JUDGMENT OF THE COURT (Fourth Chamber)

25 March 2021 (*)

(Appeal – Competition – Agreements, decisions and concerted practices – Pharmaceutical products – Market for antidepressants (citalopram) – Settlement agreements relating to disputes concerning process patents concluded by a manufacturer of originator medicines who is the holder of those patents and manufacturers of generic medicines – Article 101 TFEU – Potential competition – Restriction by object – Characterisation – Calculation of the amount of the fine)

In Case C-588/16 P,

APPEAL under Article 56 of the Statute of the Court of Justice of the European Union, brought on 18 November 2016,

Generics (UK) Ltd, established in Potters Bar (United Kingdom), represented by I. Vandenborre, advocaat, T. Goetz, Rechtsanwalt, and M. Brealey QC,

appellant,

the other parties to the proceedings being:

European Commission, represented by F. Castilla Contreras, T. Vecchi, B. Mongin and C. Vollrath, acting as Agents, by B. Rayment and D. Bailey, Barristers, and by G. Peretz QC and S. Kingston, Senior Counsel,

defendant at first instance,

supported by:

United Kingdom of Great Britain and Northern Ireland, represented initially by D. Guðmundsdóttir, Z. Lavery and D. Robertson, acting as Agents, and J. Holmes QC, and subsequently by D. Guðmundsdóttir, acting as Agent, and J. Holmes QC,

intervener in the appeal,

THE COURT (Fourth Chamber),

composed of M. Vilaras, President of the Chamber, D. Šváby (Rapporteur), S. Rodin, K. Jürimäe and P.G. Xuereb, Judges,

Advocate General: J. Kokott,

Registrars: M. Aleksejev, Head of Unit, and C. Strömholm, Administrator,

having regard to the written procedure and further to the hearing on 24 January 2019,

having decided, after hearing the Advocate General, to proceed to judgment without an Opinion,

gives the following

Judgment

1 By its appeal, Generics (UK) Ltd (‘GUK’) asks the Court of Justice to set aside the judgment of the General Court of the European Union of 8 September 2016, *Generics (UK)* v *Commission* (T-469/13,

not published, EU:T:2016:454; 'the judgment under appeal'), by which the General Court dismissed its action seeking, first, annulment in part of Commission Decision C(2013) 3803 final of 19 June 2013 relating to a proceeding under Article 101 [TFEU] and Article 53 of the EEA Agreement (Case AT/39226 – Lundbeck) ('the decision at issue') and, second, reduction of the amount of the fine imposed by that decision.

Legal context

2 Article 23(2)(a) of Council Regulation (EC) No 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles [101 and 102 TFEU] (OJ 2003 L 1, p. 1) provides:

'The Commission may by decision impose fines on undertakings and associations of undertakings where, either intentionally or negligently:

(a) they infringe Article [101 or Article 102 TFEU] …'

3 Article 31 of that regulation provides:

'The Court of Justice shall have unlimited jurisdiction to review decisions whereby the Commission has fixed a fine or periodic penalty payment. It may cancel, reduce or increase the fine or periodic penalty payment imposed.'

Background to the dispute

4 The present appeal is one of six related appeals brought against six judgments of the General Court that were delivered following actions for annulment brought against the decision at issue, namely, in addition to the present appeal: the appeal lodged in Case C-586/16 P (*Sun Pharmaceutical Industries and Ranbaxy (UK)* v *Commission*) against the judgment of 8 September 2016, *Sun Pharmaceutical Industries and Ranbaxy (UK)* v *Commission* (T-460/13, not published, EU:T:2016:453); the appeal lodged in Case C-591/16 P (*Lundbeck* v *Commission*) against the judgment of 8 September 2016, *Lundbeck* v *Commission* (T-472/13, EU:T:2016:449); the appeal lodged in Case C-601/16 P (*Arrow Group and Arrow Generics* v *Commission*) against the judgment of 8 September 2016, *Arrow Group and Arrow Generics* v *Commission* (T-467/13, not published, EU:T:2016:450); the appeal lodged in Case C-611/16 P (*Xellia Pharmaceuticals and Alpharma* v *Commission*) against the judgment of 8 September 2016, *Xellia Pharmaceuticals and Alpharma* v *Commission* (T-471/13, not published, EU:T:2016:460), and the appeal lodged in Case C-614/16 P (*Merck* v *Commission*) against the judgment of 8 September 2016, *Merck* v *Commission* (T-470/13, not published, EU:T:2016:452).

5 The background to the dispute was set out in paragraphs 1 to 36 of the judgment under appeal as follows:

'I – The companies involved in the present case

1 H. Lundbeck A/S ("Lundbeck") is a company governed by Danish law which controls a group of companies specialising in the research, development, manufacture, marketing, sale and distribution of pharmaceuticals for the treatment of disorders in the central nervous system, including depression.

2 Lundbeck is an "originator" undertaking, namely an undertaking whose activities are focused on researching new medicinal products and bringing them to the market.

3 Merck KGaA … is a company governed by German law specialising in the pharmaceutical sector which, at the time the agreements concerned were concluded, indirectly held 100% – through the group Merck Generics Holding GmbH … – of its subsidiary [GUK], a company responsible for the development and marketing of generic pharmaceutical products in the United Kingdom. The Commission regarded Merck and GUK as constituting a single undertaking for the purpose of competition law at the time of the infringement ("Merck (GUK)").

II – The relevant product and the applicable patents

4 The relevant product for the purposes of the present case is the antidepressant medicinal product containing the active pharmaceutical ingredient ("API") citalopram.

5 In 1977, Lundbeck filed a patent application in Denmark for the citalopram API and two processes – a cyanation process and an alkylation process – to produce that API. Patents for that API and those two processes ("[Lundbeck's] original patents") were issued in Denmark and in a number of Western European countries between 1977 and 1985.

6 As regards the European Economic Area (EEA), the protection afforded by [Lundbeck's] original patents and, where appropriate, the supplementary protection certificates (SPCs) provided for in Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products (OJ [1992] L 182, p. 1), expired between 1994 (as regards Germany) and 2003 (as regards Austria). In particular, in the case of the United Kingdom, [Lundbeck's] original patents expired in January 2002.

7 Over time, Lundbeck developed other, more effective, processes for the production of citalopram, in respect of which it applied for and often obtained patents in several EEA countries and also from the World Intellectual Property Organisation (WIPO) and the European Patent Office (EPO).

8 Thus, on 13 March 2000 Lundbeck filed a patent application with the Danish authorities relating to a process for the production of citalopram which envisaged a method of purification of the salts used by means of crystallisation. Similar applications were filed in other EEA countries and also with the WIPO and the EPO. Lundbeck obtained patents protecting the crystallisation process in a number of Member States during the first half of 2002, in particular on 30 January 2002 in the case of the United Kingdom … The EPO granted a crystallisation patent on 4 September 2002.

9 Lastly, Lundbeck planned to launch a new antidepressant medicinal product, Cipralex, based on the escitalopram API (or S-citalopram), by the end of 2002 or the beginning of 2003. That new medicinal product was designed for the same patients as those who could be treated by Lundbeck's patented medicinal product Cipramil, based on the citalopram API. The escitalopram API was protected by patents valid until at least 2012.

III – The agreements [in question]

10 During 2002 Lundbeck entered into six agreements concerning citalopram ("the agreements in question") with four undertakings active in the production and/or sale of generic medicinal products (["the manufacturers of generic medicines"]), including Merck (GUK).

11 The first agreement between Lundbeck and Merck (GUK) came into effect on 24 January 2002, for a period of one year, and covered only the territory of the United Kingdom ("the UK agreement"). That agreement was subsequently extended for a period of six months, ending on 31 July 2003. Next, after Merck (GUK) briefly entered the United Kingdom market between 1 and 4 August 2003, a second extension of the agreement was signed by the parties on 6 August 2003, for a maximum period of six months, which could be reduced if Lundbeck failed to initiate legal proceedings against other [manufacturers of generic medicines] which attempted to enter the market or on determination of the litigation between Lundbeck and Lagap Pharmaceuticals Ltd, [one of the other manufacturers of generic medicines].

12 According to the terms of the UK agreement:

– there was a risk that certain actions envisaged by GUK in respect of the marketing, distribution and sale of the "Product" might constitute an infringement of Lundbeck's intellectual property rights and could give rise to claims on the part of Lundbeck (Article 2.1 of the UK agreement), the "Products" being defined in Article 1.1 of the agreement as "the citalopram products developed by GUK in raw material, bulk product

and finished pack form as set out in the Schedule and manufactured in accordance with the specification for Products as supplied by GUK at the date of signature. Attached to Schedule 2";

– Lundbeck would pay GUK the sum of 2 million pounds sterling (GBP), in consideration for the delivery of the "Products", in the quantities set out in the agreement, on 31 January 2002 (Article 2.2 of the UK agreement);

– GUK also undertook, in consideration of a further payment of GBP 1 million, to deliver the "Products", as specified in the schedule, on 2 April 2002 (Article 2.3 of the UK agreement);

– the payments made and the delivery of the "Products" by GUK pursuant to Articles 2.2 and 2.3 of the agreement would constitute full and final settlement of any claim that Lundbeck might have against GUK for infringement of its intellectual property rights in connection with the "Products" delivered by GUK up to that date (Article 2.4 of the UK agreement);

– Lundbeck undertook to sell its "Finished Products" to GUK and GUK undertook to purchase those "Finished Products" exclusively from Lundbeck for resale by GUK and its affiliates in the United Kingdom during the term and subject to the conditions of the agreement (Article 3.2 of the UK agreement), those "Finished Products" being defined in paragraph 1.1 of the agreement as "products containing citalopram in finished pack form to be supplied by [Lundbeck] to GUK pursuant to this Agreement";

– Lundbeck undertook to pay the sum of GBP 5 million guaranteed net profits to GUK, on condition that GUK ordered the agreed volume of "Finished Products" during the term of the agreement (or a lesser amount to be calculated pro rata to the volume ordered) (Article 6.2 of the UK agreement).

13 The first extension of the UK agreement provided, in particular, for monthly payments of the sum of GBP 400 000 per month for the implementation of Article 6.2 of the agreement by GUK and amended the definition of "net profits".

14 The second extension of the UK agreement provided, in particular, for monthly payments of the sum of GBP 750 000 per month for the implementation of Article 6.2 of that agreement by GUK.

15 The UK agreement expired on 1 November 2003, following the settlement of the [litigation between Lundbeck and Lagap Pharmaceuticals]. In total, over the entire term of the agreement, Lundbeck transferred the equivalent of EUR 19.4 million to GUK.

