JUDGMENT OF THE COURT (Fourth Chamber)

25 March 2021(*)

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

In Case C-586/16 P,

APPEAL under Article 56 of the Statute of the Court of Justice of the European Union, brought on 17 November 2016,

Sun Pharmaceutical Industries Ltd, formerly Ranbaxy Laboratories Ltd, established in Vadodara (India),

Ranbaxy (UK) Ltd, established in Hayes (United Kingdom),

represented by R. Vidal, Solicitor, and B. Kennelly QC, and by L. Penny, Solicitor,

appellants,

the other parties to the proceedings being:

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

defendant at first instance,

supported by:

United Kingdom of Great Britain and Northern Ireland, represented initially by D. Guðmundsdóttir, Z. Lavery and D. Robertson, acting as Agents, and by J. Holmes QC, and subsequently by D. Guðmundsdóttir, acting as Agent, and by 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, Sun Pharmaceutical Industries Ltd and Ranbaxy (UK) Ltd seek to have set aside the judgment of the General Court of the European Union of 8 September 2016, *Sun Pharmaceutical Industries and Ranbaxy (UK)* v *Commission* (T-460/13, not published, 'the judgment under appeal', EU:T:2016:453), by which the General Court dismissed their action which sought, 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 Article 23(2)(a) of Council Regulation (EC) No 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles [101 and 102 TFEU] (OJ 2003 L 1, p. 1) provides:

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

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

3 Article 25(3) and (4) of that regulation provides:

'3. Any action taken by the Commission or by the competition authority of a Member State for the purpose of the investigation or proceedings in respect of an infringement shall interrupt the limitation period for the imposition of fines or periodic penalty payments. The limitation period shall be interrupted with effect from the date on which the action is notified to at least one undertaking or association of undertakings which has participated in the infringement. Actions which interrupt the running of the period shall include in particular the following:

(a) written requests for information by the Commission or by the competition authority of a Member State;

(b) written authorisations to conduct inspections issued to its officials by the Commission or by the competition authority of a Member State;

(c) the initiation of proceedings by the Commission or by the competition authority of a Member State;

(d) notification of the statement of objections of the Commission or of the competition authority of a Member State.

4. The interruption of the limitation period shall apply for all the undertakings or associations of undertakings which have participated in the infringement.'

The 2001 Guidelines on horizontal cooperation agreements

4 Points 25 and 26 of the Guidelines on the applicability of Article [101 TFEU] to horizontal cooperation agreements (OJ 2001 C 3, p. 2; 'the 2001 Guidelines on horizontal cooperation agreements') state:

'Agreements that almost always fall under Article [101](1)

25. Another category of agreements can be assessed from the outset as normally falling under Article [101](1). This concerns cooperation agreements that have the object to restrict competition by means of price fixing, output limitation or sharing of markets or customers. These restrictions are considered to be the most harmful, because they directly interfere with the outcome of the competitive process. Price fixing and output limitation directly lead to customers paying higher prices or not receiving the desired quantities. The sharing of markets or customers reduces the choice available to customers and therefore also leads to higher prices or reduced

output. It can therefore be presumed that these restrictions have negative market effects. They are therefore almost always prohibited.

Agreements that may fall under Article [101](1)

26. Agreements that do not belong to the abovementioned categories need further analysis in order to decide whether they fall under Article [101](1). The analysis has to include market-related criteria such as the market position of the parties and other structural factors.'

2006 Guidelines on the method of setting fines

5 Points 6, 13 and 22 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 on the method of setting fines') state:

'6. 'The combination of the value of sales to which the infringement relates and of the duration of the infringement is regarded as providing an appropriate proxy to reflect the economic importance of the infringement as well as the relative weight of each undertaking in the infringement. Reference to these factors provides a good indication of the order of magnitude of the fine and should not be regarded as the basis for an automatic and arithmetical calculation method.

…

13. In determining the basic amount of the fine to be imposed, the Commission will take the value of the undertaking's sales of goods or services to which the infringement directly or indirectly relates in the relevant geographic area within [the European Economic Area (EEA)]. It will normally take the sales made by the undertaking during the last full business year of its participation in the infringement (hereafter "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.'

The 2014 Guidelines on technology transfer agreements

6 Under the heading 'Pay-for-restriction in settlement agreements', points 238 and 239 of the Guidelines on the application of Article 101 [TFEU] to technology transfer agreements (OJ 2014 C 89, p. 3; 'the 2014 Guidelines on technology transfer agreements') are worded as follows:

'238. "Pay-for-restriction" or "pay-for-delay" type settlement agreements often do not involve the transfer of technology rights, but are based on a value transfer from one party in return for a limitation on the entry and/or expansion on the market of the other party and may be caught by Article 101(1).

239. If, however, such a settlement agreement also includes a licensing of the technology rights concerned by the underlying dispute, and that agreement leads to a delayed or otherwise limited ability for the licensee to launch the product on any of the markets concerned, the agreement may be caught by Article 101(1) and would then need to be assessed in particular in the light of Articles 4(1)(c) and 4(1)(d) of [Commission Regulation (EU) No 316/2014 of 21 March 2014 on the application of Article 101(3) [TFEU] to categories of [technology transfer agreements]… If the parties to such a settlement agreement are actual or potential competitors and there was a significant value transfer from the licensor to the licensee, the Commission will be particularly attentive to the risk of market allocation/market sharing.'

Background to the dispute and the decision at issue

7 The present appeal is one of six related appeals against six judgments of the General Court delivered following the actions for annulment brought against the decision at issue, namely, in addition to the present appeal: the appeal 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 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 in Case C-601/16 P *(Arrow Group and Arrow Generics* v *Commission*) against the judgment of 8 September 2016, *Arrow Group and Arrow Generics* v *Commission* (T-467/13, not published, EU:T:2016:450); the appeal in Case C-611/16 P (*Xellia Pharmaceuticals and Alpharma* v *Commission*) against the judgment of 8 September 2016, *Xellia Pharmaceuticals and Alpharma* v *Commission* (T-471/13, not published, EU:T:2016:460), and the appeal 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 34 of the judgment under appeal as follows:

‘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” laboratory, namely an undertaking whose activities are focused on researching new medicinal products and bringing them to the market.

3 Ranbaxy Laboratories Ltd was a company governed by Indian law specialising in the development and production of generic active pharmaceutical ingredients (“APIs”) and generic medicinal products. On 25 March 2015, it ceased to exist following its merger with [Sun Pharmaceutical Industries], a company governed by Indian law.

4 Ranbaxy (UK) … is a company governed by English law which was a subsidiary of Ranbaxy Laboratories, responsible for the sale of the latter’s products in the United Kingdom. It is now a subsidiary of Sun Pharmaceutical Industries.

The relevant product and the applicable patents

5 The relevant product for the purposes of the present case is the antidepressant medicinal product containing an 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 (“the [original Lundbeck patents]”) 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 the [original Lundbeck 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, the [original Lundbeck 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 In particular, first, in 1998 and 1999 Lundbeck applied to the EPO for two patents relating to the production of citalopram by processes using iodo and amide, respectively. The EPO granted

Lundbeck a patent protecting the process using amide ("the amide patent") on 19 September 2001 and a patent protecting the process using iodo ("the iodo patent") on 26 March 2003.

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

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.

The agreement concluded between Lundbeck and Ranbaxy Laboratories

12 In 2002 Lundbeck entered into six agreements concerning citalopram ("the agreements in question") with undertakings active in the production or sale of generic medicinal products ("the generic undertakings"), including Ranbaxy Laboratories.

