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-601/16 P,

APPEAL under Article 56 of the Statute of the Court of Justice of the European Union, brought on 24 November 2016,

Arrow Group ApS, established in Gentofte (Denmark),

Arrow Generics Ltd, established in Barnstaple (United Kingdom),

represented by C. Firth, S. Kon and C. Humpe, Solicitors,

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, Arrow Group ApS and Arrow Generics Ltd seek to have set aside the judgment of the General Court of the European Union of 8 September 2016, *Arrow Group and Arrow Generics* v *Commission* (T-467/13, not published, 'the judgment under appeal', EU:T:2016:450), by which the General Court dismissed their action which sought, first, the 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, a reduction of the amount of the fine imposed on them by that decision.

Legal context

2 Article 23(2) 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]

…

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.

…'

Background to the dispute

3 The present appeal is one of six related appeals against six judgments of the General Court delivered following actions for annulment brought against the decision at issue, namely, in addition to the present appeal: the appeal 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 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-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).

4 The background to the dispute was set out in paragraphs 1 to 40 of the judgment under appeal as follows:

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

3 Arrow Group A/S, which was renamed Arrow Group ApS in August 2003 … is a company governed by Danish law at the head of a group of companies present in several Member States, which since 2001 has been active in the development and sales of generic medicinal products.

4 Arrow Generics Ltd is a company incorporated in the United Kingdom, a subsidiary owned at first as to 100% and then as to 76% by Arrow Group.

5 Resolution Chemicals Ltd is a company incorporated in the United Kingdom specialising in the production of active pharmaceutical ingredients ("APIs") for generic medicinal products. Until September 2009 it was controlled by Arrow Group.

2. The relevant product and the applicable patents

6 The relevant product for the purposes of the present case is the antidepressant medicinal product containing an API called citalopram.

7 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.

8 As regards the European Economic Area (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 (for Germany) and 2003 (for Austria). In particular, in the case of the United Kingdom, those patents expired in January 2002.

9 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).

10 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.

11 Secondly, on 12 March 2001, Lundbeck filed a patent application with the United Kingdom [of Great Britain and Northern Ireland] authorities 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 … However, that patent was revoked on 23 June 2004 for lack of novelty by comparison with another Lundbeck patent. Lundbeck obtained a similar patent in Denmark on 29 June 2002.

12 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.

3. The agreements concluded by Lundbeck with Arrow Group, Arrow Generics and Resolution Chemicals, and other background factors

13 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 Arrow Group, Arrow Generics and Resolution Chemicals (together "Arrow").

14 For the purposes of the present case, two agreements are relevant, namely:

– first, the agreement concluded on 24 January 2002 between Lundbeck, on the one hand, and Arrow Generics and Resolution Chemicals (together "Arrow UK"), on the other hand, concerning the territory of the United Kingdom ("the UK agreement");

– secondly, the agreement concluded on 3 June 2002 between Lundbeck and Arrow Group, concerning the territory of Denmark ("the Danish agreement").

15 The initial term of the UK agreement was until 31 December 2002 or, if earlier, until the date on which a final decision had been delivered in the action which Lundbeck intended to bring against Arrow UK before the United Kingdom courts concerning Arrow UK's alleged infringement of its patents ("the UK infringement action") (Article 4.1 of the UK agreement). Next, that agreement was extended on two occasions by the signing of addenda. The first extension covered the period from 1 January until 31 March 2003 (Article 3.1 of the first addendum to the UK agreement), while the second extension provided that the agreement was to end either on 31 January 2004 or seven days after signature of the court decision determining the dispute between Lundbeck and Lagap Pharmaceuticals Ltd …, another undertaking active in the production of generic citalopram (Article 4.1 of the second addendum to the UK agreement). As that litigation was settled on 13 October 2003, the UK agreement terminated on 20 October 2003. It follows that the overall duration of that agreement was from 24 January 2002 until 20 October 2003 ("the term of the UK agreement").

16 The Danish agreement, which was not extended, was concluded for a period from the date of signature until 1 April 2003 or, if earlier, until the date on which a final decision had been delivered in the UK infringement action. As no such decision was delivered, the agreement was in force from 3 June 2002 until 1 April 2003 …

17 As regards the content of the UK agreement, it should be observed that:

– the first recital in the preamble to that agreement ("the UK preamble") refers, inter alia, to the fact that Lundbeck is the holder [of the patent protecting the crystallisation process as regards the United Kingdom] and [of the patent relating to the film distillation method referred to in paragraph 11 of the judgment under appeal] ("Lundbeck's new [process] patents");

– the fourth recital in the UK preamble states that "Arrow [UK] has obtained a licence from a third party to import into the [United Kingdom] citalopram not manufactured by Lundbeck or with the consent of Lundbeck ("the said Citalopram", which definition shall for the avoidance of doubt comprise only Citalopram for marketing and sale in the [United Kingdom] and shall exclude citalopram for marketing and sale in other countries)";

– the sixth recital in the UK preamble states that Lundbeck performed a laboratory analysis of "the said Citalopram" which gave it substantial reason to believe that that citalopram infringed, in particular, the patents referred to in the first indent above;

– the seventh recital in the UK preamble states that Arrow UK does not consider that it has infringed those patents or consider that they are valid, but accepts that Lundbeck has a reasonable belief that they may be valid and have been infringed, which Arrow UK is unable to disprove by incontrovertible evidence;

– the eighth recital in the UK preamble observes that Lundbeck has threatened to seek an interim injunction and that it intends to initiate the UK infringement action;

– Article 1.1 of that agreement ("Article 1.1 UK") provides that "Arrow [UK] on its own behalf and on behalf of all associated and related entities undertakes during the [term of the UK agreement] not in the [United Kingdom] to make, dispose of, offer to dispose of, use or, after the Second Delivery date, … import or keep for disposal or otherwise (1) the said Citalopram or (2) any other Citalopram which Lundbeck alleges to infringe its [intellectual

property] Rights and, to enable Lundbeck to ascertain if there may be an infringement, during the [term of the UK agreement] to provide Lundbeck with sufficient samples for analysis purposes at least one month prior to any threatened manufacture, importation, sale or offer for sale pending a final unappealable decision in [the UK infringement action]";

– Article 1.2 of that agreement states that Arrow UK has agreed that the undertakings given by it and referred to in Article 1.1 UK may be incorporated in an order that Lundbeck might ask the competent United Kingdom court to make;

– Article 2.1 of that agreement states that Lundbeck will commence the UK infringement action as soon as possible and in any event no later than 31 March 2002;

