Reports of Cases

JUDGMENT OF THE COURT (Fourth Chamber)

25 March 2021 *

[Text rectified by order of 3 September 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 – Rights of the defence – Reasonable time – Loss of documents due to the passage of time – General duty of care – Regulation (EC) No 1/2003 – Second subparagraph of Article 23(2) – Maximum amount of the fine – Taking into account the business year preceding that in which the European Commission's decision was adopted – Last full year of normal economic activity)

In Case C-611/16 P,

APPEAL under Article 56 of the Statute of the Court of Justice of the European Union, brought on 25 November 2016,

Xellia Pharmaceuticals ApS, established in Copenhagen (Denmark),

Alpharma LLC, formerly Zoetis Products LLC, established in Parsippany, New Jersey (United States),

represented by D.W. Hull, solicitor,

appellants,

the other parties to the proceedings being:

[As rectified by order of 3 September 2021] **European Commission**, represented by F. Castilla Contreras, T. Vecchi, B. Mongin and C. Vollrath, acting as Agents, and B. Rayment, Barrister,

defendant at first instance,

* Language of the case: English.

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 their appeal, Xellia Pharmaceuticals ApS and Alpharma LLC ask the Court of Justice to set aside the judgment of the General Court of the European Union of 8 September 2016, *Xellia Pharmaceuticals* and *Alpharma* v *Commission* (T-471/13, not published, EU:T:2016:460; 'the judgment under appeal'), by which the General Court dismissed their 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 on them by that decision.

Legal context

Regulation (EC) No 1/2003,

2 Under the heading 'Investigations into sectors of the economy and into types of agreements', the first subparagraph of Article 17(1) 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:

'Where the trend of trade between Member States, the rigidity of prices or other circumstances suggest that competition may be restricted or distorted within the [internal market], the Commission may conduct its inquiry into a particular sector of the economy or into a particular type of agreements across various sectors. In the course of that inquiry, the Commission may request the undertakings or

associations of undertakings concerned to supply the information necessary for giving effect to Articles [101and 102 TFEU] and may carry out any inspections necessary for that purpose.'

3 Article 21(3) of that regulation provides:

'A decision adopted pursuant to paragraph 1 cannot be executed without prior authorisation from the national judicial authority of the Member State concerned. The national judicial authority shall control that the Commission decision is authentic and that the coercive measures envisaged are neither arbitrary nor excessive having regard in particular to the seriousness of the suspected infringement, to the importance of the evidence sought, to the involvement of the undertaking concerned and to the reasonable likelihood that business books and records relating to the subject matter of the inspection are kept in the premises for which the authorisation is requested. The national judicial authority may ask the Commission, directly or through the Member State competition authority, for detailed explanations on those elements which are necessary to allow its control of the proportionality of the coercive measures envisaged.

However, the national judicial authority may not call into question the necessity for the inspection nor demand that it be provided with information in the Commission's file. The lawfulness of the Commission decision shall be subject to review only by the Court of Justice.'

4 Article 23(2) of that regulation 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 102 TFEU]; or

…

For each undertaking and association of undertakings participating in the infringement, the fine shall not exceed 10% of its total turnover in the preceding business year.

…'

The 2006 Guidelines on the method of setting fines

5 Points 19 to 22 and 37 of 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; 'the 2006 Guidelines'), state as follows:

'19. The basic amount of the fine will be related to a proportion of the value of sales, depending on the degree of gravity of the infringement, multiplied by the number of years of infringement.

20. The assessment of gravity will be made on a case-by-case basis for all types of infringement, taking account of all the relevant circumstances of the case.

21. As a general rule, the proportion of the value of sales taken into account will be set at a level of up to 30% of the value of sales.

22. In order to decide whether the proportion of the value of sales to be considered in a given case should be at the lower end or at the higher end of that scale, the Commission will have regard to a number of factors, such as the nature of the infringement, the combined market share of all the undertakings concerned, the geographic scope of the infringement and whether or not the infringement has been implemented.

…

37. Although these Guidelines present the general methodology for the setting of fines, the particularities of a given case or the need to achieve deterrence in a particular case may justify departing from such methodology or from the limits specified in point 21.'

The decision of 15 January 2008 initiating an inquiry into the pharmaceutical sector

6 Recitals 3 to 5 and recital 8 of the Commission decision of 15 January 2008 initiating an inquiry into the pharmaceutical sector, pursuant to Article 17 of Regulation (EC) No 1/2003 (Case No COMP/D2/39.514) ('the decision of 15 January 2008 initiating an inquiry into the pharmaceutical sector') are worded as follows:

'(3) Certain circumstances relating to competition by innovative and generic medicines in general suggest that competition may be restricted or distorted in the pharmaceutical sector in Europe, such as a decline in innovation as measured by the number of novel medicines reaching the market and instances of lacking timely entry by suppliers of generic medicines.

(4) There are indications of commercial practices by pharmaceutical suppliers including notably patenting or the exercise of patents which may not serve to protect innovation but to block innovative and/or generic competition, litigation, which may be vexatious, and agreements, which may be collusive.

(5) These practices may cause market distortion when they unduly fence off incumbent suppliers of drugs from innovative or generic competition, for example, due to de facto extended patent protection through unilateral conduct or agreements. Such practices may limit consumer choice, reduce economic incentives to invest in research and development of new products and damage public and private health budgets.

…

(8) To the extent that the inquiry into the pharmaceutical sector reveals the possible existence of anticompetitive agreements or practices or abuses of a dominant position, the Commission or, where appropriate, the national competition authorities could envisage taking the appropriate measures to restore competition in the sector, including opening investigations against individual entities possibly resulting in decisions based on Article [101] and/or Article [102 TFEU].'

Background to the dispute

7 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-588/16 P (*Generics (UK)* v *Commission*) against the judgment of 8 September 2016, *Generics (UK)* v *Commission* (T-469/13, not published, EU:T:2016:454); 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), 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).

8 The background to the dispute was set out in paragraphs 1 to 38 of the judgment under appeal as follows:

'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 Alpharma Inc. was a company incorporated in the United States of America active in the pharmaceutical sector on a worldwide scale, in particular in generic medicinal products. Until December 2008 it was controlled by A.L. Industrier AS[,] a company governed by Norwegian law. It was subsequently bought by a United Kingdom pharmaceutical undertaking, which, in turn, was bought by a United States pharmaceutical undertaking. In the context of those restructurings, Alpharma Inc. became, first of all, in April 2010, Alpharma LLC, and then, on 15 April 2013, Zoetis Products LLC ("Zoetis") and, finally, on 6 July 2015, it returned to being Alpharma LLC.

4 Alpharma Inc. controlled all the shares in Alpharma ApS, a company governed by Danish law, which had a number of subsidiaries in the European Economic Area (EEA) (hereinafter referred to, overall, as the "Alpharma group"). Following a number of company restructurings, on 31 March 2008 Alpharma ApS became Axellia Pharmaceuticals ApS, renamed Xellia Pharmaceuticals ApS … in 2010.

The relevant product and the applicable patents

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

6 In 1977, Lundbeck filed a patent application in Denmark for the citalopram API and two processes – an alkylation process and a cyanation process – to produce that API. Patents for that API and those processes … were issued in Denmark and in a number of western European countries between 1977 and 1985.

7 As regards the EEA, the protection afforded by [those 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, [those patents] expired in January 2002.

8 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).

9 First, 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 ("the crystallisation patents") 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 and on 11 February 2002 in the case of Denmark. The EPO granted a crystallisation patent on 4 September 2002. In addition, in the Netherlands, Lundbeck had already obtained, on 6 November 2000, a utility model for that process … that is to say, a patent valid for six years, granted without a prior examination.

10 Secondly, on 12 March 2001, Lundbeck filed a patent application with the [authorities of the United Kingdom of Great Britain and Northern Ireland] for a citalopram production process using a salt purification method by film distillation. The United Kingdom authorities granted Lundbeck a patent for that film distillation method on 3 October 2001 ("the film distillation patent"). However, that patent was revoked on 23 June 2004 for lack of novelty by comparison with another Lundbeck patent.

11 Lastly, Lundbeck planned to launch a new antidepressant medicinal product, Cipralex, based on the API known as escitalopram (or S-citalopram), by the middle 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.

Agreement entered into by Lundbeck with the Alpharma group and other matters relating to the background

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

13 The relevant agreement for the purposes of the present case ("the agreement at issue") was concluded between Lundbeck and Alpharma ApS on 22 February 2002 and covered the period running from that date until 30 June 2003 ("the relevant period").

14 Before concluding that agreement, in January 2002 the Alpharma group had bought from Alfred E. Tiefenbacher GmbH & Co. ("Tiefenbacher") a stock of generic citalopram tablets produced on the basis of the API of the Indian company Cipla and had ordered further supplies.

15 As regards the preamble to the agreement at issue ("the preamble"), it should be observed, in particular, that:

– the first recital states that "Lundbeck owns intellectual property rights including, in particular, patent rights relating to the manufacture of the [API] 'Citalopram' [(written with an upper case 'C' throughout the agreement)], including the patents set out in Appendix A" to that agreement …;

– the second recital states that Lundbeck produces and sells pharmaceutical products containing "Citalopram" in all Member States and also in Norway and Switzerland, those countries being together defined as "the Territory";

– the third and fourth recitals mention that the Alpharma group has produced or purchased pharmaceutical products containing "Citalopram" in "the Territory", without Lundbeck's consent;

– the fifth and sixth recitals state that the Alpharma group's products have been subjected to laboratory analyses by Lundbeck, the results of which gave Lundbeck substantial reason to believe that the production methods used to produce those products infringed its intellectual property rights;

– the seventh recital recalls that, on 31 January 2002, Lundbeck filed a lawsuit with a United Kingdom court ("the UK infringement action") seeking an injunction "against [the] Alpharma [group's] sale of products containing Citalopram for infringing Lundbeck's intellectual property rights";

– the eighth recital states that the Alpharma group acknowledges that Lundbeck's findings are correct and undertakes to refrain from marketing "such products";

– the ninth and tenth recitals state that Lundbeck:

  – "has agreed to compensate [the] Alpharma [group] in order for Lundbeck to avoid … patent litigation", the outcome of which cannot be predicted with absolute certainty and which would be costly and time-consuming;

  – "in order to settle the dispute, [has] agreed to purchase all of [the] Alpharma [group's] stock of products containing Citalopram and to compensate [it] for such products".

16 As regards the body of the agreement at issue, it should be observed, in particular, that:

– Article 1.1 [of the agreement at issue] stipulates that the Alpharma group and its "Affiliates" "shall cancel, cease and desist from any importation, … production, … or sale of pharmaceutical products containing Citalopram in the Territory … during [the relevant period]" and that Lundbeck is to withdraw the UK infringement action;

– Article 1.1 also specifies that it is not to apply to "any product containing escitalopram";

– Article 1.2 provides that "in the event of any breach of the obligation set forth in Article 1.1 [of the agreement at issue] or at the request of Lundbeck, [the] Alpharma [group] … will voluntarily submit to an interim injunction by any competent court in any applicable country in the Territory" and that Lundbeck is to be entitled to obtain such injunction without providing any kind of security;

– Article 1.3 states that, as compensation for the obligations set out in that agreement and in order to avoid the costs and time of litigation, Lundbeck is to pay to the Alpharma group the sum of [12 million United States dollars (USD)], of which USD 11 million is to be for the Alpharma group's products containing "Citalopram", in three instalments of USD 4 million, to be paid on 31 March 2002, 31 December 2002 and 30 June 2003 respectively;

– Article 2.2 establishes that, no later than 31 March 2002, the Alpharma group is to deliver to Lundbeck its entire current stock of products containing "Citalopram", namely the 9.4 million tablets already in its possession at the time of conclusion of the agreement at issue and the 16 million tablets which it had ordered.

17 Appendix A [to the agreement at issue] contains a list of 28 intellectual property rights applications lodged by Lundbeck before the signature of [that agreement], including nine which had already been granted by that date. Those intellectual property rights related to the processes used to produce the citalopram API covered by the crystallisation [patents] and [the] film distillation [patent].

18 Furthermore, it should be noted that on 2 May 2002 a United Kingdom court granted a consent order staying all proceedings in the UK infringement action because of the conclusion of an agreement between Lundbeck and, among others, the Alpharma group, under which the latter would "cancel, cease and desist from all importation … production … or sale, in [the Member States], Norway and Switzerland ('the Relevant Territories') of pharmaceutical products containing citalopram manufactured using processes claimed in [the crystallisation patents and the film distillation patent granted by the United Kingdom authorities] or any equivalent patent granted or applied for in relation to the Relevant Territories … until 30 June 2003" …

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

19 In October 2003, the Commission … was informed of the agreements in question by the Konkurrence- og Forbrugerstyrelsen (the Danish authority for [the protection of] competition and consumers, ["the Danish Competition Authority"]).