13 The agreement of relevance to the present case ("the agreement at issue"), concluded between Lundbeck and Ranbaxy Laboratories, took effect on 16 June 2002, for a term of 360 days. Under an addendum signed on 19 February 2003 ("the addendum"), that agreement was extended until 31 December 2003. The total duration of the agreement is therefore from 16 June 2002 until 31 December 2003 ("the relevant period").

14 According to the preamble to the agreement at issue ("the preamble"):

– Ranbaxy Laboratories filed two process patent applications in India relating to citalopram and manufactured medicinal products containing citalopram with the intention of marketing such products, in particular in the EEA (second and third recitals in the preamble and annex A to the agreement at issue);

– Lundbeck performed laboratory analyses of that citalopram and concluded that the processes used infringed the amide patent and the iodo patent [referred to in paragraph 9 of the judgment under appeal], the latter not having yet been granted (see paragragh 9 [of the judgment under appeal]) whereas Ranbaxy Laboratories disputed the existence of such infringements (fifth to eighth recitals in the preamble);

– Lundbeck and Ranbaxy Laboratories arrived at an agreement in order to avoid costly and time-consuming patent litigation, the outcome of which could not be predicted with absolute certainty (ninth recital in the preamble).

15 According to the agreement at issue, in particular:

– "Subject to the terms and conditions of this Agreement and subject to payment of the Settlement Amount by Lundbeck, [Ranbaxy Laboratories] shall not … claim any rights on the Patent Application [referred to in the preamble] or any production method used by [Ranbaxy Laboratories] and shall cancel, cease and desist from any manufacture or sale of pharmaceutical products based hereon [in particular in the EEA] during the term of this Agreement" (Article 1.1 of the agreement at issue ("Article 1.1") and Article 1.0 of the addendum);

– “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”, Ranbaxy Laboratories and Ranbaxy (UK) would voluntarily submit to an interim injunction by any competent national court, without Lundbeck providing any kind of security or any undertaking other than the undertakings arising under that agreement (Article 1.2 of the agreement at issue);

– in consideration of the agreement arrived at between the parties, Lundbeck was to pay to Ranbaxy Laboratories the sum of 9.5 million United States Dollars (USD), in instalments over the relevant period (Article 1.3 of the agreement at issue and Article 2.0 of the addendum);

– Lundbeck was to sell Cipramil tablets (see paragraph 11 [of the judgment under appeal]) to Ranbaxy Laboratories or Ranbaxy (UK) with a discount of 40% on the ex-factory price, so that they could sell those tablets on the United Kingdom market (Article 1.3 of, and Appendix B to, the agreement at issue);

– Lundbeck and Ranbaxy Laboratories undertook, during the relevant period, not to initiate legal proceedings against each other on the basis of any of the patents referred to earlier in the agreement at issue itself (Article 1.4 of the agreement at issue).

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

16 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].

17 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.

18 Between 2003 and 2006, the Commission carried out inspections within the meaning of Article 20(4) 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) 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.

19 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 medicines for human consumption on to the market.

20 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.

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

22 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 … Ranbaxy Laboratories and Ranbaxy (UK).

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

…

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

The [decision at issue]

28 By the [decision at issue], the Commission considered that the agreement at issue, like the other agreements in question, constituted restrictions of competition by object for the purpose 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 by Ranbaxy Laboratories and Ranbaxy (UK) (together "Ranbaxy") (Article 1(4) of the [decision at issue]).

29 As is apparent from the summary set out in recital 1174 of the [decision at issue], the Commission relied, in particular, when making that finding, on the following factors:

– at the moment when they concluded the agreement at issue, Lundbeck and Ranbaxy were at least potential competitors in the EEA;

– under the agreement at issue, Lundbeck transferred significant value to Ranbaxy;

– that transfer of value was linked to Ranbaxy's acceptance of the limitations on its entry to the market set out in that agreement, and in particular to Ranbaxy's commitment not to manufacture or sell citalopram in the EEA during the relevant period, whether through its own subsidiaries or via third parties;

– that transferred value considerably exceeded the profit that Ranbaxy could have expected to make by selling the generic citalopram it had manufactured until then;

– Lundbeck could not have obtained those limitations by enforcing its process patents, since the obligations on Ranbaxy as a result of that agreement 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 Ranbaxy if the latter entered the market with its generic citalopram after the expiry of that agreement.

30 The Commission also imposed fines on all the parties to the agreements in question. To that end, it applied the [2006 Guidelines on the method of setting fines]. Although, in the case of Lundbeck, the Commission followed the general methodology described in the 2006 Guidelines [on the method of setting fines], 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]).

31 Thus, as regards the parties to the agreements in question other than Lundbeck, including Ranbaxy, 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]).

32 As regards Ranbaxy, the Commission considered that the total amount which it had received from Lundbeck corresponded to the payments provided for in the agreement at issue and the addendum thereto, that is to say USD 9.5 million, plus the value of the 40% discount on the purchase of Cipramil from Lundbeck which Ranbaxy had been granted under that agreement (see the fourth indent of paragraph 15 [of the judgment under appeal]), which was estimated as amounting to [3 million pounds sterling (GBP)]. When converted into euro, that total amount was EUR 12.7 million (recital 587 [of] the [decision at issue]). However, in order to take account

of the distribution costs incurred by Ranbaxy, the Commission applied a reduction of 10% to its turnover from the distribution of Cipramil purchased from Lundbeck (recital 1373 and footnote [2264] [of] the [decision at issue]). The basic amount was thus set at EUR 11.5 million (recital 1374 [of] the [decision at issue]).

33 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]).

34 On the basis of those considerations, the Commission imposed a fine of EUR 10 323 000 jointly and severally on Ranbaxy Laboratories and Ranbaxy (UK) (Article 2(4) 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, Sun Pharmaceutical Industries and Ranbaxy (UK) (together, 'Sun Pharmaceutical') brought an action for annulment in part of the decision at issue and for a reduction of the fine imposed on them by the Commission.

10 In support of its action, Sun Pharmaceutical relied on four pleas in law, alleging, in essence, first, 'that the agreement at issue does not constitute a "restriction by object"'; second, that there were 'manifest errors of assessment as regards potential competition'; third, that there were manifest errors of assessment in the interpretation of the agreement at issue; and fourth, that the fine imposed was unjustified and disproportionate.

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

The procedure before the Court

12 By document lodged at the Registry of the Court of Justice on 18 November 2016, Sun Pharmaceutical brought the present appeal.

13 Following Sun Pharmaceutical's request to lodge a reply, the President of the Court, by decision of 13 February 2017, refused that request.

14 By documents lodged at the Court Registry on 28 July 2017, the United Kingdom of Great Britain and Northern Ireland requested leave to intervene in support of the form of order sought by the Commission in the present case and in Cases C-588/16 P (*Generics (UK)* v *Commission*), C-601/16 P (*Arrow Group and Arrow Generics* v *Commission*), C-611/16 P (*Xellia Pharmaceuticals and Alpharma* v *Commission*) and C-614/16 P (*Merck* v *Commission*), referred to in paragraph 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 of Justice granted those requests. However, having regard in particular to 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 President of the Court of Justice ordered, in respect of all those cases, that, in particular, the confidential version of the decision at issue be treated as confidential as regards that Member State, since only a non-confidential version had been served on the United Kingdom.

15 On 27 November 2018 the Court decided that the present case would be assigned to the Fourth Chamber to adjudicate following a joint hearing with Cases 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*), C-611/16 P (*Xellia Pharmaceuticals and Alpharma* v *Commission*) and C-614/16 P (*Merck* v *Commission*) and after hearing an Opinion.

