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-614/16 P,

APPEAL under Article 56 of the Statute of the Court of Justice of the European Union, brought on 28 November 2016,

Merck KGaA, established in Darmstadt (Germany), represented by B. Bär-Bouyssière and S. Smith, Solicitors, and by R. Kreisberger QC, and D. Mackersie, Barrister,

appellant,

the other parties to the proceedings being:

European Commission, represented by T. Vecchi, F. Castilla Contreras, 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,

Generics (UK) Ltd,

intervener at first instance,

THE COURT (Fourth Chamber),

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

Advocate General: J. Kokott,

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

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

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

gives the following

Judgment

1 By its appeal, Merck KGaA seeks to have set aside the judgment of the General Court of the European Union of 8 September 2016, *Merck* v *Commission* (T-470/13, not published, 'the judgment under appeal', EU:T:2016:452), by which the General Court dismissed its action seeking, first, annulment 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 it 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] …'

The 2004 Notice on informal guidance

3 Point 4 of the Commission Notice on informal guidance relating to novel questions concerning Articles [101 and 102 TFEU] that arise in individual cases (guidance letters) (OJ 2004 C 101, p. 78; 'the 2004 Notice on informal guidance') provides:

'Alongside the reform of the rules implementing Articles [101 and 102 TFEU] brought about by Regulation 1/2003, the Commission has conducted a review of block exemption regulations, Commission notices and guidelines, with a view to further assist self-assessment by economic operators. The Commission has also produced guidelines on the application of Article [101](3) [TFEU]. This allows undertakings in the vast majority of cases to reliably assess their agreements with regard to Article [101 TFEU]. Furthermore, it is the practice of the Commission to impose more than symbolic fines only in cases where it is established, either in horizontal instruments or in the case-law and practice that a certain behaviour constitutes an infringement.'

The Guidelines on the application of Article [101](3) [TFEU]

4 Point 21 of the Guidelines on the application of Article [101](3) [TFEU] (OJ 2004 C 101, p. 97) states:

'Restrictions of competition by object are those that by their very nature have the potential of restricting competition. These are restrictions which in light of the objectives pursued by the [EU] competition rules have such a high potential of negative effects on competition that it is unnecessary for the purposes of applying Article [101(1) TFEU] to demonstrate any actual effects on the market. This presumption is based on the serious nature of the restriction and on experience showing that restrictions of competition by object are likely to produce negative effects on the market and to jeopardise the objectives pursued by the [EU] competition rules. Restrictions by object such as price fixing and market sharing reduce output and raise prices, leading to a misallocation of resources, because goods and services demanded by customers are not produced. They also lead to a reduction in consumer welfare, because consumers have to pay higher prices for the goods and services in question.'

The 2004 Guidelines on technology transfer agreements

5 Point 209 of the Guidelines on the application of Article [101 TFEU] to technology transfer agreements (OJ 2004 C 101, p. 2; 'the 2004 Guidelines on technology transfer agreements') provides:

'In the context of a settlement and non-assertion agreement, non-challenge clauses are generally considered to fall outside Article [101(1) TFEU]. It is inherent in such agreements that the parties

agree not to challenge *ex post* the intellectual property rights covered by the agreement. Indeed, the very purpose of the agreement is to settle existing disputes and/or to avoid future disputes.'

Background to the dispute

6 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-601/16 P (*Arrow Group and Arrow Generics* v *Commission*) against the judgment of 8 September 2016, *Arrow Group and Arrow Generics* v *Commission* (T-467/13, not published, EU:T:2016:450), and the appeal 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).

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

'I – The companies involved in the present case

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

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

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

II – The relevant product and the applicable patents

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

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

6 As regards the European Economic Area (EEA), the protection afforded by 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.

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

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

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

III – The agreements at issue

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

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

12 According to the terms of the UK agreement:

– there was a risk that certain actions envisaged by GUK in respect of the marketing, distribution and sale of the "Product" might constitute an infringement of Lundbeck's intellectual property rights and could give rise to claims on the part of Lundbeck (Article 2.1 of the UK agreement), the "Products" being defined in Article 1.1 of [that] agreement as "the citalopram products developed by GUK in raw material, bulk product and finished pack form as set out in the Schedule and manufactured in accordance with the specification for Products as supplied by GUK at the date of signature. Attached to Schedule 2";

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

…

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

V – [The decision at issue]

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

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

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

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

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

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

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

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

32 The Commission also imposed fines on all the parties to the agreements in question. To that end, it applied the Guidelines on the method of setting fines imposed pursuant to Article 23(2)(a) of Regulation No 1/2003 (OJ 2006 C 210, p. 2 …). In Lundbeck's case, the Commission followed the general methodology described in [those guidelines], based on the value of sales of the relevant product made by each participant in an infringement (recitals 1316 to 1358 of the

[decision at issue]). In the case of the other parties to the agreements in question, namely the [manufacturers of generic medicines], it made use of the possibility, provided for in point 37 of those guidelines, to depart from that methodology, in view of the particularities of the case so far as those parties were concerned (recital 1359 of the [decision at issue]).

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

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

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

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

The procedure before the General Court and the judgment under appeal

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

9 In support of its action, Merck raised 13 pleas in law alleging that: (i) the Commission erred in its interpretation of the concept of 'restriction by object' within the meaning of Article 101 TFEU; (ii) the 'theory of harm' applied by the Commission was fundamentally flawed; (iii) the Commission's approach was contrary to the principle of legal certainty; (iv) the Commission erred in failing to take proper account of the factual, economic and legal context, which would have shown that in the absence of the agreements at issue Merck (GUK) would not have launched citalopram any more quickly on the United Kingdom or other EEA markets; (v) there was an error of assessment by the Commission as to the scope of the agreements at issue; (vi) the Commission made an error of law and fact in finding that Lundbeck and Merck (GUK) were potential competitors; (vii) the Commission made a manifest error of assessment in finding that Merck (GUK) had an anticompetitive intention in concluding the agreements at issue; (viii) the Commission made an error of fact in its findings as to the size and purpose of the value transfer between Lundbeck and Merck (GUK); (ix) the Commission had not correctly assessed Merck's arguments under Article 101(3) TFEU; (x) the Commission had failed to have due regard to evidence provided by Merck for the purpose of rebutting the presumption of Merck's decisive influence over its subsidiary GUK and erred in law in finding that that presumption was not rebutted; (xi) there had been a breach of the 'reasonable time' requirement; (xii) there had been a breach of the parties' right to be heard; and (xiii) there had been an error of assessment by the Commission as to the penalties imposed.

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

Procedure before the Court of Justice

11 By document lodged at the Registry of the Court of Justice on 28 November 2016, Merck brought the present appeal.

12 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-586/16 P (*Sun Pharmaceutical Industries and Ranbaxy (UK)* v *Commission*), C-588/16 P (*Generics (UK)* v *Commission*), C-601/16 P (*Arrow Group and Arrow Generics* v *Commission*) and C-611/16 P (*Xellia Pharmaceuticals and Alpharma* v *Commission*). 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 had been served on the United Kingdom.