16 A second agreement was concluded between Lundbeck and GUK on 22 October 2002, covering the EEA excluding the United Kingdom ("the EEA agreement"). That agreement provided for payment of the sum of EUR 12 million, in consideration whereof GUK undertook not to sell or supply pharmaceutical products containing citalopram throughout the EEA (excluding the United Kingdom) and to use all reasonable efforts to ensure that Natco Pharma Ltd ("Natco") – the manufacturer of the generic citalopram that Merck (GUK) had intended to market ("the Natco citalopram") – ceased to supply citalopram and products containing citalopram in the EEA during the term of the agreement (Articles 1.1 and 1.2 of the EEA agreement). Lundbeck undertook not to bring legal proceedings against GUK, on condition that it complied with its obligations under Article 1.1 of the agreement (Article 1.3 of the EEA agreement).

17 The EEA agreement expired on 22 October 2003. In total, Lundbeck transferred the equivalent of EUR 12 million to GUK under that agreement.

IV – Steps taken by the Commission in the pharmaceutical sector and administrative procedure

18 In October 2003, the Commission was informed of the agreements in question by the Konkurrence- og Forbrugerstyrelsen (KFST, the Danish authority for [the protection of]

competition and consumers).

19 Since most of those agreements concerned the whole of the EEA or, … in any event, Member States other than [the Kingdom of Denmark], it was agreed that the Commission would examine their compatibility with competition law, while the KFST would not pursue the matter.

20 Between 2003 and 2006, the Commission carried out inspections within the meaning of Article 20(4) of [Regulation No 1/2003] at the premises of Lundbeck and other companies active in the pharmaceutical sector. It also sent Lundbeck and another company requests for information within the meaning of Article 18(2) of that regulation.

21 On 15 January 2008, the Commission adopted the decision initiating an inquiry into the pharmaceutical sector pursuant to Article 17 of Regulation No 1/2003 (Case No COMP/D2/39514). The single article of that decision stated that the inquiry would relate to the introduction of innovative and generic medicinal products for human consumption on to the market.

22 On 8 July 2009, the Commission adopted a communication summarising its report of the inquiry into the pharmaceutical sector. That communication included, in a technical annex, the full version of the inquiry report, in the form of a Commission working document, available only in English.

23 On 7 January 2010, the Commission opened formal proceedings against Lundbeck.

24 In 2010 and the first half of 2011, the Commission sent requests for information to Lundbeck and, among others, to the companies which were parties to the agreements in question, including [GUK].

25 On 24 July 2012, the Commission opened proceedings against the companies which were parties to the agreements in question and sent them, and Lundbeck, a statement of objections.

…

29 On 19 June 2013, the Commission adopted [the decision at issue].

The [decision at issue]

30 By the [decision at issue], the Commission considered that the UK agreement and the EEA agreement (together "the agreements at issue"), as well as the other agreements in question, constituted a restriction of competition "by object" within the meaning of Article 101(1) TFEU and Article 53(1) of the [Agreement on the European Economic Area of 2 May 1992 (OJ 1994 L 1, p. 3)] (Article 1(1) of the [decision at issue]). The agreements at issue were considered to have constituted a single and continuous infringement lasting from 24 January 2002 until 1 November 2003.

31 As is apparent from the summary set out in recitals 824 and 874 of the [decision at issue], the Commission relied, in particular, on the following factors:

– at the time of concluding the agreements at issue, Lundbeck and Merck (GUK) were at least potential competitors in the United Kingdom and in the EEA and actual competitors in the United Kingdom before the second extension of the UK agreement;

– Lundbeck transferred significant value to Merck (GUK) pursuant to those agreements;

– that transfer of value was linked to the acceptance by Merck (GUK) of the limitations on market entry set out in those agreements, notably its commitment not to sell the Natco citalopram or any other generic citalopram in the United Kingdom and in the EEA during the period concerned;

– that transferred value corresponded approximately to the profits Merck (GUK) expected to make if it had successfully entered the market;

– Lundbeck could not have obtained those limitations on entry through enforcement of its process patents, since the obligations on Merck (GUK) under the agreements at issue went beyond the rights granted to holders of process patents;

– the agreements at issue contained no commitment from Lundbeck to refrain from infringement proceedings if Merck (GUK) entered the market with generic citalopram after the expiry of the agreements at issue.

32 The Commission also imposed fines on all the parties to the agreements in question. To that end, it applied the Guidelines on the method of setting fines imposed pursuant to Article 23(2)(a) of Regulation No 1/2003 (OJ 2006 C 210, p. 2). In Lundbeck's case, the Commission followed the general methodology described in … those guidelines, based on the value of sales of the relevant product made by each participant in an infringement (recitals 1316 to 1358 of the [decision at issue]). In the case of the other parties to the agreements in question, namely the [manufacturers of generic medicines], it made use of the possibility, provided for in point 37 of those guidelines, to depart from that methodology, in view of the particularities of the case so far as those parties were concerned (recital 1359 of the [decision at issue]).

33 Thus, as regards the parties to the agreements in question other than Lundbeck, including Merck (GUK), the Commission considered that, in order to determine the basic amount of the fine and to ensure that the fine would have a sufficient deterrent effect, it was appropriate to take account of the value of the sums transferred to them by Lundbeck pursuant to the agreements in question, without differentiating between the infringements on the basis of their nature or geographic scope, or on the basis of the market share of the undertakings concerned, those factors being addressed only for the sake of completeness (recital 1361 of the [decision at issue]). In order to take account of the distribution costs incurred by Merck (GUK), the Commission nonetheless applied a reduction of 10% to that undertaking's turnover (recital 1373 of the [decision at issue]).

34 In view of the total length of the investigation, the Commission granted a reduction of 10% of the fines imposed on all the addressees of the [decision at issue] (recitals 1349 and 1380 of the [decision at issue]).

35 In the light of the separation of Merck from GUK in 2007, the Commission applied the maximum amount of 10% of turnover provided for in [the second subparagraph of] Article 23(2) of Regulation No 1/2003 separately to Merck and GUK (recital 1382 of the [decision at issue]).

36 On the basis of those considerations, the Commission imposed a fine of EUR 21 411 000 on Merck, of which EUR 7 766 843 jointly and severally with GUK (Article 2(1) of the [decision at issue]).'

The procedure before the General Court and the judgment under appeal

6 By document lodged at the Registry of the General Court on 30 August 2013, GUK brought an action for annulment in part of the decision at issue and reduction of the fine imposed on it by the Commission.

7 In support of its action, GUK relied on seven pleas in law. The first, second and third pleas allege, in essence, errors of law and of assessment concerning the interpretation of the concept of 'restriction by object' arising from Article 101(1) TFEU and its application to the agreements at issue. The fourth plea concerns the finding that Merck (GUK) and Lundbeck were potential competitors at the time the agreements at issue were concluded. In essence, the fifth and sixth pleas allege, respectively, infringements of Article 101(3) TFEU and of GUK's rights of defence, while the seventh concerns 'a request for annulment or reduction of the amount of the fine' imposed on it.

8 The General Court dismissed the action in its entirety.

Procedure before the Court of Justice

9 By document lodged at the Registry of the Court of Justice on 18 November 2016, GUK brought the present appeal.

10 Following GUK's application, the President of the Court of Justice granted that company leave to file a reply.

11 By documents lodged at the Registry of the Court of Justice on 28 July 2017, the United Kingdom of Great Britain and Northern Ireland sought leave to intervene in support of the form of order sought by the Commission in this case and in Cases C-586/16 P (*Sun Pharmaceutical Industries and Ranbaxy (UK)* v *Commission*), C-601/16 P (*Arrow Group and Arrow Generics* v *Commission*), C-611/16 P (*Xellia Pharmaceuticals and Alpharma* v *Commission*) and C-614/16 P (*Merck* v *Commission*), referred to in paragraph 4 of the present judgment. By orders of 25 October 2017, *Sun Pharmaceutical Industries and Ranbaxy (UK)* v *Commission* (C-586/16 P, not published, EU:C:2017:831), of 25 October 2017, *Generics (UK)* v *Commission* (C 588/16 P, not published, EU:C:2017:829), of 25 October 2017, *Arrow Group and Arrow Generics* v *Commission* (C-601/16 P, not published, EU:C:2017:826), of 25 October 2017, *Xellia Pharmaceuticals and Alpharma* v *Commission* (C-611/16 P, not published, EU:C:2017:825) and of 25 October 2017, *Merck* v *Commission* (C-614/16 P, not published, EU:C:2017:828), the President of the Court granted those applications. However, in the light, in particular, of the order of the President of the Court of 5 July 2017, *Lundbeck* v *Commission* (C-591/16 P, not published, EU:C:2017:532), the latter ordered, in all of those cases, that the confidential version of the decision at issue, inter alia, was to be treated as confidential in relation to the United Kingdom, and only a non-confidential version of that decision was served on the United Kingdom.

12 On 27 November 2018, the Court of Justice decided that the present case would be assigned to the Fourth Chamber, which was to give judgment following a joint hearing in respect of the present case and Cases C-586/16 P (*Sun Pharmaceutical Industries and Ranbaxy (UK)* v *Commission*), C-591/16 P (*Lundbeck* v *Commission*), C-601/16 P (*Arrow Group and Arrow Generics* v *Commission*), C-611/16 P (*Xellia Pharmaceuticals and Alpharma* v *Commission*) and C-614/16 P (*Merck* v *Commission*) and having heard an Opinion of the Advocate General.

13 On the basis of Article 61(2) of the Rules of Procedure of the Court of Justice, on 29 November 2018 the Court sent a set of written questions to the parties to the proceedings in the present case to be answered orally at the hearing and a provisional plan for the hearing of oral submissions which set out in detail how the hearing was to be conducted. Following the observations of those parties, a final plan for the hearing was sent to them on 22 January 2019.

14 The hearing in this case and in the cases referred to in paragraph 12 of the present judgment was held on 24 January 2019.

15 On 6 February 2020, the Advocate General, on the basis of Article 62 of the Rules of Procedure, sent a question to the parties to the proceedings in the present case to be answered in writing ('the question to be answered in writing of 6 February 2020') in which she invited them to state their views on the possible effect of the judgment of 30 January 2020, *Generics (UK) and Others* (C-307/18, EU:C:2020:52) on the grounds of appeal raised in the present case relating to the existence of potential competition between Lundbeck and the manufacturers of generic medicines and to the characterisation of the agreements concluded between Lundbeck and the latter as 'restrictions by object'. The answers to that question were received by the Court on 6 March 2020.