16 On 29 November 2018, on the basis of Article 61(2) of the Rules of Procedure of the Court of Justice, the Court sent the parties to the proceedings in the present case a series of written questions to be answered orally at the hearing and a provisional plan for the hearing, detailing the course of that hearing. Following those parties' comments, a final plan for the hearing was sent to them on 22 January 2019.

17 The joint hearing in the present case and the cases referred to in paragraph 15 above was held on 24 January 2019.

18 On 6 February 2020 the Advocate General, on the basis of Article 62 of the Rules of Procedure, put to the parties to the proceedings in the present case a question for written response ('the 6 February 2020 question for written response'), by which she invited them to express their views on the possible impact 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 concerning the existence of potential competition between Lundbeck and the manufacturers of generic medicinal products ('generic medicines') and concerning the characterisation of the agreements between Lundbeck and those manufacturers as 'restrictions by object'. The answers to that question were received by the Court on 6 March 2020.

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

Forms of order sought by the parties before the Court

20 By its appeal, Sun Pharmaceutical claims that the Court should:

– set aside the judgment under appeal in so far as it concerns Sun Pharmaceutical;

– annul Article 1(4) of the decision at issue, in so far as it concerns Sun Pharmaceutical;

– annul Article 2(4) of the decision at issue, in so far as it imposes fines on Sun Pharmaceutical or, in the alternative, reduce the amount thereof; and

– order the Commission to pay the costs and other expenses incurred by Sun Pharmaceutical in the present case and to take any other measures that the Court considers appropriate.

21 The Commission contends that the Court should:

– dismiss the appeal; and

– order Sun Pharmaceutical to pay the costs.

22 The United Kingdom contends that the Court should dismiss the appeal in its entirety.

The appeal

23 In support of its appeal, Sun Pharmaceutical relies on three grounds of appeal.

24 By its first ground of appeal, Sun Pharmaceutical criticises the General Court for having misapplied the concept of 'restriction by object' within the meaning of Article 101(1) TFEU. By its second ground of appeal, Sun Pharmaceutical complains that the General Court erred in law and/or distorted the clear sense of the evidence in finding that Sun Pharmaceutical and Lundbeck were potential competitors. Finally, by its third ground of appeal, Sun Pharmaceutical submits that the General Court erred in law and/or manifestly distorted the evidence by upholding the fine imposed on it by the Commission.

25 The second ground of appeal will be examined first, followed by the first ground of appeal and finally the third ground of appeal.

The second ground of appeal

The relevant paragraphs of the judgment under appeal

26 Having recalled, in paragraphs 58 to 74 of the judgment under appeal, the principles and case-law applicable to assessing whether undertakings are potential competitors, the General Court assessed in turn the various items of evidence used by the Commission to establish that Sun Pharmaceutical and Lundbeck were potential competitors.

27 In that context, in paragraphs 82 to 110 of the judgment under appeal, the General Court considered that the minutes of a meeting held on 17 April 2002 between Sun Pharmaceutical and Lundbeck ('the 17 April 2002 meeting'), the content of which it reiterated, in particular Sun Pharmaceutical's assertion that it had a process which did not infringe Lundbeck's process patents, enabled it to find, in paragraph 87 of that judgment, that Lundbeck had decided to conclude the agreement at issue, which demonstrated that it was taking seriously the threat posed by Sun Pharmaceutical, a perception which could be taken into consideration for the purpose of assessing whether the two manufacturers of medicines were in competition with each other at the time when the agreement was concluded. In paragraphs 97 to 109 of that judgment, the General Court also took into consideration other factors relied on by the Commission for that purpose, concerning, in particular, the situation of the market which was opening to generic medicines and the steps taken by Sun Pharmaceutical to prepare for its market entry with its generic citalopram.

28 In paragraphs 112 to 162 of the judgment under appeal, the General Court rejected Sun Pharmaceutical's arguments that the steps it took to obtain the authorisations necessary for its market entry could not be completed within the period referred to in the minutes of the 17 April 2002 meeting. While stating that those arguments were ineffective, the General Court found that those arguments could not call into question the finding that Lundbeck had felt under competitive pressure from Sun Pharmaceutical.

29 In paragraphs 138 to 150 of the judgment under appeal, the General Court added that that finding could not be called into question by the presumption of validity of the amide and iodo patents, since that presumption cannot be equated with a presumption of illegality of generic products which the patent holder deems to be infringing those patents.

Arguments of the parties

30 By its second ground of appeal, Sun Pharmaceutical claims that the General Court erred in law and/or manifestly distorted the clear sense of the evidence in the file in finding that there was significant 'potential competition' between Sun Pharmaceutical and Lundbeck. In that regard, its view is that the General Court misapplied the standard of proof which it nevertheless correctly identified in paragraphs 65 and 66 of the judgment under appeal, making crucial findings in the absence of supporting evidence and, in the alternative, exercising its discretion in the Commission's favour.

31 In the present case, Sun Pharmaceutical complains that the General Court examined evidence originating solely from Lundbeck, which was not available to it and which cast no light on the common intention of the parties to the agreement at issue. Sun Pharmaceutical also complains that the General Court took the view that the documents held by Lundbeck were reliable, whereas the evidence adduced gave rise to legitimate doubts. In that regard, Sun Pharmaceutical maintains that the General Court was naïve and manifestly distorted the clear sense of the evidence in taking the view that Sun Pharmaceutical was entirely truthful in its negotiations with Lundbeck. Finally, in the view of Sun Pharmaceutical, the General Court confined itself to an extremely small amount of direct evidence from Sun Pharmaceutical. Accordingly, it is necessary, Sun Pharmaceutical argues, to start from the premiss that Sun Pharmaceutical was unable to market citalopram without non-infringing API in the EEA and without first obtaining a marketing authorisation ('MA') or a major variation of that MA, known as 'type II', within the meaning of Article 3 of Commission Regulation (EC) No 541/95 of 10 March 1995 on the examination of variations to the terms of a marketing authorisation granted by the competent authority of a Member State (OJ 1995 L 55, p. 7).

32 Sun Pharmaceutical denies that it stated at the 17 April 2002 meeting that it was convinced that there was no risk of patent infringement, as appears from paragraphs 85 and 94 to 96 of the judgment under appeal. It also takes the view that the General Court erred in law in accepting the real and concrete possibility of market entry on the basis of the minutes of the 17 April 2002 meeting and, therefore, the erroneous and subjective view of one of the parties to the agreement at issue, while accepting, in paragraph 88 of that judgment, that Lundbeck's perception cannot be sufficient on its own. First, as regards obtaining an MA, Sun Pharmaceutical claims that all the evidence shows that, on 17 April 2002, it was not in a position to be able to file an MA application and that its statements to the contrary made to Lundbeck were exaggerated and unrealistic. Moreover, the period of eight months to obtain an MA is, it claims, highly unrealistic, as is confirmed by footnote 1889 of the decision at issue. In addition, Sun Pharmaceutical claims that the finding, referred to in paragraph 118 of the judgment under appeal, that it was not in a hurry to obtain an MA, and the General Court's assertion, in paragraphs 116 to 119 of that judgment, that the period necessary for an MA to be issued to Sun Pharmaceutical was of little importance for the purpose of identifying a relationship of potential competition, are the result of a distortion of the clear sense of the facts or of the evidence. Second, as regards the possibility of a type II variation, as mentioned in paragraph 31 of the present judgment, Sun Pharmaceutical claims that there was absolutely no evidence that there was a potential partner in Northern Europe or any agreement with Alfred E. Tiefenbacher GmbH & Co., which is a manufacturer of generic medicines. In addition, the statistical approach used by the General Court in paragraph 133 of the judgment under appeal to find that Sun Pharmaceutical continued to have real possibilities of varying an existing MA within the period indicated at the 17 April 2002 meeting is, in Sun Pharmaceutical's view, purely theoretical. Third, as regards the possibility of purchasing an MA, Sun Pharmaceutical claims that that has not been proved in any way. Moreover, it argues that the other limited evidence used by the General Court cannot remedy the distortion of the clear sense of the facts alleged by Sun Pharmaceutical.