– Article 2.2 of that agreement states that, in consideration of the undertakings in Article 1.1 UK and Arrow [UK] not seeking a "cross-undertaking in damages" (i.e. the amount which, in accordance with the laws of England and Wales, Lundbeck would have had to deposit with the Court if it intended to seek an injunction in the UK infringement action), Lundbeck is to pay Arrow UK [5 million pounds sterling (GBP)], in four instalments, that sum having subsequently been increased by GBP 450 000 under Article 2.1 of the first addendum to the UK agreement, and by GBP 1.35 million in application of Articles 2.1 and 3 of the second addendum to the UK agreement (see recitals 446 and 447 of the [decision at issue]);

– Article 2.3 of that agreement establishes that, in the event that the final decision in the UK infringement action should find that Arrow UK had not infringed Lundbeck's intellectual property rights, the amount specified in Article 2.2 of that agreement would constitute the full and final compensation that Arrow UK could obtain from Lundbeck for loss sustained as a result of the obligations arising under Article 1.1 UK;

– Article 3.4 of that agreement … provides that Arrow UK is to deliver to Lundbeck its stock "of said Citalopram" in two stages, the first of which, covering approximately 3.975 million packed tablets, by no later than 6 February 2002 and the second, covering around 1.1 million bulk tablets, by no later than 15 February 2002.

18 It should be observed, moreover, that on 6 February 2002, Lundbeck obtained the order referred to in Article 1.2 of the UK agreement …

19 As regards the Danish agreement, it should be observed that:

– the first, third and fifth to ninth recitals in the preamble … correspond, in essence, to the first, fourth and sixth to eighth recitals in the UK preamble, it being noted that the ninth recital in the Denmark preamble refers to the [order referred to in paragraph 18 of the judgment under appeal];

– Article 1.1 of that agreement … provides that 'Arrow [Group] consents to cancel, cease and desist from any importation, manufacture, production, sale or other marketing of products containing Citalopram which Lundbeck alleges to infringe its intellectual property rights in the [Danish] Territory for the term of [the Danish agreement]';

– Article 2.1 of that agreement states that, as compensation for the undertakings given by Arrow Group, Lundbeck is to pay Arrow Group the sum of 500 000 United States dollars (USD);

– Article 2.2 of that agreement establishes that, in the event that the final decision in the UK infringement action should find that Arrow Group had not infringed Lundbeck's intellectual property rights, the amount specified in Article 2.1 of that agreement would constitute the full and final compensation that Arrow Group could obtain from Lundbeck for loss sustained as a result of the obligations arising under Article 1.1 of the Danish agreement;

– Article 3.1 of that agreement adds that Lundbeck is to purchase Arrow Group's stock of citalopram, consisting of approximately 1 million tablets, for the price of USD 147 000.

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

20 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]").

21 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.

22 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.

23 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.

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

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

26 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 Arrow Group and Arrow Generics.

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

…

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

5. The [decision at issue]

32 By the [decision at issue], the Commission considered that the agreements in question constituted restrictions 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)].

33 In particular, the Commission found, first, that the UK agreement and the Danish agreement (together "the agreements at issue") constituted a single and continuous infringement by Lundbeck and by Arrow Group and, secondly, that Arrow Generics and Resolution Chemicals had also infringed Article 101(1) TFEU and Article 53(1) of the EEA Agreement by participating in the UK agreement (Article 1(2) of the [decision at issue]).

34 As is apparent from the summaries in recitals 962 and 1013 of the [decision at issue], concerning the UK agreement and the Danish agreement respectively, the Commission based its assessment, in particular, on the following factors:

– at the time of concluding the agreements at issue, Lundbeck and Arrow were at least potential competitors in the United Kingdom and in Denmark;

– Lundbeck transferred significant value to Arrow pursuant to those agreements;

– that transfer of value was linked to Arrow's acceptance of the limitations on its entry to the citalopram market in the United Kingdom and in Denmark set out in those agreements, in particular Arrow's commitment not to sell generic citalopram which Lundbeck regarded as infringing its [process] patents, during the relevant terms of the agreements at issue;

– that transferred value corresponded approximately to the profits Arrow expected to make if it had successfully entered the market;

– Lundbeck could not have obtained those limitations through enforcement of its new [process] patents, since the obligations on Arrow following those agreements went beyond the rights granted to holders of process patents;

– the agreements at issue contained no commitment from Lundbeck to refrain from bringing infringement proceedings against Arrow if the latter entered the United Kingdom or Danish markets with generic citalopram after the expiry of one of those agreements.

35 The Commission also imposed fines on all the parties to the agreements in question. To that end, it applied the Guidelines on the method of setting fines imposed pursuant to Article 23(2)(a) of Regulation No 1/2003 (OJ 2006 C 210, p. 2 …). Although, in Lundbeck's case, the Commission followed the general methodology described in the 2006 Guidelines, based on the value of sales of the relevant product made 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]).

36 Thus, as regards those parties to the agreements in question other than Lundbeck, including Arrow, the Commission considered that, in order to determine the basic amount of the fine and to ensure that the fine would have a sufficient deterrent effect, it was appropriate to take account of the value of the sums transferred to them by Lundbeck pursuant to the agreements in question, without differentiating between the infringements on the basis of their nature or geographic scope, or on the basis of the market share of the undertakings concerned, those factors being addressed only for the sake of completeness (recital 1361 of the [decision at issue]).

37 As regards Arrow Group and Arrow UK, the Commission considered that the sums which Lundbeck had paid them came to EUR 10.4 million under the UK agreement (recital 447 of the [decision at issue]) and USD 684 000 (recital 472 of the [decision at issue]) under the Danish agreement, giving a total basic amount of EUR 11.1 million (recital 1373 of the [decision at issue]).

38 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]).

39 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 Arrow Group and to Arrow Generics, on the one hand, and to Resolution Chemicals, on the other, since it was no longer controlled by Arrow Group (recital 1383 of the [decision at issue]).

40 On the basis of those considerations, the Commission imposed a fine of EUR 9 975 000 on Arrow Group, jointly and severally with Arrow Generics for the sum of EUR 9 360 000 and also with Resolution Chemicals for the sum of EUR 823 735 (recital 1396 and Article 2(2) of the [decision at issue]).'

The procedure before the General Court and the judgment under appeal

5 By document lodged at the Registry of the General Court on 28 August 2013, the appellants 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.

6 In support of their action, the appellants raised six pleas in law, alleging, in essence, (i) breach of essential procedural requirements in the procedure leading to the adoption of the decision at issue; (ii) that they were not in potential competition with Lundbeck; (iii) that the agreements at issue did not constitute 'restrictions by object'; (iv) errors of law concerning the imposition of a fine in the present case; (v) in the alternative, incorrect characterisation of the agreements at issue as a 'single and continuous infringement'; and (vi) further in the alternative, that the amount of the fine imposed on them was disproportionate.