20 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 Danish Competition Authority] would not pursue the matter.

21 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.

22 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.

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

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

25 In 2010 and the first half of 2011, the Commission sent requests for information to Lundbeck and, among others, to the other companies which were parties to the agreements in question, including the Alpharma group.

26 On 24 July 2012, the Commission opened proceedings against the [manufacturers of generic medicines] which were parties to the agreements in question and sent them, and also Lundbeck, a statement of objections.

…

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

The [decision at issue]

31 By the [decision at issue], the Commission considered that the agreement at issue, and likewise 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)], committed by Lundbeck and also by Alpharma ApS, Alpharma Inc. and A.L. Industrier (Article 1(3) of the [decision at issue]).

32 As is apparent from the summary set out in recital 1087 of the [decision at issue], the Commission relied, in particular … on the following factors:

– at the time when they concluded the agreement at issue, Lundbeck and the Alpharma group were at least potential competitors in a number of EEA countries;

– under that agreement, Lundbeck transferred significant value to the Alpharma group;

– that transfer of value was linked to the Alpharma group's acceptance of the limitations on market entry contained in that agreement, and in particular to the Alpharma group's commitment not to sell any generic citalopram in the EEA during the relevant period;

– that transferred value corresponded approximately to the profit that the Alpharma group could have made if it had successfully entered the market;

– Lundbeck would not have been able to obtain those limitations through enforcement of the crystallisation [patents] and [the] film distillation [patent] ("Lundbeck's new [process] patents"), since the obligations placed on the Alpharma group under the agreement at issue went beyond the rights granted to holders of process patents;

– the agreement at issue contained no commitment from Lundbeck to refrain from bringing infringement proceedings against the Alpharma group if the latter entered the market with generic citalopram after the expiry of the agreement at issue.

33 The Commission also imposed fines on all the parties to the agreements in question. To that end, it applied [the 2006 Guidelines]. Although, in the case of Lundbeck, the Commission followed the general methodology described in the 2006 Guidelines, based on the value of sales of the product achieved by that undertaking (recitals 1316 to 1358 of the [decision at issue]), in the case of the other parties to the agreements in question, however, 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]).

34 Thus, as regards the parties to the agreements in question other than Lundbeck, including the Alpharma group, 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 those agreements, 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]).

35 As regards the Alpharma group, the Commission considered that the sums which Lundbeck had paid to it amounted to USD 11.1 million, equivalent to EUR 11.7 million, according to the average exchange rate in 2002. That amount consisted of (i) USD 10.1 million for the purchase of the Alpharma group's stock of citalopram, allowing for a reduction of USD 900 000 applied to the instalment paid by Lundbeck on 31 December 2002 (see the fourth indent of paragraph 16 [of the judgment under appeal]) on the ground that the number of tablets received had been lower than the agreed level, and (ii) USD 1 million in respect of the litigation costs saved as a result of the conclusion of the agreement at issue (recitals 545, 547, 1071 and 1374 and footnote [1867] of the [decision at issue]).

36 In view of the total length of the investigation, the Commission reduced by 10% the amount of the fines imposed on all the addressees of the [decision at issue] (recitals 1349 and 1380 of the [decision at issue]).

37 Last, the Commission applied the second subparagraph of Article 23(2) of Regulation No 1/2003 (which provides that, for each undertaking participating in an infringement, the fine is not to exceed 10% of its total turnover in the preceding business year) separately to [Xellia Pharmaceuticals], Zoetis and A.L. Industrier, since those companies no longer belonged to the same undertaking at the time of adoption of the [decision at issue] (recital 1384 of the [decision at issue]). In the case of A.L. Industrier, the Commission took into account the turnover achieved in 2011, and not that achieved in 2012, since it considered that the figures for 2012 did not relate to a year of normal economic activity (recitals 1386 and 1387 of the [decision at issue]).

38 On the basis of those considerations, the Commission imposed a fine of EUR 10 530 000 jointly and severally on [Xellia Pharmaceuticals] and Zoetis, while the joint and several liability of A.L. Industrier was limited to an amount of EUR 43 216 (recital 1396 and Article 2(3) of the [decision at issue]).'

The procedure before the General Court and the judgment under appeal

9 By document lodged at the Registry of the General Court on 28 August 2013, Xellia Pharmaceuticals ('Xellia') and Zoetis, now Alpharma LCC, brought an action for annulment in part of the decision at issue and reduction of the fine imposed on them by the Commission.

10 In support of their action, Xellia and Zoetis raised eight pleas in law, alleging, in essence, first, a manifest error of assessment as regards the Commission's interpretation of the scope of the agreement at issue; second, errors of law and of assessment as regards the characterisation of the Alpharma group as a potential competitor of Lundbeck; third, a manifest error of assessment in the characterisation of the agreement at issue as a 'restriction of competition by object'; fourth, an error of law as regards the finding of the existence of such a restriction when that agreement reflects the exclusionary power of Lundbeck's new process patents; fifth, breach of the rights of the defence; sixth, breach of the principle of non-discrimination owing to the fact that Zoetis is an addressee of the decision at issue; seventh, errors affecting the calculation of the amount of the fine imposed on the appellants; and, eighth, a manifest error of assessment in connection with the maximum amount of the fine in respect of which A.L. Industrier is jointly and severally liable.

11 By the judgment under appeal, the General Court dismissed that action in its entirety.

Procedure before the Court of Justice

12 By document lodged at the Registry of the Court of Justice on 25 November 2016, Xellia and Alpharma LLC ('the appellants') brought the present appeal.

13 By documents lodged at the Registry of the Court of Justice on 28 July 2017, the United Kingdom sought leave to intervene in support of the form of order sought by the Commission in the present case and in Cases C-586/16 P (*Sun Pharmaceutical Industries and Ranbaxy (UK)* v *Commission*), C-588/16 P (*Generics (UK)* v *Commission*), C-601/16 P (*Arrow Group and Arrow Generics* v *Commission*) and C-614/16 P (*Merck* v *Commission*), referred to in paragraph 7 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.

14 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-588/16 P (*Generics (UK)* v *Commission*), C-591/16 P (*Lundbeck* v *Commission*), C-601/16 P (*Arrow Group and Arrow Generics* v *Commission*) and C-614/16 P (*Merck* v *Commission*) and having heard an Opinion of the Advocate General.

15 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 the parties to the proceedings, a final plan for the hearing was sent to them on 22 January 2019.

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

17 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 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 those manufacturers as 'restrictions by object'. The replies to that question were received by the Court on 6 March 2020.

18 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

19 By their appeal, the appellants claim that the Court of Justice should:

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

– annul the decision at issue in whole or in part;

– cancel or substantially reduce the fine imposed on them;

– in the alternative, refer the case back to the General Court for determination in accordance with the judgment of the Court of Justice; and

– order the Commission to pay the costs of the present proceedings and the costs incurred before the General Court.

20 The Commission contends that the Court of Justice should:

– dismiss the appeal as being entirely unfounded;

– order the appellants to pay the costs.

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

The appeal

22 In support of their appeal, the appellants rely on nine grounds.

23 The first ground concerns a failure to recognise the presumption of validity of Lundbeck's new process patents as part of the assessment of the existence of potential competition between Lundbeck and the Alpharma group, and the second ground alleges a reversal of the burden of proof and reliance by the General Court, in the context of that assessment, on evidence which was not contained in the decision at issue.

24 The third and fourth grounds allege, respectively, mischaracterisation of the agreement at issue as a 'restriction by object' and a failure to assess whether the Commission proved its allegations on the scope of the restrictions laid down in the agreement at issue with respect to the Alpharma group.

25 The fifth to ninth grounds allege, respectively, first, an error of law in the assessment of the duration of the Commission's inquiry and harm to the appellants' rights of defence; second, discriminatory treatment of Alpharma LLC; third, legal uncertainty which should have precluded the imposition of a fine on the Alpharma group; fourth, a failure to take account of the gravity of the infringement in setting the amount of the fine imposed on the Alpharma group by the decision at issue; and, fifth, an error in law in that the General Court applied the wrong legal standard to determine the relevant business year to be used to determine the maximum amount of the fine that could be imposed on A.L. Industrier.

26 It is appropriate to start by examining the first and second grounds together, then to move on to the third and fourth grounds, also together, and finally to examine the fifth to ninth grounds in turn.

First and second grounds of appeal

The relevant paragraphs of the judgment under appeal

27 By their second plea raised in their action for annulment, the appellants claimed that the Commission had made several errors of law and of assessment regarding the characterisation of the Alpharma group as a potential competitor of Lundbeck.

28 The General Court rejected that plea in paragraphs 49 to 156 of the judgment under appeal.

29 As a preliminary point, the General Court summarised the analysis of potential competition carried out in the decision at issue, in which it stated the following in paragraphs 51 to 58 of the judgment under appeal:

> ‘51 In recitals 615 to 620 of the [decision at issue], the Commission examined the specific characteristics of the pharmaceutical sector and identified two phases in which potential competition could occur in that sector.
>
> 52 The first phase may begin several years before the impending expiry of the patent on an API, when [manufacturers of generic medicines] that want to launch a generic version of the medicinal product concerned begin developing viable processes leading to a product that meets regulatory requirements. Next, in the second phase, in order to prepare for actual market entry, a [manufacturer of generic medicines] must apply for marketing authorisations (“MAs”) for the purposes of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ 2001 L 311, p. 67), order tablets from one or more [manufacturers of generic medicines] or produce them itself and find distributors or set up its own distribution network, that is to say, it must take a series of preliminary steps, without which there would never be any effective competition on the market.
>
> …
>
> 54 In those phases of potential competition, [manufacturers of generic medicines] are often confronted with issues concerning patent law and intellectual property law. Nevertheless, they generally find a way to avoid infringing existing patents, such as process patents. They have various options in that respect, …
>
> …
>
> 58 As regards, in particular, the examination of competition between Lundbeck and the Alpharma group at the time of conclusion of the agreement at issue, the Commission, in recitals 1016 to 1039 of the [decision at issue], noted, inter alia, that the Alpharma group:
>
> – had already entered into an agreement with Tiefenbacher, under which it could purchase generic citalopram produced by the Indian companies, Cipla or Matrix, and use the MAs that Tiefenbacher already held;
>
> – had obtained MAs in the Netherlands, Finland, Denmark and Sweden and expected to receive one imminently in the United Kingdom as well;

– had 9.4 million generic citalopram tablets in stock, produced using Cipla's process, and had ordered 16 million more;

– had published sales prices in the United Kingdom;

– was planning to enter the market in a number of EEA countries within a period of two to six weeks;

– had reached the conclusion that the process used by Cipla to produce citalopram infringed [Lundbeck's patent protecting the crystallisation process in the United Kingdom] but considered that it had a reasonable chance of avoiding an injunction blocking its market entry and of securing invalidation of that patent;

– had the option of switching to citalopram produced by Matrix, which was using a process that was considered not to infringe Lundbeck's new [process] patents.'

30 As regards the possibility that the Alpharma group might enter the market, the General Court assessed two possible routes.

31 With regard to the first route, namely market entry by means of tablets manufactured using the process employed by Cipla to produce citalopram ('the Cipla process') which the Alpharma group had already received or ordered, the General Court recalled, in paragraph 85 of the judgment under appeal, the content of an email dated 19 February 2002 from a managing director of that group ('the email of 19 February 2002'), mentioned in recital 1027 of the decision at issue, which referred, inter alia, to applications for declarations of invalidity in respect of Lundbeck's new process patents, which had reasonable chances of success, and alluded to the possibility of using citalopram produced via the process employed by Matrix, which he regarded as not giving rise to problems with regard to Lundbeck's new process patents. In paragraph 88 of that judgment, the General Court inferred from the above that the Alpharma group itself acknowledged that it considered that its chances of invalidating Lundbeck's patent protecting the crystallisation process in the United Kingdom were reasonable.

32 In paragraphs 91 and 92 of that judgment, the General Court noted that the Alpharma group had taken numerous steps and made significant investments in order to enter the market, which the Court listed.

33 In paragraph 108 of that judgment, the General Court noted that it was apparent from an Alpharma group internal email of 14 February 2002 and from the email of 19 February 2002 that that group, whilst aware of the risks that market entry might entail, would not necessarily have abandoned its plans if it had not been able to conclude a sufficiently advantageous agreement with Lundbeck.

34 In paragraph 123 of the judgment under appeal, the General Court added that, although the fact that, on 30 January 2002, Lundbeck obtained the patent protecting the crystallisation process in the United Kingdom surprised the Alpharma group, since it had expected Lundbeck's application to be refused, that group continued to consider that, despite the existence of certain risks, it had a reasonable chance of having that patent annulled and that, in view in particular of the steps already taken and the investments already made, market entry thus remained a real concrete possibility, which was an alternative option to concluding a sufficiently advantageous agreement with Lundbeck.