33 The Commission takes the view that the second ground of appeal is unfounded.

Findings of the Court

34 As a preliminary point, it must be noted that the second ground is divided, in essence, into two parts, the first relating to the test applied by the General Court in order to establish that Sun Pharmaceutical and Lundbeck were potential competitors, and the second relating to the assessment of the evidence by the General Court, following which it concluded that Sun Pharmaceutical and Lundbeck were in fact, at the time the agreement at issue was concluded, in such a relationship of competition.

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

36 The latter requirement means, with respect to horizontal cooperation agreements entered into by undertakings that operate at the same level of the production or distribution chain, that the coordination involves undertakings who are in competition with each other, if not in reality, then at least potentially (see, to that effect, judgment of 30 January 2020, *Generics (UK) and Others*, C-307/18, EU:C:2020:52, paragraph 32).

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

38 When the agreements at issue, such as the agreement at issue in the present case, have the effect of temporarily keeping a number of undertakings outside a market, it must be determined, having regard to the structure of the market and the economic and legal context within which it operates, whether there would have existed, in the absence of those agreements, real and concrete possibilities for those undertakings to enter that market and compete with the undertaking 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).

39 As regards more particularly such agreements arising in the context of the opening of a market, of a medicine containing an active ingredient that has recently entered the public domain, to the manufacturers of generic medicines, it must be determined, taking due account of the regulatory constraints that are characteristic of the medicines sector and the intellectual property rights and in particular the patents held by the manufacturers of originator medicines relating to one or more processes of manufacturing 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 that market entry 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).

40 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, the 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 even though the manufacturer of generic medicines 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).

41 As regards, in particular, the assessment of whether there are insurmountable barriers to entry on the market concerned, the Court has stated 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, notwithstanding the presumption of validity attached to that patent, since it sheds no light, for the purposes of the application of 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).

42 Consequently, the existence of such a patent cannot, 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 the originator medicines concerned (judgment of 30 January 2020, *Generics (UK) and Others*, C-307/18, EU:C:2020:52, paragraph 46).

43 Furthermore, the Court has also stated that it is not for the competition authority concerned to carry out a review of the strength of the patent in question 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 the 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).

44 It follows that, in the present case, and contrary to Sun Pharmaceutical’s assertions, the General Court cannot be accused of any error of law in the assessment and application of the test used to find, in paragraph 162 of the judgment under appeal, that Sun Pharmaceutical had, at the time when the agreement at issue was concluded, real and concrete possibilities of entering the market with its API

within a sufficiently short period of time for it to be characterised as a potential competitor of Lundbeck, and did not meet any insurmountable barrier to entry.

45 Indeed, in accordance with the case-law of the Court of Justice (see, to that effect, judgment of 30 January 2020, *Generics (UK) and Others,* C-307/18, EU:C:2020:52, paragraph 44) and as the Court of Justice has stated in the judgment delivered on today's date in Case C-591/16 P, *Lundbeck* v *Commission* (paragraph 88), the General Court relied on a consistent body of evidence establishing, in the present case, both the objective situation of the parties to the agreement at issue on the market for citalopram and the subjective perception that each of them had of the other party and of the strength of the process patents in question, while taking due account of the regulatory constraints that are characteristic of the medicines sector and of intellectual property rights.

46 Accordingly, the General Court found, in paragraphs 82 to 96 of the judgment under appeal, that the minutes of the 17 April 2002 meeting constituted very relevant probative evidence in order to establish that Sun Pharmaceutical and Lundbeck were potential competitors but also, in paragraphs 97 to 109 of that judgment, that Lundbeck's original patents had expired, thereby allowing manufacturers of generic medicines to enter the market by using the processes covered by those patents, and that several factors constituted evidence of steps taken by Sun Pharmaceutical to prepare its entry to the market for generic citalopram. Moreover, in paragraphs 112 to 161 of the judgment under appeal, the General Court added, so far as it was relevant, first, that, in the light of the steps taken by Sun Pharmaceutical to prepare its entry to the market with generic citalopram, including as regards the process necessary to obtain an MA or equivalent authorisation, Sun Pharmaceutical had a real and concrete possibility of entering the market, which had caused Lundbeck to decide to conclude the agreement at issue with it and, second, that the presumption of validity of the amide patent and of the iodo patent did not preclude, in the light of the circumstances of the case, that conclusion.

47 As regards, in the second place, the evidence taken into consideration by the General Court, it should be recalled that 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 limited to points of law. The General Court, therefore, has exclusive jurisdiction to find and appraise the relevant facts and to assess the evidence. The assessment of those facts and that evidence does not, therefore, save where it distorts those facts and evidence, constitute a point of law which is, as such, subject upon appeal to review by the Court of Justice. Such distortion must be obvious from the documents on the Court of Justice's file, without there being any need to carry out a new assessment of the facts and the evidence (judgment of 12 January 2017, *Timab Industries and CFPR* v *Commission*, C-411/15 P, EU:C:2017:11, paragraph 89).

48 First, in so far as Sun Pharmaceutical complains that the General Court was naïve in taking the view that Sun Pharmaceutical was entirely truthful in its negotiations with Lundbeck, it must be pointed out not only that Sun Pharmaceutical fails to identify the paragraph of the judgment under appeal in which that finding is alleged to have been made, but above all fails to indicate precisely the evidence the sense of which is alleged to have been distorted by the General Court and to show the errors of appraisal which, in its view, led to the alleged distortion. Consequently, that allegation by Sun Pharmaceutical must also be rejected as being inadmissible (see, to that effect, judgment of 20 October 2011, *PepsiCo* v *Grupo Promer Mon Graphic*, C-281/10 P, EU:C:2011:679, paragraph 78 and the case-law cited).

49 Second, inasmuch as Sun Pharmaceutical complains that the General Court held, in paragraph 118 of the judgment under appeal, that Sun Pharmaceutical was is no particular hurry to obtain an MA, it is sufficient to state that, in any event, that allegation is ineffective in so far as, even if it were established, it is directed against a ground of the judgment under appeal included for the sake of completeness, as is apparent from paragraphs 114 to 117 of that judgment. It is settled case-law that complaints directed against a ground expressed for the sake of completeness in a decision of the General Court cannot lead to the annulment of that decision and are therefore ineffective (judgment of 16 September 2020, *Edison* v *EUIPO*, C-121/19 P, EU:C:2020:714, paragraph 44).

50 Third, in so far as Sun Pharmaceutical complains that, in paragraphs 116 to 119 of the judgment under appeal, the General Court distorted the clear sense of the facts or the evidence in finding that the period

required for an MA to be issued to Sun Pharmaceutical was of little importance for the purpose of identifying that company and Lundbeck as potential competitors, it must be observed that such an allegation is based on a misreading of those paragraphs. It is clear from paragraph 119 of that judgment not that the period required for an MA to be issued to Sun Pharmaceutical was of little importance for the purpose of identifying that company and Lundbeck as potential competitors, but rather only that, 'although the success of [the procedure for an MA to be issued] is indispensable in order for effective competition to exist, the path to obtaining such an MA, when it is taken by an undertaking which has for a long time been seriously preparing its market entry, constitutes potential competition, even though it may in fact take longer than envisaged by the interested parties'. Moreover, and in any event, such an argument is ineffective for the reasons set out in the preceding paragraph.