13 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-601/16 P (*Arrow Group and Arrow Generics* v *Commission*) and C-611/16 P (*Xellia Pharmaceuticals and Alpharma* v *Commission*) and after hearing an Opinion.

14 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.

15 The joint hearing in the present case and the cases referred to in paragraph 13 of the present judgment was held on 24 January 2019.

16 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.

17 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

18 By its appeal, Merck claims that the Court should:

– set aside point 1 of the operative part of the judgment under appeal;

– annul Article 1(1) and Article 2(1) of the decision at issue as well as Articles 3 and 4 thereof in so far as they concern Merck;

– in the alternative, annul or reduce the penalty imposed on it;

– annul point 2 of the operative part of the judgment under appeal; and

– order the Commission to bear its own costs and to pay those incurred by Merck in relation to both the proceedings at first instance and the appeal.

19 The Commission contends that the Court should:

– dismiss the appeal in its entirety, and

– order Merck to pay the costs.

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

The appeal

21 In support of its appeal, Merck relies on three grounds of appeal.

22 By its first ground of appeal, Merck complains that the General Court erred in law in characterising the agreements at issue as 'restrictions of competition by object'. By its second ground of appeal, Merck complains that the General Court erred in concluding that Lundbeck and Merck (GUK) were potential competitors. By its third ground of appeal, Merck submits that the General Court erred in upholding the fine imposed on it by the Commission.

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

The second ground of appeal

The relevant paragraphs of the judgment under appeal

24 By a part of its fourth plea in law and by its sixth plea in law in support of its action for annulment, Merck claimed that the Commission had erred in law and in fact in finding that Lundbeck and Merck (GUK) were potential competitors.

25 Those pleas were rejected by the General Court after it had recalled the analysis concerning potential competition carried out in the decision at issue and the principles and applicable case-law, in the context of which the General Court stated, in paragraph 86 of the judgment under appeal, that the very fact that an undertaking already present on a market sought to conclude agreements or to establish information exchange mechanisms with other undertakings which were not present on the market provided a strong indication that the market in question was not impenetrable.

26 First, in assessing whether there was a real and concrete possibility for Merck (GUK) to enter the markets in the United Kingdom and in the EEA and to compete with Lundbeck, the General Court considered, in paragraphs 120 to 124 of the judgment under appeal, that an 'at-risk' launch by Merck (GUK) of its generic product constituted a concrete possibility of market entry despite the process patents held by Lundbeck and that it was difficult to dispute that Lundbeck's process patents did not constitute insurmountable barriers for manufacturers of generic medicines such as Merck (GUK), which were not only willing but also ready to enter the citalopram market and which had already made considerable investments to that end at the time the agreements at issue were concluded, which the General Court reiterated in paragraph 129 of that judgment. In paragraph 128 of that judgment, the General Court found that, even if Lundbeck had brought infringement actions against Merck (GUK) and the latter's products had been found to be infringing, it would nevertheless have been able, within a reasonable period, to obtain citalopram which had not been held to be infringing from other sources.

27 Next, in paragraphs 146 to 168 of the judgment under appeal, the General Court rejected all Merck's arguments concerning the lack of routes to market which would have enabled Merck (GUK) to launch its generic product on the market before the agreements at issue expired.

28 In that context, the General Court considered, in particular, in paragraphs 150 to 161 of the judgment under appeal, first, that Merck could not maintain that any market entry of citalopram would have been entirely impossible before the expiry of the agreements at issue, even in the absence of those agreements, as a result of legal actions which could have been brought by Lundbeck, second, that it was not for the Commission to establish that, in the absence of the agreements at issue, Merck (GUK) would undoubtedly have entered the market before those agreements expired, but only that it had real and concrete possibilities of doing so, third, that the Commission was not required to show that those possibilities would undoubtedly have materialised, fourth, that, in the light of the administrative steps taken by Merck (GUK), at least two of the eight possible routes to the market identified by the Commission in recital 635 of the decision at issue and referred to in paragraphs 147, 154 and 156 of the judgment under appeal, namely the 'at-risk' launch by Merck (GUK) of its generic product and the possibility of having Lundbeck's process patents declared invalid before the national courts, were real and concrete possibilities for Merck (GUK) to enter the market and, fifth, that Merck could not maintain that the fifth to eighth possible routes to the market identified by the Commission did not represent real possibilities.

29 In paragraphs 163 to 168 of the judgment under appeal, lastly, the General Court rejected Merck's claim that the Commission ought to have considered whether Merck (GUK) and Lundbeck were potential competitors in each EEA Member State in order to be able to conclude that there was potential competition between them in the whole of the EEA. To that end, it stated in particular, in paragraph 167 of that judgment, as follows:

'… the very fact that the EEA agreement covered the whole EEA territory (with the exception of the United Kingdom) demonstrates that Lundbeck perceived Merck (GUK) as a potential threat in the whole of that territory and that the latter had real concrete possibilities of entering the EEA markets at the time the agreements at issue were concluded.'

Arguments of the parties

30 By its second ground of appeal, which comprises three parts, Merck submits that the General Court erred in law when it concluded that Merck (GUK) and Lundbeck were potential competitors.

31 As a preliminary point, Merck claims that to be a potential competitor presupposes that there are real and concrete possibilities – and not purely theoretical possibilities – for the undertaking concerned to enter a market, that entry into that market is an economically viable strategy and that that entry can take place sufficiently quickly. It adds that potential competition must be demonstrated on the basis of facts and not mere hypothesis, based, in essence, on the ability and not on the intentions of the undertaking concerned.

32 Within the first part of that ground of appeal, which concerns paragraphs 146 to 168 of the judgment under appeal, Merck takes the view that the General Court erred in law by failing to consider whether the eight possible routes to the market identified by the Commission, which, according to Merck, are hypothetical and posited in the abstract, were economically viable or practically achievable within a sufficiently short period of time. In addition, in so far as the General Court considered that at least two of those routes, namely the 'at risk' launch, by Merck (GUK), of its generic product and the possibility of obtaining a court declaration that Lundbeck's process patents were invalid, constituted real and concrete possibilities of entering the market, Merck argues that the General Court did not justify its conclusions or demonstrate that those routes could have been achieved sufficiently quickly to exercise a competitive constraint. Merck further submits that the fact that it took steps to prepare for market entry does not demonstrate that those routes were economically viable and does not provide the level of certainty required to demonstrate that Merck (GUK) and Lundbeck were potential competitors. Finally, the assertion, in paragraph 128 of the judgment under appeal, that Merck (GUK) could have obtained citalopram from other suppliers, which had not been held to be infringing, is, in Merck's view, entirely abstract and disconnected from any test of whether it was achievable from a technical, commercial or legal standpoint. Furthermore, Merck criticises the General Court for having taken account of Lundbeck's perception that Merck (GUK) constituted a potential threat.

33 Within the second part of the second ground of appeal, which concerns paragraphs 124 and 150 of the judgment under appeal, Merck criticises the General Court for having reversed the burden of proof in considering that Merck (GUK) had to demonstrate that those possible routes to the market concerned were impossible or insurmountable, whereas it was for the Commission to demonstrate that those routes were real and concrete.

