the sharp fall in the prices of the other ACE medicinal products, but held that the stability of the price of perindopril was not sufficient to rule out the existence of competitive pressure on perindopril from those other medicinal products. The General Court did not dismiss the relevance of the analysis of the volume of perindopril sales, but merely disapproved of the importance which the Commission had attached to the price stability of perindopril. It also noted, in paragraphs 1499 and 1500 of the judgment under appeal, that the quantities of the other ACE inhibitor medicinal products sold had also increased more significantly for ramipril than for perindopril. As regards Servier's profitability, the General Court found in paragraph 1559 of that judgment that the Commission had never relied on that factor in order to define the relevant market. The General Court carried out an overall analysis of the competitive constraints, without prioritising them.
- Servier submits, next, that the Commission's line of argument concerning the lack of price-sensitivity of prescribers is inadmissible, since it relates to findings of fact made by the General Court. In any event, that line of argument is unfounded. The General Court did not downplay price-related factors but assessed them taking account of the fact that the particular characteristics of the pharmaceutical sector limited competitive price pressure, without failing to have regard to the function of market definition.
- Lastly, the General Court did not disregard the competitive pressure exerted by generic medicines on perindopril. On the contrary, it held, in paragraph 1579 of the judgment under appeal, that the fall in the price of that medicinal product following the market entry of generic versions did not support the conclusion that there was an absence of competitive constraints before that entry. The fact that those generics are the closest competitors of perindopril does not mean that other ACE inhibitor medicinal products did not exert competitive pressure on that medicinal product, such pressure being evidenced by Servier's promotional policy and internal strategy, as is apparent from paragraphs 1550, 1577 and 1590 of that judgment.

(b) Findings of the Court

- As a preliminary point, it should be noted that, contrary to Servier's contention, the Commission's line of argument relating to the fact that doctors' choices concerning the prescription of a medicinal product are dictated less by considerations relating to the price of that medicinal product than by considerations of a therapeutic nature does not pertain to findings of fact made by the General Court but to the legal characterisation of those findings. That line of argument seeks to challenge both the statement of reasons and the legal criteria on the basis of which the General Court held that, in the decision at issue, the Commission had attached too much importance to the price of perindopril when defining the relevant market. The plea of inadmissibility alleging that the eighth ground of appeal is inadmissible in part must therefore be rejected.
- As regards the substantive assessment of that ground of appeal, it must be borne in mind that the definition of the relevant market, in the application of Article 102 TFEU, is, as a general rule, a prerequisite for any assessment of whether the undertaking concerned holds a dominant position (see, to that effect, judgment of 21 February 1973, *Europemballage and Continental Can v Commission*, 6/72, EU:C:1973:22, paragraph 32), the objective being to define the boundaries within which it must be assessed whether that undertaking is able to behave, to an appreciable

extent, independently of its competitors, customers and consumers (see, to that effect, judgments of 9 November 1983, *Nederlandsche Banden-Industrie-Michelin* v *Commission*, 322/81, EU:C:1983:313, paragraph 37, and of 30 January 2020, *Generics (UK) and Others*, C-307/18, EU:C:2020:52, paragraph 127).

- The definition of the relevant market involves defining, first, the product market and then, second, the geographical market (see, to that effect, judgment of 14 February 1978, *United Brands and United Brands Continentaal* v *Commission*, 27/76, EU:C:1978:22, paragraphs 10 and 11).
- As regards the product market, it is clear from the case-law of the Court of Justice that the concept of the relevant market implies that there can be effective competition between the products or services which form part of it and this presupposes that there is a sufficient degree of interchangeability between all the products or services forming part of the same market in so far as a specific use of such products or services is concerned. Interchangeability or substitutability is not assessed solely in relation to the objective characteristics of the products and services at issue The competitive conditions and the structure of supply and demand on the market must also be taken into consideration (judgment of 23 January 2018, *F. Hoffmann-La Roche and Others*, C-179/16, EU:C:2018:25, paragraph 51 and the case-law cited).
- It follows from those considerations that the assessment of the substitutability of two products is not limited to determining whether those products are, from a functional point of view, capable of satisfying the same need, but also requires a determination as to whether, from an economic point of view, those products are in fact substitutable. Economic substitutability between two products may be found where changes in their relative prices lead to a shift in the sales of one to the other. In that regard, it must be pointed out that, as is apparent from paragraph 13 of the Notice on market definition, referred to in paragraph 2 of this judgment and to which the General Court made reference in paragraph 1384 of the judgment under appeal, from an economic point of view, demand substitutability constitutes the most immediate and effective disciplinary constraint on the suppliers of a given product. The assessment of that substitutability consists essentially in assessing the cross-price elasticity of demand by determining whether consumers of a product subject to a small but permanent price increase would switch to substitute products.
- In the present case, the General Court noted, in paragraph 1404 of the judgment under appeal, the relative price inelasticity of demand for perindopril in relation to the other ACE inhibitor medicinal products and pointed out, in paragraph 1573 of that judgment, that Servier had not challenged that factual matter. That statement is based on the observation, set out in recitals 2460 to 2495 of the decision at issue, that, despite the sharp fall in the prices of ACE inhibitors for the same therapeutic use as perindopril, the price of perindopril had remained stable and its sales volumes had increased during the reference period.
- The General Court considered, however, in essence, in paragraphs 1574 to 1586 of the judgment under appeal, that the fact that demand for perindopril remained stable despite the sharp fall in the prices of the other ACE inhibitors 'does not support the conclusion that there was an absence of qualitative and non-price competitive pressure' until the entry of generic versions of perindopril, on the ground that, on account, in particular, of the particular features of the pharmaceutical sector, competition is based not only on price, but also on the quality of the medicinal products, as recognised by prescribers, in particular through promotional activities by the manufacturers of the other ACE inhibitor medicinal products. In paragraph 1584 of that judgment, the General Court concluded that, in the decision at issue, the Commission had attached excessive importance to the price factor in the definition of the relevant product market.

It must, however, be pointed out that, for the purposes of defining the relevant market, the price and quantity sold of a product are not the expression of a distinct type of competition, which could be contrasted with competition which depends on the quality of that product or the efforts made to ensure its commercial promotion. On the contrary, economic substitutability reflects all the characteristics of the products in question, including those relating to their promotional costs and their intrinsic or perceived quality. The incentive to supply a quality product ultimately depends on the consumer's willingness to pay for that quality, irrespective of the fact that demand for medicinal products is, as the General Court rightly pointed out, guided by prescribing doctors' choices more than by their patients' choices and that those patients generally do not bear the full price – whether regulated or not – because of the intervention of various health insurance mechanisms.

It follows that, irrespective of the specific characteristics of the pharmaceutical sector which are associated with the applicable legislation, with the role of prescribing doctors and with the fact that the price of medicinal products is covered by insurance mechanisms, 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. A finding that there is no such substitutability reveals the existence of a distinct market, whatever the reasons for that finding, whether it be the intrinsic quality of the medicinal product or products falling within that market or the promotional activities undertaken by their manufacturers.

Those considerations were, moreover, duly taken into account by the General Court when, in paragraphs 1380 to 1398 of the judgment under appeal, it set out the principles applicable to the definition of a relevant product market in the pharmaceutical sector. It stated, first, in paragraph 1386 of that judgment, that 'the specific features which characterise competitive mechanisms in the pharmaceutical sector do not negate the relevance of price-related factors in the assessment of competitive constraints, although those factors must be assessed in their specific context'. Second, it stated, in paragraph 1390 of that judgment, that 'the fact that competitive price pressure is largely mitigated in the pharmaceutical sector ... may justify a narrow market definition' and, in paragraph 1391 of that judgment, that where a 'group of products is not subject to a significant extent to competitive constraints from other products, so that that group may be considered to form a relevant product market, the type or nature of the factors that shield that group of products from any significant competitive constraint is of only limited relevance, since the finding of an absence of such competitive constraints leads to the conclusion that an undertaking in a dominant position on the market thus defined would be able to affect the interests of consumers on that market by preventing, through abusive behaviour, the maintenance of effective competition'.

The General Court could not therefore, without manifestly contradicting itself and disregarding those principles, which it had just rightly set out, hold, in paragraphs 1399 to 1405 and 1574 to 1586 of the judgment under appeal, that the relative price inelasticity of demand for perindopril was of little relevance for the purposes of determining the relevant market because it could be explained or justified by the quality of that medicinal product and the importance of its manufacturer's promotional efforts. The General Court therefore erred in law and vitiated by illegality paragraphs 1399 to 1405 and 1574 to 1586 of that judgment.