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

Procedure before the Court

8 By document lodged at the Registry of the Court of Justice on 24 November 2016, the appellants brought the present appeal.

9 By documents lodged at the Court Registry on 28 July 2017, the United Kingdom requested 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-611/16 P (*Xellia Pharmaceuticals and Alpharma* v *Commission*) and C-614/16 P (*Merck* v *Commission*), referred to in paragraph 3 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 Justice 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 of that decision had been served on the United Kingdom.

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

11 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.

12 The joint hearing in the present case and the cases referred to in paragraph 10 of the present judgment was held on 24 January 2019.

13 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, 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 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.

14 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 of Justice

15 By their appeal, the appellants claim that the Court should:

– set aside the judgment under appeal and/or Articles 1, 2 and 3 of the decision at issue, in so far as they concern the appellants;

– in the alternative, set aside the judgment under appeal and refer the case back to the General Court;

– further in the alternative, set aside the judgment under appeal in so far as it upheld the fine imposed on the appellants under Article 2(2) of the decision at issue or reduce the amount thereof; and

– order the Commission to pay the costs.

16 The Commission contends that the Court should:

– dismiss the appeal in its entirety, and

– order the appellants to pay the costs.

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

The appeal

18 In support of their appeal, the appellants rely on three grounds of appeal.

19 By their first ground of appeal, the appellants submit that the General Court erred in law by applying incorrectly the legal test for assessing whether they were potential competitors of Lundbeck. By their second ground of appeal, the appellants criticise the General Court for having erred in holding that the agreements at issue had as their object the restriction of competition. By their third ground of appeal, the appellants complain that the General Court erred in law in finding that they had acted intentionally or negligently in committing the alleged infringement.

The first ground of appeal

The relevant paragraphs of the judgment under appeal

20 By their second plea in law relied on in support of their action for annulment, the appellants claimed, contrary to the Commission's findings in the decision at issue, that they were not potential competitors of Lundbeck.

21 That plea was rejected by the General Court after it had, in particular, recalled the analysis concerning potential competition carried out by the Commission in the decision at issue, stating, in particular, in paragraph 57 of the judgment under appeal, that the manufacturers of generic medicines had several ways of entering the market without infringing existing patents, such as process patents, but also, in paragraph 61 of that judgment, that, in the examination of the competitive relationship between the appellants and Lundbeck, the Commission had stated as follows:

'… At the time of conclusion of the agreements at issue …, the applicants:

– had already concluded an agreement with Alfred E. Tiefenbacher GmbH & Co. (“Tiefenbacher”), which allowed them to purchase generic citalopram produced by the Indian companies Cipla or Matrix, without that agreement preventing them from purchasing citalopram produced by other companies, subject to a royalty payment to Tiefenbacher;

– had a stock of citalopram amounting to 9 222 000 tablets, produced in accordance with the process used by Cipla at the time (“the Cipla I process”);

– had received, in December 2001, a positive opinion from the competent United Kingdom authority concerning their [application for a marketing authorisation (MA)], based, under the mutual recognition procedure provided for in [Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicines for human use (OJ 2001 L 311, p. 67)], on the MA that Tiefenbacher had already obtained in the Netherlands;

– considered, as Lundbeck did, that that authority would grant the MA in question in the near future;

– while being concerned that the Cipla I process might infringe the [patent protecting the process using crystallisation] which Lundbeck had applied for, but not yet obtained, in the United Kingdom, were not certain in that regard;

– expected to be able swiftly to obtain an MA in Denmark, on the basis of the MA obtained by Tiefenbacher for another [manufacturer of generic medicines [also in Denmark] on 2 May 2002;

– had the option of switching to citalopram produced by Matrix, which at the time of conclusion of the agreements at issue, used a process which was not regarded as infringing Lundbeck’s new [process] patents …, of working with Cipla and Matrix to develop other processes and of switching to citalopram produced by the [manufacturer of generic medicines] Ranbaxy Laboratories Ltd …, which used a different process.’

22 Next, the General Court rejected various submission made by the appellants, holding, in particular, in paragraph 81 of the judgment under appeal, that ‘the steps necessary for obtaining MAs and preparing for market entry constitute potential competition, when they are carried out by [manufacturers of generic medicines] which have made significant investments in terms of human and economic resources in order to launch their generic medicinal product’ but also in paragraph 88 of that judgment, that ‘the perception that Lundbeck had of [the appellants] is a factor that may be taken into consideration, although it does not suffice, by itself, to demonstrate the existence of potential competition’ and further, in paragraph 101 of the same judgment, that ‘the expiry of the original [Lundbeck] patents was an important factor in the assessment of potential competition’.

23 In rejecting the appellants’ arguments that the presumption of validity of Lundbeck’s new process patents precluded a finding that there was potential competition between them and Lundbeck, the General Court stated, in essence, in paragraphs 106, 107, 110 and 111 of the judgment under appeal, that the existence of risk and uncertainty is inherent in market entry by a manufacturer of generic medicines, but that the Commission must nevertheless demonstrate that there is a real and concrete possibility of such manufacturer entering the market within a reasonable period, whilst the General Court added that the existence of a patent does not protect its holder against actions seeking to challenge its validity. The General Court concluded, therefore, that the presumption of validity which all patents enjoy cannot be equated with a presumption of illegality of any product placed on the market which the patent holder deems to be infringing that patent.

24 Furthermore, the General Court rejected all the allegations of factual errors put forward by the appellants.

25 Having considered, in paragraph 117 of the judgment under appeal, that the Commission was fully entitled to take as its point of reference the time when the agreements at issue were concluded in order to assess whether the appellants and Lundbeck were potential competitors and that the Commission was entitled to take into consideration evidence subsequent to such conclusion of agreements provided

that the effect of that evidence is to clarify those parties' positions at the time, to confirm or rebut their arguments in that regard and to allow a better understanding of how the market concerned operates, the General Court stated, in paragraphs 117 to 120, 123, 127, 132, 141 and 142 of that judgment, that the appellants had purchased from Tiefenbacher the MAs which Tiefenbacher had requested in several EEA countries in relation to generic citalopram as well as generic citalopram tablets which they had received prior to the agreements at issue being concluded and that doubts as to whether the citalopram supplied by Tiefenbacher infringed the patents had not caused them to give up their intention to enter the United Kingdom market, the appellants being prepared to take the risk of such entry. Finally, the General Court held, in paragraph 143 of that judgment, that the appellants continued to take steps to sell their generic medicines on the Danish market even after Lundbeck obtained, in Denmark, the patent protecting the crystallisation process.