51 Sun Pharmaceutical's argument concerning other errors in the assessment of the facts or evidence made by the General Court must be rejected as being inadmissible in accordance with the case-law cited in paragraph 47 of the present judgment.

52 In the light of the foregoing, the second ground of appeal must be rejected.

The first ground of appeal

The relevant paragraphs of the judgment under appeal

53 Following the preliminary observations set out in paragraphs 206 to 212 of the judgment under appeal, which recalled the case-law of the Court of Justice concerning 'restrictions by object' and the summary, in paragraphs 213 to 220 of that judgment, of the decision at issue in the context of which it was stated, in particular, in paragraph 218 of the judgment under appeal, that the Commission had not asserted that all patent settlements containing reverse payments were contrary to Article 101(1) TFEU, the General Court examined whether there was a 'restriction by object' in the present case.

54 In that context, the General Court first of all stated, in paragraphs 221 and 222 of the judgment under appeal, that, under the agreement at issue, which could be treated as a market exclusion agreement, Sun Pharmaceutical, a potential competitor of Lundbeck, had undertaken not to enter the market during the relevant period.

55 In paragraphs 233 to 241 of that judgment, the General Court then found, inter alia, that the agreement at issue had not settled any dispute, that it had a much broader scope than that of any legal actions that Lundbeck could have brought against Sun Pharmaceutical and that, in any event, Sun Pharmaceutical had accepted significant limitations on its commercial autonomy in return for a payment by Lundbeck, the amount of which was determined by taking account of the expected profits if Sun Pharmaceutical had entered the market with its generic citalopram and which was therefore closely linked to those expected profits.

56 In paragraphs 247 to 250 of the judgment under appeal, the General Court rejected the argument that the agreement at issue was pro-competitive in nature, stating that its provisions concerning the distribution of Cipramil, which were accompanied by a discount of 40% on the 'ex-factory' price of that medicine sold by Lundbeck, resulting in a loss of revenue of GBP 3 million for Lundbeck, served to supplement the consideration given to Sun Pharmaceutical in return for it refraining from the production and sale of its own citalopram during the relevant period.

57 In paragraphs 252 to 262 of the judgment under appeal, the General Court further upheld the analogy drawn by the Commission between the agreement at issue and the agreements in question in the case which gave rise to the judgment of 20 November 2008, *Beef Industry Development Society and Barry Brothers* (C-209/07, EU:C:2008:643) and held that the Commission was fully entitled to apply by analogy the case-law arising from that judgment.

58 In paragraphs 265 to 267 of the judgment under appeal, the General Court accepted that, for the purposes of characterising a concerted practice as a 'restriction by object', the intention of the parties in question could be taken into account.

59 In paragraphs 270 to 279 of the judgment under appeal, the General Court refused to rule out the agreement at issue being characterised as a 'restriction by object' on account of an alleged lack of precedent or legal uncertainty, taking the view, in paragraph 272 of that judgment, that the requirement for experience concerning the negative effects on competition of such restrictions did not require the Commission to have previously adopted that characterisation in respect of similar agreements.

Arguments of the parties

60 By its first ground of appeal, Sun Pharmaceutical criticises the General Court for having misapplied the concept of a 'restriction by object' within the meaning of Article 101(1) TFEU, in characterising the agreement at issue as such, since that agreement was intended, prima facie, to settle a patent dispute between Sun Pharmaceutical and Lundbeck, which required the Commission to examine the effects of that agreement.

61 In the present case, Sun Pharmaceutical maintains, first, that both the General Court, in paragraph 242 of the judgment under appeal, and the Commission accepted that patent settlement agreements could be legitimate and lawfully concluded before any litigation commenced. It argues that that finding involves each agreement being assessed on a case-by-case basis, having regard to the facts, background and circumstances, but not the parties' intentions, since they involve subjective assessments which are not compatible with the requirement that a 'restriction by object' must be easily identifiable. With regard to the latter point, in Sun Pharmaceutical's view, it is clear from the Opinion of Advocate General Wahl in *CB* v *Commission* (C-67/13 P, EU:C:2014:1958, points 44 and 110) that taking account of the intention of the parties to an agreement for the purposes of assessing that agreement is contrary to the requirement that the context and the parties' intention may only reinforce or neutralise the existence of an infringement by object, as is apparent from the judgment of 11 September 2014, *CB* v *Commission* (C-67/13 P, EU:C:2014:2204, paragraph 88). Sun Pharmaceutical claims that it was not easily identifiable that such an agreement constituted an infringement, since it was for the Commission to examine whether the agreement at issue was motivated principally by (i) the strength of the process patents in question, the soundness of which the Commission must assess, or (ii) the reverse payment.

62 According to Sun Pharmaceutical, the General Court itself acknowledged, in paragraphs 239 to 241 of the judgment under appeal, that Lundbeck had a powerful incentive to pay the amounts provided for in the agreement at issue since even if Sun Pharmaceutical had been able to defend its process patents, the unlawful market entry of the generic medicine sold by Sun Pharmaceutical would have resulted in a 20% fall in the price of the medicine sold by Lundbeck. Similarly, if Sun Pharmaceutical had been unsuccessful in the patent dispute against Lundbeck, the damages it would have had to pay would have exceeded the profits that it would have made in the interim.

63 In addition, it is the appellants' view that the General Court contradicted itself by characterising the agreement at issue as a 'restriction by object' on account of the significant amount of the reverse payments made, while acknowledging, also in paragraphs 239 to 241 of the judgment under appeal, that it was not in a position to assess those payments and that the Commission had not adduced evidence in that regard.

64 Sun Pharmaceutical also criticises the distinction made in paragraphs 242 and 243 of the judgment under appeal between the agreement at issue and the agreement concluded between Lundbeck and Neolab Ltd, which had not been regarded as problematic even though it also involved market exclusion.

65 Sun Pharmaceutical further criticises the General Court for failing to take into consideration the pro-competitive effects of Lundbeck supplying Cipramil and for finding that there was no difference in competition terms between a cash payment and the supply of a product on a discounted basis which allowed it to enter the market and which benefited the customer, as it had already stated in its reply to the 6 February 2020 question for written response.

66 Second, Sun Pharmaceutical maintains that the General Court failed to identify any 'experience' showing that restrictions, such as those at issue, contained in a patent dispute settlement agreement had been constantly prohibited, as required by the judgment of 11 September 2014, *CB* v *Commission* (C-67/13 P, EU:C:2014:2204, paragraph 51). In paragraph 279 of the judgment under appeal, it argues

that the General Court referred to such experience – which the Commission did not do – without, however, providing supporting material. In addition, Sun Pharmaceutical argues that the General Court's treatment of the agreement at issue as equivalent to a market exclusion agreement is not only inadmissible, since the Commission had not done so, but also incorrect in so far as the agreement at issue clearly differed from that at issue in the case giving rise to the judgment of 20 November 2008, *Beef Industry Development Society and Barry Brothers* (C-209/07, EU:C:2008:643), which was not a patent settlement agreement and which had been concluded between actual competitors. In the present case, the manufacturers of generic medicines might have found it necessary not to enter the market because of Lundbeck's lawful exercise of its rights or even the fact of no MA having been issued to them. Furthermore, Sun Pharmaceutical refers to a number of judgments of the Court of Justice in which it was held, in the context of intellectual property rights, that export bans, absolute territorial protection or open exclusive licences were not characterised as a 'restriction by object'. In addition, it states that, in paragraph 235 of the judgment under appeal, the General Court found that the agreement at issue amounted to a 'restriction by object', in that that agreement 'reflected the parties' [justified] recognition that Lundbeck was entitled to the exclusivity agreed'. Such reasoning is, in its view, contrary to points 238 and 239 of the 2014 Guidelines on technology transfer agreements, under which agreements, such as the agreement at issue, concluded in the field of technology transfers are not characterised as a 'restriction by object', and contrary to point 17 of the Commission's 6th Report on the Monitoring of Patent Settlements of 2 December 2015.