34 In the third part of that ground of appeal, which concerns paragraphs 86 and 167 of the judgment under appeal, Merck maintains that the General Court erred in law in taking account, for the purposes of assessing whether they were potential competitors, of the fact that Merck (GUK) and Lundbeck concluded the agreements at issue. It argues that if there is a genuine dispute between the parties to an agreement concerning a patent, the fact that the dispute is settled does not in itself provide any information as to whether they are potential competitors.

Findings of the Court

35 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 (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 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).

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 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).

40 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).

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 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).

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 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 holder of that patent 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 In the present case, the General Court held, in paragraphs 120 to 129 of the judgment under appeal, first, that Lundbeck's process patents did not constitute an insurmountable barrier for the manufacturers of generic medicines such as Merck (GUK) and, second, that Merck (GUK) was not only willing but also ready to accept the risk of market entry despite Lundbeck's process patents and that it had taken significant steps for that purpose and had made considerable investments. The General Court also noted, in paragraph 149 of the judgment under appeal, that Merck (GUK) had already obtained a marketing authorisation (MA) for the United Kingdom on 9 January 2002 and that it was planning to obtain similar MAs in several other EEA Member States.

45 It follows that the General Court was fully entitled to find that Merck (GUK) and Lundbeck were, at the time the agreements at issue were concluded, potential competitors.

46 That conclusion cannot be called into question by Merck's argument that the General Court erred in law by failing to consider whether the eight possible routes to the market, as identified by the Commission in the decision at issue, were economically viable or practically achievable within a sufficiently short period of time.

47 In that regard, it must be recalled that, for the purposes of establishing whether undertakings such as Merck (GUK) and Lundbeck are potential competitors, and as the General Court was fully entitled to state in paragraphs 151 and 152 of the judgment under appeal, it must be demonstrated not that the undertaking which is not present on the market concerned will in fact, and with certainty, enter the market concerned, and, even further, that it will be capable, thereafter, of retaining its place there, but solely that there are real and concrete possibilities for that undertaking to enter that market and compete with the undertaking already present on that market (see, to that effect, judgment of 30 January 2020, *Generics (UK) and Others*, C-307/18, EU:C:2020:52, paragraphs 36 and 38 and the case-law cited).

48 Therefore, contrary to Merck (GUK)'s assertions, the General Court was not required to consider whether the routes to market available to Merck (GUK), as identified by the Commission in the decision at issue, were economically viable.

49 Nor was the General Court required, as it noted in essence in paragraph 153 of the judgment under appeal, to consider whether all those routes to the market were practically achievable or constituted real and concrete possibilities of entry to the market, since, first, as is apparent from that paragraph, at least two of those routes to the market, namely the launch 'at risk' by Merck (GUK) of its generic product and the possibility of having Lundbeck's process patents declared invalid before the national courts, constituted for Merck (GUK) real and concrete opportunities to enter the market and, second, the General Court explained in detail, in paragraphs 149 to 161 of the judgment under appeal, the reasons justifying its assessment.

50 Furthermore, even if, by its line of argument, Merck disputes the General Court's assessment of whether there was a real and concrete possibility of Merck (GUK) entering the market either by Merck (GUK) launching its generic product 'at risk' or by means of having Lundbeck's process patents declared invalid before the national courts, suffice it to state 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 the clear sense of those facts and evidence, constitute a point of law which is, as such, subject upon appeal to review by the Court of Justice.

51 Indeed, Merck has not, in that regard, alleged any distortion of the clear sense of the facts or the evidence by the General Court. Consequently, its line of argument on that point is inadmissible.

52 In addition, Merck cannot complain that the General Court, in paragraph 167 of the judgment under appeal, took account, in order to establish that Merck (GUK) and Lundbeck were potential competitors, of Lundbeck's perception that Merck (GUK) constituted a potential threat.

53 While the issue 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 40 of the present judgment, the fact remains that it can 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.

54 It is apparent from paragraphs 115 to 162 of the judgment under appeal that the General Court, following the Commission, relied essentially on objective evidence, as is apparent from paragraphs 107 and 108 of the judgment under appeal.

55 Finally, in so far as Merck criticises paragraph 128 of the judgment under appeal – according to which, even if Lundbeck had brought infringement actions against Merck (GUK) and Merck (GUK)'s products had been found to be infringing, Merck (GUK) would nevertheless have been able within a reasonable period to obtain citalopram, which had not been held to be infringing from other suppliers – it must be stated that that consideration falls within the General Court's assessment of the facts and evidence available to it and that Merck has not in any way alleged that the clear sense of the facts and evidence were distorted by the General Court. Therefore, on the same grounds as those set out in paragraph 50 of the present judgment, that complaint must be rejected as being inadmissible.

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

57 As regards the second part of the present ground of appeal, which concerns paragraphs 124 and 150 of the judgment under appeal, and by which Merck claims that the General Court reversed the burden of proof, which obliged Merck (GUK) to demonstrate that the possible routes to the market concerned were impossible or insurmountable, suffice it to state that Merck's line of argument is based on a misreading of those paragraphs.

58 In those paragraphs, the General Court considered solely, in support of an adequate statement of reasons, first, that Lundbeck's process patents did not constitute insurmountable barriers and, second, that Merck could not claim that the market entry of citalopram would have been entirely impossible

before the expiry of the agreements at issue, even in the absence of those agreements, as a result of legal actions that could have been brought by Lundbeck.

59 Consequently, the General Court neither expressly or implicitly required Merck to demonstrate that the possible routes to the market concerned were impossible or insurmountable.

60 In that regard, the fact that the General Court did not uphold Merck's arguments in no way implies, contrary to Merck's assertions, that it reversed the burden of proof, but solely that it considered that the arguments put forward by Merck were not sufficiently convincing.

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

62 As regards, finally, the third part of the present ground of appeal which concerns paragraphs 86 and 167 of the judgment under appeal, suffice it to state that, by that part, Merck criticises the General Court for having taken into consideration, in order to assess whether Merck (GUK) and Lundbeck were potential competitors, the fact that they concluded the agreements at issue, whereas such a factor is entirely relevant, indeed constitutes a strong indication to that end (judgment of 30 January 2020, *Generics (UK) and Others*, C-307/18, EU:C:2020:52, paragraph 55).

63 Accordingly, the third part of the second ground of appeal must be rejected and the second ground of appeal must be rejected in its entirety as being in part inadmissible and in part unfounded.

The first ground of appeal

The relevant paragraphs of the judgment under appeal

64 By its first, second, fourth, fifth, seventh and eighth pleas in law in support of its action for annulment which concerned, in essence, infringement of Article 101(1) TFEU, Merck claimed that the Commission had made several errors of law and of assessment in taking the view that the agreements at issue ought to be characterised, in the decision at issue, as 'restrictions by object'.

65 After identifying, in paragraphs 185 to 199 of the judgment under appeal, the principles and applicable case-law relevant to characterisation as a 'restriction by object' and the Commission's analysis in the decision at issue, the General Court rejected each of those pleas in paragraphs 200 to 422 of that judgment.