16 By decision of 10 March 2020, the Court decided, following delivery of the judgment of 30 January 2020, *Generics (UK) and Others* (C-307/18, EU:C:2020:52), to give judgment in the present case without an Opinion.

Forms of order sought by the parties before the Court of Justice

17 By its appeal, GUK claims that the Court of Justice should:

– set aside the judgment under appeal, in whole or in part; and

– order any other measure deemed appropriate.

18 The Commission contends that the Court of Justice should:

– dismiss the appeal in its entirety; and

– order GUK to pay the costs.

19 The United Kingdom claims that the Court of Justice should dismiss the appeal in its entirety.

The appeal

20 In support of its appeal, GUK relies on six grounds.

21 By its first ground, GUK criticises the General Court for having wrongly characterised the agreements at issue as 'restrictions by object' within the meaning of Article 101(1) TFEU. By its second ground, GUK submits that the evidence relied on by the General Court in support of that characterisation is insufficient. By its third ground, GUK complains that the General Court reversed the burden of proof of the existence of a 'restriction by object'. By its fourth ground, GUK claims that the General Court erred in its application of Article 101(3) TFEU to the agreements at issue. By its fifth ground, GUK submits that the General Court's exercise of its power of judicial review was *ultra vires* when it found an infringement of Article 101(1) TFEU which is not identified in the decision at issue. Last, by its sixth ground, GUK submits that the General Court misapplied Article 23(2) of Regulation No 1/2003.

22 In the context of the second part of its second ground, GUK seeks to call into question the General Court's conclusion that Merck (GUK) was a potential competitor of Lundbeck.

23 It is therefore appropriate to start by examining the second part of the second ground, then to move on to look at the first, second and third grounds together – with the exception of the second part of the second ground – and, subsequently, to consider the remaining grounds in turn.

Second part of the second ground of appeal

The relevant paragraphs of the judgment under appeal

24 In rejecting the fourth plea seeking annulment, alleging that Merck (GUK) and Lundbeck were not potential competitors at the time the agreements at issue were concluded, the General Court held, inter alia, in paragraph 102 of the judgment under appeal, that the case-law requires only that it be shown that Merck (GUK) had real concrete possibilities of entering the market and the ability to do so, which, according to the General Court, is certainly the case where a manufacturer of generic medicines is able to enter the market, even at its own risk. The General Court also held, in paragraph 113 of that judgment, that the Commission did not err in finding that the existence of legal obstacles arising from the existence of a patent was not enough to preclude there being potential competition between Merck (GUK) and Lundbeck at the time the agreements at issue were concluded, since it does not appear from the file that those obstacles were insurmountable and that they were perceived as such by the parties to those agreements.

Arguments of the parties

25 By the second part of its second ground of appeal, GUK first of all states that the General Court concluded that GUK was a potential competitor of Lundbeck, since it was common ground that the market entry of a manufacturer of generic medicines can occur even though its product is infringing a patent, though the General Court recognised that it was not certain that GUK would be successful in any litigation proceedings. In that regard, GUK then submits that the General Court could not decide that the burden of proving that Lundbeck's process patents has been infringed rested with Lundbeck, find that it was doubtful that Lundbeck could obtain interim measures, and rely on the fact that GUK's

generic citalopram had been briefly sold in the United Kingdom and in the EEA in order to support its failure to assess the risk of litigation. The first two findings are incorrect, while the third does not constitute an adequate basis for holding that GUK was a potential competitor, since it sold its product in Sweden briefly and through a distributor.

26 Furthermore, the General Court failed to take account of the judgment of the High Court of Justice (England & Wales), Chancery Division (United Kingdom) of 23 October 2001 in *Smithkline Beecham Plc* v *Generics (UK) Ltd* ((2002) 25(1) IPD 25005), in which that court required manufacturers of generic medicines to provide adequate and timely information about the launch of a generic medicine in order to avoid injunctive relief, and of the fact that GUK was liable to pay compensation of EUR 55 million in the event that it entered the market with an infringing product. Therefore, according to GUK, the General Court could not merely find that the barriers to market entry linked to patent litigation were 'not insurmountable', but had to ascertain whether such entry was an economically viable strategy, in accordance with the case-law cited in paragraph 71 of the judgment under appeal.

27 The Commission contends that the second part of the second ground of appeal must be rejected.

Findings of the Court

28 It should be noted at the outset that the second part of the second ground of appeal raised by GUK does not concern an infringement of Article 101(1) TFEU due to the characterisation of the agreements at issue as 'restrictions by object', as suggested by the heading of that ground, according to which 'the evidence supporting the [General Court's] findings does not meet the requirement of accurate, reliable, consistent and comprehensive evidence, which [the Court of Justice] has identified as necessary to meet the burden of proving a by object infringement'.

29 By that part, GUK is in fact criticising the finding that Merck (GUK) and Lundbeck are potential competitors, which forms part of the preliminary assessment, as shown by the order in which the pleas of law were dealt with in the judgment under appeal; it is therefore appropriate to examine that part in the first place.

30 In particular, GUK criticises the General Court for having found, in paragraph 102 of the judgment under appeal, that Merck (GUK) had real concrete possibilities of entering the market 'even at its own risk' and for having concluded, in paragraph 113 of that judgment, that obstacles arising from patent litigation were 'not … insurmountable'. GUK claims that it is not sufficient for the General Court to observe that the obstacles that Merck (GUK) faced were not 'insurmountable', since it held in paragraph 71 of the judgment under appeal that an undertaking cannot be described as a potential competitor if its entry into a market is not an economically viable strategy.

31 In that regard, it should be recalled at the outset that, if the conduct of undertakings is to be subject to the prohibition in principle laid down in Article 101(1) TFEU, that conduct must not only reveal the existence of coordination between them – in other words, an agreement between undertakings, a decision by an association of undertakings or a concerted practice – but that coordination must also have a negative and appreciable effect on competition within the internal market (judgment of 30 January 2020, *Generics (UK) and Others*, C-307/18, EU:C:2020:52, paragraph 31).

32 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 who are in competition with each other, if not in reality, then at least potentially (see, to that effect, judgment of 30 January 2020, *Generics (UK) and Others*, C-307/18, EU:C:2020:52, paragraph 32).

33 In order to assess whether an undertaking that is not present in a market is a potential competitor of one or more other undertakings that are already present in that market, it must be determined whether there are real and concrete possibilities of the former joining that market and competing with one or more of the latter (judgment of 30 January 2020, *Generics (UK) and Others*, C-307/18, EU:C:2020:52, paragraph 36 and the case-law cited).

34 In the case of agreements such as the agreements at issue, the effect of which is temporarily to keep several undertakings outside a market, it must be determined, having regard to the structure of the market and the economic and legal context within which it operates, whether there would have existed, in the absence of those agreements, real and concrete possibilities for those undertakings to enter that market and compete with the undertakings established in that market (see, to that effect, judgment of 30 January 2020, *Generics (UK) and Others*, C-307/18, EU:C:2020:52, paragraphs 37 and 39).

35 Specifically, with regard to such agreements occurring in the context of the opening of the market, for a medicine containing an active ingredient that has recently entered the public domain, to the manufacturers of generic medicines, it should be established, by taking due account of the regulatory constraints that are characteristic of the medicine sector and of the intellectual property rights and, in particular, the patents held by the manufacturers of originator medicines relating to one or more processes for the manufacture of an active ingredient that is in the public domain (see, to that effect, judgment of 30 January 2020, *Generics (UK) and Others*, C 307/18, EU:C:2020:52, paragraphs 40 and 41), whether the manufacturer of generic medicines has in fact a firm intention and an inherent ability to enter the market, and 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, paragraph 58).

36 In order to do so, it is necessary to assess, first, whether, at the time when those agreements were concluded, that manufacturer 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. 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 and 45). 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 at a time when the former was not present on the market concerned (see, to that effect, judgment of 30 January 2020, *Generics (UK) and Others*, C-307/18, EU:C:2020:52, paragraphs 54 to 56).

37 Specifically, with regard to the assessment of whether there are barriers to entry into the market concerned which are insurmountable, the Court has held 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 such an insurmountable barrier, regardless of the presumption of validity attached to that patent, since that presumption sheds no light, for the purposes of applying Articles 101 and 102 TFEU, on the outcome of any dispute in relation to the validity of that patent (see, to that effect, judgment of 30 January 2020, *Generics (UK) and Others*, C-307/18, EU:C:2020:52, paragraphs 46 to 51).

38 Consequently, the existence of such a patent does not, as such, mean that a manufacturer of generic medicines who has in fact a firm intention and an inherent ability to enter the market, and who, 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).

39 It follows from the above that, in the present case, and contrary to what is maintained by GUK, the General Court cannot be criticised for making an error of law on the ground that, in essence, it found, in paragraph 102 of the judgment under appeal, that the criterion to be taken into consideration in order to conclude that a manufacturer of originator medicines and a manufacturer of generic medicines are competitors is that the latter must have real and concrete possibilities of entering the market and the ability to do so. Nor did the General Court err in law when it found, in paragraph 113 of the judgment under appeal, that the existence of legal obstacles arising from the existence of a patent was not enough to preclude there being potential competition between Merck (GUK) and Lundbeck at the time the agreements at issue were concluded, since, in its assessment of the facts which is not open to review, it was not apparent from the file that those obstacles were insurmountable or that they were perceived as such by the parties to those agreements.

40 Accordingly, the second part of the second ground of appeal must be rejected as being unfounded.

First, second and third grounds of appeal

The relevant paragraphs of the judgment under appeal

41 By paragraphs 130 to 343 of the judgment under appeal, the General Court rejected the first, second and third pleas relied on by GUK in support of its action for annulment alleging infringement of Article 101(1) TFEU in so far as the agreements at issue were characterised as 'restrictions by object'.