67 The Commission contends that the first ground of appeal is unfounded.

Findings of the Court

68 As regards the characterisation of a concerted practice as a 'restriction by object' in accordance with Article 101(1) TFEU, the Court of Justice has already had occasion to state, as the General Court pointed out in paragraphs 207 to 209 of the judgment under appeal, that the concept of restriction of competition 'by object' must be interpreted strictly and can be applied only to certain agreements between undertakings which reveal, in themselves and having regard to the content of their provisions, their objectives, and the economic and legal context of which they form part, a sufficient degree of harm to competition for the view to be taken that it is not necessary to assess their effects, 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).

69 As regards agreements similar to dispute settlements relating to a process patent for the manufacture of an active ingredient that is in the public domain concluded between a manufacturer of originator medicines and a number of manufacturers of generic medicines and which had the effect of delaying the entry of generic medicines on the market in return for monetary or non-monetary transfers of value from the former to the latter, the Court has held that such agreements cannot in all cases be regarded as 'restrictions by object' within the meaning 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), which the Commission also stated in the decision at issue, as is apparent from paragraph 218 of the judgment under appeal.

70 However, the characterisation as a 'restriction by object' must be adopted where it is plain from the analysis 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, in so far as agreements by which competitors deliberately substitute practical cooperation between them for the risks of competition clearly can be characterised as 'restrictions by object' (see, to that effect, judgment of 30 January 2020, *Generics (UK) and Other*s, C-307/18, EU:C:2020:52, paragraphs 83 and 87).

71 For the purposes of that analysis, it is necessary, in each individual case, to assess whether the net gain from the transfers of value by the manufacturer of originator medicines to the manufacturer of generic medicines was sufficiently large to act as an incentive to the manufacturer of generic medicines to refrain from entering the market concerned and, therefore, not to compete on the merits with the manufacturer of originator medicines, without it being necessary for that net gain necessarily to be greater than the profits which the manufacturer of generic medicines would have made if it had been

successful in the patent proceedings (see, to that effect, judgment of 30 January 2020, *Generics (UK) and Others*, C-307/18, EU:C:2020:52, paragraphs 93 and 94).

72 In the present case, it is apparent from paragraphs 221, 233, 234, 236 and 241 of the judgment under appeal that the agreement at issue, which did not settle any dispute between the parties, had the effect of keeping Sun Pharmaceutical, which was a potential competitor of Lundbeck, outside the generic citalopram market, regardless of its manufacturing process, in return for transfers of value by Lundbeck.

73 As regards, more specifically, the amount of those transfers of value, the General Court noted, in paragraphs 236, 237 and 241 of the judgment under appeal, that they were a decisive element in limiting Sun Pharmaceutical's commercial autonomy and that they are closely linked to the profits expected by Sun Pharmaceutical in the event of market entry with citalopram produced in accordance with the processes available to it at the time the agreement at issue was concluded.

74 In the light of those findings of fact and without it being necessary to determine whether the General Court was fully entitled, in paragraph 222 of the judgment under appeal, to treat the agreement at issue as a market exclusion agreement or as a market-sharing agreement or even to find, following the Commission, in paragraphs 252 to 261 of the same judgment, that the agreements in question were comparable to those at issue in the case which 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 could, without committing any error of law, conclude that the agreement at issue could be characterised as a 'restriction by object' in accordance with Article 101(1) TFEU.

75 That finding cannot be called into question by the arguments put forward by Sun Pharmaceutical.

76 First, Sun Pharmaceutical cannot reasonably maintain, in order to rule out the agreement at issue being characterised as a 'restriction by object' that, by that agreement, Lundbeck was pursuing legitimate objectives, namely defending its process patents and preventing unlawful market entry of the generic medicine sold by Sun Pharmaceutical, which could, as the General Court observed in paragraphs 239 to 241 of the judgment under appeal, lead to a 20% fall in the price of the medicine sold by Lundbeck.

77 As the Court held in the judgment delivered on today's date in Case C-591/16 P, *Lundbeck* v *Commission* (paragraph 121), while the conclusion by the holder of a patent with a party allegedly infringing that patent of a settlement agreement that does not exceed the scope and duration of remaining validity of that patent does constitute an expression of the intellectual property right of that holder, which permits that holder, inter alia, to oppose any infringement, the fact remains that that patent does not permit its holder to enter into contracts that are contrary to Article 101 TFEU (see, to that effect, judgment of 30 January 2020, *Generics (UK) and Others*, C-307/18, EU:C:2020:52, paragraph 97). That is also the case even if those contracts seek to protect the commercial interests of the holder of the patent at issue which it considers to be harmed by legislation which does not protect sufficiently its intellectual property rights, since it is for the public authorities and not private undertakings both to define the relevant legal framework and to ensure compliance with it (see, to that effect, judgment of 30 January 2020, *Generics (UK) and Others*, C-307/18, EU:C:2020:52, paragraph 88).

78 Accordingly, the fact that, by the agreement at issue, Lundbeck sought to prevent unlawful market entry of the generic medicine sold by Sun Pharmaceutical which could lead to a 20% fall in the price of the medicine which it sold cannot justify an infringement of Article 101 TFEU nor even more so a concerted practice which has been found to involve a sufficient degree of harm to competition to be characterised as a 'restriction by object' and thus cannot justify (i) ruling out, notwithstanding that finding, such a characterisation and (ii) requiring the Commission to demonstrate the anticompetitive effects of such a practice.

79 Second, Sun Pharmaceutical cannot complain that the General Court did not carry out an assessment of the strength of the process patents in question for the purpose of characterising the agreement at issue.

80 Indeed, as is apparent from paragraph 60 of the judgment delivered on today's date in Case C-591/16 P, *Lundbeck* v *Commission*, no more than 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), is the assessment of the strength of the process patents at issue of any relevance for the purposes of a characterisation as a 'restriction by object', where it is established that it is the prospect of that transfer of value by the manufacturer of originator medicines which has induced the manufacturer of generic medicines to refrain from entering the market (see, to that effect, judgment of 30 January 2020, *Generics (UK) and Other*s, C-307/18, EU:C:2020:52, paragraph 89).

81 Third, Sun Pharmaceutical cannot criticise the General Court for failing to take into consideration the pro-competitive effects of the agreement at issue, alleged by Sun Pharmaceutical, in order to rule out that agreement being characterised as a 'restriction by object'.

82 While it is true that the existence of pro-competitive effects in the context of settlement agreements, such as the agreement at issue, is capable of calling into question the overall assessment of whether the concerted practice concerned revealed a sufficient degree of harm to competition and, consequently, of whether it should be characterised as a 'restriction by object', the fact remains that those effects must be demonstrated and relevant and specifically related to the agreement concerned, so that they justify a reasonable doubt as to whether that agreement caused a sufficient degree of harm to competition (judgment of 30 January 2020, *Generics (UK) and Others*, C-307/18, EU:C:2020:52, paragraphs 103, 106 and 107).