35 In paragraph 132 of that judgment, the General Court held that, also according to Lundbeck, the Alpharma group had a real and concrete possibility of entering the market.

36 Lastly, in paragraph 136 of that judgment, that court held that the fact that it was probable that the Cipla process infringed Lundbeck's patent protecting the crystallisation process in the United Kingdom did not represent for the Alpharma group a barrier to market entry of such magnitude that the group could not be considered to be a potential competitor of Lundbeck.

37 As regards the second route of market entry, by means of citalopram produced via the process used by Matrix, the General Court noted, in paragraphs 139, 143 and 154 respectively of the judgment under appeal, that the contract concluded between Tiefenbacher and the Alpharma group permitted the latter to obtain citalopram produced in accordance with the processes used by Cipla and Matrix, that the Alpharma group took the view that the process that Matrix was using at the time to produce citalopram could allow the group to enter the market without infringing Lundbeck's patent protecting the crystallisation process in the United Kingdom, and that, on that basis, at the time of conclusion of the agreement at issue, even the switch to citalopram produced in accordance with the Matrix process constituted for the Alpharma group a real and concrete possibility of market entry.

38 Consequently, in paragraph 155 of the judgment under appeal, the General Court held that the Alpharma group had at least two real and concrete possibilities of entering the market and, owing to those possibilities, was exerting competitive pressure on Lundbeck.

39 Last, in response to the appellants' fourth plea in support of their action for annulment, alleging an error of law as regards the finding of the existence of a 'restriction by object' when the agreement at issue reflected the exclusionary power of Lundbeck's new process patents, the General Court held, inter alia, in paragraph 339 of the judgment under appeal, as follows:

> '339 … in the light of the principles deriving from the case-law set out in paragraphs 315 and 316 [of the judgment under appeal], the presumption of validity enjoyed by all patents cannot be equated with a presumption of illegality of any product placed on the market which the patent holder deems to be infringing his patent. As the Commission submits, in the present case it was for Lundbeck to prove before the national courts, in the event that generic medicinal products entered the market, that they infringed one of its process patents, since entry "at risk" by a [manufacturer of generic medicines] is not in itself unlawful. Moreover, in the context of an infringement action, the defendant could have challenged the validity of the patent on which Lundbeck relied by bringing a counter-claim. Such claims occur frequently in patent litigation and lead, in numerous cases, to a declaration of invalidity of the process patent relied on by the patent holder, as the Commission noted in recital 76 of the [decision at issue].'

Arguments of the parties

40 By their first ground of appeal, directed against, inter alia, paragraphs 54 and 339 of the judgment under appeal, the appellants criticise the General Court for concluding that the Alpharma group was a potential competitor of Lundbeck despite evidence which clearly showed that that group's products infringed Lundbeck's new process patents, which had to be presumed to be valid.

41 According to the appellants, it was for the General Court to satisfy itself that the Commission had submitted evidence showing to the requisite legal standard that Lundbeck's new process patents were weak, failing which those patents had to be presumed to be valid and the entry of infringing products presumed to be unlawful. By failing to do so, the General Court allegedly infringed the basic principle that patents are to be presumed to be valid and disregarded the fact that a patent grants its holder an exclusive right and not merely a right to claim an exclusionary power by court action. In so doing, the General Court 'dissociated' its assessment under Article 101 TFEU from the principles deriving from patent law.

42 In that regard, the appellants claim that the status of being a competitor depends on whether the patent concerned is valid, which is uncertain until a final judicial decision is adopted, while maintaining that there is a presumption in competition law that patents are valid, and that presumption obliges the Commission, if it wishes to establish the existence of a restriction of competition, to demonstrate that the patent concerned is weak. In addition, they add that, if the presumption that patents are valid were not recognised, every settlement agreement would always be a restriction of competition.

43 The appellants argue that, in the present case, the Commission's evidence that Lundbeck's patent protecting the crystallisation process in the United Kingdom is weak was not examined by the General Court and cannot be established simply by referring to an email from an executive of the Alpharma group or to statements made by Lundbeck. In that regard, the Commission merely found, as is apparent from paragraph 54 of the judgment under appeal, that process patents are more vulnerable than the other types of patent.

44 In addition, the appellants claim that the Commission disregarded contemporaneous evidence showing that the two parties to the agreement at issue held the view that the Alpharma group's products infringed Lundbeck's new process patents.

45 By their second ground of appeal, the appellants complain that the General Court failed to verify whether the Commission had proved that, on the date of the agreement at issue, the Alpharma group actually had real possibilities of entering the market with the infringing tablets that it had purchased, thus reversing the burden of proof.

46 In accordance with the judgment of 29 June 2012, *E.ON Ruhrgas and E.ON* v *Commission* (T-360/09, EU:T:2012:332, paragraph 114), where a party is preparing to enter the market and encounters an unforeseen obstacle – in the present case, the infringing nature of its products – it is for the Commission to prove that, despite that obstacle, entry to the market remains, in spite of everything, an economically viable strategy. Thus, the appellants maintain that, in the present case, the Commission was required to prove that the probability that the Alpharma group would not succeed in litigation in respect of Lundbeck's new process patents was relatively low in order for market entry to remain an economically viable strategy. The Commission did not adduce that evidence and merely stated that it was not certain that Lundbeck would be able to use its new process patents to block the Alpharma group's market entry, as is apparent from recital 1039 of the decision at issue.

47 Moreover, the appellants claim that the General Court reversed the burden of proof by requiring the appellants to prove that Lundbeck's new process patents prevented market entry from being an economically viable strategy, proof which was particularly difficult to adduce given that the Commission waited six to seven years before notifying its objections to the Alpharma group.

48 Furthermore, in paragraph 108 of the judgment under appeal, the General Court relied on evidence which was not contained in the decision at issue without allowing the appellants to dispute the relevance of that evidence and, therefore, infringed their rights of defence.

49 The Commission claims that the first and second grounds of appeal must be dismissed.

Findings of the Court

50 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).

51 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 (judgment of 30 January 2020, *Generics (UK) and Others*, C-307/18, EU:C:2020:52, paragraph 32).

52 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; however, that criterion does not require in any way that it be demonstrated with certainty that the former undertaking will in fact enter the market concerned and, a fortiori, that it will be capable, thereafter, of retaining its place there (judgment of 30 January 2020, *Generics (UK) and Others*, C-307/18, EU:C:2020:52, paragraphs 36 and 38).

53 When the agreements in question are ones which have the effect of temporarily keeping several undertakings outside a market, such as the agreement at issue, 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).

54 Specifically, with regard to such agreements occurring in the context of the opening, to the manufacturers of generic medicines, of the market, for a medicine containing an active ingredient that has recently entered the public domain, 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).

55 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).

56 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).

57 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).

58 Furthermore, the Court has also held that it is not for the competition authority concerned to carry out a review of the strength of the patent at issue or of the probability of a dispute between the patent holder and a manufacturer of generic medicines being brought to an end with a finding that that patent is valid and has been infringed (judgment of 30 January 2020, *Generics (UK) and Others*, C-307/18, EU:C:2020:52, paragraph 50).

59 In the present case, it is apparent from the judgment under appeal – specifically, from paragraphs 58, 85, 91, 92, 123, 139, 143 and 154 thereof – that not only had the Alpharma group taken numerous steps to obtain MAs and made significant investments in order to enter the generic citalopram market, but also that it had at least two real and concrete possibilities of entering the market at the time the agreement at issue was concluded. The first, namely market entry with tablets manufactured using the Cipla process, which the Alpharma group had received or ordered from Tiefenbacher, had not been called into question by the new information brought to the attention of the Alpharma group in January and February 2002 as to whether the Cipla process was potentially infringing. The second possibility was that of entering the market with citalopram tablets manufactured via the Matrix process, which entailed no risk of infringement; the Alpharma group did not have such tablets at its disposal, but could obtain them in the short term through its contract with Tiefenbacher.

60 In addition, the General Court held, in paragraphs 88 and 136 of the judgment under appeal, that the Alpharma group considered that Lundbeck's patent protecting the crystallisation process in the United Kingdom did not constitute a barrier to its market entry and that, in the event of litigation, that group had reasonable chances of having that process patent annulled.

61 Moreover, the General Court noted, in paragraph 132 of that judgment, that, according to Lundbeck itself, the Alpharma group was a potential competitor.

62 In the light of those findings, the General Court was entitled to find that the Alpharma group and Lundbeck were potential competitors at the time of conclusion of the agreement at issue, and, in particular, did not infringe the presumption of validity enjoyed by Lundbeck's new process patents or reverse the burden of proof in coming to that finding.

63 That conclusion cannot be called into question by the appellants' claim that the General Court disregarded evidence contemporaneous with the agreement at issue which shows that the Alpharma group and Lundbeck considered that the products of that group infringed Lundbeck's new process patents. That claim is inadmissible, not only because it does not, in accordance with Article 169(2) of the Rules of Procedure, identify precisely a point in the grounds of the judgment under appeal that is contested, but also since it is not clear what evidence contemporaneous with the agreement at issue was disregarded by the General Court.

64 Finally, as regards the appellants' claim that, in paragraph 108 of the judgment under appeal, the General Court relied on evidence that is not contained in the decision at issue, without allowing them to refute its relevance and thus infringed their rights of defence, it is sufficient to note, as is shown by the phrase 'in any event' at the beginning of paragraph 108 of the judgment under appeal, that that paragraph sets out a ground of the judgment under appeal which is included for the sake of completeness, as compared with those set out in paragraphs 104 to 106 of that judgment, which are not contested by the appellants, the purpose of which is to provide reasons for the rejection of the appellants' argument summarised in paragraph 103 of that judgment. Consequently, the appellants' argument relating to paragraph 108 of the judgment under appeal must be rejected as being ineffective (see, to that effect, judgment of 14 December 2016, *SV Capital* v *EBA*, C-577/15 P, EU:C:2016:947, paragraph 65).

65 In the light of the foregoing, the first ground of appeal must be rejected as being inadmissible in part and unfounded in part, while the second ground of appeal must be rejected as being ineffective in part and unfounded in part.

Third and fourth grounds of appeal

The relevant paragraphs of the judgment under appeal

66 In the context of the rejection of the second plea raised by the appellants in support of their action for annulment, alleging errors of law and of assessment as regards the characterisation of the Alpharma group as a potential competitor of Lundbeck, the General Court stated, in paragraphs 119 and 120 of the judgment under appeal, as follows:

> '119 … it is certainly noteworthy that the fact that Lundbeck obtained, on 30 January 2002, the [patent protecting the crystallisation process] in the United Kingdom came as a surprise to the Alpharma group since it was not expecting the patent application filed by Lundbeck on 12 March 2001 to be granted, as can be seen from a statement made by the director of the Alpharma group responsible inter alia for intellectual property … produced by the [appellants].
>
> 120 Similarly, whilst it follows from the email of 17 September 2001 – cited in part in recital 482 of the [decision at issue] and produced in full before the [General] Court – that Tiefenbacher had reassured the Alpharma group that the Cipla process did not infringe Lundbeck's new [process] patents, the group subsequently came to the conclusion that that process infringed [Lundbeck's patent protecting the crystallisation process in the United Kingdom], as is apparent inter alia from the email of 19 February 2002.'

67 By their first plea in law raised in their action for annulment, the appellants claimed that, by finding that, in the agreement at issue, the Alpharma group had undertaken not to sell any generic citalopram during the relevant period, the Commission had made a manifest error of assessment in its interpretation of the scope of that agreement.

68 In order to reject that plea, the General Court, in paragraphs 164 to 243 of the judgment under appeal, rejected in turn the arguments put forward by the appellants relating to the wording of Article 1.1 of the agreement at issue, its preamble, the circumstances in which it was concluded, the consent order made following the agreement at issue in order to put an end to the UK infringement action and the date on which the Alpharma group entered the market.

69 In paragraphs 244 to 247 of that judgment, the General Court ultimately held that the appellants had not succeeded in rebutting the evidence by which the Commission proved that the agreement at issue included restrictions which went beyond those that Lundbeck could have obtained by relying on its new process patents and winning its case in the event of litigation in that regard.

70 By their third plea in law raised in their action for annulment, the appellants claimed that the Commission had made a manifest error of assessment as regards the characterisation of the agreement at issue as a 'restriction of competition by object'.

71 The General Court rejected that plea in paragraphs 248 to 333 of the judgment under appeal.

72 To that end, the General Court started by setting out, in paragraphs 251 to 257 of the judgment under appeal, preliminary observations in which it recalled the case-law of the Court of Justice relating to characterisation as a 'restriction by object'.