26 Second, the General Court rejected the appellants' arguments that the Commission had failed to demonstrate that it was possible for them to obtain citalopram produced in accordance with processes other than those used by Tiefenbacher. In that regard, in paragraphs 148, 149, 152 and 153 of the judgment under appeal, it stated, inter alia, that the fact that the appellants had already made considerable investments to buy citalopram produced in accordance with the Cipla I process was not sufficient to establish that, had the agreements at issue not been concluded, the appellants would have been deprived of the possibility of entering the market in the United Kingdom and Denmark using citalopram produced in accordance with other processes.

27 Finally, the General Court refused, in paragraphs 169 to 174 of the judgment under appeal, to take account of the judgment of the High Court of Justice (England & Wales), Chancery Division of 23 October 2001, *Smithkline Beecham Plc* v *Generics (UK) Ltd* (2002) 25(1) IPD 25005 ('the *Paroxetine* judgment'), on the ground that there were a number of differences between the instant case and the case which gave rise to that judgment, while adding that the appellants had not even attempted to explain why Lundbeck preferred to conclude a costly agreement such as the UK agreement, by which it obtained only a delay in their entry to the United Kingdom market, instead of applying for an interim measure for the same purpose, a measure which, if the interpretation of the *Paroxetine* judgment was correct, would surely have been granted.

Arguments of the parties

28 By its first ground of appeal, which has six parts, the appellants complain that the General Court misapplied the legal test, which is nevertheless correctly referred to in paragraph 64 of the judgment under appeal, for the purpose of determining whether there was potential competition between them and Lundbeck.

29 In the first part of that ground of appeal, the appellants complain that the General Court exempted the Commission from its obligation to establish the existence of that potential competition, by ascertaining whether there were real and concrete possibilities for them to enter the market.

30 First, they complain that the General Court failed to satisfy itself, in particular in paragraph 132 of the judgment under appeal, that the Commission had demonstrated to the requisite legal standard that it was unlikely that the problems relating to the infringement of Lundbeck's patent protecting the crystallisation process as regards the United Kingdom ('Lundbeck's UK crystallisation patent') by the Cipla I process, used by Tiefenbacher and therefore indirectly by the appellants, prevented them from gaining access to the market. According to the appellants, it was for the Commission to demonstrate that the risk of infringement of that patent was unfounded and not for them to demonstrate that there was infringement of that patent.

31 Second, the appellants criticise the General Court for being satisfied, in particular in paragraphs 141 and 142, 152 and 153 of the judgment under appeal, with unproven assertions that they had means other than the Cipla I process to bring a generic version of citalopram to the market. In doing so, the appellants argue that the General Court required them to demonstrate the absence of real and concrete possibilities to enter the market, whereas the burden of proof to show otherwise rests on the Commission, which is required to demonstrate the possibility to enter the market with a non-infringing product. Thereby, the appellants maintain that the General Court incorrectly criticised them for not

having demonstrated with certainty that the process used by Matrix, referred to in the seventh indent of paragraph 21 of the present judgment, as well as the new process developed by Matrix at a date subsequent to the date when the agreements at issue were concluded and the new process developed by Cipla during the period covered by the agreements at issue infringed Lundbeck's UK crystallisation patent. The appellants also criticise the General Court for having relied, in paragraphs 96 to 98 of the judgment under appeal, on the Commission's finding that they could have entered the market by using the processes covered by the original Lundbeck patents, even though the Commission did not address that question.

32 Under the second part of their first ground of appeal, the appellants take the view that the General Court erred in law, in paragraphs 57, 106 and 107 of the judgment under appeal, by accepting that the Commission could establish the existence of potential competition between them and Lundbeck on the basis of general and speculative assertions that there was an economically viable non-infringing process, without relying on precise and existing evidence or on their specific factual position.

33 Under the third part of their first ground of appeal, the appellants submit that the General Court, in paragraphs 67 and 127 of the judgment under appeal, placed undue weight on Lundbeck's perception, misapplying the case-law arising from the judgments of 12 July 2011, *Hitachi and Others* v *Commission* (T-112/07, EU:T:2011:342, paragraph 226), and of 21 May 2014, *Toshiba* v *Commission* (T-519/09, not published, EU:T:2014:263, paragraph 231), to the present case in which Lundbeck's position was protected by a patent, which was an objective factor which could not be affected by Lundbeck's subjective perception. In that situation, the appellants argue that no or only limited weight can be attributed to Lundbeck's perception, which nevertheless cannot constitute evidence of there being potential competition between Lundbeck and the appellants. In addition, in paragraph 117 of the judgment under appeal, the appellants maintain that the General Court incorrectly assessed the probative value of the events that took place after the agreements at issue had been signed, taking the view that those agreements could not be decisive even though they corroborated the appellants' arguments that the Cipla I process infringed Lundbeck's UK crystallisation patent.

34 Under the fourth part of their first ground of appeal, the appellants maintain that the General Court failed to examine the relevance and the impact of the *Paroxetine* judgment on the ground set out in paragraph 169 of the judgment under appeal that it was not necessary to give a ruling on the interpretation and exact scope of that judgment, given the differences between the present case and the case that gave rise to that judgment.

35 By the fifth part of their first ground of appeal, the appellants complain that the General Court inferred that there was potential competition between them and Lundbeck on the basis of their taking measures to prepare themselves to enter the market, whereas the issue of potential competition must be assessed at the time each of the agreements at issue was concluded, which follows from the judgment of 6 December 2012, *AstraZeneca* v *Commission* (C-457/10 P, EU:C:2012:770). In the view of the appellants, contrary to the General Court's statements in paragraphs 81 and 149 of the judgment under appeal, the fact of taking steps to obtain an MA or varying an existing MA is not capable, by itself, of substantiating the existence of potential competition, without considering the nature of the steps taken, the probability of those steps being successful, the duration of those measures or even the ability of the MA applicant to enter the market.

36 Under the sixth part of their first ground of appeal, which concerns paragraph 111 of the judgment under appeal, the appellants take the view that the General Court erred in law by applying a presumption of provisional invalidity for Lundbeck's new process patents and in finding that the product that they had obtained from a third party did not infringe those patents. In so doing, the appellants maintain that the General Court acted as if Lundbeck's new process patents did not exist and could not therefore act as a barrier to manufacturers of generic medicines entering the market, which runs counter to existing intellectual property rights, protected by Article 345 TFEU, as well as the jurisprudence of the General Court that an intellectual property right is normally assumed to be valid and an undertaking's ownership of that right is assumed to be lawful. In the present case, the appellants argue that the General Court subordinates the presumption of validity of Lundbeck's new process patents to a final court judgment, thereby undermining the exercise of its rights and the existence and lawfulness of those rights *ab initio*.

37 The Commission takes the view that the first ground of appeal must be rejected as being in part inadmissible and in part unfounded.

Findings of the Court

38 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).

39 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).

40 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).