391 The eighth ground of appeal must therefore be upheld in its entirety.

3. The ninth and tenth grounds of appeal

By its ninth ground of appeal, the Commission submits that the General Court erred in law when it cast doubt, in paragraphs 1418 to 1566 of the judgment under appeal, on the analysis, for the purposes of determining the perindopril market, of therapeutic substitutability between that medicinal product and the other ACE inhibitor medicinal products. By its tenth ground of appeal, the Commission criticises the General Court for having accepted, in paragraphs 1461 to 1463 of that judgment, the admissibility of certain documents annexed by Servier to its pleadings at first instance in order to challenge the Commission's assessment of that therapeutic substitutability.

In the light of the answer given to the eighth ground of appeal, from which it is apparent that the General Court's finding, in paragraph 1585 of the judgment under appeal, that the Commission had wrongly determined on the basis of an analysis of the substitutability of the products based on economic considerations relating to prices that perindopril and the other ACE inhibitor medicinal products were not substitutable is vitiated by contradictory reasoning, it is not necessary to rule on the ninth and tenth grounds of appeal, in so far as those other grounds relate to the therapeutic substitutability of those medicinal products.

4. The eleventh ground of appeal

(a) Arguments of the parties

By its eleventh ground of appeal, the Commission criticises the General Court for having held, in paragraphs 1611 to 1622 of the judgment under appeal, that the definition of the technology market relating to the active ingredient of perindopril and the finding of Servier's dominant position on that market were incorrect. The General Court relied exclusively on the errors which it had found with regard to the definition of the perindopril market. The Commission puts forward three complaints in that regard.

By its first complaint, it submits that those two markets, although neighbouring markets, have different characteristics, both on the supply and demand side. Consequently, the General Court could not state, in paragraph 1615 of the judgment under appeal, that the invalidation of the definition of the perindopril market automatically had to entail the invalidation of the definition of the technology market relating to that medicinal product and, by implication, a finding of Servier's dominant position on that market. The General Court was wrong, in support of that reasoning, to state that it is apparent from recitals 2648 to 2651 of the decision at issue that the demand for technology relating to the active ingredient of perindopril derives from the demand for perindopril. There is nothing in those recitals to suggest that demand for technology relating to the active ingredient of perindopril depends on the definition of the market for that medicinal product.

By its second complaint, the Commission claims that the General Court erred in law in holding, in paragraphs 1618 to 1621 of the judgment under appeal, that the decision at issue could not infer that Servier held a dominant position on the technology market relating to the active ingredient of perindopril on the basis of manifestations of that position on the market, given that, according to what the General Court had held, that market was not limited solely to perindopril. Since those two markets are different, the finding that Servier held a dominant position on the first market does not depend on the existence of its dominant position on the second one.

- By its third complaint, the Commission criticises the General Court for having disregarded the analysis of the technology market relating to the active ingredient of perindopril set out in the decision at issue, in particular in recitals 2632 to 2647, as regards the characteristics of demand, and in recitals 2671 to 2757, as regards Servier's dominant position on that market. The General Court thus failed to respond to the pleas raised before it.
- Servier contends that this ground of appeal is, as a whole, ineffective, since it criticises an assessment concerning the definition of the technology market relating to the active ingredient of perindopril, whereas the General Court did not rule on that issue. Contrary to what the Commission maintains, the General Court did not rule on the definition of that market, but criticised the findings made in the decision at issue with regard to the existence of a dominant position on the part of Servier on that market, on account of errors in the definition of the perindopril market as a medicinal product.
- Furthermore, that ground of appeal cannot lead to the judgment under appeal being set aside, since the Commission did not challenge paragraphs 1627 to 1631 of that judgment on which the operative part of that judgment is based. It is apparent from those paragraphs that the General Court stated (i) that 'Servier's lack of a dominant position on the [perindopril] market calls into question, in itself, the existence of the abuse of a dominant position alleged against Servier' on the technology market relating to the active ingredient of perindopril and (ii) that the decision at issue does not refer to any conduct on the part of that undertaking the infringing nature of which is independent of its alleged dominant position on the perindopril market.
- In addition, Servier submits that the Commission's three complaints are ineffective and lack any factual basis.
- The first complaint concerns factual errors and distorts the judgment under appeal, since the General Court merely found, in paragraph 1615 of that judgment, that, in the decision at issue, the Commission had used the definition of the perindopril market to analyse the technology market relating to the active ingredient of that medicinal product.
- Similarly, the second complaint is based on a distortion of paragraphs 1618 and 1619 of the judgment under appeal, by which the General Court stated that the decision at issue had not examined the two markets at issue independently of each other. On the contrary, it is apparent from Section 7.2.1.2.3 of that decision that demand for technology relating to the active ingredient of perindopril derives from demand for perindopril. The Commission relied on Servier's dominant position on the market for that medicinal product in order to infer that that undertaking held a dominant position on the technology market relating to the active ingredient of that medicinal product.
- As regards the third complaint, it is ineffective, since the Commission did not dispute the General Court's assessment that the errors affecting the definition of the perindopril market had an impact on the definition of the market for the technology relating to the active ingredient of that medicinal product. Servier adds that the Commission merely relies on a failure to respond to a plea, without specifying which plea is concerned.

(b) Findings of the Court

- In paragraph 1615 of the judgment under appeal, the General Court held that, as regards the definition of the market for technology relating to the active ingredient of perindopril, it is apparent from the decision at issue that 'the demand for [that] technology derives from the demand for the finished medicinal product of perindopril (recitals 2648 to 2651 of [that decision])' and that 'the Commission therefore used the erroneous definition of the relevant market which it adopted for the finished product market in its analysis of the technology market, in particular with regard to the assessment of demand on the technology market'.
- However, it is apparent from a reading of recitals 2648 to 2651 of the decision at issue that, although the Commission found that the demand for the technology relating to the active ingredient of perindopril derives from demand for that medicinal product, it also stated, in recital 2649 of that decision, that that characteristic does not mean that the demand conditions for that technology exactly mirrored those of the demand for perindopril.
- On the basis of those factors, the Commission found, in recital 2651 of that decision, that, in view of the relative inelasticity of demand for perindopril, demand for the technology relating to the active ingredient of that medicinal product was also likely to be inelastic. It follows from those factors that, contrary to what is apparent from the wording of paragraph 1615 of the judgment under appeal, the elements set out in recitals 2648 to 2651 of the decision at issue concerning the characteristics of the demand for technology relating to the active ingredient of perindopril are based not on the definition of the perindopril market as such, but on the links between the demand for that technology and the demand for that medicinal product, those two products being complementary, the former being an input used for the production of the second.
- While it is therefore true that the General Court, in paragraph 1615 of the judgment under appeal, set out in a partial and inaccurate manner the content of the decision at issue by implying that the Commission had defined the market for technology relating to the active ingredient of perindopril by merely reproducing the definition of the market for that medicinal product, it limited, in paragraph 1616 of that judgment, the scope of that error, stating that, 'as the Commission argues, it also used, in its analysis of the technology market, other elements to define that market, in particular an analysis of supply-side substitutability (recital 2657 et seq. of the [decision at issue])'.
- Therefore, regardless of the error just found, the Commission's first complaint, by which it alleges, in essence, distortion of the decision at issue, in that the General Court failed to take into consideration the differences between the two markets, both on the supply side and on the demand side, is unfounded.
- Moreover, in paragraphs 1617 to 1619 of the judgment under appeal, the General Court considered that it was not necessary to rule whether or not the definition of the technology market relating to the active ingredient of perindopril was incorrect in order to assess the plea alleging errors in the Commission's finding that Servier held a dominant position on that market, on the ground that the Commission 'relied decisively' on the definition of the perindopril market in order to conclude that Servier was in a dominant position on the technology market relating to the active ingredient of that medicinal product. In paragraph 1621 of that judgment, the General Court drew the logical conclusions from its assessment of the incorrect definition of the perindopril market. It held that the Commission had not been able to demonstrate that Servier was in a dominant position on the technology market relating to the active ingredient of that medicinal product and held, consequently, in paragraph 1622 of that judgment, that it was

necessary to uphold the plea at first instance alleging errors in the Commission's finding that Servier held a dominant position on the technology market relating to the active ingredient of perindopril.

It is apparent from paragraphs 380 to 390 of the present judgment that the General Court's finding relating to the incorrect nature of the definition of the perindopril market is itself vitiated by an error of law. It must therefore be held that the findings made by the General Court in paragraphs 1611 to 1622 of the judgment under appeal concerning Servier's dominant position on the technology market relating to the active ingredient of perindopril are based on an incorrect premiss and are, therefore, vitiated by illegality. Since those findings had a direct influence on point 3 of the operative part of the judgment under appeal, by which the General Court annulled the decision at issue in so far as it found that Servier had infringed Article 102 TFEU, the eleventh ground of appeal must be upheld.