73 The General Court then stated, in a summary of the analysis contained in the decision at issue as to whether there was a restriction of competition by object, inter alia, the following:

> '261 It can … be seen from the [decision at issue] that, even if the restrictions set out in the agreements in question fell within the scope of [Lundbeck's new process] patents – that is to say, that the agreements prevented only the market entry of generic citalopram produced by a process deemed by the parties to the agreements to potentially infringe those patents without covering every type of generic citalopram – they would nevertheless constitute restrictions on competition by object, since, inter alia, they prevented or rendered pointless any type of challenge to Lundbeck's [new 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]).
>
> 262 In other words, according to the Commission, the agreements in question transformed the uncertainty in relation to the outcome of such litigation into the certainty that the generics would not enter the market, which may also constitute a restriction on competition by object when such limits do not result from an assessment, by the parties to those agreements, of the merits of the exclusive right at issue, but rather from the size of the reverse payment provided for which, in such a case, overshadows that assessment and induces the [manufacturer of generic medicines] not to pursue its independent efforts to enter the market (recital 641 of the [decision at issue]).
>
> 263 It must be noted, in that respect, that the Commission did not assert, in the [decision at issue], that all patent settlement agreements containing reverse payments were contrary to Article 101(1) TFEU; 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 [new process] patents – led to the conclusion that the object of the agreements in question was to restrict competition, within the meaning of Article 101(1) TFEU, in the present case (see recitals 661 and 662 of the [decision at issue]).'

74 Finally, the General Court assessed the existence of a 'restriction by object' in the present instance in paragraphs 266 to 333 of the judgment under appeal.

75 In that context, the General Court held, inter alia, in paragraph 268 of that judgment, that, even assuming that the scope of the agreement at issue coincided with that of Lundbeck's new process patents, it would have to be concluded that the Alpharma group had foregone, in return for a reverse payment, the possibility of entering the market with citalopram produced in accordance with the Cipla process, which was alleged to infringe a patent in respect of which there was a reasonable chance of a declaration of invalidity, at a time when that possibility was real and concrete for the Alpharma group, with the result that the payment was a determining factor in its decision to forego that possibility.

76 In paragraphs 277 to 279 of that judgment, the General Court refused to characterise the agreement at issue as a settlement agreement. To that end, it noted, first, the case-law of the Court of Justice according to which an agreement is not exempt from competition law merely

because it concerns a patent or is intended to settle a patent dispute. Second, it held that the agreement at issue had a broader scope than that of the UK infringement action and that that action had simply been stayed for the duration of that agreement, which precluded that agreement from resolving proceedings.

77 In paragraph 287 of that judgment, in order to reject the appellants' argument that the Commission had not established with certainty that the Alpharma group would be successful in potential litigation relating to Lundbeck's new process patents, the General Court held that the Commission was not required to establish with certainty that the Alpharma group would have been successful if it had opted for litigation.

78 As regards the amount of the payment made by Lundbeck to the Alpharma group, the General Court found, inter alia, in paragraphs 296 and 298 respectively of that judgment, that the Commission had correctly observed that the amount of that payment was linked to the profits expected by the Alpharma group and that that amount represented a definite profit for that group, whereas the profits that could arise from market entry were uncertain.

79 In paragraphs 301 to 310 of the judgment under appeal, the General Court held that the Commission was entitled to treat the circumstances of the present case in the same way as those in the case that gave rise to the judgment of 20 November 2008, *Beef Industry Development Society and Barry Brothers* (C-209/07, EU:C:2008:643).

80 In paragraphs 311 to 326 of that judgment, the General Court also refused to uphold the appellants' argument that the agreement at issue could not be characterised as a 'restriction by object' in the absence of precedent and because of the legal uncertainty surrounding that type of agreement.

81 To that end, the General Court started by recalling, in paragraphs 315 to 317 of that judgment, the case-law of the Court of Justice on the application of competition law in the specific field of intellectual property rights. It then found, in paragraph 318 of that judgment, that both Lundbeck and the Alpharma group were aware that their conduct was at least capable of posing problems from the point of view of competition law. In paragraphs 319 and 320 to 325 of the judgment under appeal, the General Court held, respectively, that it was not necessary that an agreement of the same type as the agreement at issue should already have been censured by the Commission in order for that agreement to be regarded as a 'restriction of competition by object', and that the press release of 28 January 2004 from the Danish Competition Authority ('the Danish Competition Authority press release'), relied on by the appellants, did not preclude such a characterisation in the present case. The General Court then concluded, in paragraph 326 of the judgment under appeal, that 'at the time of conclusion of the agreement at issue, it was already established that a patent holder was not entitled to pay a potential competitor to give up some or indeed all real concrete possibilities of entering the market in exchange for a sum paid by that holder and determined on the basis of the profits expected by that competitor in the event of market entry'.

Arguments of the parties

82 By their third ground of appeal, directed against paragraphs 248 to 333 of the judgment under appeal, the appellants submit that the General Court erred in law by confirming, in breach of the judgment of 11 September 2014, *CB* v *Commission* (C-67/13 P, EU:C:2014:2204), that the agreement at issue constituted a 'restriction by object'.

83 First, in paragraphs 57 and 58 of that judgment, the Court stated that, in order to characterise behaviour as a 'restriction by object', there must be a significant likelihood of restricting competition and that assessment must be made strictly, since it deprives the defendants of fundamental procedural safeguards and must not lead to the prohibition of agreements which may prove to be pro-competitive. In the present case, the appellants criticise paragraph 287 of the judgment under appeal, by which the General Court inferred from the fact that the Alpharma group was a potential competitor of Lundbeck, *quod non*, the fact that the agreement at issue was capable of restricting competition with a high degree of probability. Even if the Alpharma group had been a potential competitor of Lundbeck, that would allow it to be inferred not that the agreement at issue was highly likely to restrict competition, but only that it was likely to restrict competition.

84 In that regard, the appellants submit that it was essential to establish the 'counterfactual scenario', namely to determine what would have happened in the absence of the agreement at issue. Thus, in order to demonstrate that the agreement at issue was highly likely to give rise to adverse effects on competition, the Commission should have demonstrated that, in the absence of the agreement at issue, it would have been highly likely either that the Alpharma group would have been successful in litigation relating to Lundbeck's new process patents or that it would have concluded a less restrictive agreement than the agreement at issue, allowing it to enter the market sooner. Even if the Alpharma group's chances of success as envisaged by Lundbeck – namely a 50% to 60% chance of Lundbeck's patent protecting the crystallisation process in the United Kingdom being declared invalid – are assumed, that would not allow it to be inferred that the agreement at issue was highly likely to restrict competition, particularly as the Alpharma group discovered at the last minute that its product was infringing, as is apparent from paragraphs 119 to 121 of the judgment under appeal.

85 Furthermore, according to the appellants, the solution adopted by the General Court may border on the absurd if it were ultimately to be established that Lundbeck's new process patents were valid. The agreements in question would still constitute restrictions by object even if the patent concerned is subsequently deemed to be valid and the sale of infringing products to be unlawful.

86 Second, the appellants claim that, in the judgment of 11 September 2014, *CB* v *Commission* (C-67/13 P, EU:C:2014:2204), the Court of Justice stressed the importance of past experience in relation to types of agreements similar to the agreement at issue. In paragraphs 311 to 326 of the judgment under appeal, the General Court wrongly rejected the argument that it was inappropriate to characterise the agreement at issue as a 'restriction by object' because there is no experience in the field of patent dispute settlement agreements providing for reverse payments. In so doing, the General Court not only failed to identify any specific feature of the agreement at issue in the context of the EU's decision-making and judicial practice concerning competition law in connection with intellectual property rights, but also disregarded very widely held academic opinions on that type of agreement. In addition, the appellants submit that the General Court could not infer, in paragraph 318 of the judgment under appeal, that the agreement at issue constituted a 'restriction by object' from the fact that Lundbeck and the Alpharma group were aware that their agreement was capable of posing problems from the point of view of competition law and had been the subject of legal advice. Similarly, the appellants submit that, in paragraph 319 of the judgment under appeal, unless the requirement that the concept of 'restriction by object' be interpreted strictly was to be disregarded, the General Court could not find that experience in dealing with that general form of collusion made it possible to adopt that characterisation in the present case, in view of the specific features of settlement agreements which cover patent disputes and provide for reverse payments, which lie at the

intersection of competition law and patent law and which, it may be added, are clearly distinguishable from those referred to in the judgment of 20 November 2008, *Beef Industry Development Society and Barry Brothers* (C-209/07, EU:C:2008:643), cited by the General Court in paragraphs 301 to 310 of the judgment under appeal. The agreement at issue could be explained by Lundbeck's legitimate desire to protect itself against an infringing entry to the market for its medicines and the resulting consequences, and by the legitimate desire of the Alpharma group to avoid the financial and legal consequences of its market entry, the unlawfulness of which was only discovered at the last minute, and of managing a large stock of infringing products. The appellants also criticise the fact that the General Court, in paragraphs 320, 321 and 325 of the judgment under appeal, failed to take account of the Danish Competition Authority press release according to which the agreements in question were in a 'legal grey zone' or of the Commission's doubts as to how those agreements should be characterised, which justified a sector inquiry at the end of which the Commission found that such agreements had to be examined on a case-by-case basis, taking into account all the relevant facts. Such factors do not support the conclusion, reached by the General Court in paragraph 326 of the judgment under appeal, that the agreement at issue could be characterised as a 'restriction by object'.

87 By their fourth ground of appeal, directed against paragraphs 160 to 247 of the judgment under appeal, the appellants claim that the General Court erred in law and was in breach of the principle of the presumption of innocence by failing to examine whether the Commission had proved its claims that, first, the restriction laid down in the agreement at issue went beyond the scope of Lundbeck's new process patents and, second, that the Alpharma group was contractually prohibited from selling citalopram made with a process that did not infringe Lundbeck's patents, which is what the appellants maintained in their first plea in law seeking annulment. In so doing, in paragraph 162 of the judgment under appeal, the General Court discharged the Commission of the burden of proof incumbent on it and, therefore, reversed that burden by requiring the appellants, in paragraphs 162 to 243 of that judgment, to prove that there was no restriction on the sale of non-infringing citalopram.

Findings of the Court

88 As a preliminary point, it should be noted that, by their fourth ground of appeal, the appellants complain that the General Court was in breach of the principle of the presumption of innocence and reversed the burden of proof by rejecting their first plea in law relied on in support of their action for annulment, alleging a manifest error of assessment as regards the Commission's interpretation of the scope of the agreement at issue.

89 In that regard, it is apparent from paragraph 157 of the judgment under appeal that the appellants submitted in that first plea that the Commission had made a manifest error of assessment in finding that, by the agreement at issue, the Alpharma group had undertaken not to sell any generic citalopram during the relevant period, since the Commission did not have evidence to that effect.

90 It is also apparent from paragraphs 244 to 247 of that judgment that the General Court found that the Commission had proved to the requisite legal standard that the literal, contextual and teleological interpretation of the agreement at issue allowed the conclusion that the obligations assumed by the Alpharma group under Article 1.1 of that agreement were not limited to citalopram produced in accordance with processes which that group and Lundbeck had acknowledged infringed Lundbeck's new process patents, by rejecting, in paragraphs 162 to 243

of that judgment, all the appellants' arguments in turn which related to the wording of the agreement at issue, the circumstances in which it was concluded and the events which came after it.

91 Therefore, by their fourth ground of appeal, the appellants are merely asking the Court of Justice to re-examine all the facts and evidence submitted to the General Court regarding the scope of the agreement at issue.

92 In that regard, it follows from Article 256 TFEU and from the first paragraph of Article 58 of the Statute of the Court of Justice of the European Union that an appeal is to be limited to points of law. The General Court thus 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.

93 The appellants have neither alleged nor, a fortiori, shown a distortion of the clear sense of the facts or evidence by the General Court.

94 Moreover, the fact that the General Court did not uphold their line of argument does not mean, as the appellants claim, that it was in breach of the principle of the presumption of innocence or reversed the burden of proof, but only that it found that the arguments put forward by them were not sufficiently convincing.

95 Consequently, the fourth ground of appeal must be rejected as being inadmissible.

96 With regard to the third ground of appeal, it should be noted that the Court of Justice has held previously, as the General Court observed in paragraphs 252 to 254 and in paragraph 256 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).

97 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).

98 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).

99 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).

100 In the present case, it is apparent from the judgment under appeal, and in particular from paragraphs 261, 263, 268, 296, 298 and 326 thereof, first of all, that the agreement at issue contained an undertaking given by the Alpharma group not to enter the market during the term of that agreement, in return for the payments made to it by Lundbeck, the amount of which was linked to the profits expected by the Alpharma group. The General Court also stated that, even if that amount had to be decreased to an amount less than the USD 10 million found by the Commission, it would nonetheless constitute a definite profit for the Alpharma group since the profits that might arise from market entry were uncertain.