42 After recalling the applicable principles and case-law in paragraphs 132 to 138 of the judgment under appeal, the General Court summarised the decision at issue in paragraphs 142 to 145 of that judgment; those paragraphs stated, inter alia, as follows:

> '142 It can … be seen from the [decision at issue] that, although the restrictions set out in the agreements at issue fell within the scope of the Lundbeck [process] patents (that is to say that those agreements prevented only the market entry of generic citalopram deemed by the parties to those agreements to potentially infringe those patents and not that of every type of generic citalopram), they were nevertheless restrictions on competition "by object", since, inter alia, they prevented or rendered pointless any type of challenge to Lundbeck's [process] patents before the national courts, whereas, according to the Commission, that type of challenge is part of normal competition in relation to patents (recitals 603 to 605, 625, 641 and 674 of the [decision at issue]).
>
> 143 In other words, according to the Commission, the agreements at issue had transformed the uncertainty in relation to the outcome of such litigation into the certainty that the generics would not enter the market, which could also constitute a restriction on competition by object when such limits did not result from an assessment, by the parties, of the merits of the exclusive right at issue, but rather from the size of the reverse payment which, in such a case, overshadowed that assessment and induced the [manufacturer of generic medicines] not to pursue its independent efforts to enter the market (recital 641 of the [decision at issue]).
>
> 144 It must be noted, in that respect, that the Commission did not find, in the [decision at issue], that all patent settlement agreements containing reverse payments were contrary to Article 101(1) TFEU; it found only that the disproportionate nature of such payments, combined with several other factors – such as the fact that the amounts of those payments seemed to correspond at least to the profit anticipated by the [manufacturers of generic medicines] if they had entered the market, the absence of provisions allowing the [manufacturers of generic medicines] to launch their product on the market upon the expiry of the agreement without having to fear infringement actions brought by Lundbeck, or the presence, in those agreements, of restrictions going beyond the scope of Lundbeck's [process] patents – led to the conclusion that the agreements at issue, in the present case, had as their object the restriction of competition, within the meaning of Article 101(1) TFEU (see recitals 661 and 662 of the [decision at issue]).'

43 Next, the arguments raised by GUK were rejected by the General Court in view of the content of the agreements at issue, in paragraphs 154 to 205 of the judgment under appeal, their purpose, in paragraphs 206 to 236 of that judgment, and their context, in paragraphs 237 to 343 of that judgment.

44 Within that framework, the General Court observed, in paragraph 151 of the judgment under appeal, that it is not necessary that agreements of the same type as the agreements at issue have already been censured by the Commission in order for the latter to be held to constitute a restriction of competition by object.

45 With regard to the UK agreement, the General Court noted in particular, in paragraphs 170 to 177 of the judgment under appeal, that even if the Commission had not established to the requisite legal standard that the restrictions set out in the that agreement went beyond the scope of Lundbeck's process patents, that agreement had to be characterised as a 'restriction by object' since, far from settling any patent dispute between the parties to the UK agreement, GUK's commitments had been obtained in exchange for significant reverse payments the purpose of which was to prevent Merck (GUK) from entering the market with its generic products containing the Natco citalopram during the term of that agreement. According to the General Court, by doing so, the UK agreement transformed

the uncertainty regarding the outcome of any infringement actions into the certainty that Merck (GUK) would not enter the market with its generic products during the term of that agreement, whereas the limitations on Merck (GUK)'s commercial autonomy arose not exclusively from an evaluation, by the parties to the agreement, of Lundbeck's process patents, but rather from the size of the reverse payment which, in such circumstances, overshadowed that evaluation and induced Merck (GUK) not to pursue its efforts to enter the market. In addition, the General Court held in paragraphs 176 and 177 of the judgment under appeal that, even though Merck (GUK) could, in theory, have sold types of finished products other than those of Lundbeck, Merck (GUK) had no incentive to do so, since it was able, without taking any risks, to obtain GBP 5 million as guaranteed profits for the sale of Cipramil, a sum described as 'net profits' under the UK agreement.

46 As regards the EEA agreement, the General Court noted, inter alia, in paragraph 192 of the judgment under appeal, that its objective was not only to keep Merck (GUK) out of the EEA markets, as a seller of generic products based on the Natco citalopram, but also to keep out Natco as a producer of generic citalopram in that territory.

47 In paragraphs 196 and 205 of that judgment, the General Court also found that the agreements at issue were not capable of resolving a dispute or potential litigation between Merck (GUK) and Lundbeck.

48 In paragraphs 213 and 214 of that judgment, the General Court also stated that, in order to establish the existence of a 'restriction by object' in the present case, the Commission was not required to assess the scope of Lundbeck's process patents by showing that Merck (GUK) objectively had a realistic prospect of success in litigation concerning those patents, but could rely instead on the perception that the parties to the agreements at issue had of their position as regards patents and of their chances of succeeding in the event of litigation at the time those agreements were concluded, by taking into account objective elements, which is what the Commission did.

49 In paragraphs 243 to 245 and paragraph 250 of the judgment under appeal, the General Court found that GUK could not rely on the presumption of validity enjoyed by Lundbeck's process patents, since the existence of such patents does not entail the right to exclude temporarily or definitively an actual or potential competitor from the market, under the guise of settling certain disputes, where the outcome of those disputes is highly uncertain and where it can be seen both from the content of the agreements concerned and from their context that the purpose of those agreements is to restrict competition, which is consistent with the case-law deriving from the judgment of 25 February 1986, *Windsurfing International* v *Commission* (193/83, EU:C:1986:75).

50 In paragraphs 260 to 263 and paragraph 268 of the judgment under appeal, the General Court held, by relying in particular on the judgment of the Supreme Court of the United States of 17 June 2013, *Federal Trade Commission* v *Actavis* (570 U.S. (2013)), that, even though the existence of a reverse payment in the context of a patent settlement agreement is not always problematic, the existence of a reverse payment may constitute an indication that there is a 'restriction by object' where it is apparent that that payment induced the manufacturer of generic medicines not to pursue its efforts to enter the market, as in the present case. In paragraph 261 of that judgment, the General Court also stated that, in the view of the Commission, the reverse payments at issue were disproportionate.

51 In paragraphs 271 to 274 of the judgment under appeal, the General Court also stated that the Commission's characterisation of the agreements at issue as 'restrictions by object', was consistent with the judgments of 20 November 2008, *Beef Industry Development Society and Barry Brothers* (C-209/07, EU:C:2008:643), and of 11 September 2014, *CB* v *Commission* (C-67/13 P, EU:C:2014:2204).

52 Last, in paragraphs 293 to 296 of the judgment under appeal, the General Court rejected GUK's argument that characterising the agreements at issue as 'restrictions by object' presupposed that the reverse payments at issue exceeded the profits expected by Merck (GUK). In that regard, the General Court found that that factor had been only a contextual element, taken into consideration by the Commission, when the General Court distinguished, in paragraphs 293 and 294 of that judgment, the agreements at issue from the agreement concluded between Lundbeck and Neolab Ltd which had also

given rise to a reverse payment but which the General Court concluded was in fact intended to settle a dispute but not, however, to delay the market entry of generic medicines.

Arguments of the parties

53 By its first ground of appeal, GUK submits that the agreements at issue were wrongly characterised as 'restrictions by object' by the General Court, contrary to the case-law arising from the judgment of 11 September 2014, *CB* v *Commission* (C-67/13 P, EU:C:2014:2204). The finding in paragraph 274 of the judgment under appeal that the agreements at issue had made it possible to delay GUK's entry into the markets concerned, as well as the finding in paragraphs 142 and 143 of that judgment that the agreements at issue transformed the uncertainty regarding the outcome of an infringement action into certainty that a manufacturer of generic medicines would not enter a market, were, it argues, insufficient to establish the existence of a 'restriction by object', especially since the General Court stated on several occasions that its conclusions regarding the content of the settlement agreements and their implications were open to question, in particular in paragraphs 221, 233 and 296 of the judgment under appeal. GUK argues that the General Court expressed doubts and uncertainty concerning essential elements of the analysis, in particular as to the likelihood of GUK entering the market, the date of that entry and the impact of the sums which it received.

54 According to GUK, the General Court also misapplied the requirement relating to prior experience of agreements constituting 'restrictions by object', as explained in paragraph 21 of the judgment of 26 November 2015, *Maxima Latvija* (C-345/14, EU:C:2015:784). While the General Court does not consider the patent dispute settlement agreements to be 'shams', it does not make reference to any evidence to support its conclusion that those agreements reveal, as such, a sufficient degree of harm. In that regard, the General Court cannot rely, in paragraph 263 of the judgment under appeal, on the judgment of the Supreme Court of the United States of 17 June 2013, *Federal Trade Commission* v *Actavis* (570 U.S. (2013)), since the General Court's conclusion is absolutely at variance with its reading of that judgment. Nor can it rely on the judgments of 20 November 2008, *Beef Industry Development Society and Barry Brothers* (C-209/07, EU:C:2008:643); of 19 March 2015, *Dole Food and Dole Fresh Fruit Europe* v *Commission* (C-286/13 P, EU:C:2015:184), and of 16 July 2015, *ING Pensii* (C-172/14, EU:C:2015:484), which do not concern the exercise of exclusive rights.

55 By its second ground of appeal – with the exception of the second part thereof, which has previously been rejected as unfounded in paragraph 40 of the present judgment – GUK submits that the evidence relied on by the General Court does not constitute accurate, reliable, consistent and comprehensive evidence which allows the agreements at issue to be characterised as 'restrictions by object', given that the General Court failed to carry out an in-depth review of that evidence, in accordance with paragraphs 44 and 45 of the judgment of 11 September 2014, *CB* v *Commission* (C-67/13 P, EU:C:2014:2204).

56 First, GUK claims that the General Court's conclusion that the EEA agreement contained restrictions going beyond the scope of Lundbeck's process patents is based on an interpretation of that agreement which has no regard for context and is contrary to its interpretation of the UK agreement, which took into account the exclusive supply agreement in respect of the Natco citalopram concluded between GUK and Schweizerhall Pharma International GmbH.

57 Second, GUK claims that the General Court could not infer from the evidence that Merck (GUK) was confident that its product was non-infringing, given the doubts that that party and Lundbeck were found to have had in that regard in the judgment under appeal.

58 Third, GUK criticises the General Court for having found, in paragraphs 144 and 261 of the judgment under appeal, that the amount of the reverse payments was 'disproportionate', despite the fact that it found, in paragraph 296 of that judgment, that the Commission was not required to show that those payments exceeded the expected profits and that the General Court acknowledged, in paragraph 260 of that judgment, that the existence of reverse payments is not always problematic. In addition, according to GUK, the General Court could not infer from the finding that those payments were disproportionate and from other factors that the object of the agreements at issue was to restrict competition, nor could it assert that GUK had not provided a plausible explanation as to why Lundbeck paid it the amounts in

question, and that those agreements made no reference to the costs linked to any litigation. Furthermore, in so far as it relied on the judgment of the Supreme Court of the United States of 17 June 2013, *Federal Trade Commission* v *Actavis* (570 U.S. (2013)), the General Court should have noted in that judgment that that court takes the view that 'the size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness' in the context of an in-depth study of the reasonableness of the restriction at issue.