83 In the present case, in paragraphs 247 to 250 of the judgment under appeal, the General Court not only took into account the provisions of the agreement at issue under which Sun Pharmaceutical distributed Cipramil produced by Lundbeck and benefited from a discount of 40% on the 'ex-factory' price of that medicine, but also considered that those provisions could not be pro-competitive since they served to supplement the consideration granted to Sun Pharmaceutical for refraining from the production and sale of its own citalopram during the relevant period. However, it is neither alleged nor, a fortiori, demonstrated, that by those paragraphs of the judgment under appeal the General Court distorted the clear sense of the facts or the evidence, which cannot, in any event, prove the point alleged by Sun Pharmaceutical, solely in its reply to the 6 February 2020 question for written response, that Lundbeck's loss of revenue resulting from that discount would have in part benefited customers.

84 Therefore, and taking account of the findings in paragraphs 72 and 73 of the present judgment, the General Court was entitled, without erring in law, and notwithstanding Sun Pharmaceutical's claims regarding the pro-competitive effects of those provisions, to characterise the agreement at issue as a 'restriction by object'.

85 Fourth, Sun Pharmaceutical cannot legitimately complain that the General Court was in error when it held, in paragraph 272 of the judgment under appeal, that the fact that the Commission had not previously censured agreements similar to the agreement at issue, and therefore that there was no prior experience in that regard, did not mean that the Commission could not characterise that agreement as a 'restriction by object'.

86 While it is true that the characterisation as a 'restriction by object' may be applied as regards concerted practices, experience of which shows that they lead to falls in production and price increases, resulting in poor allocation of resources to the detriment, in particular, of consumers (judgment of 30 January 2020, *Generics (UK) and Others*, C-307/18, EU:C:2020:52, paragraph 64 and the case-law cited), the fact that the Commission has not, in the past, considered that an agreement similar to the agreement at issue was, by its very object, restrictive of competition is not, in itself, such as to prevent it from doing so in the future, as the General Court correctly noted in paragraph 272 of the judgment under appeal. Indeed, as the General Court correctly held in that paragraph, all that matters is an individual and detailed examination of the practice concerned, which must demonstrate that that practice presents a sufficient degree of harm, in the present case the voluntary substitution of practical cooperation for the risks of competition on the merits, experience of such substitution having proven particularly harmful to free competition.

87 For the same reason, it is irrelevant that the Commission had previous knowledge of an agreement similar to the agreement at issue, in the present case the agreement concluded between Lundbeck and Neolab, regarding which it expressed no doubts, since there were significant differences between it and the agreement at issue, as the General Court pointed out in paragraphs 242 and 243 of the judgment under appeal.

88 Fifth, nor can the General Court's characterisation of the agreement at issue as a 'restriction by object' be criticised by Sun Pharmaceutical on the basis of (i) paragraphs 238 and 239 of the 2014 Guidelines on technology transfer agreements, which do not apply to the agreement at issue since Sun Pharmaceutical has failed to show that the agreement provides for licensing of technology rights, or (ii) point 17 of the report referred to in paragraph 66 of the present judgment, which does no more than state that agreements limiting access to the market and providing for transfers of value require a case-by-case assessment, as has already been stated in paragraphs 69 to 70 of the present judgment.

89 Sixth, Sun Pharmaceutical erroneously complains that the General Court relied exclusively or principally on the intention of the parties to the agreement at issue in characterising that agreement as a 'restriction by object'. Not only, as the General Court correctly pointed out in paragraphs 212 and 265 of the judgment under appeal, may the characterisation of an agreement as a 'restriction by object' take account of the parties' intention (judgment of 11 September 2014, *CB* v *Commission*, C-67/13 P, EU:C:2014:2204, paragraph 54 and the case-law cited), but, in addition, neither the General Court nor the Commission relied exclusively or principally on the intention of the parties to the agreement at issue, taking into account principally objective factors, in particular those referred to in paragraphs 72 and 73 of the present judgment.

90 Seventh, contrary to the assertions of Sun Pharmaceutical, the General Court cannot be criticised for contradicting itself by stating both, in paragraphs 239 to 241 of the judgment under appeal, that it could do no more than find that there was a 'close link' between Sun Pharmaceutical's potential loss of profit and the reverse payment made and, in paragraph 279 of that judgment, that that reverse payment was 'determined on the basis of the profits expected by that competitor in the event of market entry'. Such an allegation is based on a misreading of paragraph 241 of that judgment, in which the General Court expressly found that there was a close link between the profits expected by Sun Pharmaceutical and the amount of the sums paid by Lundbeck, which is fully supported by paragraphs 236 and 237 of that judgment.

91 In view of the foregoing, the first ground of appeal must be rejected as being unfounded.

The third ground of appeal

The relevant paragraphs of the judgment under appeal

92 After making remarks, in paragraphs 299 to 301 of the judgment under appeal, on the scope of its judicial review, the General Court rejected the three parts of the fourth plea in law relied on by Sun Pharmaceutical in support of its action for annulment, in relation to which the third ground of appeal contests the rejection of solely its first and third parts.

93 In paragraphs 304 to 313 of the judgment under appeal, the General Court rejected Sun Pharmaceutical's argument that the extensive and novel interpretation of Article 101(1) TFEU in the decision at issue, from which the fine imposed follows, infringes the principle (i) of legal certainty, (ii) that criminal offences and penalties must be defined by law (*nullum crimen, nulla poena sine lege*), (iii) that a novel interpretation of a provision establishing an infringement is not retrospective in nature and (iv) of the protection of legitimate expectations. In that regard, it took the view that those principles could not be interpreted as precluding the gradual clarification of the rules of criminal liability, since that clarification was reasonably foreseeable, which it found to be the case, referring, in paragraph 307 of the judgment under appeal, to the analysis of the third plea for annulment, and having regard to the characteristics of the agreement at issue and to the context in which it took effect.

94 In paragraphs 357 to 375 of the judgment under appeal, the General Court rejected the allegation that the duration of the inquiry, referred to in paragraph 19 of the judgment under appeal, was unreasonable, on the one hand, by ruling out, in paragraph 367 of that judgment, any infringement of Article 25 of

Regulation No 1/2003 on account of penalties in respect of the agreement at issue being time-barred, and, on the other hand, by finding, in paragraphs 370 to 374 of that judgment, first, that a press release issued by the Danish Competition Authority on 28 January 2004, from which it was apparent, according to Sun Pharmaceutical, that the Commission had come to the view that agreements such as the agreement at issue were in a 'grey area', could not have encouraged it to refrain from taking measures to defend itself, second, that Sun Pharmaceutical had done no more than make general statements that it could have provided internal emails and other documents providing evidence of the difficulties arising from the length of the administrative proceedings in question and, third, that in the light of the Danish Competition Authority press release and the inquiry referred to in paragraph 19 of the judgment under appeal, a diligent undertaking should have retained any documents that might prove useful in its defence in the event of proceedings being initiated in respect of an infringement of competition law, at least until the expiry of the maximum limitation period prescribed by EU law.

Arguments of the parties

95 By its third ground of appeal, which is divided into three parts and concerns paragraphs 283, 307, 367 and 372 of the judgment under appeal, Sun Pharmaceutical maintains that the General Court was incorrect in upholding in its entirety the fine imposed on it by the Commission.

96 First, according to Sun Pharmaceutical, even if the Court were to uphold the agreement at issue being characterised as a 'restriction by object', account should be taken of the fact that, as regards mitigating circumstances in the present case and the calculation of the amount of the fine, it is novel, in view of the Danish Competition Authority press release of 28 January 2004, which has not been corrected by the Commission and is even confirmed by point 29 of the 2014 Guidelines on technology transfer agreements, but also in view of the fact that it was only after that press release that the Commission developed its view regarding characterisation as a 'restriction by object'.