101 In paragraphs 278 and 279 of that judgment, the General Court then held that the agreement at issue had a broader scope than that of the UK infringement action, which related specifically to the tablets which the Alpharma group had already received or ordered, and which, indeed, was only stayed by the agreement at issue, as confirmed by Lundbeck's statement, cited in the decision at issue, that that agreement did not resolve any dispute.

102 In so doing, the General Court agreed with the assessment made by the Commission in the decision at issue and referred to in paragraph 262 of the judgment under appeal that, in essence, the agreement at issue had transformed uncertainty as to the outcome of litigation relating to Lundbeck's new process patents into certainty that the Alpharma group would not enter the market, even though that agreement had been concluded not following an analysis, by that group, of the merits of the process patents at issue, but rather on account of the size of the reverse payment provided for, which gave it an incentive not to pursue its efforts to enter the market.

103 Therefore, and without it being necessary to determine whether the General Court was entitled, in paragraphs 301 to 310 of the judgment under appeal, to treat the agreement at issue in the same way as the agreements in the case that gave rise to the judgment of 20 November 2008, *Beef Industry Development Society and Barry Brothers* (C-209/07, EU:C:2008:643), it must be held that the General Court did not err in law in finding that the agreement at issue should be characterised as a 'restriction by object' within the meaning of Article 101(1) TFEU.

104 That finding cannot be called into question by the arguments put forward by the appellants.

105 First, they are not justified in criticising the General Court for not having held, in paragraph 287 of the judgment under appeal, that the Commission was required to assess objectively the Alpharma group's real prospects of succeeding in litigation concerning Lundbeck's new process patents.

106 In that regard, as is apparent from paragraph 60 of the judgment delivered today in Case C-591/16 P, *Lundbeck* v *Commission* and from paragraph 80 of the judgment delivered today in Case C-588/16 P, *Generics (UK)* v *Commission*, much like the assessment of whether the parties to a settlement agreement, such as the agreement 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 characterising that agreement as a 'restriction by object', provided that it has been established, as is apparent, in essence, from paragraph 346 of the judgment under appeal, 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).

107 The characterisation of the agreement at issue as a 'restriction by object' depends solely on whether the parties to that agreement deliberately substituted practical cooperation between them for the risks of competition, as is apparent from paragraph 98 of the present judgment.

108 Second, nor can the appellants criticise the General Court for having characterised the agreement at issue as a 'restriction by object' despite the fact that that agreement addressed legitimate concerns on the part of both the Alpharma group and Lundbeck, in that it allowed that group to avoid the financial and legal consequences of unlawful market entry and managing a large stock of infringing products, and allowed Lundbeck to protect itself from against the asymmetry of risks between the process patent holder and the manufacturers of generic medicines.

109 As the General Court rightly held in paragraphs 277 and 317 of the judgment under appeal, an agreement, first, is not exempt from competition law merely because it concerns a patent or is intended to settle a patent dispute (see, to that effect, judgment of 27 September 1988, *Bayer and Maschinenfabrik Hennecke*, 65/86, EU:C:1988:448, paragraph 15), and, second, may be regarded as having a restrictive object even if it does not have the restriction of competition as its sole aim but also pursues other legitimate objectives (judgment of 20 November 2008, *Beef Industry Development Society and Barry Brothers*, C-209/07, EU:C:2008:643, paragraph 21).

110 Nor, moreover, can the fact that adopting anticompetitive conduct may constitute the most profitable or least risky solution for an undertaking preclude that conduct from being characterised as a 'restriction by object'.

111 In particular, the Court of Justice has previously refused to overturn a finding characterising agreements such as the agreement at issue as 'restrictions by object' on grounds relating to the fact that the damages to which the manufacturer of originator medicines may have a claim in the event of unlawful entry of generic medicines onto the market would often be significantly smaller than the loss suffered by the manufacturers of originator medicines since it is for public authorities and not private undertakings to ensure compliance with statutory requirements (judgment of 30 January 2020, *Generics (UK) and Others*, C-307/18, EU:C:2020:52, paragraph 88).

112 Accordingly, the interests referred to by the appellants cannot mean that an agreement which was found, in paragraph 103 of the present judgment, to reveal a sufficient degree of harm to competition to be characterised as a 'restriction by object' should be allowed to avoid such characterisation.

113 Third, the appellants cannot validly complain that the General Court accepted the anticompetitive aim of the agreement at issue without examining the 'counterfactual scenario'.

114 As is apparent from paragraph 139 of the judgment delivered today in Case C-591/16 P, *Lundbeck* v *Commission*, that examination allows the effects of a concerted practice with regard to Article 101 TFEU to be assessed when the analysis of that practice does not reveal a sufficient degree of harm to competition to enable it to be characterised as a 'restriction by object' (judgment of 30 January 2020, *Generics (UK) and Others*, C-307/18, EU:C:2020:52, paragraphs 115 and 118 and the case-law cited).

115 Consequently, as the Court of Justice held in the judgment delivered today in Case C-591/16 P, *Lundbeck* v *Commission* (paragraph 140), unless the clear distinction between the concept of 'restriction by object' and the concept of 'restriction by effect' arising from the wording itself of Article 101(1) TFEU (judgment of 30 January 2020, *Generics (UK) and Others*, C-307/18, EU:C:2020:52, paragraph 63) is to be held not to exist, an examination of the 'counterfactual scenario', the purpose of which is to make apparent the effects of a given concerted practice, cannot be required in order to characterise a concerted practice as a 'restriction by object'.

116 Furthermore, as is apparent from the judgment delivered today in Case C-601/16 P, *Arrow Group and Arrow Generics* v *Commission* (paragraph 86), the assessment which must be undertaken, in accordance with paragraphs 98 and 99 of the present judgment, in order to establish whether or not an agreement such as the agreement at issue is to be characterised as a 'restriction by object' is in no way intended to identify and to quantify the anticompetitive effects of a practice, but solely to determine its objective seriousness, which can justify precisely there being no need to assess its effects.

117 As stated in paragraph 131 of the judgment delivered today in Case C-591/16 P, *Lundbeck* v *Commission*, and in paragraph 87 of the judgment delivered today in Case C-601/16 P, *Arrow Group and Arrow Generics* v *Commission*, the fact that that assessment must be carried out, where necessary, following a detailed analysis of not only the agreement concerned and in particular of the incentive effect of the transfers of value for which it provides, but also of its objectives and the economic and legal context of which it forms part again does not imply an assessment of the anticompetitive effects of that agreement on the market. It involves solely carrying out a detailed overall assessment of the complex agreements themselves in order not only to rule out their being characterised as a 'restriction by object', where there is doubt as to whether they are sufficiently harmful to competition, but also to preclude agreements from failing to be characterised as a 'restriction by object' by reason of their complexity alone and even though an assessment of those agreements would demonstrate that they reveal, objectively, a sufficient degree of harm to competition.

118 Fourth, the appellants cannot validly rely on the fact that the experience which case-law dictates is necessary in order to characterise the agreement at issue as a 'restriction by object' was lacking in the present case.

119 In that regard, as the General Court correctly pointed out in paragraph 319 of the judgment under appeal, it is in no way necessary that agreements of the same type as the agreement at issue should have previously been censured by the Commission in order for that agreement to be considered a restriction of competition by object, even if the agreement occurs in a specific field such as the field of intellectual property rights.

120 In order for a given agreement to be characterised as a 'restriction by object', it is only the specific characteristics of that agreement which are significant (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 it is necessary to infer any particular harmfulness for competition, where necessary following a detailed analysis of that agreement, its objectives and the economic and legal context of which it forms a part.

121 The agreement at issue, which allowed the market entry of the Alpharma group to be delayed and which was accompanied by payments made by Lundbeck to that group, which, by virtue of their size, induced that group not to continue its efforts to enter the market, belong to that category of practices which are particularly harmful to competition.

122 Fifth, the appellants cannot validly criticise the General Court for having considered that the Danish Competition Authority press release did not preclude the agreement at issue from being characterised as a 'restriction by object'.

123 As the General Court noted in paragraphs 320 to 324 of the judgment under appeal, whilst it is true that that press release refers to the Commission's position regarding the anticompetitive nature of the agreements in question, that position, aside from the fact that it was issued after only a preliminary assessment, was expressed not in a press release issued directly by the Commission or its departments, but in a press release from a national competition authority, which could not give rise to a legitimate expectation on the part of undertakings that their conduct did not infringe Article 101 TFEU.

124 In addition, it is apparent from those same paragraphs of the judgment under appeal that the Danish Competition Authority had stated in that press release that that position of the Commission related in particular to the size of the payments made by Lundbeck and that all agreements whose object is to obtain the exclusion from the market of a competitor are anticompetitive.

125 Therefore, and in the light of those findings, the General Court was fully entitled, in paragraph 326 of the judgment under appeal, to characterise the agreement at issue as a 'restriction by object' in spite of the Danish Competition Authority press release.

126 Sixth, the appellants are wrong to criticise the General Court for having found, in paragraph 318 of the judgment under appeal, that the fact that the Alpharma group and Lundbeck were aware that the agreement at issue was capable of posing problems from the point of view of competition law and the fact that that agreement had been the subject of legal advice were factors which justified characterising that agreement as a 'restriction by object'.

127 That argument is based on a misreading of paragraph 318 of the judgment under appeal. The consideration set out in that paragraph by the General Court forms part of its examination of the appellants' arguments concerning alleged legal uncertainty as to the anticompetitive nature of agreements such as the agreement at issue. In that paragraph, the General Court, in essence, confined itself to finding that, in spite of the alleged legal uncertainty, both Lundbeck and the Alpharma group were aware that their conduct was at least capable of posing problems from the point of view of competition law.

128 In the light of the foregoing, the third and fourth grounds of appeal must be rejected as being inadmissible and unfounded, respectively.

Fifth ground of appeal

The relevant paragraphs of the judgment under appeal

129 By their fifth plea in law raised in their action for annulment, the appellants claimed that the Commission had infringed their rights of defence by failing to inform them in a timely manner of the existence of an inquiry concerning them and of its objections regarding them, which had the consequence that they therefore did not have exculpatory evidence available to them.

130 In rejecting that plea, the General Court recalled, in paragraphs 353 to 358 of the judgment under appeal, the case-law relating to the compliance with the requirement that administrative procedures relating to competition policy be conducted within a reasonable period of time and the procedures for establishing an infringement of the rights of the defence by reason of a failure to conduct those procedures within a reasonable period of time, by referring, inter alia, to paragraphs 42, 43 and 54 of the judgment of 21 September 2006, *Technische Unie* v *Commission* (C-113/04 P, EU:C:2006:593), as well as paragraphs 118 and 120 to 122 of the judgment of 29 March 2011, *ArcelorMittal Luxembourg* v *Commission* and *Commission* v *ArcelorMittal Luxembourg and Others* (C-201/09 P and C-216/09 P, EU:C:2011:190).

131 In paragraphs 360 and 361 of the judgment under appeal, the General Court held, first, that neither the first nor the second phase of the administrative procedure which led to the adoption of the decision at issue had exceeded a reasonable period.

132 It then held, in paragraph 362 of that judgment, that 'in so far as the [appellants] base their plea on the date on which the Commission first became aware of the agreement at issue in order to establish that the Commission failed to fulfil its obligation to adopt a decision within a reasonable period and thus infringed their rights of defence, it must be stressed that nowhere is that approach followed in the case-law, which takes as its starting point the date of the initial measures implying an accusation of infringement'.

133 Finally, in rejecting any infringement of the reasonable duration of the administrative procedure, the General Court held as follows in paragraphs 367 to 371 of the judgment under appeal:

> '367 … the [General] Court notes that the [appellants] merely put forward in support of their argument the loss of three categories of documents, namely drafts and comments relating to the agreement at issue (for example the draft mentioned in the email [from an Alpharma group executive] of 20 February 2002), citalopram business plans and documents of outside counsel.
>
> 368 In that regard, even if the [appellants'] claims fulfilled the conditions of precision and specificity required by the case-law referred to in paragraph 357 [of the judgment under appeal], it must be stated that, in view of the [Danish Competition Authority] press release and the sector inquiry opened by the Commission, a diligent undertaking should have retained – at least until the expiry of the maximum limitation period prescribed by EU law (see paragraph 363 [of the judgment under appeal]) – any documents that might prove useful in its defence in the event of proceedings being initiated in respect of an infringement of competition law.

369 Diligence is among the conditions which the case-law (see paragraph 358 [of the judgment under appeal]) requires a party to meet in order to be able successfully to plead infringement of its rights of defence owing to the allegedly unreasonable length of the proceedings.