41 When the agreements at issue, such as those 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 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).

42 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 medicine 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).

43 In order to do so, it is necessary to assess, first, whether, at the time 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).

44 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 relating 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).

45 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).

46 In the present case, the General Court found that the appellants had taken sufficient preparatory steps to enable them to enter the market concerned within such a period of time as would impose competitive pressure on Lundbeck. As the Commission had noted, the General Court accordingly stated, in paragraphs 118, 120, 123, 124, 127, 132, 142, and 143 of the judgment under appeal, in particular, that the appellants had concluded a contract to purchase MAs in a number of EEA States, had ordered a large volume of tablets from a supplier and had maintained their intention (i) to enter the United Kingdom market despite doubts as to whether the tablets ordered might infringe the patents and (ii) to enter the Danish market despite Lundbeck having obtained, in Denmark, the patent protecting the crystallisation process.

47 In addition, in paragraphs 101, 110 and 111 of that judgment, the General Court noted that Lundbeck's process patents did not constitute insurmountable barriers, since Lundbeck's original patents had expired, but also because, in accordance with the case-law referred to in paragraph 44 of the present judgment, the presumption of validity of a patent does not equate with a presumption of illegality of any product placed on the market which the holder of that patent deems to be infringing it and that an 'at risk entry' was not unlawful and could lead the appellants to challenge the validity of Lundbeck's process patents in any litigation.

48 It follows, there being no need to give a ruling on the question whether the General Court, in paragraphs 148 to 153 of the judgment under appeal, had established to the requisite legal standard that the appellants had real and concrete possibilities to enter the market by means of citalopram produced in accordance with processes other than those used by Tiefenbacher, that the General Court was fully entitled, and without discharging the Commission from the burden of proof which rests on it, or calling into question the presumption of validity of Lundbeck's process patents, or establishing any presumption of provisional invalidity in respect of those patents, to find that the appellants and Lundbeck were, at the time when the agreement at issue were concluded, potential competitors.

49 That conclusion cannot be called into question by the submission put forward by the appellants in the context of the first part of the present ground of appeal, that (i) the Commission was required to demonstrate that it was unlikely that the problems relating to the infringement of Lundbeck's UK crystallisation patent by the Cipla I process precluded the appellants from gaining access to the market and (ii) by failing to impose that requirement on the Commission, the General Court imposed on the appellants a requirement to demonstrate that the generic medicines that it intended to market derived from a patent infringement.

50 Apart from the fact that it does not follow either expressly or even implicitly from paragraph 132 of the judgment under appeal, to which the appellants refer, that they would have been required to provide such a demonstration, it must be recalled that, as regards agreements such as the agreements at issue, it is not for the Commission to carry out a review of the strength of the patent in question or of the probability of a dispute between the holder of that patent and a manufacturer of generic medicines being brought to an end with a finding that that patent is valid and has been infringed (see, to that effect, judgment of 30 January 2020, *Generics (UK) and Others*, C-307/18, EU:C:2020:52, paragraph 50).

51 Nor can the conclusion reached by the General Court be called into question on the ground, first, that it took into consideration, in paragraphs 81 and 149 of the judgment under appeal, factors which predated the conclusion of the agreements at issue, as the appellants claim in the fifth part of the first

ground of appeal, and, second, that it erred in holding, in paragraph 117 of that judgment, that the facts which postdated the conclusion of those agreements were not decisive, as relied on by the appellants under the third part of the first ground of appeal.

52 While it is true that the matter of whether, on the one hand, a manufacturer of originator medicines who is the holder of a patent which protects the manufacturing process of an active ingredient that is in the public domain and, on the other, a manufacturer of generic medicines preparing to enter the market of the medicine containing that active ingredient are potential competitors of each other is to be made by reference to the time when the agreement between them was concluded (judgment of 30 January 2020, *Generics (UK) and Others*, C-307/18, EU:C:2020:52, paragraph 43), it cannot be inferred in particular, as the appellants maintain, that the events and conduct of the parties to that agreement which predated the conclusion of that agreement must not be taken into account. On the contrary, and as is apparent from the case-law referred to in paragraphs 42 and 43 of the present judgment, such events and conduct, for example the steps to obtain an MA or to modify an existing MA, are decisive for the purposes of that assessment, in that they contribute to establishing the firm intention and the inherent ability of the manufacturer of generic medicines to enter the market.

53 Conversely, as has already been held in paragraphs 68 and 69 of the judgment delivered on today's date in Case C-591/16 P, *Lundbeck* v *Commission*, evidence relating to events which postdate the conclusion of that agreement, and in particular evidence concerning the subsequent outcome of the dispute which had justified concluding that agreement, could not be taken into consideration in order to assess, and where necessary, retrospectively to cast doubt on the claim that the parties to the agreement concerned were potential competitors at the time when that agreement was concluded, since that evidence was not capable of influencing the decision of those parties to conclude the agreement in question.

54 Similarly, the appellants cannot reasonably criticise the General Court, under the third part of the present ground of appeal, for having, in paragraphs 67 and 127 of the judgment under appeal, placed undue weight on Lundbeck's perception of the appellants.

55 As the Court held in the judgment delivered on today's date in Case C-591/16 P, *Lundbeck* v *Commission* (paragraph 74), while the matter of whether two undertakings operating at the same level of the production chain are potential competitors must be assessed in the light of the objective factors identified in paragraph 43 of the present judgment, that matter can nevertheless be confirmed by additional factors (judgment of 30 January 2020, *Generics (UK) and Others*, C-307/18, EU:C:2020:52, paragraph 54), including factors which are subjective in nature (judgment of 30 January 2020, *Generics (UK) and Others*, C-307/18, EU:C:2020:52, paragraph 42), so long as those are not decisive for the purposes of the assessment conducted, as the General Court noted, in essence, in paragraph 88 of the judgment under appeal.

56 The subjective factors mentioned in paragraph 54 of the present judgment form only part of the evidence taken into consideration by the Commission and the General Court in order to establish the existence of real and concrete possibilities for the appellants to enter the market concerned. In addition, it cannot be inferred from the judgment under appeal that those factors were decisive, since the General Court and the Commission attached particular importance, as is apparent, inter alia, from paragraphs 61, 118, 119 or 149 of the judgment under appeal, to objective factors such as, inter alia, the agreement concluded with Tiefenbacher, the stock of citalopram tablets held by the appellants or the prior administrative steps taken by them before they entered the market.

57 Finally, the appellants cannot reasonably complain, in the context of the fourth part of their first ground of appeal, that the General Court failed to examine the relevance and the impact of the *Paroxetine* judgment.

58 In that regard, it should be noted that the reasons why the General Court considered that that judgment was not relevant and, therefore, did not have to be taken into consideration are clear from paragraphs 166 to 174 of the judgment under appeal.