59 Fourth, GUK submits that the General Court could not find, in paragraph 205 of the judgment under appeal, that the agreements at issue were not capable of resolving patent disputes, while referring to the litigation with Lagap Pharmaceuticals as a basis for terminating those agreements. In that regard, the inclusion in those agreements of an express clause in which Lundbeck waives its right to bring an action for infringement of its process patents upon the expiry of those agreements was not necessary since the agreements at issue provided that they would terminate in the event that Lundbeck was unsuccessful in its dispute with Lagap Pharmaceuticals since, in that case, Lundbeck would no longer have had any interest in bringing actions against other manufacturers of generic medicines.

60 Fifth, in GUK's opinion, the judgment under appeal is inconsistent in that its conclusions regarding the agreements at issue are different from those regarding the agreement between Lundbeck and Neolab, which was held, in paragraph 294 of the judgment under appeal, to be legitimate without any clear explanation and despite, first, the fact that that agreement provided that Neolab would suspend sales until the final judgment in *Lundbeck* v *Lagap Pharmaceuticals* in return for compensation if the patent in question was cancelled at Neolab's request, and, second, the fact that Neolab had subsequently agreed to enter into an agreement with Lundbeck in return for a cash payment.

61 By its third ground of appeal, GUK submits that the General Court erred in law by reversing the burden of proof of the existence of a 'restriction by object' by requiring GUK, in paragraphs 76, 77 and 83 of the judgment under appeal, to prove that litigation would certainly have occurred and that it would certainly have been unsuccessful if Lundbeck had brought an action. In that regard, GUK states that the judgment of 12 April 2013, *CISAC* v *Commission* (T-442/08, EU:T:2013:188), to which the General Court refers, is not applicable to the present case since it concerned evidence of a concerted practice. Moreover, the General Court relied several times on factors which, by its own admission, were uncertain or doubtful, thereby giving the Commission the benefit of that doubt, as is apparent from paragraphs 104, 122, 124 and 125 of the judgment under appeal. The General Court also held that it was not required to assess whether, on the basis of the relevant documents, there was clear and convincing evidence that Merck (GUK) had realistic prospects of success in litigation, and took into account, in paragraphs 212 and 214 of the judgment under appeal, only the perception of the parties to the agreements at issue as to their chances of success in litigation at the time those agreements were concluded, which is contrary to the judgment of 1 July 2010, *AstraZeneca* v *Commission* (T-321/05, EU:T:2010:266, paragraph 362). GUK also argues that a patent dispute settlement agreement does not help to establish the existence of an infringement, but merely reflects the exercise of a right conferred by a patent and shows that such agreements are not shams. In that regard, GUK observes that the Court of Justice, in paragraphs 26 and 28 of the judgment of 25 February 1986, *Windsurfing International* v *Commission* (193/83, EU:C:1986:75), held that the Commission '[could] not refrain from all action when the scope of the patent [concerned] is relevant for the purposes of determining whether there has been an infringement of Article [101] or [102 TFEU]', and claims that the General Court must examine whether 'the Commission has made a reasonable assessment of the scope of the patent', which the General Court failed to do. Finally, while it is true that the fact that agreements may prove to be the most profitable or least risky solution does not exclude the application of Article 101 TFEU, it is however still necessary to establish the existence of the infringement.

62 The Commission contends that the first, second and third grounds of appeal are inadmissible in part and are unfounded in any event.

Findings of the Court

63 As a preliminary point, it should be noted that, under the second subparagraph of Article 256(1) TFEU and the first paragraph of Article 58 of the Statute of the Court of Justice of the European Union, an appeal lies on points of law only. The General Court has exclusive jurisdiction to find and appraise the

relevant facts and to assess the evidence. The appraisal of those facts and the assessment of that evidence therefore do not, save where the clear sense of 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.

64 With regard to GUK's arguments put forward in the context of its second ground of appeal and relating to the findings made by the General Court concerning the scope of the EEA agreement, on the fact that the agreements at issue were not capable of resolving a dispute or potential litigation between Merck (GUK) and Lundbeck (paragraph 205 of the judgment under appeal), or on the fact that Merck (GUK) was confident that its product was non-infringing, it should be noted that they seek to call into question a finding, an appraisal of the facts or an assessment of the evidence made by the General Court, without GUK having alleged or, a fortiori, shown any distortion of the clear sense of the facts or evidence by that court.

65 Those arguments are therefore inadmissible.

66 As to the remainder, with regard to the characterisation of a concerted practice as a 'restriction by object' within the meaning of Article 101(1) TFEU, the Court of Justice has held previously, as the General Court pointed out in paragraphs 133 to 137 of the judgment under appeal, that the concept of restriction of competition 'by object' must be interpreted strictly and can be applied only to some 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, since some forms of coordination between undertakings can be regarded, by their very nature, as being harmful to the proper functioning of normal competition (judgment of 30 January 2020, *Generics (UK) and Others*, C-307/18, EU:C:2020:52, paragraph 67 and the case-law cited).

67 With regard to similar settlement agreements that cover disputes over a process patent for the manufacture of an active ingredient that is in the public domain which have been concluded between a manufacturer of originator medicines and several manufacturers of generic medicines and have the effect of delaying the market entry of generic medicines in exchange for monetary or non-monetary transfers of value from the former to the latter, the Court has held that such agreements cannot be considered to be 'restrictions by object' in all cases for the purpose of Article 101(1) TFEU (judgment of 30 January 2020, *Generics (UK) and Others*, C-307/18, EU:C:2020:52, paragraphs 84 and 85).

68 However, such characterisation as a 'restriction by object' must be adopted when it is plain from the examination of the settlement agreement concerned that the transfers of value provided for by it cannot have any explanation other than the commercial interest of both the holder of the patent and the party allegedly infringing the patent not to engage in competition on the merits, since agreements whereby competitors deliberately substitute practical cooperation between them for the risks of competition can clearly be characterised as 'restrictions by object' (see, to that effect, judgment of 30 January 2020, *Generics (UK) and Others*, C 307/18, EU:C:2020:52, paragraphs 83 and 87).

69 For the purpose of that examination, it is appropriate to assess on a case-by-case basis whether the net gain of the transfers of value from the manufacturer of originator medicines to the manufacturer of generic medicines was sufficiently significant actually to act as an incentive to the latter to refrain from entering the market concerned and, consequently, not to compete on the merits with the manufacturer of originator medicines; however, there is no requirement that the net gain should necessarily be greater than the profits which that 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 93 and 94).

70 In the present case, it is apparent from paragraphs 143, 173, 196, 268 and 274 of the judgment under appeal that the agreements at issue were not intended to settle a patent dispute, made it possible to delay the market entry of Merck (GUK) and were accompanied by payments made by Lundbeck to Merck (GUK) which, due to their size, induced Merck (GUK) not to continue its efforts to enter the market.

71 As regards the UK agreement, the General Court held, in paragraph 174 of that judgment, that that agreement had, in any event, transformed the uncertainty regarding the outcome of any infringement

actions into the certainty that Merck (GUK) would not enter the market with its generic medicines during the term of that agreement given the size of the transfer of value which induced it not to pursue its efforts to enter the market. The General Court also noted, in paragraphs 176 and 177 of that judgment, notwithstanding some equivocal findings such as those mentioned by GUK, that, in the light of the amount of that transfer of value, Merck (GUK) had no incentive to sell types of finished products other than those of Lundbeck, since it was able, without taking any risks, to obtain GBP 5 million as guaranteed profits for the sale of Cipramil produced by Lundbeck.

72 Similarly, as regards the EEA agreement, the General Court held, in paragraph 192 of the judgment under appeal, that the objective of that agreement was not only to keep out Merck (GUK) from the EEA markets, as a seller of the Natco citalopram, but also to keep out Natco as a producer of generic citalopram in that territory.

73 In view of these findings of fact, which are significantly better substantiated than GUK claims, and there being no need to ascertain, first, whether the General Court was right, in paragraphs 271 to 274 of the judgment under appeal, to treat the agreements at issue in the same way as those in question in the judgment of 20 November 2008, *Beef Industry Development Society and Barry Brothers* (C-209/07, EU:C:2008:643), or in other judgments not referred to in the judgment under appeal, and, second, whether the General Court correctly interpreted the judgment of the Supreme Court of the United States of 17 June 2013, *Federal Trade Commission* v *Actavis* (570 U.S. (2013)), which cannot bind it in any case, it must be found that the General Court did not err in law when it arrived at the conclusion that the agreements at issue should be characterised as 'restrictions by object' within the meaning of Article 101(1) TFEU.

74 That finding cannot be called into question by the arguments put forward by GUK.

75 First, in order to establish that the agreements at issue should not be characterised as 'restrictions by object', GUK cannot rely on the fact that those agreements reflected the exercise of a right granted under a patent.

76 While the conclusion by the holder of a patent with a party allegedly infringing that patent of a settlement agreement that does not exceed the scope and duration of remaining validity of the patent does constitute an expression of the intellectual property right of its 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 (judgment of 30 January 2020, *Generics (UK) and Others*, C-307/18, EU:C:2020:52, paragraph 97).

77 Thus, the fact that the agreements at issue reflected the exercise of a right granted under a patent cannot legitimise an infringement of Article 101 TFEU, much less a concerted practice which has been found to reveal the sufficient degree of harm to competition to be characterised as a 'restriction by object', as the General Court noted, in essence, in paragraphs 243 to 245 of the judgment under appeal.

78 Second, nor can GUK criticise the General Court for having characterised the agreements at issue as 'restrictions by object' where it has not previously held such agreements to be 'restrictions by object', contrary to paragraph 21 of the judgment of 26 November 2015, *Maxima Latvija* (C-345/14, EU:C:2015:784).

79 As the General Court correctly pointed out in paragraph 151 of the judgment under appeal, it is in no way necessary that the same type of agreement has already been censured by the Commission in order for such agreements to constitute a restriction of competition by object, and that remains the case even if they occur in a specific context, such as that of intellectual property rights.

80 In order for a given agreement to be characterised as a 'restriction by object', all that matters are the specific characteristics of that agreement (see, to that effect, judgment of 30 January 2020, *Generics (UK) and Others*, C 307/18, EU:C:2020:52, paragraphs 84 and 85) from which any particular harmfulness of that agreement for competition can be inferred, where necessary as a result of a detailed analysis of that agreement, its objectives and the economic and legal context of which it forms part, which is borne out by paragraph 21 of the judgment of 26 November 2015, *Maxima Latvija* (C-345/14, EU:C:2015:784).