370 As the [appellants] have failed to give details about the occurrence of specific events which might explain why the documents in question have gone astray, other than the mere passage of time, their argument cannot be upheld.

371 As regards more particularly the documents of the Alpharma group's external counsel, which that counsel destroyed in 2007 in accordance with the regulations of the Danish Law Society, the [General] Court observes that the [appellants] have not provided further particulars concerning those regulations and that, in any event, had they been diligent, they could themselves have kept copies of those documents.'

Arguments of the parties

134 By their fifth ground of appeal, directed against paragraphs 361 to 364 and 366 to 371 of the judgment under appeal, the appellants claim, first, that the General Court erred in law in its assessment of the duration of the inquiry and infringed their rights of defence, in breach of paragraph 341 of the judgment of 15 July 2015, *SLM and Ori Martin* v *Commission* (T-389/10 and T-419/10, EU:T:2015:513). They argue that the General Court wrongly took into consideration only the period after the Alpharma group had been notified of measures which stated that it was to be accused of an infringement, namely 2010 for Alpharma LLC and 2011 for Xellia, rather than the date on which the Commission received information about the infringement, namely October 2003, which corresponds to the date on which the Danish Competition Authority sent information concerning the agreements in question to the Commission. In so doing, the General Court did not hold that the Commission was required to set out the reasons why that duration was not excessive. Second, the appellants argue that the General Court wrongly imposed on the Alpharma group a heightened duty to retain the documents covering the period prior to the time when it was informed of the inquiry into that group, contrary to the judgment of 16 June 2011, *Heineken Nederland and Heineken* v *Commission* (T-240/07, EU:T:2011:284, paragraph 301). In particular, the General Court could not find that the Alpharma group was subject to such a duty on the ground that the Commission had undertaken an inquiry of Lundbeck's activities and carried out a sector inquiry, when it has not been demonstrated that that group was aware of those inquiries.

Findings of the Court

135 The fifth ground of appeal consists, in essence, of two parts.

136 By the first part, the appellants dispute the date found by the General Court to be the start date of the procedure initiated by the Commission which culminated in the decision at issue for the purposes of assessing whether the duration of that procedure was reasonable.

137 By the second part of the present ground of appeal, the appellants criticise the General Court for having refused to find that their rights of defence had been infringed, on account of the unreasonable length of that procedure, on the ground that they had not fulfilled their obligation of diligence, which should have led them to retain all useful documents in order to ensure their defence in the context of that procedure.

138 With regard to the first part of the present ground of appeal, it must be noted that, as the General Court pointed out in paragraph 356 of the judgment under appeal, for the purposes of the application of the 'reasonable time' principle, a distinction must be drawn between the two phases of the administrative procedure carried out by the Commission, namely the inquiry phase preceding the statement of objections and the phase corresponding to the remainder of the administrative procedure; the first phase is to cover the initial measures adopted by the Commission which involve an accusation of an infringement being sent to an undertaking up to the notification of the statement of objections, while the second phase is to cover that notification of the statement of objections up to the adoption of the final decision by the Commission (see, to that effect, judgment of 21 September 2006, *Technische Unie* v *Commission*, C-113/04 P, EU:C:2006:593, paragraphs 42 and 43).

139 In the present case, it is apparent from paragraphs 359 and 361 of the judgment under appeal that the initial measures involving an accusation by the Commission against Zoetis, now Alpharma LLC, and Xellia were adopted on 19 March 2010 and 14 March 2011 respectively. The appellants do not claim, nor, a fortiori, demonstrate that those dates are the result of a distortion of the clear sense of the facts, in particular in so far as the Commission's receipt of the information sent by the Danish Competition Authority in October 2003 relating to the agreements in question or any subsequent step taken by the Commission referred to in paragraph 359 of the judgment under appeal involved an allegation by the Commission against the Alpharma group.

140 Therefore, the General Court did not err in law in holding, in paragraph 361 of the judgment under appeal, that the first phase of the procedure concerning Zoetis and Xellia had commenced on 19 March 2010 and 14 March 2011 respectively.

141 As regards the second part of the present ground of appeal, it must be observed that the General Court refused, for two reasons, to uphold the appellants' claims alleging infringement of their rights of defence on account of the significant period of time between the conclusion of the agreement at issue and the adoption of the decision at issue, the result of which was that the appellants were unable to find certain documents which they considered decisive for their defence.

142 In the first place, the General Court held, in paragraph 367 of the judgment under appeal, first, that the appellants merely claimed that three categories of document had been lost, namely the drafts and comments relating to the agreement at issue, for example the draft mentioned in the Alpharma group executive's email of 20 February 2002, the business plans relating to citalopram, and the documents of that group's external counsel. Second, the General Court held, in paragraph 370 of that judgment, that the appellants did not provide details about the occurrence of specific events which might explain why the documents in question had been mislaid, other than the mere passage of time. Third, it held, in paragraph 371 of that judgment, that, as regards more particularly the documents of the Alpharma group's external counsel, which that counsel destroyed in 2007 in accordance with the rules of the Danish Law Society, the appellants had not provided further particulars concerning those rules and that, in any event, had they been diligent, they could themselves have kept copies of those documents.

143 In the second place, the General Court held, in paragraphs 368 and 369 of the judgment under appeal, that the appellants could not plead infringement of their rights of defence owing to the allegedly unreasonable length of the procedure, since they had failed to comply with their obligation of diligence, as recalled in the judgment of 29 March 2011, *ArcelorMittal Luxembourg* v *Commission* and *Commission* v *ArcelorMittal Luxembourg and Others* (C-201/09 P and C-216/09 P, EU:C:2011:190, paragraphs 120 to 122), cited in paragraph 358 of the judgment under appeal. In that regard, the General Court found that, in the light of the Danish Competition Authority press release and the sector inquiry which the Commission had initiated, a diligent undertaking ought to have kept any document which might prove useful to its defence in the context of a possible proceeding for infringement of competition law, at least until the expiry of the maximum limitation period laid down by EU law.

144 As regards the second ground upheld by the General Court, it should be noted that, in paragraphs 368 and 369 of the judgment under appeal, the General Court applies case-law that has no bearing on the submission made by the appellants and, accordingly, imposes on them an obligation of diligence derived from case-law that is not applicable to the situation in which they found themselves.

145 Even though, in the first place, the General Court rightly found in paragraph 361 of the judgment under appeal that the administrative procedure had begun in respect of Zoetis and Xellia on 19 March 2010 and 14 March 2011 respectively, and was not unreasonably long, and, in the second place, that the appellants complained, as is apparent from paragraph 349 of that judgment and from their action for annulment, that they had been informed of the inquiry initiated by the Commission in December 2003, concerning the agreements in question, only eight to nine years after the start of that inquiry, the consequence being that they were no longer in a position to gather the evidence needed to defend themselves, the General Court directly applied the case-law concerning the infringement of the rights of the defence by reason of the unreasonable length of the first phase of the administrative procedure conducted by the Commission and, in particular, paragraphs 43, 54 and 60 to 71 of the judgment of 21 September 2006, *Technische Unie* v *Commission* (C-113/04 P, EU:C:2006:593) as well as paragraphs 118 to 122 of the judgment of 29 March 2011, *ArcelorMittal Luxembourg* v *Commission* and *Commission* v *ArcelorMittal Luxembourg and Others* (C-201/09 P and C-216/09 P, EU:C:2011:190), referred to in paragraphs 357, 358, 362 and 369 of the judgment under appeal.

146 When it did so, even though the length of the administrative procedure conducted by the Commission was not contested, the General Court held, in paragraphs 368 and 369 of the judgment under appeal, that it was for that court to ensure, for the purposes of assessing the infringement of Zoetis and Xellia's rights of defence, that Zoetis and Xellia had in fact complied with their obligation of diligence which, in accordance with the judgments cited in the previous paragraph, is binding on any undertaking that has been informed of the initiation of a procedure against it.

147 Thus, even though the appellants' criticism of the Commission was that it did not initiate the administrative procedure sufficiently early in respect of Zoetis and Xellia, which entailed an infringement of their rights of defence, the General Court imposes on them an obligation of diligence derived from case-law that is applicable only to the period after the initiation of the administrative procedure by the Commission.

148 Accordingly, and as the appellants correctly claim, the General Court did err in law.

149 It must nonetheless be recalled that, if the grounds of a decision of the General Court reveal an infringement of EU law but the operative part of the judgment can be seen to be well founded on other legal grounds, that infringement is not capable of leading to the annulment of that decision and a substitution of grounds must be made (judgment of 6 November 2018, *Scuola Elementare Maria Montessori* v *Commission*, *Commission* v *Scuola Elementare Maria Montessori* and *Commission* v *Ferracci*, C-622/16 P to C-624/16 P, EU:C:2018:873, paragraph 48).

150 That is the situation in the present case.

151 While it is true that the General Court could not impose on the appellants the obligation of diligence applicable to undertakings in a different situation, such as that at issue in the judgments cited in paragraph 145 of the present judgment, the fact remains that, at least in the present case, the General Court was entitled to impose on them a specific duty of care requiring them to ensure that information enabling details of their activities to be retrieved is retained properly in their books or records, in order, in particular, that they have in their possession the necessary evidence in the event of subsequent administrative action or judicial proceedings.

152 The initiation, on 15 January 2008, of a sector inquiry on the basis of Article 17 of Regulation No 1/2003 the objective of which is, as is apparent, in essence, from paragraph 22 of the judgment under appeal, recital 12 of the decision at issue and recitals 3 to 5 of the decision of 15 January 2008 initiating an inquiry into the pharmaceutical sector, the examination of agreements concluded between pharmaceutical companies, such as settlement agreements in respect of disputes relating to process patents, in order to determine whether they infringe Articles 101 and 102 TFEU, constitutes, first, a factor of which manufacturers of generic medicines such as Zoetis and Xellia – which the General Court found, in paragraph 189 of the judgment under appeal, to be well-informed and seasoned operators in the pharmaceutical sector – could not be unaware and, second, a factor which should lead them to take precautions against the loss, due to the passage of time, of evidence that might prove to be useful to them in the context of subsequent administrative procedures or judicial proceedings.

153 It is clear both from the *travaux préparatoires* for Regulation No 1/2003 and from the first subparagraph of Article 17(1) of that regulation that sector inquiries are an instrument designed to confirm suspicions of restrictions of competition in the sector concerned by those inquiries.

154 Thus, when the Commission initiates such inquiries, undertakings belonging to the sector concerned and, in particular, those which have concluded agreements expressly referred to in the decision initiating the inquiry, as was the case with Zoetis and Xellia, must expect that individual procedures may possibly be initiated against them in the future, especially given that recital 8 of the decision of 15 January 2008 initiating an inquiry into the pharmaceutical sector expressly states that 'to the extent that the inquiry into the pharmaceutical sector reveals the possible existence of anticompetitive agreements or practices or abuses of a dominant position, the Commission … could envisage [initiating] investigations against individual entities possibly resulting in decisions based on Article [101 and/or 102 TFEU]'.

155 Accordingly, without there being any need to determine whether Zoetis and Xellia had been aware of the Danish Competition Authority press release or not, it must be held, in the light of the foregoing and of the initiation by the Commission, on 15 January 2008, of the pharmaceutical sector inquiry, that is to say, less than four and a half years after the expiry of the agreement at

issue, that the appellants cannot validly maintain that the Commission's initiation of the administrative procedure concerning Zoetis and Xellia had, by its lateness, infringed the rights of defence of those parties and that the decision at issue should therefore be annulled.

156 The same must apply a fortiori since, in paragraph 371 of the judgment under appeal, the General Court noted, without being challenged on the point by the appellants in the present appeal, that, 'as regards more particularly the documents of the Alpharma group's external counsel, which that counsel destroyed in 2007 [, that is to say, before the initiation of the sector inquiry by the Commission,] in accordance with the rules of the Danish Law Society, the [General] Court observes that the [appellants] have not provided further particulars concerning those regulations and that, in any event, had they been diligent, they could themselves have kept copies of those documents'.

157 In the light of the foregoing, the fifth ground of appeal must be rejected.

Sixth ground of appeal

The relevant paragraphs of the judgment under appeal

158 By their sixth plea in law raised in their action for annulment, the appellants argued that the Commission had infringed the principle of non-discrimination in that it had imposed a penalty, in respect of the agreement at issue, on not only A.L. Industrier, the parent company of the Alpharma group, and Xellia, a subsidiary of the Alpharma group, but also on Alpharma LLC, the intermediate parent company of the Alpharma group, whereas, as regards the agreement concluded between Lundbeck, on the one hand, and Merck KGaA and Generics (UK) Ltd, on the other, it had imposed a penalty only on Merck, the parent company of the Merck group, and Generics (UK), a subsidiary of the Merck group, and not on Merck Generics Holding GmbH, the intermediate parent company of the Merck group.