66 To reject the first plea for annulment, the General Court held, in paragraphs 200 to 215 of the judgment under appeal, that the Commission had not erred in its interpretation of the concept of 'restriction by object'. In that regard, it held, in particular, in paragraphs 210 and 212 respectively of that judgment, that the agreements at issue were akin to market exclusion agreements and that it was not necessary that agreements of the same type as the agreements at issue had already been censured by the Commission in order for the agreements at issue to be capable of being held to be 'restrictions by object'.

67 In connection with the rejection of the second plea for annulment, which alleged that the 'theory of harm' relied on by the Commission in order to conclude that the agreements at issue constituted a restriction of competition by object was fundamentally misconceived, the General Court held, in particular, in paragraphs 225 and 231 of the judgment under appeal, that while it was not for the Commission to define the scope of Lundbeck's process patents, the Commission could nevertheless take account of the existence of those patents and examine the perception, by the parties to the agreements at issue, of those patents at the date those agreements were concluded. In paragraphs 239 to 251 of that judgment, the General Court held that the agreements at issue were comparable, despite certain specific features, to market exclusion agreements which were characterised as a 'restriction by object', in the same way as, in particular, the agreements 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). In that regard, the General Court pointed out, in paragraphs 247 to 250 of the judgment under appeal, first, that the agreements at issue had enabled Merck (GUK)'s entry into the markets concerned to be delayed, thus allowing Lundbeck to maintain high prices for Cipramil and to ensure more favourable conditions for the launch of Cipralex, which was supposed soon to replace

Cipramil, second, that those agreements induced Merck (GUK) not to enter the markets concerned with its generic products during the term of those agreements by means of a considerable reverse payment and third, that those agreements transformed the uncertainty, which existed at the time the agreements at issue were concluded, as to the outcome of any infringement actions brought by Lundbeck if Merck (GUK) entered the market with its generic products into the certainty that Merck (GUK) would not enter the market with its generic products during the term of those agreements by means of considerable reverse payments.

68 In addition, the General Court recalled that an agreement may be regarded as having the object of restricting competition even if it does not have the restriction of competition as its sole aim but pursues other legitimate objectives. In paragraph 261 of the judgment under appeal, the General Court also added that, by the agreements at issue, Lundbeck and Merck (GUK) had agreed not to compete on the citalopram market during a certain period, to the detriment of consumers who could have benefited from generic medicines at a much lower price if those medicines had entered the market. In paragraphs 285 to 291 of the judgment under appeal, the General Court further held that, in relation to characterising the agreements at issue as 'restrictions by object', account should be taken of the fact that the reverse payments made by Lundbeck to Merck (GUK) corresponded, in Merck (GUK)'s view, to the profits that it estimated it would be able to obtain by entering the citalopram market with its generic products and that, in the absence of plausible alternative explanations, it was principally the size of the reverse payment to Merck (GUK) which had induced Merck (GUK) to accept the limits on its conduct and not the existence of Lundbeck's process patents or even the desire to avoid the costs of potential litigation, which the General Court reiterated in paragraph 304 of the judgment under appeal in the context of the rejection of the fourth plea for annulment.

69 To reject the fifth plea for annulment, the General Court held, in paragraphs 345 and 346 of the judgment under appeal, that, as regards the UK agreement, the Commission's error as to the scope of that agreement was of no consequence since that agreement, even if it were assumed that it did not go beyond the scope of Lundbeck's process patents, continued to restrict competition by object in so far as it had, in any event, 'transformed the uncertainty regarding the outcome of any infringement actions into the certainty that Merck (GUK) would not enter the market with its generic products during the term of that agreement, whereas the limitations on Merck (GUK)'s commercial autonomy arose not exclusively from an evaluation, by the parties to [that] agreement, of Lundbeck's [process] patents, but rather from the size of the reverse payment which, in such a case, overshadowed that evaluation and induced Merck (GUK) not to pursue its efforts to enter the market'. As regards the EEA agreement, the General Court first found, in paragraphs 352 to 366 of the judgment under appeal, that the Commission had not erred as to its scope. The General Court then noted, in paragraph 374 of the judgment under appeal, that it was at the very least doubtful that the objective of the agreements at issue was to settle a patent dispute while finding, in its response to the seventh plea for annulment and more particularly in paragraph 390 of the judgment under appeal, that the Commission had not erred in concluding that Merck (GUK) had an anticompetitive intention in concluding the agreements at issue.

70 Finally, in response to the eighth plea in law relied on in support of the action for annulment, alleging an error of fact by the Commission in its findings regarding the amount and purpose of the transfer of value between Lundbeck and Merck (GUK), the General Court found, in particular, in paragraphs 400, 406, 412 and 413 of the judgment under appeal, first, that the payments made to Merck (GUK), totalling GBP 9.65 million, under the UK agreement, had not been made in consideration for distribution services but rather by way of compensation for the profits that Merck (GUK) considered it would be able to achieve if it marketed its generic citalopram and in exchange for Merck (GUK)'s commitments under the UK agreement, and, second, that, of the GBP 3 million paid to Merck (GUK) in exchange for its commitment to deliver all its generic citalopram products to Lundbeck, GBP 2 million, paid in exchange for its commitment not to enter the market, was a net profit for Merck (GUK).

Arguments of the parties

71 By its first ground of appeal, which comprises seven parts, Merck claims that the General Court erred in law in finding that the patent settlement agreements constituted 'restrictions of competition by

object', with no regard for the judgment of 11 September 2014 (*CB* v *Commission*, C-67/13 P, EU:C:2014:2204).

72 As a preliminary point, Merck submits, first, that the concept of 'restriction by object' must be interpreted restrictively, in so far as that concept provides predictability and therefore legal certainty for undertakings, is a source of procedural economy for the competition authorities, has a deterrent effect and contributes to the prevention of anticompetitive conduct. Therefore, according to Merck, agreements which have ambivalent effects on the market cannot be characterised in that way, if the condemnation of benign agreements which have not been demonstrated to have negative effects on competition is to be avoided. Merck further submits that, in order to characterise an agreement as a 'restriction by object', experience is important, as is apparent in particular from paragraph 51 of the judgment of 11 September 2014, *CB* v *Commission* (C-67/13 P, EU:C:2014:2204), from paragraph 21 of the Commission Guidelines on the application of Article [101](3) TFEU, referred to in paragraph 4 of the present judgment, and from the case-law of the Supreme Court of the United States. Therefore, when a practice is scrutinised for the first time, the competition authorities may not use the shortcut of 'restriction by object', at least where the effects of that agreement on competition are unclear or depend on new analysis which remains to be established. Finally, in accordance with paragraphs 56 and 69 of the judgment of 11 September 2014, *CB* v *Commission* (C-67/13 P, EU:C:2014:2204), Merck argues that practices which have merely potential effects on competition cannot be characterised as a 'restriction by object', in so far as they do not reveal a sufficient degree of harm, since they are solely capable of restricting competition but do not actually restrict it, nor, a fortiori, in a manner which is clear, as is apparent from paragraph 22 of the judgment of 26 November 2015, *Maxima Latvija* (C-345/14, EU:C:2015:784).