81 The agreements at issue, which allowed the market entry of Merck (GUK) to be delayed and which were accompanied by payments made by Lundbeck to Merck (GUK), which, by virtue of their size, induced Merck (GUK) not to continue its efforts to enter the market, belong to that category of practices which are particularly harmful to competition.

82 Third, there is no basis for GUK's criticisms, in its third ground of appeal, that the General Court failed to require the Commission to assess objectively Merck (GUK)'s real prospects of succeeding in the event of patent litigation and, at the same time, for having taken into account the perception of the parties to the agreements at issue.

83 In that regard, as is apparent from paragraph 60 of the judgment delivered today in Case C-591/16 P, *Lundbeck* v *Commission*, much like the assessment of whether the parties to a settlement agreement, such as the agreements at issue, are potential competitors, (see, to that effect, judgment of 30 January 2020, *Generics (UK) and Others*, C-307/18, EU:C:2020:52, paragraph 50), an assessment of the strength of the process patents at issue or of the prospects of success of one or other of the parties to the settlement agreement concerned is not relevant for the purpose of characterisation as a 'restriction by object', provided that it has been established that it is the prospect of the transfer of value by the manufacturer of originator medicines which induced the manufacturer of generic medicines to refrain from entering the market (see, to that effect, judgment of 30 January 2020, *Generics (UK) and Others*, C-307/18, EU:C:2020:52, paragraph 89), which the General Court did establish, inter alia, in paragraphs 174, 176 and 177 of the judgment under appeal.

84 No conclusion to the contrary can be inferred from paragraphs 26 and 28 of the judgment of 25 February 1986, *Windsurfing International* v *Commission* (193/83, EU:C:1986:75). All that is apparent from paragraph 26 of that judgment is that the Commission may not refrain from all action when the scope of a patent is relevant for the purposes of determining whether there has been an infringement of Articles 101 and 102 TFEU. There is no such relevance where, as in the present case, despite any uncertainty as to the scope of a patent or precisely because of such uncertainty, it is possible to establish that the patent holder and other undertakings capable of entering the relevant market by assuming the risk of infringing that patent are potential competitors.

85 In any event, paragraphs 26 and 28 of the judgment of 25 February 1986, *Windsurfing International* v *Commission* (193/83, EU:C:1986:75), cannot be understood as requiring the Commission to carry out the same analysis as that of the courts called upon to rule on the merits of patent actions, since paragraph 27 of that judgment states that the findings which the Commission may make do not in any way pre-empt the determinations made later by national courts in disputes brought before them on the subject of patent rights.

86 When deciding whether to characterise the agreements at issue as 'restrictions by object', it is also important to note that, contrary to what is argued by GUK, the General Court was entitled to take into account how the parties perceived their position with regard to patents and their chances of success in the event of litigation at the time they concluded the agreements at issue, as it did in paragraph 214 of the judgment under appeal, in accordance with both the principle that evidence may be freely adduced under EU law (judgment of 27 April 2017, *FSL and Others* v *Commission*, C-469/15 P, EU:C:2017:308, paragraph 38 and the case-law cited) and also with paragraph 26 of the judgment of 25 February 1986, *Windsurfing International* v *Commission* (193/83, EU:C:1986:75), as is apparent from paragraph 250 of the judgment under appeal.

87 Furthermore, it should be added in that regard that, also in paragraph 214 of the judgment under appeal, it is stated that, in relying on the perception of the parties to the agreements at issue for the purposes of characterising those agreements as 'restrictions by object', the Commission had recourse to objective elements such as documents or evidence from the parties to the agreements *in tempore non suspecto*.

88 Fourth, GUK cannot validly criticise the General Court for having found, in paragraph 296 of the judgment under appeal, that, in order to establish the existence of a 'restriction by object', the Commission could not be required to show that the reverse payments exceeded the profits expected by Merck (GUK) if it had marketed its generic medicines.

89 Taking into account the uncertainty as to the outcome of patent dispute proceedings, there is no requirement that the transfers of value should necessarily be greater than the profits which the manufacturer of generic medicines concerned would have made if it had ultimately been successful in those proceedings. All that matters is that those transfers of value are shown to be sufficiently beneficial to encourage that manufacturer of generic medicines to refrain from entering the market concerned and not to compete on the merits with the manufacturer of originator medicines concerned (judgment of 30 January 2020, *Generics (UK) and Others*, C-307/18, EU:C:2020:52, paragraph 94).

90 As has already been noted in paragraph 70 of the present judgment, the General Court found, in paragraph 268 of the judgment under appeal, that, in the present case, the payments made by Lundbeck to GUK induced that manufacturer of generic medicines not to pursue its efforts to enter the market.

91 It must therefore be concluded that, in view of the size of the reverse payments in the present case, the General Court was fully entitled to characterise the agreements at issue as 'restrictions by object', and was acting entirely in line with the case-law in doing so, regardless, first, of the fact, established by the General Court in paragraphs 260 and 293 of the judgment under appeal, that the existence of reverse payments in the context of a patent settlement agreement is not always problematic, particularly where that payment is linked to the strength of that patent, and, second, of the fact, referred to in paragraphs 293 and 294 of the same judgment, that an agreement which gave rise to reverse payments, but which the General Court has found to have significant differences as compared with the agreements at issue, could be regarded by the Commission as unproblematic.

92 Fifth, GUK cannot complain that the General Court reversed the burden of proof on the ground that it relied on facts of which there was some doubt to characterise the agreements at issue as 'restrictions by object', as the Commission had also done, thereby requiring GUK to show that Lundbeck would have brought an action and that GUK would in any event have been unsuccessful.

93 Aside from the fact that, in that respect, GUK criticises a large number of paragraphs in the judgment under appeal which relate to the rejection of the fourth plea in law in support of annulment, alleging that Merck (GUK) and Lundbeck were not potential competitors at the time the agreements at issue were concluded, and not to the rejection of the first, second and third pleas in law concerning the characterisation of those agreements as 'restrictions by object', it is apparent from the judgment under appeal that the General Court merely found that some of the evidence was open to question, such as Lundbeck's bringing of legal proceedings against Merck (GUK) in the event of its 'at-risk' entry into the market, the success of Lundbeck in the event of such proceedings or, conversely, the success of Merck (GUK), in order to infer therefrom, as is apparent in particular from paragraph 174 of the judgment under appeal, that, by means of the agreements at issue, Lundbeck and Merck (GUK) replaced the uncertainty as to the outcome of possible infringement actions with the certainty that Merck (GUK) would not enter the market with its generic medicines for the duration of the disputed agreements.

94 In so doing, the General Court in no way imposed on GUK the burden of proving that Lundbeck would have brought an action against GUK and that GUK would have been unsuccessful in any event.

95 It follows from the foregoing that the first, second and third grounds of appeal must be rejected as being inadmissible in part and unfounded in part.

Fourth ground of appeal

The relevant paragraphs of the judgment under appeal

96 In rejecting the first, second and third pleas in law raised by GUK in support of its action for annulment, alleging infringement of Article 101(1) TFEU due to the characterisation of the agreements at issue as 'restrictions by object', the General Court held, inter alia, in paragraph 266 of the judgment under appeal, that 'the fact that the adoption of [anticompetitive] behaviour may be the most cost-effective or least risky course of action for an undertaking in no way excludes the application of Article 101 TFEU …, particularly if that behaviour consists in paying actual or potential competitors not to enter the market and sharing with those competitors the profits resulting from the monopoly rent, to the detriment of consumers, as in the present case'.

97 In order to reject the fifth plea in law raised by GUK in support of its action for annulment, alleging that the Commission erred in concluding that the agreements at issue did not satisfy the conditions for exemption under Article 101(3) TFEU, the General Court rejected, in paragraphs 347 to 367 of the judgment under appeal, GUK's allegations that the agreements at issue had enabled Merck (GUK) to achieve other legitimate objectives, namely to accelerate the launch of generic citalopram and to avoid significant litigation costs and exposure to damages. In that regard, the General Court found, in paragraph 351 of that judgment, that those agreements had instead delayed the market entry of Merck (GUK) and led NM Pharma, Merck (GUK)'s distributor for Sweden, to withdraw from the Swedish market. In paragraphs 353 and 354 of that judgment, it also held that the desire to avoid significant costs associated with any litigation proceedings had not been established in so far as, first, the agreements at issue contained no undertaking by Lundbeck not to bring an action after the expiry of those agreements and, second, GUK had not sufficiently demonstrated that the avoidance of such costs could constitute efficiency gains.

Arguments of the parties

98 By its fourth ground of appeal, GUK submits that the General Court erred in law by failing to review fully the Commission's rejection of the justification for the agreements at issue pursuant to Article 101(3) TFEU.

99 GUK argues, in that regard, that the General Court, in the first place, failed to examine seriously its submissions concerning the effects of the agreements at issue, which were that GUK avoided an 'at-risk' launch that would have imposed significant liabilities on GUK and potentially would have impeded GUK from launching its Natco citalopram. Nor did the General Court examine its argument that the duration of the agreements at issue was significantly shorter than the average duration of patent litigation. GUK also disputes the General Court's conclusion, in paragraph 351 of the judgment under appeal, that the agreements at issue 'rather allowed Merck (GUK)'s potentially immediate market entry … to be delayed' by assessing the value of Lundbeck's process patents, while at the same time finding, in paragraph 212 of the judgment under appeal, that it was not for the Commission to assess the scope and validity of those patents.

100 In the second place, the General Court did not seriously examine and rejected with a summary statement of reasons, in paragraph 266 of the judgment under appeal, the relevant, reliable and credible economic studies provided by GUK which show that payments such as those at issue could be legitimate and necessary in order to reach the compromise solution envisaged by the agreements at issue.

Findings of the Court

101 By the second part of its fourth ground of appeal, alleging infringement of Article 101(3) TFEU, which it is appropriate to examine first, GUK criticises the General Court for having taken insufficient account of and having rejected, in paragraph 266 of the judgment under appeal, without providing a sufficient statement of reasons, the economic studies produced by GUK in order to establish that the payments at issue were capable of being legitimate.

102 In that regard, suffice it to note that that part of that ground of appeal is expressly directed against one paragraph of the reasoning of the judgment under appeal which enabled the General Court to reject not the fifth plea in support of annulment, alleging infringement of Article 101(3) TFEU, but the first, second and third pleas in support of annulment, alleging infringement of Article 101(1) TFEU due to the characterisation of the agreements at issue as 'restrictions by object'.