D. Conclusion on the appeal

Since the first to eighth grounds of appeal and the eleventh ground of appeal have been upheld, it is necessary, in accordance with the form of order sought by the Commission, to set aside points 1 to 3 of the operative part of the judgment under appeal, by which the General Court had annulled, first, Article 4 of the decision at issue in so far as it found that Servier had participated in the Krka agreements, second, Article 6 of that decision, which found that Servier had infringed Article 102 TFEU, and third, Article 7(4)(b) and Article 7(6) of that decision, which set the amount of the fine imposed on Servier for the infringements referred to in Articles 4 and 6 of that decision respectively.

VIII. The consequences of setting aside the judgment under appeal

- In accordance with the first paragraph of Article 61 of the Statute of the Court of Justice of the European Union, the Court of Justice may, where it sets aside the decision of the General Court, either itself give final judgment in the matter, where the state of the proceedings so permits, or refer the case back to the General Court for judgment.
- In the present case, as regards the pleas in law of the action at first instance seeking annulment of Article 4 of the decision at issue, which relates to the infringement of Article 101 TFEU, the Court of Justice considers that the state of the proceedings does not permit final judgment to be given on the matter in its entirety. By the second part of its ninth ground of appeal, Servier submits that the Commission made several errors of assessment in characterising the Krka assignment and licence agreement as a restriction of competition by object. As is apparent from paragraph 307 of the present judgment, the General Court invalidated that characterisation on the sole ground that it had rejected the same characterisation in relation to the Krka settlement and licence agreements without, however, ruling on the substance of that second part. The case must therefore be referred back to the General Court for it to rule on the second part of the ninth plea in law of the action at first instance.
- As regards the pleas in law of the action at first instance seeking annulment of Article 6 of the decision at issue, which relates to the infringement of Article 102 TFEU, it is apparent from the response to the eighth ground of appeal that the General Court erred in law in holding that the Commission had wrongly restricted the definition of the relevant market to that of perindopril. The General Court considered that that assessment was sufficient to uphold the fourteenth plea

at first instance, without its being necessary to rule on the first part of that plea, by which Servier alleged several irregularities affecting the Commission's econometric analysis. Since the General Court did not rule on that first part, the state of the proceedings does not permit final judgment to be given on that point.

- In addition, it is apparent from the response to the eleventh ground of appeal in paragraphs 404 to 410 of the present judgment that the General Court did not examine, independently, Servier's sixteenth and seventeenth pleas at first instance, directed against the definition of the technology market relating to the active ingredient of perindopril and the existence of Servier's dominant position on that market, but merely set out the grounds which had led it to uphold Servier's fourteenth plea at first instance, alleging an error in the definition of the perindopril market. The state of the proceedings does not therefore permit final judgment to be given in the matter and the case must therefore be referred back to the General Court for it to rule on the pleas at first instance relating to the infringement of Article 102 TFEU.
- In that context, the Commission requested the Court of Justice to refer the case back to the General Court for judgment by a differently constituted panel of Judges from that which adopted the judgment under appeal.
- However, in accordance with Article 216(1) of the Rules of Procedure of the General Court, where the Court of Justice sets aside a judgment of a Chamber, the case may be assigned to another Chamber sitting with the same number of Judges, and that decision rests with the President of the General Court. In that regard, the Court of Justice has already had occasion to point out that the referral of the case back to a Chamber with an entirely different composition from that which first heard and determined that case may not, under EU law, be regarded as a general obligation (see, to that effect, judgment of 1 July 2008, *Chronopost and La Poste* v *UFEX and Others*, C-341/06 P and C-342/06 P, EU:C:2008:375, paragraph 57). It is not therefore appropriate to grant the Commission's request.
- In the light of the foregoing considerations, it is necessary to refer the case back to the General Court for it to rule on the second part of Servier's ninth plea at first instance, concerning the characterisation of the Krka assignment and licence agreement as a restriction of competition by object, on the fourteenth to seventeenth pleas at first instance, relating to the infringement of Article 102 TFEU, and on the pleas put forward in the alternative at first instance, seeking to challenge the amount of the fine.

IX. The action before the General Court

- In the context of its action at first instance, Servier challenges, by the first part of its ninth plea, the characterisation of the Krka settlement and licence agreements as a restriction of competition by object. By its tenth plea, it disputes the characterisation of the Krka settlement agreement and the Krka assignment and licence agreement as restrictive of competition by effect.
- In the light, in particular, of the fact that those pleas were the subject of an exchange of arguments before the General Court and that their examination does not require the adoption of any additional measure of organisation of procedure or inquiry, the Court of Justice considers that the state of the proceedings permits final judgment to be given in respect of the first part of the ninth plea and of the tenth plea.

A. The first part of the ninth plea in law in the action at first instance

1. Arguments of the parties

By the first part of its ninth plea, Servier disputes the characterisation of the Krka settlement and licence agreements as a restriction of competition by object and sets out, in that regard, five complaints. It submits, first, that 'the Decision distorts the facts by concluding that Krka had the ability to enter the markets within a short period of time', second, that 'the Decision distorts the intentions of the parties and the objectives sought that were nevertheless legitimate', third, that 'the Decision wrongly characterises the agreements as market sharing', fourth, that 'the content of the agreements does not further justify their characterisation as a restriction by object, but rather demonstrates their legitimacy' and, fifth, that 'the Decision wrongly characterises the agreements as restrictions of competition by object whereas their restrictive effects were hypothetical'. It is for the Court to determine whether the Commission's finding of an infringement consisting in the sharing of the perindopril markets by means of the Krka settlement and licence agreements is based on the errors of law and of fact alleged by Servier in the context of those five complaints.

The Commission disputes those arguments.

2. Findings of the Court

- As a preliminary point, it should be recalled that the existence of an infringement of the competition rules can only be correctly determined if the evidence upon which the contested decision is based is considered, not in isolation, but as a whole, account being taken of the specific features of the market of the products in question (judgment of 14 July 1972, *Imperial Chemical Industries* v *Commission*, 48/69, EU:C:1972:70, paragraph 68). The scope of judicial review provided for in Article 263 TFEU extends to all the elements of Commission decisions relating to proceedings under Articles 101 and 102 TFEU, in respect of which it is necessary to ensure an in-depth review, in law and in fact, in the light of the pleas raised by the parties (judgments of 11 September 2014, *CB* v *Commission*, C-67/13 P, EU:C:2014:2204, paragraph 44, and of 21 January 2016, *Galp Energía España and Others* v *Commission*, C-603/13 P, EU:C:2016:38, paragraph 72).
- In that regard, although the first part of the ninth plea in law at first instance consists of five complaints, all the arguments put forward by Servier in that context relate either to the issue whether Krka was a potential competitor of Servier at the time of the conclusion of the Krka settlement and licence agreements, notwithstanding the successive legal defeats suffered by Krka in its attempts to have the 947 patent invalidated, or to the issue whether those agreements, taken together, constituted a market-sharing agreement falling within the characterisation of a restriction of competition by object within the meaning of Article 101(1) TFEU. It should be noted that those arguments of Servier, which are specific to the Krka settlement and licence agreements, overlap with those put forward in the context of its fourth plea at first instance, relating to the inherently legitimate nature of patent dispute settlement agreements and patent licence agreements.
- In accordance with what has been held in paragraph 131 of the present judgment, it is necessary to ascertain, first of all and in so far as Servier raised that question before the General Court, whether the Commission was entitled to characterise the Krka agreements as a restriction of potential

competition exerted by Krka on Servier. To that end, it is necessary to examine whether, on the date on which the Krka settlement and licence agreements were concluded, there were real and concrete possibilities for Krka to enter the perindopril market and compete with Servier. That examination requires that it be determined whether Krka had taken sufficient steps for it to be established that it had the firm intention and inherent ability to enter the market within a period of time capable of putting competitive pressure on Servier, and that it be verified that there were no insurmountable barriers to that entry, bearing in mind that any finding of potential competition can, in appropriate cases, be confirmed by additional factors.