59 Those reasons consist in, first, the differences between the case that gave rise to that judgment and the present case and, second, the appellants' failure to explain the fact that Lundbeck did not act on the

implications of that judgment even though those implications were favourable to Lundbeck.

60 Accordingly, the General Court did not fail to fulfil its obligation to state reasons since the statement of reasons of the judgment under appeal enables the appellants to know why it has not upheld their arguments and provides the Court of Justice with sufficient material for it to exercise its power of review (judgment of 5 July 2011, *Edwin* v *OHIM*, C-263/09 P, EU:C:2011:452, paragraph 64 and the case-law cited).

61 Even if, by the fourth part of the first ground of appeal, the appellants criticise the General Court's interpretation of the *Paroxetine* judgment, it must be recalled that, as regards the General Court's interpretation of national case-law, the Court of Justice has jurisdiction, on appeal, only to determine whether that case-law was distorted, and the distortion must be obvious from the documents on its file (see, to that effect, judgments of 21 December 2016, *Commission* v *Hansestadt Lübeck*, C-524/14 P, EU:C:2016:971, paragraph 20, and of 5 July 2011, *Edwin* v *OHIM*, C-263/09 P, EU:C:2011:452, paragraph 53). However, the appellants have neither alleged nor, a fortiori, established such distortion.

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

The second ground of appeal

The relevant paragraphs of the judgment under appeal

63 By their third plea in law relied on in support of their action for annulment, in respect of which the rejection of solely the second, third, fourth and fifth parts is contested in the present appeal, the appellants claimed that the agreements at issue did not constitute 'restrictions by object'.

64 In connection with its rejection of those parts, the General Court, first, undertook, in paragraphs 214 to 220 and 221 to 228 of the judgment under appeal, a restatement of the case-law applicable to characterisation as a 'restriction by object' and of the decision at issue, in relation to which it pointed out, inter alia, in paragraphs 222 and 225 of that judgment, that the Commission had noted, first, that the fact that the original Lundbeck patents had expired before the conclusion of those agreements, but that Lundbeck had in the interim obtained or applied for a number of new process patents, including the crystallisation patents, was a significant element of the economic and legal context in which the agreements at issue were concluded and, second, that those agreements had transformed the uncertainty in relation to the outcome of the litigation regarding the validity of Lundbeck's new process patents into the certainty that the manufacturers of generic medicines would not enter the market, which might also constitute a restriction of competition by object when such limits resulted not 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, overshadowed that assessment and induced the manufacturers of generic medicines not to pursue their independent efforts to enter the market.

65 Next, the General Court noted, in paragraph 229 of the judgment under appeal, that, under the agreements at issue, the appellants agreed not to enter the markets in the United Kingdom and Denmark during the respective terms of those agreements in exchange for the payments made by Lundbeck. In paragraphs 241 and 242 of that judgment, it also considered that the agreements at issue had a much wider scope than that of possible legal proceedings that Lundbeck could have brought against the appellants and that they did not resolve any dispute. In paragraph 293 of that judgment, the General Court further held that it was not the strength of Lundbeck's new process patents that had convinced the appellants to conclude the agreements at issue. On the contrary, and as is apparent from paragraphs 310 and 311 of the judgment under appeal, the parties to those agreements regarded the payments by Lundbeck as compensation for the loss of profit that they could have made had they entered the markets of the United Kingdom and Denmark and, in any event, as a guarantee for the appellants of receiving a definite payment from Lundbeck, whereas the expected profits were subject to the vagaries inherent in any commercial transaction, in particular those concerning the outcome of an infringement action.

66 Finally, in paragraphs 326 and 327 of the judgment under appeal, the General Court rejected the appellants' claims that the Commission had erred as regards the 'counterfactual scenario', on the ground that the Commission was in no way required to make any further comparison of the situation which arose following the conclusion of the agreements at issue with the situation which would have prevailed had they not been concluded.

Arguments of the parties

67 By their second ground of appeal, which is made up of three parts, the appellants criticise the General Court for, in essence, taking the view that the agreements at issue had the object of restricting competition on the ground that they had given up the chance of having Lundbeck's UK crystallisation patent declared invalid.

68 Under the first part of the second ground of appeal, the appellants complain that the General Court disregarded the fact that an agreement which is merely capable of restricting competition is not a 'restriction by object' where it has not been established that the restriction at issue reveals a sufficient degree of harm to competition, as is apparent from paragraph 69 of the judgment of 11 September 2014, *CB* v *Commission* (C-67/13 P, EU:C:2014:2204). In that respect, the appellants state that whilst there was a chance that they could have had Lundbeck's UK crystallisation patent declared invalid, there was also a reasonable chance that they would have failed to do so. Therefore, they argue that the agreements at issue solely may have had the potential to restrict competition, which is not sufficient to characterise them as a 'restriction by object', having regard to the harm threshold required in paragraph 57 of that judgment and the requirement in paragraph 58 of the same judgment that the concept of 'restriction by object' be interpreted restrictively.

69 Under the second part of the second ground of appeal, the appellants criticise the General Court for having considered the agreements at issue to be, in essence, market exclusion agreements. First, the appellants argue that the agreements at issue differ from market exclusion agreements in that market exclusion agreements prevent lawful market entry whereas the appellants could not have legally entered the market if Lundbeck's UK crystallisation patent had been valid and infringed. Second, the appellants maintain that a market exclusion agreement would lead directly to market exclusion whereas, in the present case, the agreements at issue would have been capable of causing such an exclusion only where Lundbeck's UK crystallisation patent had been declared invalid. Third, in the appellants' view, the General Court erred in considering that manufacturers of generic medicines have a duty to bring legal proceedings unless they can obtain an unconditional commitment that they would be allowed onto the market. Fourth, the appellants argue that the General Court erred in law in paragraph 306 of the judgment under appeal by treating the payments 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) as equivalent to those received by the appellants in the present case, which had a reasonable justification.

70 Under the third part of the second ground of appeal, the appellants criticise the General Court for having accepted that the Commission could establish the anticompetitive object of the agreements at issue without having to consider the 'counterfactual scenario'. In that regard, the appellants submit that an assessment of the 'counterfactual scenario' does not constitute an inquiry into the effects of those agreements, contrary to what is claimed by the General Court in paragraph 327 of the judgment under appeal.

Findings of the Court

71 As the General Court stated in essence in paragraphs 215 to 219 of the judgment under appeal, 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).

72 As regards similar dispute settlement agreements 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 medicine 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).

73 However, 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 that settlement agreement 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 Others*, C-307/18, EU:C:2020:52, paragraphs 83 and 87).

74 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).