103 Consequently, since it has not been claimed or, a fortiori, demonstrated that the General Court distorted GUK's argument in support of which it provided economic studies, and since it has not been shown that those studies were submitted in the context of the fifth plea in support of annulment, the second part of the present ground of appeal must be regarded as raising, on appeal, a new line of argument and, therefore, must be rejected as being inadmissible.

104 By the first part of the fourth ground of appeal, GUK criticises the General Court, first, for having failed sufficiently to examine GUK's arguments seeking to demonstrate the advantageous nature of the

agreements at issue for Merck (GUK) and the significantly shorter duration of those agreements as compared with that of patent litigation and for having failed to provide sufficient reasons for rejecting those arguments, and, second, for having contradicted itself in paragraphs 212 and 351 of the judgment under appeal.

105 In that respect, it must be recalled, first, that, in the context of an appeal, the purpose of review by the Court of Justice is, inter alia, to consider whether the General Court addressed, to the requisite legal standard, all the arguments raised by the appellant and, second, that the plea alleging that the General Court failed to rule on arguments relied on at first instance amounts essentially to relying on a breach of the obligation to state reasons which derives from 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, and from Article 117 of the Rules of Procedure of the General Court (judgment of 15 October 2020, *Deza* v *Commission*, C-813/18 P, not published, EU:C:2020:832, paragraph 57 and the case-law cited).

106 In that context, the Court of Justice does not require the General Court to provide an account which follows exhaustively and one by one all the arguments put forward by the parties to the case and the General Court's reasoning may therefore be implicit, on condition that it enables the persons concerned to know why the General Court has not upheld their arguments and provides the Court of Justice with sufficient material for it to exercise its power of review (judgment of 26 May 2016, *Rose Vision* v *Commission*, C-224/15 P, EU:C:2016:358, paragraph 25 and the case-law cited).

107 It is apparent from paragraphs 349 to 366 of the judgment under appeal that the General Court rejected GUK's claim alleging failure, in the present case, to satisfy the conditions for the exemption laid down in Article 101(3) TFEU, noting, first of all, that GUK had not shown, first, that the agreements at issue enabled it to achieve legitimate objectives and, second, that those agreements were necessary to generate efficiency gains, such gains which, moreover, the General Court found were not sufficiently demonstrated.

108 That statement of reasons enabled GUK to know why the General Court did not uphold its arguments seeking to establish that, at the very least, two of the four cumulative conditions laid down in Article 101(3) TFEU were not satisfied in the present case.

109 Specifically, as regards GUK's first claim that the General Court did not sufficiently examine Merck (GUK)'s legitimate interests in concluding the agreements at issue in order to avoid incurring significant liability, it should be noted that, in paragraphs 353 and 354 of the judgment under appeal, the General Court expressly held, first, that those agreements did not make it possible to avoid the costs associated with potential litigation, since they did not contain any undertaking from Lundbeck not to initiate such litigation after the expiry of those agreements, and, second, that GUK had not made it sufficiently apparent how avoiding such costs could constitute an efficiency gain.

110 In so doing, the General Court not only fulfilled its duty to state reasons by providing an intelligible and relevant response to the arguments developed by GUK in the context of its action for annulment which seek to establish the favourable effects of the agreements at issue for Merck (GUK), but also reached the standard of review required of it in the context of the assessment of whether the evidence is sufficiently cogent, such evidence having to be put forward by undertakings relying on the exemption under Article 101(3) TFEU, with due regard, moreover, to the Court of Justice's case-law (judgment of 6 October 2009, *GlaxoSmithKline Services and Others* v *Commission and Others*, C-501/06 P, C-513/06 P, C-515/06 P and C-519/06 P, EU:C:2009:610, paragraphs 82, 83 and 92 to 95).

111 Although, by its arguments, GUK seeks to challenge the appraisal of the facts and the assessment of the evidence carried out by the General Court, it is sufficient to note, as has been stated above in paragraph 63 of the present judgment, that such an appraisal or assessment does not, save where the clear sense of those facts or that evidence has been distorted, which has not been alleged in the present case, constitute a point of law which is subject, as such, to review by the Court of Justice on appeal.

112 As regards GUK's second allegation that the General Court did not examine its argument relating to the duration of the agreements at issue, which, in its view, is significantly shorter than the average duration of patent litigation, it is true that the General Court did not reply expressly to that argument.

However, from the reasons given by the General Court in paragraph 351 of the judgment under appeal it can readily be understood why it did not uphold that argument. The General Court states in that paragraph, first, that the agreements at issue rather allowed Merck (GUK)'s potentially immediate market entry in the United Kingdom, and in other EEA markets, to be delayed, and even led to NM Pharma withdrawing from the Swedish market even though it had been present on that market successfully for over five months, and, second, that there was no certainty that Lundbeck would have brought infringement actions against Merck (GUK).

113 As to the second argument put forward in the first part of the present ground, alleging a contradiction in the reasoning in paragraphs 212 and 351 of the judgment under appeal, it should be noted that, as is the case with regard to the assessment as to whether the parties to agreements such as the agreements at issue are potential competitors and the assessment of their potential or actual effects on competition where they are not characterised as 'restrictions by object' (judgment of 30 January 2020, *Generics (UK) and Others*, C-307/18, EU:C:2020:52, paragraphs 50 and 119), although it is not for the competition authorities or the national courts to assess the strength of the patent concerned or the likelihood that litigation between the patent owner and a manufacturer of generic medicines may lead to a finding that the patent is valid and has been infringed in order to determine whether agreements such as the agreements at issue fall within the characterisation of 'restrictions by object' – which is what the General Court found, in essence, in paragraph 212 of the judgment under appeal – the fact remains that those authorities and courts cannot disregard all questions relating to patent law which might influence how such agreements are to be characterised.

114 In paragraph 351 of the judgment under appeal, the General Court did not in any way assess Lundbeck's prospects of success in its infringement actions against Merck (GUK) in the event that it made an 'at-risk' market entry, but merely noted that there was no certainty as to the chances of success of those actions, which is a factor capable of influencing the characterisation of the agreements at issue (see, to that effect, judgment of 30 January 2020, *Generics (UK) and Others,* C-307/18, EU:C:2020:52, paragraph 98).

115 Accordingly, the criticism cannot be made that the General Court contradicted itself in paragraphs 212 and 351 of the judgment under appeal.

116 In view of the foregoing, the fourth ground of appeal must be rejected as being inadmissible in part and unfounded in part.

Fifth ground of appeal

The relevant paragraphs of the judgment under appeal

117 In its response to the first, second and third pleas in support of annulment, alleging infringement of Article 101(1) TFEU due to the characterisation of the agreements at issue as 'restrictions by object', the General Court, in paragraphs 154 to 205 of the judgment under appeal, rejected GUK's arguments relating to the assessment of the UK agreement.

118 In order to do so, the General Court, in paragraphs 155 to 179 of that judgment, inter alia, assessed the content of the UK agreement and concluded that GUK's argument that that agreement did not contain restrictions going beyond the scope of Lundbeck's process patents, even if it were well founded, had to be rejected as ineffective, and that the argument that the UK agreement was not intended to restrict Merck (GUK)'s activities had to be rejected as being unfounded.

119 In support of that conclusion, the General Court stated, inter alia, in paragraphs 170 to 174 of the judgment under appeal, as follows:

> '170 … it must be found that the Commission did not establish to the requisite legal standard, in the [decision at issue], that the restrictions set out in the UK [agreement] went beyond the scope of Lundbeck's [process] patents, that is to say that such restrictions could not have been obtained by Lundbeck before a court with jurisdiction to rule on patent-related matters if the generic products based on the Natco citalopram that Merck (GUK) intended to bring to the market had been held to be infringing and if those patents had survived any counter-claims challenging their validity.

171 However, that finding is not capable of affecting the examination of the lawfulness of the [decision at issue], since the complaint put forward by [GUK] is ineffective, for the reasons set out below.

172 First, it must be noted that [GUK] does not dispute that, under Article 1.1 of the UK agreement, it undertook not to enter the market with the Natco citalopram and that, under Articles 2.2 and 2.3 of the same agreement, it undertook to deliver the entirety of its stock of citalopram (recitals 771 and 772 of the [decision at issue]) to Lundbeck, nor the fact that it obtained GBP 3 million from Lundbeck in exchange for that commitment … Similarly, [GUK] does not dispute that, under Article 2.7 of the UK [agreement], it undertook not to grant or license, during the term of that agreement, a copy of the [market authorisations ("MAs")] it had already obtained in the United Kingdom.

173 As the Commission submits, such commitments are, in any event, anticompetitive by their very object, whether or not they went beyond the scope of Lundbeck's [process] patents, since, far from resolving any patent dispute between the parties to the UK agreement, they were obtained in exchange for significant reverse payments and they were intended to prevent Merck (GUK) from entering the market during the term of the agreement with its generic products containing the Natco citalopram, on which it had hitherto based its entire strategy for competing with Lundbeck on the United Kingdom market.

174 As the Commission emphasised in recitals 641 and 820 of the [decision at issue], what matters, in that respect, is that the UK agreement transformed the uncertainty regarding the outcome of any infringement actions into the certainty that Merck (GUK) would not enter the market with its generic products during the term of that agreement, whereas the limitations on Merck (GUK)'s commercial autonomy did not arise exclusively from an evaluation, by the parties to the agreement, of Lundbeck's [process] patents, but rather from the size of the reverse payment which, in such a case, overshadowed that evaluation and induced Merck (GUK) not to pursue its efforts to enter the market …'

Arguments of the parties

120 By its fifth ground of appeal, GUK complains that the General Court's exercise of its power of judicial review was *ultra vires* by finding, in paragraphs 171 to 178 of the judgment under appeal, a new infringement of Article 101(1) TFEU which was not found in the decision at issue, and by substituting its own observations for those of the Commission, thus also infringing the right to effective judicial protection and its rights of defence. Although the General Court held that the Commission had not established that the restrictions contained in the UK agreement went beyond the scope of Lundbeck's process patents and the Commission had considered a conclusion to the contrary to be an essential ingredient in its finding, the General Court itself held, in the absence of any finding by the Commission in that regard in the decision at issue, that the UK agreement was in any event anticompetitive by its object, thereby substituting its reasoning for that of the Commission.