426 If that is the case, it will then be necessary to determine, second, in accordance with what has been held in paragraph 107 of the present judgment, whether the Krka settlement and licence agreements constituted a market-sharing agreement which restricted competition by object within the meaning of Article 101(1) TFEU, as the Commission found to be so in the decision at issue. To that end, it will be necessary to examine the objectives of those agreements and the economic link which, according to the decision at issue, existed between them. More specifically, it will be necessary to assess whether the transfer of value by Servier to Krka, by means of the Krka licence agreement, was sufficiently significant to induce Krka to agree to share the national markets for perindopril with Servier, by refraining, even if only temporarily, from entering Servier's core markets in return for the assurance that it would be able to market its generic version of perindopril on its own core markets, without incurring the risk that it would be the subject of infringement actions brought by Servier. Lastly, it will be necessary to take into account, in so far as Servier raises that issue in a relevant manner, the intentions of the parties to the Krka agreements, as they may contribute to establishing the objective aims that those agreements were intended to achieve.

(a) The potential competition exerted by Krka on Servier

- According to recitals 1672 to 1700 of the decision at issue, Krka was the first manufacturer of generic medicines to challenge Servier's position on the perindopril market. Those two undertakings were already actual competitors on the markets in the Czech Republic, Lithuania, Hungary, Poland and Slovenia, where Krka had started marketing a generic version of perindopril. On the other national markets within the European Union, Krka was a potential competitor of Servier. Krka was preparing its entry to those other markets by means of concrete and sufficient steps, having, inter alia, obtained marketing authorisations in France, the Netherlands and the United Kingdom, and already had a product ready to be launched. On some of those other markets, it benefited from cooperation from commercial partners. The Commission found, in recital 1685 of that decision, that it was apparent from numerous items of documentary evidence predating the EPO decision of 27 July 2006 that Krka was at that time confident of success in proceedings between Krka or its commercial partners and Servier concerning the validity of the 340 and 947 patents.
- Thus, according to the decision at issue, before the conclusion of the Krka settlement and licence agreements, Krka was already competing with Servier on certain national markets and, on those where it was not yet present, it not only had the ability to enter within a short period of time, but also had the firm intention of doing so. In the light of those elements, Krka could be considered to be a potential competitor of Servier.
- Servier does not dispute these elements as such, even though it claims that Krka's strategy 'focused on the central and eastern European markets and not on the western European markets'. It submits that the Commission could not consider that, at the time the Krka settlement and

licence agreements were concluded, Krka could still be considered to be its potential competitor. Servier complains, in essence, that the Commission distorted the intentions of the parties, and more particularly those of Krka, by refusing to accept that the series of court defeats which Krka had suffered convinced it that the 947 patent was valid and that it was therefore preferable for it to negotiate with Servier with a view to obtaining a licence for that patent on its core markets. Those legal defeats suffered by Krka as a result of the EPO decision of 27 July 2006 and the decision of the High Court of 3 October 2006 allegedly constituted an insurmountable barrier to Krka's entering Servier's core markets in the short term. An internal Krka document dated 13 September 2006 is said to show that, as a result of the EPO decision of 27 July 2006, Krka had changed its strategy by deciding to abandon the marketing of its perindopril, composed of the alpha crystalline form of erbumine protected by the 947 patent, in order to invest in the development of a non-infringing form of that medicinal product.

- In addition, Servier notes that, immediately after the EPO decision of 27 July 2006, it was contacted by Krka, which wished to raise the possibility of a patent licence for certain national markets and that, moreover, in the United Kingdom, it initiated proceedings for infringement of the 340 and 947 patents, together with an application for an injunction, against Krka. Although Krka brought a counterclaim for a declaration of invalidity of those patents, it had, according to Servier, little interest in that litigation, which was moreover costly and risky.
- In the present case, in order to determine whether Servier is justified in claiming that, on account of the EPO decision of 27 July 2006 and the decision of the High Court of 3 October 2006, Krka no longer had the ability or the firm intention to enter Servier's core markets, and therefore no longer constituted a source of potential competition, it should be borne in mind that the existence of a patent which protects the manufacturing process of an active ingredient that is in the public domain cannot, as such, be regarded as an insurmountable barrier, and does not mean that a manufacturer of generic medicines which has in fact a firm intention and an inherent ability to enter the market, and which, by the steps taken, shows a readiness to challenge the validity of that patent and to take the risk, upon entering the market, of being subject to infringement proceedings brought by the patent holder, cannot be characterised as a potential competitor of the manufacturer of originator medicines concerned (judgment of 30 January 2020, Generics (UK) and Others, C-307/18, EU:C:2020:52, paragraph 46). Moreover, as it has been held in paragraph 132 of the present judgment, where disputes between them on the question of the validity of the patent in question are still pending, it is necessary to examine all the relevant elements before reaching the conclusion that the holder of the patent and such a manufacturer of generic medicines are not potential competitors.
- As regards Krka's firm intention to continue its efforts to market its perindopril, and the question whether the legal defeats suffered by Krka constituted an insurmountable barrier to its entry within a period of time capable of putting competitive pressure on Servier on the latter's core markets, within the meaning of the case-law referred to in paragraph 101 of the present judgment, it is apparent from the evidence cited by the Commission in recitals 1686 to 1691 of the decision at issue that neither the EPO decision of 27 July 2006 nor the decision of the High Court of 3 October 2006 prompted Krka to cease its efforts to enter those markets. Furthermore, during that period, as is apparent from recitals 1687 and 1700 of the decision at issue, which Servier does not dispute, Krka succeeded in obtaining, in Hungary, in September 2006, the rejection of Servier's application for interim measures relating to the 947 patent, whereas Krka already marketed, on the Hungarian market, its perindopril composed of the alpha crystalline form of erbumine protected by the 947 patent.

- More specifically, in recitals 1687 and 1688 of the decision at issue, the Commission referred to documents showing, on the contrary, that Krka was critical of the EPO decision of 27 July 2006 and determined not to resign itself to it. It follows, inter alia, from the testimony of one of Krka's employees, quoted in full in recitals 895 and 1688 of that decision, that 'especially what bothers us is that the trial was discriminative against [the] generic industry and we shall not let them go just like that'. Such an assertion, made on behalf of Krka, casts doubt on Servier's claim that Krka had given up on challenging the validity of the 947 patent with a view to being able to enter Servier's core markets. In addition, the specific actions taken by Krka after the EPO decision of 27 July 2006 confirm that that undertaking had not accepted the validity of that patent, since it continued to challenge its validity before the EPO and, on 1 and 8 September 2006, filed counterclaims against Servier for invalidity of the 947 and 340 patents in the context of the infringement proceedings brought by Servier in the United Kingdom.
- Moreover, no document contemporaneous with the Krka settlement and licence agreements indicates that the EPO decision of 27 July 2006 and the decision of the High Court of 3 October 2006 changed Krka's perception of the validity of the 947 patent to such an extent as to lead it to abandon its marketing plans for its own perindopril. In particular, Krka's internal documents, dated 13 September 2006, to which Servier refers, and according to which Krka's perindopril-related activities were to cease in favour of work on the development of a non-infringing version of that medicinal product, cannot be interpreted as reflecting a strategic decision of Krka's management. As the Commission stated in recital 1687 of the decision at issue, that internal document merely recorded views expressed at operational meetings within that undertaking's Research and Development Department, the interpretation of which by Servier is, in any event, contradicted by the fact that Krka continued producing its perindopril, composed of the alpha crystalline form of erbumine protected by the 947 patent, as demonstrated by the same internal documents of Krka, as the Commission noted in footnote 2260 to that decision. In any event, in the light of the evidence to the contrary relied on by the Commission in recitals 1686 to 1691 of that decision, that internal document does not convincingly establish that Krka, as Servier asserts, definitively abandoned its intention to enter Servier's core markets with that perindopril following the EPO decision of 27 July 2006. That evidence shows objectively that Krka continued to have an inherent ability to gain access to Servier's core markets and the intention of entering those markets.
- In so far as Servier complains that the Commission 'distorted' the parties' intentions, it should be borne in mind that the Commission acknowledged, in recitals 1688 and 1690 of the decision at issue, that Krka was no longer so firmly convinced of the strength of its litigation position following the EPO decision of 27 July 2006 and that it was in reaction to that decision that Krka had taken the initiative of contacting Servier in order to consider the possibility of Servier's granting it a licence under the 947 patent for certain geographic markets.
- However, nor does that initiative by Krka show that that undertaking had decided not to compete with Servier on the latter's core markets by means of its perindopril composed of the alpha crystalline form of erbumine protected by the 947 patent. As is apparent from the evidence relied on by the Commission in recitals 912 and 1688 of the decision at issue, Krka was aware that Servier had agreed to negotiate with it following the EPO decision of 27 July 2006 because it represented 'a serious threat' to Servier, which 'believed that Krka had [some] of the best and most comprehensive evidence in the opposition before the EPO and in [the] UK revocation'. It follows that the existence of the dispute between Krka and Servier concerning the validity of the 947 patent, which was the subject of proceedings pending before the EPO and in the United Kingdom and which those two undertakings regarded as serious, constitutes further evidence of

the potential competitive relationship between them (see, to that effect, judgment of 30 January 2020, *Generics (UK) and Others*, C-307/18, EU:C:2020:52, paragraph 52), that competition being, moreover, likely to crystallise within a period of time capable of putting competitive pressure on Servier within the meaning of the case-law cited in paragraph 101 of the present judgment. That is necessarily the case since the existence of that competition actually influenced Servier's commercial conduct by leading it to grant a licence to Krka on Krka's core markets.