159 In rejecting that plea, the General Court held as follows in paragraphs 387 to 392 of the judgment under appeal:

'387 … it must be stated that, during the relevant period, Alpharma ApS, Alpharma Inc. and A.L. Industrier formed a single undertaking, whilst that was no longer the case at the time of the adoption of the [decision at issue]. In fact, at that point, Xellia, which was the successor to Alpharma ApS, Zoetis, which was the successor to Alpharma Inc., and A.L. Industrier each formed part of different undertakings, as is clear from recitals 50 to 52 and 1269 to 1275 of the [decision at issue].

…

389 It is clear from the [decision at issue], in particular from recitals 43, 1275, 1284 and 1286, that the Commission held that A.L. Industrier, which controlled Alpharma Inc., formed with that company a single undertaking that also included Alpharma ApS. Moreover, the [appellants] do not dispute that those three companies formed a single undertaking at the time of the conclusion of the agreement at issue.

390 As regards the Merck group, it follows from the [decision at issue] (footnote [31]) that Generics UK, which was the company that entered into the two agreements in question with Lundbeck, was, during the period covered by those agreements, controlled by Merck Generics Holding, which was in turn controlled by Merck. The [decision at issue] also explains that, in 2007, Generics UK was sold to another undertaking, with the result that it left the Merck group (recital 33).

391 However, it follows from the Commission's answer to a question put by the [General] Court and from a document produced by the Commission on the same occasion that, at the time of the adoption of the [decision at issue], Merck and Merck Generics Holding still formed part of the same undertaking. Although, as the [appellants] submit, that fact was not mentioned in the [decision at issue], the [General] Court notes that the document in question is part of the Commission's administrative file and was accordingly available to the Commission when it adopted that decision.

392 Furthermore, it should be observed that, in view of the financial situation of A.L. Industrier, the Commission was wholly justified in holding Zoetis jointly and severally liable for the infringement committed by Xellia, since, otherwise, Xellia alone would have been liable for almost the entirety of the fine related to the infringement committed by the Alpharma group, which would have made it less certain that the fine would have been paid. By contrast, as long as Merck controls Merck Generics Holding, the financial resources of the latter may be used to pay the fine imposed on the Merck group, without it being essential for that purpose to refer to it in the operative part of the [decision at issue].'

Arguments of the parties

160 By their sixth ground of appeal, directed against paragraphs 378 to 394 of the judgment under appeal, the appellants claim that the General Court infringed the principle of equal treatment by upholding the decision at issue in so far as it was addressed to Zoetis, now Alpharma LLC, and not to Merck Generics Holding, although there is nothing in that decision to justify distinguishing the situations of those two undertakings. In addition, the appellants complain that the General Court substituted grounds and infringed the case-law according to which a failure to state reasons cannot be remedied by the fact that the person concerned learns the reasons for the decision at issue during the proceedings before the EU Courts, by referring to paragraph 74 of the judgment of 19 July 2012, *Alliance One International and Standard Commercial Tobacco* v *Commission* (C-628/10 P and C-14/11 P, EU:C:2012:479).

161 The Commission submits that that ground of appeal is unfounded.

Findings of the Court

162 By the first part of the sixth ground of appeal, the appellants complain, in essence, that the General Court infringed the principle of equal treatment by rejecting their sixth plea in support of their action for annulment.

163 In that regard, it should be noted that when such an undertaking infringes the EU competition rules, it is for that undertaking, according to the principle of personal responsibility, to answer for that infringement (judgment of 27 April 2017, *Akzo Nobel and Others* v *Commission*, C-516/15 P, EU:C:2017:314, paragraph 49).

164 Where such an undertaking consists of several natural or legal persons, Article 23(2)(a) of Regulation No 1/2003 does not determine which legal or natural person the Commission is required to hold liable for the infringement or on which of them the Commission is to impose a fine (judgment of 27 April 2017, *Akzo Nobel and Others* v *Commission*, C-516/15 P, EU:C:2017:314, paragraphs 50 and 51 and the case-law cited).

165 Nonetheless, in the exercise of its power to impose penalties as outlined in the case-law referred to in the previous paragraph, the Commission cannot infringe the principle of equal treatment, which requires that comparable situations must not be treated differently and that different situations must not be treated in the same way unless such treatment is objectively justified (judgment of 24 September 2020, *Prysmian and Prysmian Cavi e Sistemi* v *Commission*, C-601/18 P, EU:C:2020:751, paragraph 101 and the case-law cited), as the General Court noted in paragraph 386 of the judgment under appeal.

166 On the other hand, it must be borne in mind that, where an undertaking has acted in breach of Article 101 TFEU, it cannot escape being penalised altogether on the ground that another undertaking has not been fined (judgment of 9 March 2017, *Samsung SDI and Samsung SDI (Malaysia)* v *Commission*, C-615/15 P, not published, EU:C:2017:190, paragraph 37 and the case-law cited). In particular, an undertaking on which a fine has been imposed for its participation in a cartel, in breach of the competition rules, cannot request the annulment or reduction of that fine, on the ground that another participant in the same cartel was not penalised in respect of a part, or all, of its participation in that cartel (judgment of 9 March 2017, *Samsung SDI and Samsung SDI (Malaysia)* v *Commission*, C-615/15 P, not published, EU:C:2017:190, paragraph 38 and the case-law cited).

167 In the present case, the General Court found, in any event, in paragraphs 387 to 392 of the judgment under appeal, that Alpharma LLC and Merck Generics Holding were in different situations at the time the decision at issue was adopted, on account, first, of the fact that, Xellia, Zoetis, now Alpharma LLC, and A.L. Industrier each belonged to different undertakings whereas Merck and Merck Generics Holding, respectively the ultimate parent company and the parent company of Generics (UK), which left the Merck group after the expiry of the agreements in question, were part of the same undertaking and, second, of the particular financial situation of the companies involved in the agreements in question.

168 Accordingly, since they were not in a situation comparable to that of Merck Generics Holding, the appellants cannot validly complain that the General Court infringed the principle of equal treatment.

169 That conclusion cannot be called into question by the fact relied on by the appellants in the second part of the present ground of appeal, according to which, in order to justify the difference in treatment between Zoetis, now Alpharma LLC, and Merck Generics Holding, the General Court allegedly supplemented the statement of reasons in the decision at issue by stating that Zoetis was not part of the same undertaking as A.L. Industrier at the time the decision at issue was adopted.

170 In addition to the fact that that point, made by the General Court in the second sentence of paragraph 387 of the judgment under appeal is only one of the two grounds for distinguishing the appellants' situation from that of Merck Generics Holding, since the second reason linked to the specific financial situation of the companies involved in the agreements in question, as set out

in paragraph 392 of the judgment under appeal, is not disputed by the appellants, it should be noted that, as the General Court stated in paragraph 387 of the judgment under appeal, that point is apparent from the decision at issue itself.

171 To the extent that the statement of reasons for an act must be assessed with regard not only to its wording, but also to its context and to all the legal rules governing the matter in question (see, to that effect, judgment of 14 February 1990, *Delacre and Others* v *Commission*, C-350/88, EU:C:1990:71, paragraph 16 and the case-law cited) while taking into account, where necessary, the fact that that act was adopted in circumstances known to the addressee of that act (see, to that effect, judgment of 17 September 2020, *Rosneft and Others* v *Council*, C-732/18 P, not published, EU:C:2020:727, paragraph 77 and the case-law cited), the fact that an explanation which has been provided by the Commission in its written observations before the General Court, as is clear from paragraph 379 of the judgment under appeal, is not set out explicitly and exhaustively in the decision at issue does not necessarily have the effect of preventing the General Court from taking into account that explanation and the information in that decision when responding to an appellant's argument (see, by analogy, judgment of 30 September 2003, *Freistaat Sachsen and Others* v *Commission*, C-57/00 P and C-61/00 P, EU:C:2003:510, paragraph 62 and 63).

172 This is particularly so where the General Court has to respond to an argument, such as that put forward by the appellants, that the Commission infringed the principle of equal treatment at the stage of drafting the decision at issue, whereas, as was pointed out in paragraph 164 of the present judgment, the Commission is in principle free to choose, within an undertaking made up of several natural or legal persons, which of them it holds liable for the infringement and cannot reasonably be required to explain in its decision, in respect of each company to which it is addressed, the reasons why it holds responsible either all or only some of the natural or legal persons making up the undertaking or undertakings which took part in a practice contrary to Article 101 or Article 102 TFEU.

173 In view of the foregoing, the sixth ground of appeal must be rejected as being unfounded.

Seventh ground of appeal

The relevant paragraphs of the judgment under appeal

174 In paragraphs 401 to 407 of the judgment under appeal, the General Court rejected the second part of the seventh plea raised by the appellants in support of their action for annulment, by which they claimed that the Commission had, for the purposes of calculating the fine imposed on them, failed to take into consideration the absence of legal certainty as to how the agreement at issue would be assessed for the purposes of competition law.

175 First, the General Court noted, in paragraphs 403 to 405 of the judgment under appeal, the case-law of the Court of Justice relating to the requirement of foreseeability of infringements and the case-law relating to the condition that the infringement of Articles 101 and 102 TFEU be committed 'intentionally or negligently' within the meaning of the first subparagraph of Article 23(2) of Regulation No 1/2003. The General Court also held, in paragraph 407 of that judgment, that the Alpharma group was not unaware that the conclusion of the agreement at issue could be problematic from the point of view of competition law.

176 Second, the General Court stated that it followed from paragraphs 314 and 318 of the judgment under appeal that there was no absence of legal certainty regarding the possibility of characterising as a 'restriction by object' an agreement which had the characteristics of the agreement at issue and which came about in the context of that agreement.

Arguments of the parties

177 By their seventh ground of appeal, directed against paragraphs 401 to 407 of the judgment under appeal, the appellants complain that the General Court infringed the principle of legal certainty by finding that there was no absence of legal certainty as regards the characterisation of the agreement at issue as a restriction by object and, consequently, by allowing the Commission to impose a very high fine on them. This absence of legal certainty was demonstrated by the statements of the Danish Competition Authority but also by the duration of the sector inquiry which preceded the procedure that ultimately led to the adoption of the decision at issue, and by the length of that decision.

178 The Commission contends that the ground is unfounded.

Findings of the Court

179 As the General Court correctly pointed out in paragraph 405 of the judgment under appeal, a penalty may be imposed on an undertaking for conduct falling within the scope of Article 101(1) TFEU where it cannot be unaware of the anticompetitive nature of its conduct, whether or not that undertaking is aware that it is infringing the competition rules of the Treaty (see, to that effect, judgment of 18 June 2013, *Schenker & Co. and Others*, C-681/11, EU:C:2013:404, paragraph 37).

180 It follows from the above, as the General Court recalled in paragraph 404 of the judgment under appeal and as the Court of Justice held in the judgment delivered today in Case C-588/16 P, *Generics (UK)* v *Commission* (paragraph 137), that the fact that such an undertaking has erred in its legal characterisation of the conduct on which the finding of the infringement is based cannot have the effect of exempting it from the imposition of a fine in so far as it could objectively determine that that conduct was anticompetitive, if necessary by taking appropriate advice (see, to that effect, judgment of 18 June 2013, *Schenker & Co. and Others*, C-681/11, EU:C:2013:404, paragraph 38).

181 In the present case, the General Court rightly pointed out, in paragraphs 315 to 317 of the judgment under appeal, to which paragraph 406 of that judgment refers, that it was settled case-law, as recalled in paragraph 109 of the present judgment, that an agreement is not exempt from competition law merely because it concerns a patent or is intended to settle a patent dispute.

182 Furthermore, the General Court noted, in essence, in paragraph 318 of the judgment under appeal, which is also referred to in paragraph 406 of that judgment, that, from both Lundbeck's and the Alpharma group's perspective, the agreement at issue was at the very least capable of posing problems in the area of competition law, since Lundbeck had considered that 'the conclusion of agreements with [manufacturers of generic medicines] was considered "difficult" from the point of view of competition law' and as the Alpharma group had sent a draft of the agreement at issue to an advisor with expertise in competition law matters.

183 Therefore, the General Court was entitled to hold, in paragraph 407 of the judgment under appeal, that the Alpharma group was not unaware that the conclusion of the agreement at issue could be problematic from the point of view of competition law. Accordingly, the appellants cannot complain that the General Court infringed the principle of legal certainty by allowing the Commission to impose a fine on them because they entered into the agreement at issue.

184 That conclusion cannot be called into question by the Danish Competition Authority press release, for the same reasons as those set out in paragraphs 123 and 124 of the present judgment.

185 If that press release does not preclude the agreement at issue from being characterised as a 'restriction by object', it cannot a fortiori prevent a penalty from being imposed in respect of that agreement, even in the form of a fine of an amount regarded by the appellants as being very high.