73 Second, Merck submits that the correct approach to assessing whether written agreements reveal a sufficient degree of harm to competition must focus principally on the wording of those agreements, in accordance with paragraph 65 of the judgment of 11 September 2014, *CB* v *Commission* (C-67/13 P, EU:C:2014:2204), and must attach only limited significance to the legal and economic context, the analysis of which must not be confused with the full analysis of the effects of those agreements, as confirmed by points 41 and 44 of the Opinion of Advocate General Wahl in *CB* v *Commission* (C-67/13 P, EU:C:2014:1958). However, Merck maintains that the General Court did not consider whether the wording of the agreements at issue revealed a sufficient degree of harm to competition.

74 By the first part of the first ground of appeal, which concerns paragraphs 185 to 192 and 208 to 212 of the judgment under appeal, Merck submits that, in order to characterise the agreements at issue as a 'restriction by object', the General Court erred in failing to take sufficient account of the wording of those agreements. Merck submits that the General Court also erred in denying the fact that experience of agreements of the same type as the agreements at issue is a relevant consideration. In Merck's view, prior to the decision at issue, there was no experience in Europe in the field of patent settlement agreements, as the Commission itself found in 2004, and as is apparent from the Danish Competition Authority press release. Furthermore, Merck maintains that the General Court circumvented the need to rely on experience by relying, in paragraph 212 of the judgment under appeal, on the individual and detailed examination of the agreements at issue.

75 By the second part of the first ground of appeal, Merck submits that the General Court did not adopt the correct approach in order to determine whether the patent settlement agreements revealed a sufficient degree of harm to competition. According to Merck, the General Court should have examined the wording of the agreements at issue in order to determine whether they revealed a sufficient degree of harm to competition. In that regard, it is apparent from a summary analysis of the agreements at issue that Merck (GUK)'s non-deployment of citalopram had to be understood in the context of a patent infringement dispute between the parties. In that context, Merck argues that the agreements at issue did not reveal a sufficient degree of harm to competition, since, if Merck (GUK)'s citalopram infringed Lundbeck's process patents, its non-deployment would not restrict competition. However, in Merck's view, the General Court relied on matters which were extraneous to the agreements at issue themselves, in the present case the sector inquiry carried out by the Commission and a new theory of harm concerning reverse payments. Accordingly, Merck maintains that the agreements at issue could not have a negative effect on competition, without consideration of the legal and economic context of those agreements, as occurred in the cases giving rise to the judgments of

25 February 1986, *Windsurfing International* v *Commission* (193/83, EU:C:1986:75) and of 6 December 2012, *AstraZeneca* v *Commission* (C-457/10 P, EU:C:2012:770), in which the examination of the context permitted the finding that there was no dispute between the parties. In Merck's view, that is not so in the present case. According to Merck (GUK), the dispute between it and Lundbeck was 'genuine', since (i) Lundbeck was the holder of the patent protecting the crystallisation process as regards the United Kingdom, which was lawfully registered, (ii) Lundbeck pursued an aggressive general strategy towards manufacturers of generic medicines, (iii) Lundbeck could have obtained interim relief to prevent Merck (GUK) from entering the market and (iv) there was no certainty regarding the outcome of litigation, as is apparent from paragraphs 123, 125, 242, 250 and 261 of the judgment under appeal. Therefore, Merck's view is that it cannot be presumed with the necessary degree of certainty that the agreements at issue harm competition. In addition, Merck states that the General Court itself recognised that the agreements at issue may have had the objective of avoiding the uncertainties of potential litigation.

76 By the third part of the first ground of appeal, which concerns paragraphs 210 and 239 to 251 of the judgment under appeal, Merck submits that the General Court erred in law in finding that the agreements at issue revealed a sufficient degree of harm to competition on the ground that they were equivalent to market exclusion agreements, similar to the agreement 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 concerned a straightforward market exclusion agreement. However, in Merck's view, the facts of that case are not comparable to the facts of the present case since, as the General Court acknowledged in paragraph 245 of the judgment under appeal, Lundbeck held process patents allowing it to prevent the market entry of infringing products.

77 By the fourth part of the first ground of appeal, which concerns paragraph 250 of the judgment under appeal, Merck maintains that the General Court erred in law in finding that the patent settlement agreements reveal a sufficient degree of harm to competition on the ground that they avoid litigation the outcome of which is uncertain. According to Merck, that approach, first, is based on an assumption of such agreements' potential effects on competition and not on the observation of actual effects, which are dependent on the outcome of the litigation, which the Court of Justice expressly refused to take into consideration to find a 'restriction by object', and, second, is contradicted by point 209 of the 2004 Guidelines on technology transfer agreements and undermines legal certainty. Merck adds that the General Court's statement, in paragraph 248 of the judgment under appeal, that an agreement is not exempt from competition law solely because it concerns a patent or is intended to put an end to a dispute relating to a patent is not sufficient to justify the agreements at issue being characterised as a 'restriction by object'. Similarly, the statement in paragraph 225 of the judgment under appeal that the Commission may not refrain from taking any action where the scope of the patent is relevant for the purposes of determining whether there has been an infringement of Articles 101 and 102 TFEU, cannot, in Merck's view, justify the Commission's *ex ante* approach based on the parties' subjective perception of the patent concerned at the time the agreement concerned was concluded, since those two aspects are unrelated.

78 By the fifth part of the first ground of appeal, which concerns paragraphs 285 to 290 and paragraphs 345 and 346 of the judgment under appeal, Merck criticises the General Court for having considered that the payment made by Lundbeck to Merck (GUK) was one of the principal elements to be taken into account in establishing that there was a 'restriction by object', overshadowing the assessment of patent strength, and had induced Merck (GUK) not to enter the market. First, Merck argues that even if that payment had induced Merck (GUK) to conclude the agreements at issue, the terms of those agreements cannot be presumed to be anticompetitive since they may have had no impact on competition. Second, in its view, taking account of the context in which the payment was made, as is apparent from paragraph 285 of the judgment under appeal, cannot remedy the failure actually to identify an anticompetitive objective. Third, Merck submits that the assumption that a 'disproportionate' payment is a sign of a patent's weakness is directly contradicted by the General Court's own finding, in paragraphs 287 and 288 of that judgment, that the asymmetry of risks between the parties to the agreements may lead the manufacturer of originator medicines, in certain cases, to make a reverse payment in order to avoid a risk, even if minimal, that generics enter the market, even where the patent it holds is strong. Accordingly, Merck maintains that the assessment could involve factual considerations and economic factors which can form no part of a contextual assessment, which

explains why the Supreme Court of the United States rejected the presumption on which the 'per se' and 'quick look' analyses are based, in relation to reverse payments, taking into account the complexities associated with reverse payments, despite considerable earlier case-law to the contrary.