- Moreover, Servier's argument that Krka had taken the initiative in the negotiations relating to the grant of a licence confuses, on the one hand, Krka's intentions in the event that the negotiations were not successful with, on the other hand, the commercial objectives which Krka pursued in the context of those negotiations. In truth, only Krka's intentions in the event that the negotiations were not successful are relevant for assessing the existence of potential competition between Servier and Krka at the time when the Krka settlement and licence agreements were signed. The allegedly legitimate commercial objectives pursued by Krka in the context of those negotiations were relevant solely for the purpose of assessing the object of those agreements.
- It should be recalled in that regard that the conclusion of an agreement between a number of undertakings, operating at the same level in the production chain, some of which have no presence in the market concerned, constitutes a strong indication that a competitive relationship exists between those undertakings (judgment of 30 January 2020, *Generics (UK) and Others*, C-307/18, EU:C:2020:52, paragraph 55 and the case-law cited).
- If the fact that Krka negotiated with Servier with the aim of concluding agreements such as the Krka settlement and licence agreements was sufficient to demonstrate that Krka no longer had the firm intention of competing with Servier by means of its perindopril composed of the alpha crystalline form of erbumine protected by the 947 patent, or indeed that there was an insurmountable barrier to such entry into Servier's core markets, notwithstanding the existence of objective evidence such as that cited by the Commission in recitals 1686 to 1691 of the decision at issue, that would mean, contrary to the case-law recalled in the previous paragraph, that the decision of an undertaking to negotiate and then to conclude an agreement with another undertaking operating at the same level of the production chain, with the aim of substituting cooperation for competition on the merits, could result in its no longer being a potential competitor of the other party to the contract. If that were the case, the deliberate choice of an undertaking to pursue a commercial policy consisting in concluding an agreement having an anticompetitive object could remove that agreement from the scope of the prohibition laid down in Article 101(1) TFEU and thus deprive that provision of a significant part of its effectiveness.
- In the light of the foregoing, Servier's arguments do not invalidate the Commission's finding, in recital 1700 of the decision at issue, that, on the date the Krka settlement and licence agreements were concluded, Krka was a potential competitor of Servier.
- Servier's arguments relating to the potential competition exerted by Krka must therefore be rejected.

(b) The existence of a market-sharing agreement

By its second complaint, Servier submits that the Commission was wrong to consider that the object of the Krka settlement and licence agreements was to share the markets with Krka.

- Servier asserts, in the first place, that those agreements were concluded because of the recognition of the validity of the 947 patent and were aimed at finding a solution to the disputes between it and Krka. The latter could not market its perindopril because of the 947 patent and the EPO decision of 27 July 2006.
- However, by that line of argument, Servier is merely, in essence, reiterating its claims, alleging recognition of the validity of that patent, relating to the absence of potential competition exerted by Krka and to the existence of an agreement to share markets. Those arguments have already been rejected for the reasons set out in paragraphs 427 to 440 and paragraphs 178 to 184, respectively, of the present judgment.
- Servier disputes, in the second place, the existence of a market-sharing agreement whereby Krka refrained from entering Servier's core markets in return for the establishment of a de facto duopoly on Krka's core markets. According to Servier, it is apparent from the clauses of the Krka settlement and licence agreements that each of those agreements had a legitimate object. In particular, there is no evidence to suggest that the Krka licence agreement was going to establish such a duopoly. On the contrary, numerous documents contemporaneous with the conclusion of the Krka settlement and licence agreements show that competition between those two undertakings was intense. The Commission was wrong to assert, in recitals 1724 and 1728 of the decision at issue, that Servier had undertaken, by means of the Krka licence agreement, not to introduce a third competitor on Krka's core markets. In addition, Servier submits that the decision at issue distorts a document of 29 September 2005, referred to, inter alia, in recital 849 of that decision, in which a Krka employee referred to 'joint activity to control the market'.
- Servier denies that the Krka licence agreement may have induced Krka to accept the restrictions of competition set out in the Krka settlement agreement. Even if that licence agreement constituted an incentive to reach a settlement, such a circumstance would, in itself, be insufficient to find an infringement of Article 101 TFEU, since it is apparent from the parties' intentions that those agreements pursued legitimate objectives. In addition, in recital 1738 of that decision, the Commission assessed at EUR 10 million the profit that Krka could derive from that licence agreement, while minimising its pro-competitive effects, on the ground, set out in recital 1833 of that decision, that 'it is unclear to which extent the Krka settlement agreement actually enhanced competition in the licensed Member States, as Krka had already launched its perindopril in five of these Member States prior to [the Krka settlement agreement]'. Servier also emphasises the fact that, even after the conclusion of those agreements, Krka remained free to enter Servier's core markets with a non-infringing product.
- In so far as Servier relies on the allegedly 'legitimate' nature of the clauses of the Krka settlement and licence agreements, it should be noted at the outset that, although the objective aims that agreements are intended to achieve from a competition standpoint are indeed relevant to determining whether they may have an anticompetitive object, the fact that the undertakings involved acted without having an intention to prevent, restrict or distort competition and the fact that they pursued certain legitimate objectives are not decisive for the purposes of the application of Article 101(1) TFEU (judgment of 21 December 2023, *European Superleague Company*, C-333/21, EU:C:2023:1011, paragraph 167 and the case-law cited). Accordingly, the fact that a commercial strategy under which undertakings operating at the same level of the production chain negotiate such agreements between them in order to put an end to a dispute relating to the validity of a patent is logical and rational from the point of view of those undertakings in no way demonstrates that the pursuit of that strategy is justifiable from the point of view of competition law.

- Furthermore, it is indeed true, as has been held in paragraph 226 of the present judgment, that patent dispute settlement agreements, like licence agreements associated with such agreements, may be concluded with a legitimate aim and entirely lawfully on the basis of the parties' recognition of the validity of the patent in question. Moreover, settlement agreements are encouraged by the public authorities in that they make possible savings in terms of resources and are thus beneficial for the public at large (judgment of 30 January 2020, *Generics (UK) and Others*, C-307/18, EU:C:2020:52, paragraph 79). Similarly, as Servier rightly points out in its application at first instance, it is undeniable that a licence agreement allowing a manufacturer of generic medicines to enter certain markets which are closed to competition because of the existence of a patent is likely, by definition, to produce pro-competitive effects on those same markets.
- However, as is apparent from the case-law referred to in paragraph 226 of the present judgment, the fact that agreements pursue an objective which, in the abstract, may be legitimate cannot exclude those agreements from the application of Article 101 TFEU if it is established that those agreements also have the aim of sharing markets or restricting competition in other ways. Furthermore, as has been recalled in paragraphs 178 to 184 of the present judgment, the fact that an agreement takes a legal form which is in principle legitimate and that the wording of that agreement does not reveal an apparent anticompetitive object is not, in itself, decisive in determining whether the agreement gives rise to an infringement of Article 101(1) TFEU. Every agreement must be assessed in the light of its specific content and its economic context, and in particular in the light of the situation on the market concerned.
- In the present case, the arguments put forward by Servier in the context of its ninth plea in law at first instance, which relate to the content of the Krka settlement and licence agreements disregard, first, the fact that the links between those agreements are such that it was essential to examine their clauses not in isolation, but as forming a whole. Second, those arguments do not take account of the fact that the Krka licence agreement authorised Krka to market its perindopril, composed of the alpha crystalline form of erbumine protected by the 947 patent, on its core markets, to which the infringement of Article 101(1) TFEU found in the decision at issue does not relate, whereas the settlement agreement prohibited Krka from marketing that medicinal product on Servier's core markets, to which that infringement does relate.
- As regards the links between the Krka settlement and licence agreements, it is clear from the wording of those agreements and the circumstances surrounding their conclusion, as recounted by the Commission in recital 1703 of the decision at issue, that, economically, those agreements are connected in the sense that, as the Commission noted in recital 1702 of that decision, one could not have been concluded in the absence of the other. Moreover, that connection is demonstrated by the documentary evidence relied on by the Commission in recitals 1746 and 2103 of the decision at issue, from which it is apparent that Krka considered that the Krka licence agreement was a prerequisite for agreeing to refrain from entering Servier's core markets, since the restrictions laid down in the Krka settlement agreement were indispensable in order to obtain that licence. Thus, in so far as Servier seeks, without disputing the existence of those links as such, to call into question the Commission's analysis of those agreements on the basis of a line of argument which examines those agreements separately in order to establish the allegedly legitimate nature of their content, that line of argument is based on a false premiss. It also follows, as has been held in paragraph 195 of the present judgment, and contrary to Servier's line of argument, that, irrespective of whether or not the level of the royalty provided for in the Krka licence agreement was appropriate in the light of market conditions, it was the access to its core

markets with no risk of patent infringement that led Krka to refrain from selling its perindopril, composed of the alpha crystalline form of erbumine protected by the 947 patent, on Servier's core markets.