75 It follows from the foregoing that the characterisation of agreements such as the agreements at issue as a 'restriction by object' presupposes, as is also apparent from paragraph 131 of the judgment delivered on today's date in Case C-591/16 P, *Lundbeck* v *Commission*, an assessment of the specific characteristics of those agreements, which must be used to infer the potential harmfulness of that agreement for competition, where necessary as a result of a detailed analysis of those agreements, their objectives and the economic and legal context, in the context of which the amount of the transfers of value is of particular importance (see, to that effect, judgment of 30 January 2020, *Generics (UK) and Others,* C-307/18, EU:C:2020:52, paragraph 89).

76 In the present case, in paragraphs 229, 241, 242 and 293 of the judgment under appeal, the General Court held, first, that the agreements at issue, by which the appellants undertook not to enter the markets in the United Kingdom and Denmark during the respective terms of those agreements in exchange for the sums paid by Lundbeck, had a much wider scope than that of possible legal proceedings that Lundbeck could have brought against the appellants and, consequently, they neither resolved any dispute nor were justified by the strength of Lundbeck's new process patents.

77 Second, in paragraphs 222, 225, 310 and 311 of that judgment, the General Court considered, relying on the assessments made by the Commission, which were not contested, that, having regard to the specific context of the situation in the present case characterised by the expiry of Lundbeck's original patents before the conclusion of the agreements at issue and by the fact that Lundbeck applied for and subsequently obtained a number of new process patents, including the crystallisation patents, those agreements had transformed the uncertainty in relation to the outcome of litigation concerning those process patents, first, into the certainty that the appellants' generic medicines would not enter the market in exchange for significant payments which were regarded by the appellants and by Lundbeck as compensation to the appellants for the loss of the profit that they could have made had they entered the markets of the United Kingdom and of Denmark, and, second, into certainty for the appellants of significant payments, while the profits expected by them from a market entry would have been subject to the vagaries inherent in any commercial transaction, particularly those concerning the outcome of an infringement action.

78 Therefore, the General Court was fully entitled to find that the agreements at issue had to be characterised as a 'restriction by object', that finding not being based on the fact that the appellants had

given up the opportunity to have Lundbeck's UK crystallisation patent declared invalid.

79 That conclusion cannot be called into question by the fact relied on by the appellants in their reply to the question for written response of 6 February 2020, referred to in paragraph 13 of the present judgment, that the General Court failed to take account of the fact that they could legitimately have been entitled to a certain amount of compensation by means of a value transfer for having discharged Lundbeck from potential future liability under a cross-undertaking in damages.

80 In that regard, while it is true that the Court of Justice has acknowledged that the manufacturer of generic medicines may receive from the manufacturer of the originator medicine sums that correspond in fact to compensation for the costs of or disruption caused by the litigation between them, such as when the manufacturer of the generic medicines discharges undertakings, particularly financial, given by the patent holder to him or her, such as a cross-undertaking in damages (see, to that effect, judgment of 30 January 2020, *Generics (UK) and Others*, C-307/18, EU:C:2020:52, paragraph 86), it must be stated that, in the present case, apart from the fact that the appellants did not rely on that justification in support of their action for annulment and in particular within the fourth part of their third plea in law, it is common ground that, at the time when the agreements at issue were concluded, Lundbeck had provided no undertaking of that type.

81 Furthermore, the appellants cannot complain that the General Court characterised the agreements at issue as a 'restriction by object' when they were, in the appellants' view, merely capable of restricting competition in so far as there was uncertainty concerning whether the appellants could have had Lundbeck's UK crystallisation patent declared invalid. That line of argument is based on confusion regarding the nature of the agreements at issue, which were not simply capable of restricting competition, but which did in fact restrict potential competition between the appellants and Lundbeck by deliberately replacing a situation of uncertainty regarding the appellants' market entry and the outcome of the litigation concerning Lundbeck's new process patents at the time when the agreements were concluded for a situation where there was no competition between those manufacturers of medicines on the market in the United Kingdom and in Denmark for the duration of the agreements at issue.

82 It also follows from the rejection of the first part of the present ground of appeal that its second part is ineffective.

83 Indeed, even if the General Court were to have erred in finding that the agreements at issue were in essence market exclusion agreements or that the payments provided for in those agreements 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), the General Court was in any event fully entitled to characterise the agreements at issue as a 'restriction by object'.

84 Finally, in so far as, under the third part of their second ground of appeal, the appellants criticise the General Court for having accepted that the Commission could establish the anticompetitive object of the agreements at issue without having to carry out an examination of the 'counterfactual scenario', it must be stated, as is also apparent from paragraph 139 of the judgment of today's date in Case C-591/16 P, *Lundbeck* v *Commission*, that that examination enables 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).

85 Consequently, as the Court held in the judgment of today's date in Case C-591/16 P, *Lundbeck* v *Commission* (paragraph 140), and so as not to disregard the clear distinction between the concepts of 'restriction by object' and '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), 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'.

86 Furthermore, it must be stated that the assessment which must be undertaken, in accordance with paragraphs 73 and 74 of the present judgment, in order to establish whether or not an agreement such as the agreements 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.

87 The fact, referred to in paragraph 75 of the present judgment, that that assessment must be carried out, where necessary following a detailed analysis of 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 does not also 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 the detailed assessment of those agreements demonstrates that they reveal, objectively, a sufficient degree of harm to competition.

88 Therefore, the General Court did not err in law in concluding, in paragraph 327 of the judgment under appeal, that the Commission was not required to examine the 'counterfactual scenario' to characterise the agreements at issue as a 'restriction by object'.

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

The third ground of appeal

The relevant paragraphs of the judgment under appeal

90 By their fourth plea in law relied on in support of their action for annulment, the appellants alleged that the Commission made a number of errors of law concerning the very principle of imposing a fine.

91 That plea was rejected by the General Court, inter alia, on the following grounds:

'369 It must be recalled that, according to case-law, the principle that penalties must be provided for by law and the principle of legal certainty cannot be interpreted as prohibiting the gradual clarification of the rules of [criminal] liability but may preclude the retroactive application of a new interpretation of a rule establishing an offence. That is particularly true of a judicial interpretation which produces a result that was not reasonably foreseeable at the time when the offence was committed, especially in the light of the interpretation put on the provision in the case-law at the material time (see [, to that effect, judgment of 10 July 2014 in *Telefónica and Telefónica de España* v *Commission*, C-295/12 P, EU:C:2014:2062, paragraphs 147 and 148 and the] case-law cited).