79 By the sixth part of the first ground of appeal, which concerns paragraphs 198 to 292 of the judgment under appeal, Merck complains that the General Court relied on 'several other factors' to support its finding that there was a restriction by object, namely the fact that the payments – defined as payments corresponding to the profit anticipated by Merck – were disproportionate; the fact that the agreements at issue did not provide for the entry of generics on the market after their expiry; the presence of restrictions going beyond the scope of Lundbeck's process patents, all of which are extraneous to the wording of the agreements at issue and go beyond the mere consideration of the context, thus disregarding the principles set out in the judgment of 11 September 2014, *CB* v *Commission* (C-67/13 P, EU:C:2014:2204). In addition, Merck submits that the approach adopted by the General Court, which at times is based on a series of factual considerations, and at other times is based on the essential matters of the payment and the elimination of uncertainty concerning possible litigation, means it is not possible to identify whether the settlement agreements as such constitute 'restrictions by object', and leads to the conclusion that an assessment of their effects is necessary.

80 By the seventh part of the first ground of appeal, which concerns paragraphs 352 to 366 of the judgment under appeal, Merck complains that the General Court erred in law in finding that the EEA agreement exceeded, in law or in fact, the scope of Lundbeck's process patents. Accordingly, Merck submits that 'the contractual construction of the agreements at issue as to scope' should not have been taken into consideration when the General Court characterised them as a 'restriction by object'.

81 The Commission maintains that the first ground of appeal must be rejected.

Findings of the Court

82 By the seventh part of its first ground of appeal, Merck disputes the General Court's assessment of the scope of the EEA agreement and, consequently, its assessment of the facts and evidence.

83 As has been pointed out in paragraph 50 of the present judgment, such a challenge is inadmissible at the appeal stage, except where the clear sense of the facts and evidence has been distorted, which, in the present case, is neither alleged nor, a fortiori, demonstrated.

84 As regards the other parts of the present ground of appeal, it must be recalled, as the General Court stated in paragraphs 186 and 187 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).

85 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).

86 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).

87 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).

88 It follows from the foregoing that the characterisation of agreements, such as the agreements at issue, as a 'restriction by object' presupposes, as is 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 of which they form part, 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).

89 Accordingly, contrary, in essence, to Merck's submissions, in particular in relation to its preliminary observations and the first, second and sixth parts of the present ground of appeal, an agreement may not be characterised as a 'restriction by object' principally or, a fortiori, exclusively in the light of the wording of that agreement, even where that wording may be a significant factor in that regard.

90 In addition, contrary to Merck's submissions, the need to analyse the agreements at issue for the purposes of characterising them is not such as to preclude characterisation as a 'restriction by object', which is therefore not reserved solely for agreements which prima facie, or solely in the light of their wording, reveal a sufficient degree of harm to competition.

91 Similarly, the fact that a particular agreement may fall within a more general category of agreements which, as the General Court pointed out in paragraph 195 of the judgment under appeal, were considered by the Commission in particular, not to be characterised as a 'restriction by object', or not even to involve any difficulties in terms of competition law, cannot preclude the characterisation of a particular agreement as a 'restriction by object'.

92 Contrary to Merck's assertions in relation to the fifth part of the present ground of appeal, characterisation as a 'restriction by object' does not require that parties to those agreements pursue an anticompetitive objective, even though such an objective may nevertheless be taken into consideration, as has been stated in paragraph 84 of the present judgment.

93 In the present case, it is apparent from paragraphs 249, 250, 261, 285, 304, 374 and 390 of the judgment under appeal, first, that the agreements at issue, which did not have the objective of settling a patent dispute, but rather had the objective of avoiding competition on the citalopram market, induced Merck (GUK) not to enter the market with its generic medicines during the term of those agreements in return for significant reverse payments by Lundbeck, corresponding, according to Merck (GUK), to the profit it believed it could obtain by entering the market and, second, that their effect was to transform the uncertainty existing at the time those agreements were concluded regarding the outcome of any infringement actions brought by Lundbeck if Merck (GUK) were to enter the market into the certainty that Merck (GUK) would not enter the market with its generic medicines, to the detriment of consumers who could otherwise have benefited from generic medicines at a much lower price.

94 In addition, in rejecting the eighth plea for annulment, which is not the subject of dispute in the present appeal, the General Court rejected all Merck's arguments that the payments made by Lundbeck to Merck (GUK) were objectively justified. To that end, the General Court found, in particular, in paragraphs 400 and 406 of the judgment under appeal, that the payments totalling GBP 9.65 million provided for by the UK agreement were not made in consideration for distribution services, but rather in exchange for Merck (GUK)'s commitments under that agreement. As regards the GBP 3 million

paid by Lundbeck to Merck (GUK) for the purchase of the stock of generic citalopram tablets under the UK agreement, the General Court also considered, in paragraphs 412 and 413 of that judgment, that of that GBP 3 million, GBP 2 million constituted a profit for Merck (GUK), which had not, furthermore, adduced evidence to the contrary.

95 In the light of those findings of fact and there being no need to determine whether the General Court was fully entitled, in paragraphs 210 and 239 to 251 of the judgment under appeal, to treat the agreements at issue as market exclusion agreements or agreements similar to those 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) nor to assess whether the General Court, in paragraphs 272 and 273 of the judgment under appeal, correctly interpreted the judgment of the Supreme Court of the United States of 17 June 2013, *Federal Trade Commission* v *Actavis* [570 U.S. (2013)], it must be stated that the General Court made no error of law in finding that the agreements at issue constituted a 'restriction by object' within the meaning of Article 101(1) TFEU.

96 That finding cannot be called in question by the arguments put forward by Merck.

97 First, Merck cannot reasonably rely, as it does within the first part of the present ground of appeal, on the fact that the experience required by case-law in order to characterise an agreement as a 'restriction by object' was lacking in the present case.

98 In that regard, as the General Court was fully entitled to observe in paragraph 212 of the judgment under appeal, it is in no way necessary that agreements of the same type as the agreements at issue have already been censured by the Commission in order for the agreements at issue to be capable of being considered to be a restriction of competition by object, even if they occur in a specific context such as that of intellectual property rights.

99 As noted in paragraph 88 of the present judgment, in order for a given agreement to be characterised as a 'restriction by object', all that matters are the specific characteristics of that agreement (see, to that effect, judgment of 30 January 2020, *Generics (UK) and Others*, C-307/18, EU:C:2020:52, paragraphs 84 and 85), from which must be inferred the potential harmfulness of that agreement for competition, where necessary as a result of a detailed analysis of that agreement, its objectives and the economic and legal context of which it forms part.

100 As has been stated in paragraph 93 of the present judgment, the agreements at issue, which enabled Merck (GUK)'s market entry to be delayed and which provided for payments by Lundbeck to Merck (GUK) which, by their size, induced Merck (GUK) not to pursue its efforts to enter the market, belong to the category of practices which are particularly harmful to competition.

101 Second, Merck cannot, within the fourth part of the present ground of appeal, complain that the General Court took account, in order to characterise the agreements at issue as a 'restriction by object', of the perception of the parties to those agreements of the strength of Lundbeck's process patents.

102 The General Court was fully entitled to take account of the parties' perception, at the time the agreements at issue were concluded, of the strength of those patents and of the likelihood of those parties succeeding in the event of litigation, in accordance with the principle that evidence may be freely adduced under EU law (judgment of 27 April 2017, *FSL and Others* v *Commission*, C-469/15 P, EU:C:2017:308, paragraph 38 and the case-law cited) and in paragraph 26 of the judgment of 25 February 1986, *Windsurfing International* v *Commission* (193/83, EU:C:1986:75), as the General Court stated in paragraph 231 of the judgment under appeal.