- Moreover, Servier's argument based on the allegedly pro-competitive nature of the Krka licence agreement on Krka's core markets is undermined by the fact that that agreement does not cover Servier's core markets, which are the only ones to which the infringement of Article 101(1) TFEU found in the decision at issue relates. That pro-competitive nature, even if it were established, would have a positive impact on competition only on Krka's core markets. In any event, whereas the grant of a licence on certain markets in return for an undertaking by the licensee not to challenge the validity of the patent of the other contracting party in relation to those markets may, subject to an assessment of its specific content and economic context, be regarded as legitimate from a competition perspective, the same is not true where a set of agreements allows that licensee to enter certain geographic markets without risk of patent infringement while at the same time prohibiting it from entering other markets.
- A set of agreements of that sort entails, in principle, a sharing of those markets and, therefore, a restriction of competition by object, which cannot be put in context or offset by any positive or pro-competitive effects on any market whatsoever. The Commission is not to examine the effects of an agreement or of conduct in the context of its assessment of the existence of a restriction of competition by object (see, to that effect, judgment of 21 December 2023, *European Superleague Company*, C-333/21, EU:C:2023:1011, paragraphs 159 and 166 and the case-law cited).
- Furthermore, as the Commission explained in recital 1745 of the decision at issue, it is precisely because the Krka licence agreement and the non-infringement obligation arising from the Krka settlement agreement do not cover the same national markets that, in its view, that licence agreement was not legitimate but rather constituted a significant economic incentive for Krka to accept the restrictions set out in the Krka settlement agreement and, therefore, to share those markets geographically with Servier. That quid pro quo is therefore comparable, from an economic point of view, to a transfer of value within the meaning of the case-law referred to in paragraph 104 of the present judgment. In order to determine whether that analysis is well founded, it is necessary, in accordance with that case-law, to assess whether that transfer of value from Servier to Krka can be explained solely by Servier and Krka's interest in not engaging in competition on the merits.
- In that regard, as has been recalled in paragraphs 427 and 428 of the present judgment, not only did Krka already sell its perindopril on some of its core markets but, in addition, it was ahead of Servier's potential competitors in its plans for marketing a generic version of perindopril, in particular in France and the United Kingdom, two of Servier's core markets. Furthermore, it is apparent from the data relating to the sales of perindopril in, inter alia, recitals 2273 to 2401 of the decision at issue that the price at which Servier sold that medicinal product on the markets in France, the Netherlands and the United Kingdom was much higher than that at which Krka sold its perindopril on the market in Poland. In those circumstances, Servier's incentive to delay the entry of that medicinal product to its core markets was obvious and has not, moreover, been disputed.
- As regards the question whether the Commission was entitled to take the view that the Krka licence agreement constituted consideration for the Krka settlement agreement, it must be borne in mind, first of all, that the Krka licence agreement granted Krka, exclusively and irrevocably, the rights to the 947 patent on Krka's core markets, notwithstanding the possibility that Servier had

reserved for itself of also exploiting those rights, directly or through its subsidiaries or through one third party per country. It follows from that arrangement that, on each of those markets, apart from Servier, its subsidiaries or a third party designated by it, Krka was the only undertaking able to market perindopril composed of the alpha crystalline form of erbumine protected by the 947 patent without risking infringement of that patent.

- Next, as the Commission observed in recitals 1721, 1724, 1728 to 1730 and 1819 of the decision at issue, Servier's decision not to oppose the marketing by Krka, on Krka's core markets, of a generic version of perindopril amounts, from an economic point of view, to a transfer of value to Krka. As a result of that quid pro quo, Servier and Krka were each able to maintain a more favourable position on their respective core markets, Servier having succeeded in eliminating the potential competition resulting from the entry of Krka's perindopril, composed of the alpha crystalline form of erbumine protected by the 947 patent, on its core markets and Krka having obtained the certainty that it would be able to market that medicinal product on its own core markets, without risk of patent infringement.
- In that context, Servier relies on the fact that the Commission downplayed the pro-competitive effect of the Krka licence agreement on Krka's core markets and the advantage which it represented for that undertaking, in so far as Krka was already present on five of those markets. Servier infers from this that the certainty acquired by Krka of being able to market its perindopril, composed of the alpha crystalline form of erbumine protected by the 947 patent, without risk of patent infringement was the only advantage Krka derived from that agreement, according to the reasoning adopted by the Commission itself, and submits that that advantage was not sufficient to induce Krka to refrain from entering Servier's core markets. However, it follows from the evidence relied on by the Commission in recitals 913 and 1748 of the decision at issue that Krka itself indicated to the Commission, on 4 August 2009, in response to a request for information from that institution, that it had 'sacrificed' Servier's core markets, which 'were less significant for Krka', '[in return] for getting immediate access to markets in [central and eastern Europe]'. It therefore follows from the evidence in the file before the Court of Justice that the prospect thus offered to Krka of being the only manufacturer of a generic version of perindopril on its core markets was preferable, from Krka's subjective point of view - even if it had not refrained from entering Servier's core markets in the absence of the grant of a licence covering its own core markets - to the prospect of legal proceedings on Servier's core markets which were likely to be costly, the outcome of which was uncertain and which, if successful, would have benefited all the manufacturers of generic medicines, as the Commission found in recitals 844, 874, 914, 1759 and 1763 of the decision at issue.
- As regards Servier's argument that the existence of a de facto duopoly on Krka's core markets is undermined by the possibility that existed for a subsidiary of Servier or a third party authorised by Servier to enter Krka's core markets, it should be noted, as has been held in paragraph 232 of the present judgment, that the Commission concluded that there was a 'de facto' duopoly and not a 'de jure' duopoly and that, in any event, Servier renounced its de jure monopoly by undertaking to share it exclusively with Krka. In so far as Servier refers to intense competition between Krka and Servier on those markets, it should be noted that, although, in recitals 1728 and 1744 of the decision at issue, the Commission did not deny the existence of a certain degree of competition, the precise degree of competition on those markets is irrelevant because it does not alter the fact that Servier necessarily renounced market share, and therefore part of its profits, in favour of Krka.

- Lastly, as regards the question whether the transfer of value referred to in paragraph 457 of the present judgment was sufficiently significant to have induced Krka to conclude the Krka settlement agreement, it is apparent from recital 1738 of the decision at issue that Krka itself assessed the economic value thus transferred by Servier in return for its undertaking not to enter Servier's core markets at approximately EUR 10 million over a period of three years. That estimate proved to be reliable since, as is apparent from the evidence in the file cited in footnote 4112 to that decision, during the term of the Krka settlement and licence agreements, Krka's profits from the sale of perindopril on the markets in Hungary, Poland and the Czech Republic alone amounted to EUR 10 million. Even if the annual royalty payable by Krka to Servier under the Krka licence agreement is deducted from that amount of EUR 10 million, the fact remains that such a substantial transfer of value from Servier to Krka cannot be explained by any consideration from Krka other than its undertaking not to engage in competition with Servier on its core markets.
- It should be added that none of the other more specific arguments put forward by Servier undermines the Commission's finding that the Krka settlement and licence agreements established market sharing constituting a restriction of competition by object.
- According to Servier, the Commission was wrong to conclude, in recital 1747 of the decision at issue, that 'the geographic scope of the licence [granted to Krka] cannot be explained by patent differences in these territories' because, in reality, there were such differences, since Krka had already entered, at the time that licence was granted, several of the markets covered by that licence, which exposed it to the concrete and immediate risk of patent infringement actions. In putting forward that line of argument, Servier misunderstands the relevance of possible differences that may exist, as regards the patent situation, between geographic markets.
- As the Commission rightly observes in recital 1754 of the decision at issue, such differences are relevant for assessing the legitimacy, from a competition point of view, of the geographic scope of a licence only if they relate to the level of objective risk, on each of those markets, of invalidation of the patent or patents covered by the licence granted. This is because it is not legitimate to 'sacrifice' certain markets, to the detriment of competition on them, in order to obtain a licence on other markets for subjective reasons of commercial expediency. For the same reason, Servier's argument relating to the alleged 'paradox' arising from the fact that the grant of a licence covering a larger number of markets would be more likely to constitute an incentive to abandon markets not covered by that licence must also be rejected. Whatever the number of markets not covered by that licence, the fact remains that, on those markets, competition is restricted.
- Servier argues that the non-challenge and non-infringement clauses on Servier's core markets did not lead to market sharing. Although Krka was prohibited from marketing its perindopril, composed of the alpha crystalline form of erbumine protected by the 947 patent, on account of its allegedly infringing nature, Krka remained free to market a non-infringing version of that medicinal product, which it was, moreover, in the process of developing. However, it is sufficient to note, in that regard, that the fact that a market-sharing agreement limits the opportunities for a potential competitor to compete with the patent holder without, however, ruling out any possibility of competition exerted by that competitor in the long term by developing a non-infringing product, cannot invalidate the conclusion that such an agreement constitutes a restriction of competition by object.