186 Nor can that penalty be precluded by the fact put forward by the appellants that the absence of legal certainty surrounding agreements such as the agreement at issue is confirmed by the duration of the sector inquiry which preceded the procedure that ultimately led to the adoption of the decision at issue, and by the length of that decision.

187 Apart from the fact that, according to the judgment under appeal, the appellants did not put forward those factors either in their third plea for annulment, alleging infringement of Article 101(1) TFEU on account of the characterisation of the agreement at issue as a 'restriction by object', or in their seventh plea for annulment, alleging errors affecting the calculation of the amount of the fine imposed on them, suffice it to note, as is apparent from paragraphs 153 and 154 of the present judgment, that such an inquiry is initiated in order to confirm or rebut suspicions of restrictions of competition in the sector concerned by that inquiry and that there is nothing to substantiate the argument that the duration of that inquiry would allow the Commission's doubts as to the specific agreements that are the subject of that same inquiry to be dispelled.

188 Similarly, the length of a decision is irrelevant in that regard, since, as has already been pointed out in paragraph 120 of the present judgment, the characterisation of an agreement as a 'restriction by object' may presuppose a detailed analysis of that agreement, its objectives and the economic and legal context of which it forms part. As regards the decision at issue, more specifically, it should be noted that it concerned five separate undertakings and six different agreements which each required specific assessment and was addressed to 12 companies.

189 Consequently, the seventh ground of appeal must be rejected as being unfounded.

Eighth ground of appeal

The relevant paragraphs of the judgment under appeal

190 In rejecting the seventh plea in law raised by the appellants in support of their action for annulment alleging errors affecting the calculation of the amount of the fine imposed on them, the General Court held, inter alia, first of all, in paragraph 398 of the judgment under appeal, that the Commission was entitled to find that the infringement at issue was serious. Next, as regards the setting of the basic amount of the fine, the General Court noted, in paragraphs 414 to 433 of the judgment under appeal, that the Commission had used point 37 of the 2006 Guidelines in

order to depart from the general methodology for calculating fines laid down in those guidelines and had used as the basic amount the value of the payments which the Alpharma group had received from Lundbeck, something which the appellants did not dispute.

Arguments of the parties

191 By their eighth ground of appeal, the appellants complain that the General Court rejected their arguments alleging that the Commission failed to take into consideration the gravity of the infringement when determining the amount of the fine imposed on them. The General Court accepted, in breach of Article 21(3) of Regulation No 1/2003, that, as is apparent from paragraph 1361 of the decision at issue, the Commission is to set the amount of the fines imposed on the manufacturers of generic medicines without differentiating between infringements on the basis of their nature or their geographic scope or by reference to their market shares, particularly when, in the present case, the infringement was characterised as 'very serious' in the statement of objections and then merely as 'serious' in the decision at issue.

192 The Commission contends that the eighth ground of appeal must be rejected.

Findings of the Court

193 It should be noted, as is apparent from paragraphs 419 and 421 of the judgment under appeal, that the amount of the fine imposed on the Alpharma group was calculated not in accordance with the general methodology laid down in the 2006 Guidelines, but by applying a method which departed from those guidelines, as permitted by paragraph 37 thereof, which the appellants did not dispute. The Commission is not bound by those guidelines, in particular by points 19 to 22 thereof, which require it to set a basic amount of the fine by reference to the specific degree of gravity of the infringement concerned.

194 The eighth ground of appeal must therefore be understood as seeking to call into question not the methodology adopted by the Commission and confirmed by the General Court, but the actual amount of the fine imposed by the decision at issue on account of the infringement committed, which the General Court was fully entitled to find to have been serious in paragraph 398 of the judgment under appeal.

195 In that regard, it is settled case-law that it is not for the Court of Justice, when ruling on points of law in the context of an appeal, to substitute, on grounds of fairness, its own assessment for that of the General Court exercising its unlimited jurisdiction to rule on the amount of fines imposed on undertakings for infringements of EU law (judgment of 26 September 2018, *Philips and Philips France* v *Commission*, C-98/17 P, not published, EU:C:2018:774, paragraph 107 and the case-law cited).

196 Only where the Court of Justice considers that the level of the penalty is not merely inappropriate, but also excessive to the point of being disproportionate, does it have to find that the General Court erred in law, on account of the inappropriateness of the amount of a fine (judgment of 26 September 2018, *Philips and Philips France* v *Commission*, C-98/17 P, not published, EU:C:2018:774, paragraph 107 and the case-law cited).

197 Thus, a ground of appeal challenging the amount of the fine assessed by the General Court which nevertheless fails to establish the reasons why that amount is excessive to the point of being disproportionate is inadmissible (judgment of 25 July 2018, *Orange Polska* v *Commission*, C-123/16 P, EU:C:2018:590, paragraph 115).

198 In the present case, the appellants have not in any way claimed or, a fortiori, established that the fine imposed on them by the decision at issue, which was upheld by the General Court, was excessive to the point of being disproportionate.

199 Consequently, the eighth ground of appeal must be dismissed as being inadmissible.

Ninth ground of appeal

The relevant paragraphs of the judgment under appeal

200 In rejecting the eighth plea in law relied on by the appellants in their action for annulment, alleging a manifest error of assessment in relation to the maximum amount of the fine for which A.L. Industrier, parent company of the Alpharma group at the time of the agreement at issue, was jointly and severally liable in so far as the Commission used, for those purposes, the 2011 turnover instead of the higher turnover from 2012, which rendered A.L. Industrier liable for a greater portion of the fine imposed jointly and severally on A.L. Industrier, Alpharma LLC and Xellia Pharmaceuticals, the General Court, in paragraphs 449 to 456 of the judgment under appeal, first, found that the Commission had used not the last full business year preceding the date of adoption of the decision at issue, namely the 2012 business year, but the year preceding that, namely the 2011 business year, on the grounds that 2011 was the last full business year with normal activity and, second, held that the Commission was well founded in proceeding on that basis since the 2012 business year was a year which involved the selling-off of the assets of A.L. Industrier, which gave rise to revenue which fell outside the realm of normal economic activity.

201 The General Court held as follows in paragraphs 458 and 459 of the judgment under appeal:

> ‘458 It must be observed …, that, according to the case-law, the objective sought by the establishment, in Article 23(2) [of Regulation No 1/2003], of a limit of 10% of the turnover of each undertaking participating in an infringement is, inter alia, to ensure that the imposition of a fine higher in amount than that limit should not exceed the capacity of an undertaking to make payment at the time when it is identified as responsible for the infringement and a financial penalty is imposed on it by the Commission (judgment [of 4 September 2014,] *YKK* v *Commission*, [C-408/12 P], EU:C:2014:2153, paragraph 63; see also, to that effect, judgments [of 15 June 2005,] *Tokai Carbon and Others* v *Commission*, [T-71/03, T-74/03, T-87/03 and T-91/03, not published], EU:T:2005:220, paragraph 389, and of 16 November 2011[,] *Kendrion* v *Commission*, T-54/06, EU:T:2011:667, paragraph 91).
>
> 459 Consequently, the Commission, after deciding that the ceiling applicable to A.L. Industrier could not be set on the basis of 2012 – that is to say, the year immediately preceding that in which the [decision at issue] was adopted – could not go back as far as 2005 but had to use the turnover of the last year preceding 2012 in which A.L. Industrier’s business activities had been normal, irrespective of the sectors in which that company was active.’

Arguments of the parties

202 By their ninth ground of appeal, directed against paragraphs 458 and 459 of the judgment under appeal, the appellants complain that the General Court infringed Article 23(2) of Regulation No 1/2003 and the judgments of 7 June 2007, *Britannia Alloys & Chemicals* v *Commission* (C-76/06 P, EU:C:2007:326, paragraph 20) and of 15 May 2014, *1. garantovaná* v *Commission* (C-90/13 P, not published, EU:C:2014:326, paragraphs 15 to 17), by applying an incorrect criterion for identifying the relevant business year for the purpose of determining the upper limit of the fine that may be imposed on A.L. Industrier.

203 They argue that the General Court interpreted Article 23(2) of Regulation No 1/2003 too restrictively by adopting only the objective of preventing fines from exceeding the capacity of undertakings to pay without balancing it against the other objective of ensuring that the fines imposed have a sufficiently deterrent effect. In doing so, by using that company's turnover for 2011, the General Court imposed on A.L. Industrier an inappropriate fine in the light of its capacity to pay and its actual economic situation during the infringement period. In their reply, the appellants state that, in paragraph 459 of the judgment under appeal, the General Court rejected 2005 as the reference year solely on the ground that that year was not the last business year before 2012 in which A.L. Industrier's activities were normal.

204 The Commission contends, for its part, that the ninth ground of appeal is inadmissible, on the ground that the finding that the last full business year reflecting A.L. Industrier's normal economic activities is 2011 is a question of fact, and is, in any event, unfounded.

Findings of the Court

205 At the outset, it should be noted that, by the present ground of appeal, the appellants criticise not the General Court's assessment of whether the 2011 or 2005 business years were normal, which is an assessment of fact which cannot be called into question in the context of an appeal in the absence of any allegation or, a fortiori, proof by the appellants that the clear sense of the facts or evidence have been distorted, but rather the criterion used by the General Court on the basis of which it decided not to take into consideration the 2012 business year.

206 Contrary to what is claimed by the Commission, that ground of appeal is therefore admissible.

207 It is also admissible in so far as any finding of an error of law by the General Court as to the criterion applied in the choice of which business year should serve as the basis for the application of the maximum amount of the portion of the fine imposed jointly and severally on A.L. Industrier would not have the effect of imposing on that company, for which the decision at issue has become final, an increase in its portion of the joint and several liability, which, moreover, the appellants do not claim, and would have consequences only with regard to the appellants.

208 Turning to the substance, it should be noted that the second subparagraph of Article 23(2) of Regulation No 1/2003 provides a mechanism for establishing the maximum amount of the fine imposed by the Commission on undertakings for infringements of Articles 101 and 102 TFEU which seeks to prevent those fines from being disproportionate in relation to the size of the undertakings concerned (see, to that effect, judgment of 7 June 2007, *Britannia Alloys & Chemicals* v *Commission*, C-76/06 P, EU:C:2007:326, paragraph 24) and, therefore, to ensure that

those fines do not exceed 10% of the total turnover of those undertakings during the business year preceding the business year during which the Commission's decision imposing a fine on them was adopted.

209 In that regard, the Court of Justice has held previously that, in determining the 'preceding business year', the Commission must assess, in each specific case and having regard both to the context and the objectives pursued by the scheme of penalties created by Regulation No 1/2003, the intended impact on the undertaking in question, taking into account in particular a turnover which reflects the undertaking's real economic situation during the period in which the infringement was committed (judgment of 7 June 2007, *Britannia Alloys & Chemicals* v *Commission*, C-76/06 P, EU:C:2007:326, paragraph 25).

210 Thus, it is open to the Commission not to use the last business year preceding the business year in which the Commission's decision is adopted if it does not correspond to a full year of normal economic activity over a period of 12 months (judgment of 7 June 2007, *Britannia Alloys Chemicals* v *Commission*, C-76/06 P, EU:C:2007:326, paragraph 26).

211 However, having regard to the wording, the context and the objectives pursued by the system of penalties established by Regulation No 1/2003, the Commission must use the first preceding full business year of normal economic activity.

212 In the present case, it is apparent from paragraphs 451 and 459 of the judgment under appeal that the General Court found, first, that the last business year preceding the decision at issue, namely the 2012 business year, was not a business year with normal economic activity in so far as it was a business year in which assets were sold off, and, second, that the 2011 business year was a business year of normal economic activity.

213 In the light of those findings – which fall within the General Court's assessment of the facts which cannot be the subject of an appeal and in respect of which there has been no allegation by the appellants of distortion – the General Court was entitled, without there being any need to assess whether it was appropriate to use the turnover from an earlier business year, in this case the turnover for 2005, to use the turnover for the 2011 business year for the purpose of calculating the upper limit on the fine imposed on A.L. Industrier, pursuant to the second subparagraph of Article 23(2) of Regulation No 1/2003.

214 In the light of the foregoing, the ninth ground of appeal must be rejected as being unfounded and, consequently, the appeal must be dismissed in its entirety.

Costs

215 Under Article 138(1) of the Rules of Procedure, 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.

216 Since the Commission has applied for costs to be awarded against the appellants and the latter have been unsuccessful, the appellants must be ordered to bear their own costs and to pay those incurred by the Commission.

217 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.

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

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

1. **Dismisses the appeal;**

2. **Orders Xellia Pharmaceuticals ApS and Alpharma LLC to bear their 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
Registrar

M. Vilaras
President of the Fourth Chamber