103 Furthermore, it must be stated that taking account of the perception by the parties to the agreements at issue of Lundbeck' process patents is a factor which is entirely relevant in order to establish whether, as Merck submitted in the context of the first part of its second plea for annulment, the Commission had failed to have proper regard to the fact that Lundbeck held a patent protecting the crystallisation process as regards the United Kingdom.

104 Third, Merck errs in criticising the General Court, in the context of its preliminary observations and of the second and fourth parts of the present ground of appeal, for having characterised the agreements at

issue as a 'restriction by object' on the basis of presumed anticompetitive effects and not on the actual effects of those agreements, on the ground, in essence, that those agreements did not have effects which went beyond Merck (GUK) failing to place its generic citalopram on the market.

105 That line of argument is based on a premiss upon which Merck relies repeatedly but which is nevertheless incorrect, namely that it had been established, on the date the agreements at issue were concluded, that Merck (GUK) was infringing Lundbeck's process patents. As the General Court stated in paragraphs 242, 250 and 261 of the judgment under appeal, on that date, both Lundbeck and Merck (GUK) had doubts as to the validity of those patents, which was precisely what led them to conclude the agreements at issue.

106 Therefore, on the date the agreements at issue were concluded, and as follows from the rejection of the second ground of appeal, Merck (GUK) and Lundbeck were potential competitors, but those agreements lessened, if not eliminated, that potential competition, at least for the duration of those agreements, thereby allowing Lundbeck to maintain high prices for its originator medicine and to ensure more favourable conditions for the launch of its new medicine, as the General Court stated in paragraph 247 of the judgment under appeal.

107 Fourth, Merck cannot reasonably maintain, as it does in the context of the second and fifth parts of the present ground of appeal, that characterising the agreements at issue as a 'restriction by object' should have been ruled out on the ground that they pursued a legitimate objective, namely the avoidance of litigation, or even sought to address the asymmetry of risks between the patent holder and the manufacturers of generic medicines.

108 As regards, first, the argument that those agreements sought to avoid litigation intended to defend Lundbeck's process patents, it should be recalled, as the General Court was fully entitled to mention, in essence, in paragraphs 248 and 289 of the judgment under appeal, that, while the conclusion by the holder of a patent with a party allegedly infringing that patent of a settlement agreement that does not exceed the scope and duration of remaining validity of the patent does constitute an expression of the intellectual property right of its holder, which permits that holder, inter alia, to oppose any infringement, the fact remains that that patent does not permit its holder to enter into contracts that are contrary to Article 101 TFEU (judgment of 30 January 2020, *Generics (UK) and Others*, C-307/18, EU:C:2020:52, paragraph 97).

109 It is true that such an assertion does not, as such, justify characterising a concerted practice as a 'restriction by object', as Merck correctly submits. However, where that assertion is accompanied, as in the present case, by a demonstration that that practice reveals a sufficient degree of harm to competition, it may legitimately enable the General Court to reject the argument that characterisation as a 'restriction by object' must be ruled out on the ground that the agreements concerned constitute patent settlement agreements.

110 As regards, second, the argument that the agreements at issue reflect the fact, referred to by the General Court in paragraph 288 of the judgment under appeal, that the damages which may be sought by manufacturers of originator medicines in the event of unlawful market entry of generic medicines are often substantially lower than the harm suffered by the former, it should be recalled that it is for public authorities and not private undertakings to ensure compliance with statutory requirements (judgment of 30 January 2020, *Generics (UK) and Others*, C-307/18, EU:C:2020:52, paragraph 88).

111 Consequently, it is unacceptable for undertakings to attempt to mitigate the effects of legal rules which they regard as excessively unfavourable by entering into restrictive arrangements intended to offset those disadvantages on the pretext that those rules have created an imbalance detrimental to them.

112 Accordingly, the circumstances referred to by Merck cannot legitimise an infringement of Article 101 TFEU, let alone a concerted practice which has been found to reveal a sufficient degree of harm to competition to be characterised as a 'restriction by object'.

113 Fifth, Merck cannot reasonably claim that the General Court acted contrary to point 209 of the 2004 Guidelines on technology transfer agreements, since those guidelines do not apply to the agreements at issue, Merck having failed to demonstrate before the General Court, as the General Court was fully

entitled to point out in paragraph 112 of the judgment under appeal, or before the Court of Justice, that those agreements provide for licensing of technology rights.

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

The third ground of appeal

The relevant paragraphs of the judgment under appeal

115 In paragraphs 491 to 521 of the judgment under appeal, the General Court rejected the thirteenth plea relied on by Merck in support of its action for annulment, alleging an error of assessment by the Commission as regards the penalties imposed on Merck (GUK).

116 To that end, the General Court first rejected the complaint alleging that the Commission lacked competence to impose a fine in the instant case, stating as follows:

> '501 According to the case-law, it is not necessary that [Merck] was actually aware that it was infringing Article 101(1) TFEU by concluding the agreements at issue in order to find that the infringement was committed deliberately or negligently, within the meaning of the first [subparagraph] of Article 23(2) of Regulation No 1/2003; rather, it must be determined whether, in view of the content of the agreements, their legal and economic context and the conduct of the parties, the parties were aware or ought to have been aware of the fact that the restrictions imposed by those agreements were liable to affect trade between Member States. In other words, the condition laid down in the first subparagraph of Article 23(2) of Regulation No 1/2003 is satisfied when 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, judgments of 8 November 1983[,]*IAZ International Belgium and Others* v *Commission*, 96/82 to 102/82, 104/82, 105/82, 108/82 and 110/82, … EU:C:1983:310, paragraph 45; of 9 November 1983[,] *Nederlandsche Banden-Industrie-Michelin* v *Commission*, 322/81, … EU:C:1983:313, paragraph 107; and [of 18 June 2013,] *Schenker & Co. and Others*, … [C-681/11], EU:C:2013:404, paragraph 37).
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> 502 In the present case, the Commission correctly noted, in recitals 1312 and 1313 of the [decision at issue], that a literal reading of Article 101(1) TFEU made it clear that agreements between competitors for the exclusion of some of them from the market were illegal. The fact that, in the present case, the agreements at issue were concluded in the form of settlement agreements concerning intellectual property rights cannot allow [Merck] to infer that their unlawfulness in the light of competition law was completely unforeseeable.
>
> 503 It can be seen from recital 190 of the [decision at issue], for example, that, when Lundbeck proposed the same type of agreement to NM Pharma [Merck (GUK)'s distributor for Sweden], the latter stated that it could not engage in discussion on the topic due to its code of conduct and its antitrust policy. Likewise, it can be seen from recital 265 of the [decision at issue] that – reacting to an email sent to Merck (GUK) on 18 January 2002 indicating the estimated profits that would be made if Merck (GUK) purchased Lundbeck citalopram – a Lundbeck employee commented that he "strongly disagree[d] with the content of this email … [since] this [was] illegal".
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> 504 Likewise, it is not necessary, in order to establish an infringement of Article 101(1) TFEU, that the Commission show that the same types of practices or agreements have already been censured in relation to Article 101(1) TFEU, since it was already sufficiently established at the time the agreements at issue were concluded that the exclusion of actual or potential competitors from the market constituted a restriction of competition by object (paragraphs 456 to 463 [of the judgment under appeal).'