- Servier relies on alleged pro-competitive effects on Servier's core markets due to the fact that the Krka settlement agreement did not prevent Krka from entering Servier's core markets by means of its perindopril, composed of the alpha crystalline form of erbumine protected by the 947 patent, before the expiry of the 340 patent. However, that agreement prohibited Krka from marketing that perindopril on those markets until the 947 patent had expired. Thus, the 'concession' made by Servier in respect of the 340 patent does not invalidate the Commission's assessment of the anticompetitive object of that agreement, given that it prevented Krka from entering Servier's core markets in the short or even medium term.
- As regards Servier's line of argument that the Krka settlement agreement did not prevent Servier's other potential competitors from pursuing their actions seeking to invalidate the 947 patent, it must be held that such a circumstance cannot justify, from the perspective of competition law, the fact that that agreement required Krka to abandon the ongoing litigation between it and Servier in that regard. That is all the more true since, as is apparent from the evidence referred to in paragraph 436 of the present judgment, Servier 'believed that Krka had [some] of the best and most comprehensive evidence in the opposition before the EPO and in [the] UK revocation', which means that the withdrawal of its legal actions was liable significantly to reduce the chances that that patent would be invalidated and therefore to strengthen the control that Servier could exercise on the relevant markets.
- As regards Servier's argument alleging distortion of a document of 29 September 2005, in which a Krka employee referred to 'joint activity [with Servier] to control the market', it should be noted that that document indicates, at the very least, that Krka was open, one year before the conclusion of the Krka settlement and licence agreements, to the idea of cooperating with Servier on certain markets with a view to controlling them together, although that document does not make it possible to identify precisely the markets thus referred to. In any event, that item of evidence forms part of a body of consistent evidence establishing the anticompetitive nature of those agreements but does not in itself constitute indispensable support for the Commission's finding. Thus, even if Servier's claims relating to that item of evidence were in part correct, that argument cannot suffice for the present plea to be upheld.
- It should be added, so far as this point is relevant, to the extent that Servier seeks, by some of its arguments, to downplay the degree of harmfulness of the Krka agreements, that there is no doubt that the restriction of competition found by the Commission was sufficiently harmful to be classified as a restriction of competition by object, within the meaning of the case-law of the Court of Justice (see, by analogy, judgment of 30 January 2020, *Generics (UK) and Others*, C-307/18, EU:C:2020:52, paragraph 67 and the case-law cited). Indeed, as is apparent from the case-law referred to in paragraphs 97 and 238 of the present judgment, agreements which aim to share markets have, in themselves, an object restrictive of competition and fall within a category of agreements expressly prohibited by Article 101(1) TFEU.
- The assessment of all of the parties' arguments and of the evidence in the file therefore leads to the conclusion that the Commission did not make a manifest error of assessment in finding, in recital 1745 of the decision at issue, that, although a patent licence may be a legitimate means for the holder of that patent to grant a third party the right to exploit the invention protected by that patent, the Krka licence agreement had served as an inducement to obtain Krka's undertaking to refrain from entering Servier's core markets, thus allowing those two undertakings to organise a sharing of markets between themselves.

- Servier's line of argument relating to the existence of a market-sharing agreement must therefore be rejected.
- It follows from those matters that the evidence put forward in the decision at issue demonstrates the existence of a practice aimed, for Servier and Krka, at sharing the perindopril market and is sufficient to justify the characterisation of that practice as a restriction of competition by object, in accordance with the case-law of the Court of Justice recalled in paragraphs 96 and 97 of the present judgment.
- In so far as Servier claims, in the alternative, that the decision at issue should be annulled inasmuch as it found a restriction of competition by object specifically on the UK market, notwithstanding the existence of an interim injunction resulting from the decision of the High Court of 3 October 2006 prohibiting Krka from entering that market with its perindopril, composed of the alpha crystalline form of erbumine protected by the 947 patent, it must be borne in mind that such an injunction constitutes an interim measure which in no way prejudges the merits of an infringement action brought by the patent holder (see, to that effect, judgment of 30 January 2020, *Generics (UK) and Others*, C-307/18, EU:C:2020:52, paragraph 53). Thus, the competitive pressure exerted by the possibility of Krka's entering that market did not disappear following the grant of that injunction and that fact cannot therefore invalidate the conclusion reached in the preceding paragraph of the present judgment in relation to the UK market.
- In the light of the foregoing considerations, the first part of the ninth plea in the action at first instance must be rejected and it must be held that Servier has not succeeded in invalidating the characterisation in the decision at issue of the practice relating to Servier and Krka's sharing the perindopril market by means of the Krka settlement and licence agreements as a restriction of competition by object.
- Furthermore, it must be noted that, as has been mentioned in paragraph 424 of the present judgment, in so far as the first part of the fourth plea at first instance, based, in essence, on the inherently legitimate nature of settlement agreements and licence agreements in general, relates specifically to the Krka settlement and licence agreements, it overlaps with the legal arguments put forward by Servier in the context of its ninth plea at first instance. Consequently, it follows from the grounds set out in paragraphs 423 to 473 of the present judgment that, to the extent that the first part of the fourth plea at first instance concerns the Krka settlement and licence agreements, it must also be rejected.

B. The tenth plea in the action at first instance

1. Arguments of the parties

By its tenth plea in the action at first instance, Servier first of all criticises the Commission for having found, in recital 1817 of the decision at issue, that Servier held a dominant position on the market as defined in that decision, a definition which Servier contests in other pleas. It also alleges a failure to state reasons because, in its view, it is not possible to determine whether the Commission carried out a counterfactual analysis in the decision at issue. Servier then complains that the Commission erred in law in its analysis of the counterfactual scenario. First of all, the Commission should have examined the competition that would probably have existed in the

absence of the Krka agreements, taking into account the actual context in which they produced their effects. Servier submits, in that regard, that Krka's withdrawal from the proceedings relating to the validity of the 947 patent had no appreciable effect on the outcome of those proceedings.

- In the absence of the Krka agreements, Krka would probably not have entered the markets in France, the Netherlands and the United Kingdom. According to Servier, such entry was blocked in the United Kingdom by a court injunction. In France and the Netherlands, Krka had abandoned its plans to launch its perindopril. However, the Krka agreements did not eliminate Krka as a potential competitor to Servier in the event of the 947 patent being declared invalid or of the development of a non-infringing version of perindopril. As regards the Krka assignment and licence agreement, Servier submits that it had no effect on competition, since Krka's technology did not enable the 947 patent to be circumvented. Servier observes that, after the revocation of the 947 patent by the EPO decision of 6 May 2009, several manufacturers of generic medicines entered the perindopril market, which demonstrates that that agreement had no anticompetitive effect separate from that patent.
- Servier also criticises recital 1831 of the decision at issue, relating to the measures that Servier and Krka could have taken, when negotiating and concluding the Krka agreements, to prevent those agreements from giving rise to market sharing. It claims that the Commission has not shown that the parties could have reached a settlement on less restrictive terms.
- Lastly, Servier submits that the Commission failed to take into account the pro-competitive effects of the Krka licence agreement in the analysis of the effects of the Krka agreements.
- 479 The Commission disputes those arguments.