121 GUK also claims that the General Court also substituted its reasoning in finding, in paragraphs 144 and 261 of the judgment under appeal, that the payments provided for in the agreements at issue were disproportionate, despite the Commission not relying on that factor. Such a substitution of reasoning deprived GUK of the opportunity to defend itself and could not be justified by the General Court's finding, in paragraph 375 of the judgment under appeal, that the statement of objections referred to the fact that the agreements at issue might go beyond the scope of Lundbeck's process patents.

122 The Commission contends that the fifth ground of appeal is unfounded.

Findings of the Court

123 As regards the first part of the fifth ground of appeal, alleging that the General Court's exercise of its power of judicial review was *ultra vires*, it should be recalled that the EU Courts cannot, in the context of the review of legality referred to in Article 263 TFEU, substitute their own reasoning for that of the author of the contested act and that, although Article 261 TFEU and Article 31 of Regulation No 1/2003 empower the EU Courts, in addition to a mere review of the legality of the penalty, to

substitute their own assessment in relation to the determination of the amount of that penalty for that of the Commission, the scope of that unlimited jurisdiction is strictly limited to determining the amount of the fine, which means that the General Court is precluded from altering the constituent elements of the infringement lawfully determined by the Commission in the decision under examination by the General Court (see, to that effect, judgment of 21 January 2016, *Galp Energía España and Others* v *Commission*, C-603/13 P, EU:C:2016:38, paragraphs 73 to 77).

124 However, in the present case, the General Court cannot validly be criticised for having altered the constituent elements of the infringement alleged against GUK.

125 It should be recalled that, in recital 824 of the decision at issue, the Commission stated that the UK agreement constituted a 'restriction of competition by object' in the light, in particular, of six facts listed in that recital. One of those facts was that, according to the Commission, the limitations contained in the UK agreement went beyond the scope of Lundbeck's process patents, that is to say, that such limitations could not have been obtained by Lundbeck before a court with jurisdiction in respect of patents if the generic products based on the Natco citalopram, which Merck (GUK) intended to sell, had been held to be infringing and if those patents had resisted any counterclaims calling into question their validity. As is apparent from paragraph 170 of the judgment under appeal, the General Court held that the Commission had not established that fact to the requisite legal standard in the decision at issue.

126 However, for the reasons set out in paragraphs 171 to 178 of the judgment under appeal, the General Court found, in essence, that the other facts listed in recital 824 of the decision at issue were sufficient in themselves to establish that the UK agreement should be characterised as a 'restriction by object', with the result that the failure to show to the requisite legal standard that that agreement went beyond the scope of Lundbeck's process patents cannot affect that characterisation of the agreement. In so doing, the General Court did not substitute its own assessment for that of the Commission, but merely found, in essence, that the reference to the scope of the UK agreement and whether or not it went beyond the scope of Lundbeck's process patents is not an essential element for that characterisation, but is a ground included in the decision at issue purely for the sake of completeness. On that basis, the General Court was entitled to reject, in paragraph 179 of the judgment under appeal, that part of GUK's argument as being ineffective.

127 As regards the second part of the fifth ground of appeal, alleging that the General Court substituted its reasoning in that it found that the payments provided for in the agreements at issue were disproportionate, contrary to what was found in the decision at issue, it is indeed apparent that, in paragraphs 144 and 261 of the judgment under appeal, the General Court used the words 'the disproportionate nature of such payments' even though they are not used in the decision at issue.

128 However, it cannot be inferred from the above that, on that basis alone, it substituted the reasoning of the decision at issue, which is not, in fact, open to it in the context of a judicial review of that decision (see, to that effect, judgment of 18 January 2017, *Toshiba* v *Commission,* C-623/15 P, not published, EU:C:2017:21, paragraph 43).

129 Not only was such wording used only twice in the judgment under appeal, and exclusively when the General Court restated the statement of reasons contained in the decision at issue, but, most importantly, the use of such wording, regrettable though it may be, had no effect on the General Court's reasoning. As is apparent, in particular, from paragraphs 144, 174, 175, 178, 268 and 269 of the judgment under appeal, the General Court, like the Commission, assessed the characterisation of the agreements at issue as 'restrictions by object' not in the light of the disproportionate nature of the payments made by Lundbeck to Merck (GUK), but on the basis of a consistent body of evidence which includes those payments, which were taken into consideration as an incentive for Merck (GUK) not to continue its efforts to enter the market, regardless of whether they were proportionate or disproportionate.

130 For the same reason, GUK also has no basis for arguing that the use of the words 'the disproportionate nature of such payments' deprived it of the opportunity to defend itself.

131 Consequently, the second part of the fifth ground of appeal and, accordingly, the fifth ground in its entirety, must be rejected as being unfounded.

Sixth ground of appeal

The relevant paragraphs of the judgment under appeal

132 In rejecting GUK's seventh plea seeking annulment relating to 'a request for annulment or reduction of the fine' imposed on GUK by the decision at issue, the General Court held, inter alia, in paragraphs 407, 408 and 409 of the judgment under appeal, as follows:

> '407 … according to the case-law, it is not necessary that [GUK] was actually aware that it was infringing Article 101(1) TFEU by concluding the agreements at issue in order to establish that the infringement was committed intentionally or negligently, within the meaning of the first sentence of Article 23(2) of Regulation No 1/2003; what matters is to determine whether, in the light of the wording of the agreements, of their legal and economic context and of the behaviour of the parties, those parties were aware or ought to have been aware that the restrictions in those agreements were liable to infringe the rules of competition laid down in the [Treaty] (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, paragraph 45; of 9 November 1983[,] *Nederlandsche BandenIndustrie-Michelin* v *Commission*, 322/81, … EU:C:1983:313 paragraph 107; and of 18 June 2013[,] *Schenker & Co. and Others*, C-681/11, … EU:C:2013:404, paragraph 37).
>
> 408 In the present case, the Commission correctly noted, in recitals 1312 and 1313 of the [decision at issue], that a literal reading of Article 101(1) TFEU made it clear that agreements between competitors for the exclusion of some of them from the market were illegal. The fact that, in the present case, the agreements at issue were concluded in the form of settlement agreements concerning intellectual property rights cannot allow [GUK] to infer that their unlawfulness in the light of competition law was completely unforeseeable.
>
> 409 It can be seen from recital 190 of the [decision at issue], for example, that, when Lundbeck proposed the same type of agreement to NM Pharma, the latter stated that it could not engage in discussion on the topic due to its code of conduct and its antitrust policy. Likewise, it can be seen from recital 265 of the [decision at issue] that – reacting to an [email] sent to Merck (GUK) on 18 January 2002 indicating the estimated profits that would be made if Merck (GUK) purchased Lundbeck citalopram – a Lundbeck employee commented that he "strongly disagree[d] with the content of this email … [since] this [was] illegal".'

Arguments of the parties

133 By its sixth ground of appeal, which is directed against paragraphs 407 and 408 of the judgment under appeal, GUK claims that the General Court misapplied Article 23(2) of Regulation No 1/2003 by failing to refer to clear, precise and consistent evidence capable of showing that it had committed the alleged infringement intentionally or negligently, even though there was no precedent at the time when the agreements at issue were concluded.

134 The Commission contends that the sixth ground of appeal is unfounded.

Findings of the Court

135 In relation to the question whether an infringement has been committed intentionally or negligently and is, therefore, liable to be punished by a fine in accordance with the first subparagraph of Article 23(2) of Regulation No 1/2003, it is settled case-law that that condition is satisfied where the undertaking concerned cannot be unaware of the anticompetitive nature of its conduct, whether or not it is aware that it is infringing the competition rules of the Treaty (judgment of 18 June 2013, *Schenker & Co. and Others*, C-681/11, EU:C:2013:404, paragraph 37 and the case-law cited).

136 It follows that the penalty for conduct covered, inter alia, by Article 101(1) TFEU does not in any way presuppose that the undertakings concerned intended to infringe those competition rules. All that matters is whether, objectively, they could determine that their conduct was anticompetitive, including by seeking legal advice where necessary (see, to that effect, judgment of 28 June 2005, *Dansk Rørindustri and Others* v *Commission*, C-189/02 P, C-202/02 P, C-205/02 P to C-208/02 P and C-213/02 P, EU:C:2005:408, paragraph 219).

137 Accordingly, and contrary to what the General Court held in paragraph 407 of the judgment under appeal, the question is not whether GUK was aware or should have been aware of the fact that the restrictions laid down by the agreements at issue were capable of infringing the competition rules under the Treaty.

138 Nevertheless, in paragraph 408 of the judgment under appeal, the General Court correctly held that the wording of Article 101(1) TFEU objectively made it possible to understand that the agreements at issue were unlawful, notwithstanding the fact that there was no precedent at the time they were concluded, as has already been found, in essence, in paragraph 81 of the present judgment.

139 In that regard, the General Court was once again correct in finding, in paragraph 409 of the judgment under appeal, that the foreseeability of the infringing nature of the agreements at issue also followed, first, from the fact that a manufacturer of generic medicines had refused to enter into agreements similar to the agreements at issue because of its antitrust policy and, second, from the fact that an employee of Lundbeck had strongly disapproved of the steps leading to the conclusion of the agreements at issue on the ground that they were unlawful.

140 Consequently, the conclusion reached by the General Court in paragraph 408 of the judgment under appeal is consistent with the case-law referred to in paragraph 135 of the present judgment.

141 The sixth ground of appeal must therefore be rejected as being unfounded.

142 Having regard to all the findings above, the appeal must be dismissed in its entirety.

Costs

143 Under Article 138(1) of the Rules of Procedure of the Court of Justice, which applies to appeal proceedings by virtue of Article 184(1) thereof, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings.

144 Since the Commission has applied for costs to be awarded against GUK and the latter has been unsuccessful, GUK must be ordered to bear its own costs and to pay those incurred by the Commission.

145 Article 140(1) of the Rules of Procedure, which applies to appeal proceedings by virtue of Article 184(1) thereof, provides that the Member States and institutions which have intervened in the proceedings are to bear their own costs.

146 Consequently, the United Kingdom must bear its own costs.

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

1. **Dismisses the appeal;**

2. **Orders Generics (UK) Ltd to bear its own costs and to pay the costs incurred by the European Commission;**

3. **Orders the United Kingdom of Great Britain and Northern Ireland to bear its own costs.**

Vilaras Šváby Rodin

Jürimäe Xuereb

Delivered in open court in Luxembourg on 25 March 2021.

A. Calot Escobar M. Vilaras

Registrar President of the Fourth Chamber

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* Language of the case: English.