97 Second, contrary to paragraph 283 of the judgment under appeal, Sun Pharmaceutical claims that points 25 and 26 of the 2001 Guidelines on horizontal cooperation agreements provided that the scope of agreements regarded as 'restrictions by object' was limited to price fixing, market sharing and output limitation and that it was only subsequently that the Commission extended the scope of that characterisation. Sun Pharmaceutical also disputes the agreement at issue being treated in the same way as an agreement to share customers or to limit production, given the legitimate right to rely on intellectual property rights in order to exclude competitors and limit production. In addition, it argues that is not clear that the agreement at issue limited production since that agreement enabled Sun Pharmaceutical to enter the market much more quickly as a result of its purchase of Lundbeck's products at reduced prices, which it could label with its own name.

98 Third, as regards paragraph 367 of the judgment under appeal, Sun Pharmaceutical is of the view that the 10% reduction of the fine imposed on it to take account of the duration of the proceedings cannot offset the fact that the Commission did not inform it of the initiation of the proceedings until six years after the expiry of the agreement at issue, denying it the opportunity to provide exculpatory material and thus to exercise its rights of defence. In addition, since the Commission did not adopt measures in relation to Sun Pharmaceutical before 12 March 2010 and informed only Lundbeck of the proceedings which led to the decision at issue, Sun Pharmaceutical argues that the Commission's power to impose penalties is time-barred in accordance with Article 25(3) and (4) of Regulation No 1/2003.

99 For its part, the Commission considers that the third ground of appeal is unfounded. In particular, it takes the view that Sun Pharmaceutical cannot rely on the infringement of its rights of defence since Sun Pharmaceutical did not rely on it during the administrative proceedings.

Findings of the Court

100 By the first and second parts of its third ground of appeal, Sun Pharmaceutical criticises the General Court for having upheld in full the amount of the fine imposed on it.

101 In that regard, it must be observed at the outset that the second part of the present ground of appeal, concerning paragraph 283 of the judgment under appeal and claiming infringement of points 25 and 26

of the 2001 Guidelines on horizontal cooperation agreements, was raised for the first time in the present appeal and is, therefore, inadmissible.

102 Indeed, not only does paragraph 283 of the judgment under appeal, criticised by Sun Pharmaceutical, fall within the scope of the General Court's response to the first plea for annulment which claims 'that the agreement at issue does not constitute a "restriction by object"', and not the response to the fourth plea which claimed that the fine imposed by the Commission was unjustified, but in addition, points 25 and 26 of the 2001 Guidelines on horizontal cooperation agreements were at no time relied on in support of the latter plea for annulment, reference only being made, as regards the second part of that plea, to the 2006 Guidelines on the method of setting fines, as is apparent from paragraphs 314 to 352 of the judgment under appeal.

103 As regards the first part of the present ground of appeal, by which Sun Pharmaceutical claims that the novelty of the agreement at issue being characterised as a 'restriction by object' must preclude the imposition of a fine, it must be recalled, as is apparent from paragraphs 85 and 86 of the present judgment, that Sun Pharmaceutical could not rely on the Commission's lack of previous experience of agreements constituting a similar 'restriction by object' in order to preclude the agreement at issue being characterised as such, since the agreement at issue was designed to substitute practical cooperation for the risks of competition on the merits.

104 The imposition of a fine is necessary also where the parties to such an agreement could not reasonably foresee that a restriction of competition, experience of which proves that it is particularly harmful to free competition, would not be penalised in line with its effects on free competition.

105 Therefore, the General Court did not err in law and, in particular, did not infringe the principle of legal certainty in refusing, in paragraphs 307 and 308 of the judgment under appeal, to reduce the fine imposed on Sun Pharmaceutical to zero or to an amount below that set by the Commission in the decision at issue.

106 By the third part of its third ground of appeal, Sun Pharmaceutical complains that the General Court made two errors of law, the first in failing to find that the Commission's power to impose fines on Sun Pharmaceutical was time-barred in accordance with Article 25(2) and (3) of Regulation No 1/2003 and the second in failing to find that its rights of defence had been infringed because of the lateness of the action taken by the Commission.

107 As regards the alleged infringement of Article 25(2) and (3) of Regulation No 1/2003 on the ground that the Commission did not take action against Sun Pharmaceutical before 12 March 2010, namely more than six years after the expiry of the agreement at issue, it is sufficient to state, as the General Court did in paragraph 367 of the judgment under appeal, first, that, under Article 25(2) of that regulation, time begins to run, in the case of continuing infringements, as in the present case, on the day on which the infringement ceases, and, next, that pursuant to Article 25(3) and (4) of that regulation, requests for information, the initiation of proceedings and the notification of a statement of objections interrupt the limitation period as regards all the participants in an infringement and, finally, that, in accordance with Article 25(5) of that regulation, each interruption is to start time running afresh, but the limitation period is to expire at the latest on the day on which a period equal to twice the limitation period has elapsed without the Commission having imposed a fine or periodic penalty payment.

108 As is apparent in particular from paragraph 363 of the judgment under appeal, the Commission, for the purposes of adopting, on 19 June 2013, the decision at issue, inter alia, (i) carried out, in January 2005, inspections at a number of premises of Lundbeck, (ii) sent, in 2006, requests for information to Lundbeck and to other undertakings involved, (iii) opened, on 7 January 2010, the formal investigation procedure against Lundbeck, and (iv) opened, on 24 July 2012, the formal investigation procedure in particular against Sun Pharmaceutical.

109 Sun Pharmaceutical therefore cannot rely on the Commission's power to impose fines on it being time-barred.

110 As regards the alleged infringement of Sun Pharmaceutical's rights of defence by reason of the lateness of the measures adopted by the Commission in relation to it, at the outset it must be observed that the Commission is not justified in arguing that Sun Pharmaceutical cannot rely on such an infringement since Sun Pharmaceutical did not rely on it during the administrative proceedings.

111 As regards the application of Articles 101 and 102 TFEU, there is no requirement under the law of the European Union that the addressee of the statement of objections must challenge its various matters of fact or law during the administrative procedure, if it is not to be barred from doing so later at the stage of judicial proceedings (judgment of 1 July 2010, *Knauf Gips* v *Commission*, C-407/08 P, EU:C:2010:389, paragraph 89).

112 Nonetheless, it is apparent from paragraphs 370 to 374 of the judgment under appeal that, on the basis of findings of fact which are not alleged to result from a distortion of the facts and evidence, the General Court, in essence, came to the conclusion that Sun Pharmaceutical had not demonstrated to the requisite legal standard that it had experienced difficulties in defending itself against the Commission's allegations.

113 The General Court was therefore fully entitled to reject Sun Pharmaceutical's plea for annulment alleging infringement of its rights of defence.

114 Accordingly, the third ground of the present appeal must be rejected as being in part inadmissible and in part unfounded.

115 Having regard to all of the foregoing considerations, the appeal must be dismissed in its entirety.

Costs

116 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.

117 Since the Commission has applied for costs and Sun Pharmaceutical has been unsuccessful, Sun Pharmaceutical must be ordered to bear its own costs and to pay those incurred by the Commission.

118 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.

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

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

1. **Dismisses the appeal;**

2. **Orders Sun Pharmaceutical Industries Ltd and Ranbaxy (UK) Ltd to bear their own costs and to pay those incurred by the European Commission;**

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

Vilaras Šváby Rodin

Jürimäe Xuereb

Delivered in open court in Luxembourg on 25 March 2021.

A. Calot Escobar M. Vilaras

Registrar President of the Fourth Chamber

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* Language of the case: English.