117 The General Court went on to reject the complaint alleging breach of the principle that criminal offences and penalties must have a proper legal basis (*nullum crimen, nulla poena sine lege*) on the basis of a statement of reasons which is not the subject of dispute in the present appeal and the

complaint alleging that there were exceptional circumstances justifying solely the imposition of a symbolic fine.

118 In that regard, it held as follows:

> '519 It must … be noted that, even assuming that [the 2004 Notice on informal guidance and in particular point 4 of such notice] could be binding on the Commission in the same way as its guidelines (see, to that effect, judgment of 11 July 2013[,] *Ziegler* v *Commission*, C-439/11 P, …, EU:C:2013:513, paragraphs 59 and 60 and the case-law cited), it was adopted and published in the *Official Journal of the European Union* only in 2004, that is to say, after the expiry of the agreements at issue. [Merck] therefore cannot rely on that guidance in order to claim that it could not have foreseen, when it concluded the agreements at issue, that anything more than a symbolic fine would be imposed on it (see, to that effect, *Deltafina* v *Commission*, T-29/05, … EU:T:2010:355, paragraph 430).
>
> 520 In any event, it was sufficiently established in practice and in the case-law that conduct aimed at excluding competitors from the market constituted a restriction of competition within the meaning of Article 101(1) TFEU (paragraphs 185 to 188 and 512 of the judgment under appeal]).'

Arguments of the parties

119 By its third ground of appeal, which concerns paragraphs 499 to 521 of the judgment under appeal, Merck complains that the General Court erred in law in upholding the amount of the fine imposed by the Commission on the ground that Merck (GUK) could not have been unaware of the anticompetitive nature of its conduct. According to Merck, it is necessary to determine whether Merck (GUK) could not have been unaware that the agreements at issue would be treated as market exclusion agreements. Merck argues that Merck (GUK) was unaware that that was the case. In addition, Merck argues that the Commission itself was not certain that the agreements at issue restricted competition, as is apparent from paragraph 254 of the judgment under appeal, which led it to initiate an in-depth inquiry. Finally, according to Merck, the General Court could not use the fact that Lundbeck took the view that its conduct might be unlawful as an argument against Merck (GUK).

120 In the alternative, Merck submits that the General Court also erred in concluding that the Commission was entitled to impose a more than symbolic fine since, in point 4 of the 2004 Notice on informal guidance, the Commission stated that it imposed such fines only in cases where it is established that a certain behaviour constitutes an infringement. However, Merck submits that is not the case as regards reverse payments.

121 The Commission contends that the third ground of appeal is unfounded.

Findings of the Court

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

123 It follows that punishing conduct covered in particular by Article 101(1) TFEU in no way presupposes that the undertakings concerned intended to infringe those competition rules. All that matters is knowing whether, objectively, they could, where necessary by taking appropriate advice (see, to that effect, judgment of 28 June 2005, *Dansk Rørindustri and Others* v *Commission*, C-189/02 P, C-202/02 P, C-205/02 P to C-208/02 P and C-213/02 P, EU:C:2005:408, paragraph 219), determine whether their conduct was anticompetitive.

124 Consequently, and contrary to the General Court's finding in paragraph 501 of the judgment under appeal, the question is not whether the person committing the infringement in question was aware or ought to have been aware of the fact that the restrictions imposed by the agreements concerned were liable to infringe the competition rules of the Treaty.

125 Nonetheless, in paragraph 502 of the judgment under appeal, the General Court was fully entitled to find that the wording of Article 101(1) TFEU objectively made it clear that agreements could be regarded as unlawful, notwithstanding the fact that there was no precedent at the date on which those agreements were concluded, as the Court of Justice has already stated, in essence, in paragraph 100 of the present judgment.

126 To that effect, the General Court stated, again correctly, in paragraph 503 of the judgment under appeal, that the fact that it was foreseeable that the agreements at issue infringed competition law followed, first, from the fact that a manufacturer of generic medicines had refused to enter into agreements similar to the agreements at issue due to its antitrust policy and, second, from the fact that an employee of Lundbeck had strongly disapproved of the steps taken prior to the agreements at issue, on the ground that they were unlawful.

127 Accordingly, the conclusion reached by the General Court in paragraphs 502 and 503 of the judgment under appeal is consistent with the case-law referred to in paragraph 122 of the present judgment.

128 Nor can that conclusion be criticised on the ground that the Commission itself was not certain that the agreements at issue restricted competition.

129 As stated by the General Court in paragraphs 267 and 268 of the judgment under appeal – as support for its rejection of the pleas for annulment concerning infringement of Article 101(1) TFEU on the ground that the agreements at issue were characterised as 'restrictions by object' – the Commission's doubts referred to by Merck, apart from the fact that they resulted only from a preliminary assessment, were not expressed in a press release issued directly by the Commission or by its services, but rather were expressed in a press release issued by a national competition authority, which could not cause undertakings to entertain a legitimate expectation that their conduct did not infringe Article 101 TFEU.

130 In addition, it is apparent from the same paragraphs of the judgment under appeal that the Danish Competition Authority had stated in its press release that the Commission's doubts concerned, in particular, the size of the payments made by Lundbeck and that any agreement whose object was to pay to exclude a competitor from the market was anticompetitive.

131 Finally, the finding set out in paragraph 127 of the present judgment cannot reasonably be criticised on the ground that, in order to determine that Merck could not have been unaware of the anticompetitive nature of its conduct, the General Court could not rely on documents establishing that Lundbeck considered that its conduct might be unlawful.

132 As the General Court acknowledged, in essence, in paragraph 503 of the judgment under appeal, which it was fully entitled to do, and as was held by the Court of Justice in paragraph 164 of the judgment delivered on today's date in Case C-591/16 P, *Lundbeck* v *Commission*, the perception which a contractual partner or a potential contractual partner has of whether an agreement is unlawful is a factor which is entirely capable of substantiating the finding that it, like its contractual partner, could not be unaware of the anticompetitive nature of their agreement.

133 As regards the second part of the present ground of appeal, suffice it to state, as the General Court did, in essence, in paragraph 520 of the judgment under appeal, that the agreements at issue, which did not seek to settle a patent dispute, allowed the market entry of a manufacturer of generic medicines to be delayed and provided that Lundbeck would make payments to Merck (GUK), which, by their size, induced the latter not to pursue its efforts to enter the market, constituted 'restrictions of competition by object' and therefore a fortiori constituted 'restrictions of competition' within the meaning of Article 101(1) TFEU, allowing the Commission to penalise them, without departing from point 4 of the 2004 Notice on informal guidance.

134 In view of the foregoing, the third ground of appeal must be rejected as being unfounded. Consequently, the appeal must be dismissed in its entirety.

Costs

135 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.

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

137 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.

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

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

1. **Dismisses the appeal;**

2. **Orders Merck KGaA to bear its 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.