370 In that regard, it follows from the case-law that the scope of what is foreseeable depends to a considerable degree on the content of the text in issue, the field it covers and the number and status of those to whom it is addressed, and that a law may still satisfy the requirement of foreseeability even if the person concerned has to take appropriate legal advice to assess, to a degree that is reasonable in the circumstances, the consequences which a given action may entail (judgment of 28 June 2005 in *Dansk Rørindustri and Others* v *Commission*, C-189/02 P, C-202/02 P, C-205/02 P to C-208/02 P and C-213/02 P, … EU:C:2005:408, paragraph 219).

371 Moreover, with regard to whether an offence was committed intentionally or negligently and is therefore liable to be penalised by the imposition of a fine in accordance with the first subparagraph of Article 23(2) of Regulation No 1/2003, it is settled case-law that that condition is satisfied where the undertaking concerned cannot be unaware of the anticompetitive nature of its conduct, whether or not it is aware that it is infringing the competition rules of the Treaty (see[, to that effect, judgment of 18 June 2013, *Schenker & Co. and Others*, C-681/11, EU:C:2013:404, paragraph 37 and the] case-law cited).

372 In the present case, in the first place, it follows inter alia from paragraphs 109, 110 and 279 to 281 [of the judgment under appeal] that there was no legal uncertainty regarding the possibility of classifying, as a restriction by object, agreements with the characteristics of those at issue in the present case and which came about in the context of those agreements.

373 In the second place, as regards, more particularly the references made by the applicants to the [Danish Competition Authority] press release [of 28 January 2004], it suffices to refer to paragraphs 282 to 287 [of the judgment under appeal].'

92 In paragraphs 109, 110 and 279 to 281 of the judgment under appeal, referred to in paragraph 372 of that judgment, the General Court stated, in essence, (i), that the presumption of validity which all patents enjoy cannot be equated with a presumption of illegality of any product placed on the market which the patent holder deems to be infringing the patent, and, (ii) that, first, well before the date of conclusion of the agreements at issue, the Court had ruled on the application of competition law in fields characterised by the presence of intellectual property rights, second, Lundbeck was aware that its conduct was at least capable of posing problems from the point of view of competition law, and third, it is not necessary that the same type of agreement should have already been censured by the Commission in order for the agreements at issue to be regarded as a 'restriction by object'.

93 In paragraphs 282 to 287 of the judgment under appeal, referred to in paragraph 373 of that judgment, the General Court stated, in essence, that the Danish Competition Authority press release of 28 January 2004 ('the DCA press release'), to which the appellants refer, and which indicated that the Commission did not envisage initiating proceedings in relation to the agreements at issue, was not issued directly by the Commission or its departments, but rather by a national competition authority, and could not therefore give rise to legitimate expectations on the part of the undertakings that their conduct did not infringe Article 101 TFEU. The General Court also noted that that press release clearly stated that, following a preliminary assessment, there were doubts as to whether or not those agreements were anticompetitive, in view, in particular, of the size of the payment made by Lundbeck to the manufacturers of generic medicines, but also that any agreement whose object is to pay to exclude a competitor from the market is anticompetitive.

Arguments of the parties

94 By their third ground of appeal, the appellants claim that the General Court erred in law in upholding the power of the Commission to impose a fine on them in the circumstances of the present case.

95 First, they argue that the General Court was incorrect in considering, in paragraph 372 of the judgment under appeal, that there was no legal uncertainty regarding the characterisation of the agreements at issue as a 'restriction by object', in view of the DCA press release, the content of which is set out in particular in paragraph 284 of the judgment under appeal.

96 Second, the appellants submit that in order to establish the appellants' intention or negligence, the General Court erred in failing to assess whether the Commission had correctly assessed the appellants' subjective perception of their ability to enter the market at the time the agreements at issue were concluded.

Findings of the Court

97 As regards the first part of the third ground of appeal, and as the General Court correctly pointed out in paragraph 371 of the judgment under appeal, an undertaking may be punished for conduct falling within the scope of Article 101(1) TFEU where that undertaking could not have been unaware of the anticompetitive nature of its conduct, whether or not it was aware that it was 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).

98 It follows that the fact that that undertaking has characterised wrongly in law its conduct upon which the finding of the infringement is based cannot have the effect of exempting it from imposition of a fine in so far as it could not be unaware of the anticompetitive nature of that conduct (judgment of 18 June 2013, *Schenker & Co. and Others*, C-681/11, EU:C:2013:404, paragraph 38).

99 In that regard, the General Court held, in essence, in paragraph 372 of the judgment under appeal, which refers to paragraphs 282 to 287 of that judgment and which is to be read together with paragraph 371 of that judgment, first, that there was no legal uncertainty regarding the possibility of classifying agreements such as the agreements at issue as a 'restriction by object', first of all, because of settled case-law concerning the application of competition law in fields characterised by the presence of intellectual property rights, next, because of the fact that Lundbeck was aware that its conduct was at least capable of posing problems from the point of view of competition law and finally, because of the fact that it is not necessary that the same type of agreements should have already been censured by the Commission in order for the agreements at issue to be regarded as a 'restriction by object'. Those findings are not disputed in the context of the present ground of appeal.

100 Second, the General Court considered that the DCA press release did not enable those assessments to be called into question. In that regard, it stated, first, that that press release could not give rise to legitimate expectations on the part of the appellants that their conduct did not infringe Article 101 TFEU on the ground that it was not issued by the Commission, and, second, that the very wording of that press release provided no guarantee to that effect. On the contrary, the General Court stated, in essence, that whether the agreements at issue were anticompetitive depended on the size of the payments made by Lundbeck to the manufacturers of generic medicines and that any agreement whose object is to pay to exclude a competitor from the market is anticompetitive.

101 That reasoning establishes to the requisite legal standard that it is at the very least foreseeable that the agreements at issue could incur penalties.

102 As regards the second part of the third ground of appeal, it should be noted that it is based on a line of argument which was not raised before the General Court and which consequently is inadmissible at the appeal stage.

103 Although it is true that the appellants maintained, under the fourth plea relied on in support of their action for annulment, which was rejected in paragraph 377 of the judgment under appeal, that no fine should have been imposed on them because of the legal uncertainty which existed at the time the agreements at issue were concluded as to whether they could be characterised as a 'restriction by object', it is not apparent either from paragraphs 368 to 377 of that judgment or from the file at first instance, which was forwarded to the Court of Justice in accordance with Article 167(2) of the Rules of Procedure, that the appellants argued before the General Court that the no fine should have been imposed on them on the ground that the Commission's examination of the appellants' subjective perception of their ability to enter the market at the time the agreements at issue were concluded was incorrect.

104 Consequently, the third ground of appeal must be rejected as being in part inadmissible and in part unfounded.

105 Having regard to all the foregoing, the appeal must be dismissed in its entirety.

Costs

106 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.

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

108 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.

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

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

1. **Dismisses the appeal;**

2. **Orders Arrow Group ApS and Arrow Generics 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.