2. Findings of the Court

- As a preliminary point, it should be noted that Servier's arguments developed in the context of its tenth plea at first instance overlap with those put forward in the second part of its fourth plea at first instance, according to which the Commission's assessments relating to the effects of the Krka agreements are incorrect. As regards the argument by which Servier disputes the existence of its dominant position on an alleged autonomous perindopril market, a position to which the Commission referred in recital 1817 of the decision at issue, it should be noted that that reference, which is made in the context of a description of Servier's competitive position, is not decisive for the analysis which follows, in recital 1820 et seq. of that decision, of the effects of the Krka agreements on potential competition exerted by Krka on Servier.
- As regards the alleged failure to state reasons resulting from the fact that it is not possible to determine whether the Commission carried out a counterfactual analysis in the decision at issue, it is sufficient to note that, in recital 1814 of that decision, the Commission stated that it was necessary to take into consideration 'competition that would have existed in the absence of the agreement', namely, in particular, 'the competitive behaviour that Krka would have been likely to engage in, absent the agreement'. Accordingly, the decision at issue is not vitiated by a failure to state reasons in that regard.
- It follows from the matters of law set out in paragraphs 339 to 358 of the present judgment that the other arguments relating to the counterfactual scenario which have been put forward by Servier in the context of the present ground of appeal are based on a misinterpretation of the

burden on the Commission to establish proof of the restrictive effects on competition of agreements which, like the Krka agreements, are aimed at establishing market sharing by delaying the market entry of a generic medicine.

- Indeed, as has already been held in paragraph 354 of the present judgment, it was for the Commission to prove that the counterfactual scenario used was realistic and credible. As is apparent, in essence, from paragraph 355 of the present judgment, in so far as, in the present case, the restriction of competition at issue related to the elimination of the source of potential competition exerted by Krka on Servier, the analysis of the counterfactual scenario corresponded, in essence, to the analysis of the existence of that potential competition, which was eliminated by the Krka agreements. Thus, in order to determine whether the Krka agreements, which prohibited Krka from entering the markets in France, the Netherlands and the United Kingdom, had a proven effect on potential competition, it was necessary for the Commission to ascertain whether, in the absence of those agreements, Krka would have had a real and concrete possibility of entering those markets within a period of time capable of putting competitive pressure on Servier, with the result that the threat of such an entry could be regarded as realistic and credible (see, to that effect, judgment of 30 January 2020, *Generics (UK) and Others*, C-307/18, EU:C:2020:52, paragraphs 117 to 120].
- Contrary to Servier's submissions, the Commission was not therefore required to demonstrate that, in the absence of the Krka settlement agreement, Krka would been successful in the legal proceedings against the 947 patent more swiftly or more fully.
- By taking into account, in recitals 1826, 1829 and 1835 to 1846 of the decision at issue, the economic and legal context of the Krka agreements, the Commission was entitled to consider that Krka represented one of the most immediate threats for Servier, on account of the fact that it had real and concrete possibilities of entering the markets in France, the Netherlands and the United Kingdom. The fact that it is not possible to determine with certainty whether Krka would have actually entered those markets has no bearing on the fact that, although it wished to enter those markets and had the means to do so, it agreed with Servier to forego such a possibility, on terms mutually beneficial to those two undertakings.
- In the absence of the Krka agreements, that possibility of entry by Krka, by means of its perindopril, composed of the alpha crystalline form of erbumine protected by the 947 patent, would not have been eliminated. Consequently, the Commission established that the elimination, through the implementation of those agreements, of that source of potential competition had the effect of appreciably restricting competition. Such an elimination of potential competition was therefore an effect that was neither hypothetical nor potential, but real, and such as to justify the characterisation in recital 1850 of the decision at issue as a restriction of competition by effect.
- As regards Servier's argument criticising recital 1831 of the decision at issue, relating to the arrangements that Servier and Krka could have made when negotiating and concluding the Krka agreements in order to prevent those agreements from giving rise to market sharing, it is sufficient to note that, by that recital, the Commission merely observed, correctly, that nothing would have prevented Servier and Krka from concluding different agreements that do not give rise to the market sharing found in paragraphs 442 to 473 of the present judgment. Thus, Servier's argument is based on the incorrect premiss that the Krka agreements did not constitute market sharing and must therefore be rejected.

- It follows that the examination of Servier's tenth plea in the action at first instance has not revealed any error capable of calling into question the Commission's finding, in recital 1850 of the decision at issue, that the Krka agreements had had the effect of appreciably restricting the potential competition exerted by Krka on Servier.
- As regards Servier's reliance on the alleged pro-competitive effects of the Krka licence agreement, it is sufficient to recall, as is apparent in particular from paragraphs 175, 289, 452 and 454 of the present judgment, that that agreement concerns markets which do not fall within the geographic scope of the infringement of Article 101 TFEU, on account of a restriction of competition by effect found by the Commission. Therefore, any pro-competitive effects resulting from that agreement on markets other than those covered by that infringement cannot justify the presence of anticompetitive effects on the markets on which that infringement was found.
- 490 Servier's tenth plea in the action at first instance must therefore be rejected.
- Furthermore, as mentioned in paragraph 480 of the present judgment, the line of argument put forward by Servier in the second part of the fourth plea in law at first instance, according to which the Commission committed errors of law in defining the counterfactual scenario and in examining *ex ante* the effects of the Krka agreements, overlaps with that put forward by Servier in its tenth plea in law at first instance. Consequently, it follows from the grounds set out in paragraphs 480 to 490 of the present judgment that, in so far as that second part of the fourth plea at first instance concerns the characterisation of the Krka settlement and licence agreements as a restriction of competition by effect, it must also be rejected.
- It follows from all of the foregoing that, although, by the present judgment, the Court of Justice has ruled on certain pleas at first instance pursuant to Article 61 of the Statute of the Court of Justice of the European Union, the state of the proceedings does not permit final judgment to be given in its entirety, with the result that Case T-691/14 must be referred back to the General Court for it to examine Servier's pleas in law on which a final ruling has not yet been given.
- As regards the infringement of Article 101 TFEU, referred to in Article 4 of the decision at issue, the Court of Justice, in accordance with the form of order sought by the Commission, has ruled on several pleas at first instance, namely the fourth plea in law, solely to the extent that it relates specifically to the Krka settlement and licence agreements, the first part of the ninth plea in law, and the tenth plea in law. Since the Court of Justice has definitively rejected those pleas, there will no longer be any need for the General Court to examine them.
- However, by the second part of its ninth plea at first instance, Servier submits that the Commission made several errors of assessment in characterising the Krka assignment and licence agreement as a restriction of competition by object. It will be for the General Court to examine that plea after referral.
- As regards the infringement of Article 102 TFEU found by the Commission in Article 6 of the decision at issue with regard to Servier, it will be for the General Court, in the light of the grounds set out in paragraphs 380 to 390 of the present judgment, by which the Court of Justice has upheld the eighth ground of appeal relating to the definition of the perindopril market and, consequently, the eleventh ground of appeal, to rule on the fourteenth to seventeenth pleas at first instance relating to that infringement and on the pleas put forward in the alternative, in so far as they relate to the calculation of the fine imposed in respect of that infringement.

In the light of the foregoing considerations, the case must be referred back to the General Court for it to rule on the second part of the ninth plea in the action at first instance, relating to the characterisation of the Krka assignment and licence agreement as a restriction of competition by object, within the meaning of Article 101 TFEU, on the fourteenth to seventeenth pleas relating to the infringement of Article 102 TFEU, and on the pleas put forward in the alternative, in so far as they relate to the calculation of the fine imposed in respect of that infringement.

Costs

Since the case has been referred back to the General Court, the costs relating to the present appeal proceedings must be reserved.

On those grounds, the Court (First Chamber) hereby:

- 1. Sets aside points 1 to 3 of the operative part of the judgment of the General Court of the European Union of 12 December 2018, Servier and Others v Commission (T-691/14, EU:T:2018:922);
- 2. Refers the case back to the General Court for it to rule on the second part of the ninth plea in the action at first instance, relating to the characterisation of the assignment and licence agreement concluded on 5 January 2007 between Les Laboratoires Servier SAS and KRKA, tovarna zdravil, d.d. as a restriction of competition by object, within the meaning of Article 101(1) TFEU, on the fourteenth to seventeenth pleas at first instance relating to the infringement of Article 102 TFEU referred to in Article 6 of Commission Decision C(2014) 4955 final of 9 July 2014 relating to a proceeding under Article 101 and Article 102 [TFEU] (Case AT.39612 Perindopril (Servier)), and on the pleas at first instance put forward in the alternative, in so far as they relate to the calculation of the fine imposed in respect of that infringement;
- 3. Reserves the costs.

[Signatures]