JUDGMENT OF THE COURT (Fourth Chamber)

25 March 2021 (*)

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

In Case C−591/16 P,

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

H. Lundbeck A/S, established in Valby (Denmark),

Lundbeck Ltd, established in Milton Keynes (United Kingdom),

represented initially by R. Subiotto QC and T. Kuhn, Rechtsanwalt, and subsequently by R. Subiotto QC,

appellants,

the other parties to the proceedings being:

European Commission, represented by F. Castilla Contreras, T. Vecchi, B. Mongin and C. Vollrath, acting as Agents, B. Rayment and D. Bailey, Barristers, and 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, J. Turner QC, J. Holmes QC and M. Demetriou QC and T. Sebastian, Barrister, and subsequently by D. Guðmundsdóttir, acting as Agent, J. Turner QC, J. Holmes QC and M. Demetriou QC and T. Sebastian, Barrister,

intervener in the appeal,

European Federation of Pharmaceutical Industries and Associations (EFPIA), established in Geneva (Switzerland), represented by F. Carlin, Barrister, and N. Niejahr, Rechtsanwältin,

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,

after hearing the Opinion of the Advocate General at the sitting on 4 June 2020,

gives the following

Judgment

1 By their appeal, H. Lundbeck A/S and Lundbeck Ltd ask the Court of Justice to set aside the judgment of the General Court of the European Union of 8 September 2016, *Lundbeck* v *Commission* (T−472/13, EU:T:2016:449; 'the judgment under appeal'), by which the General Court dismissed their action seeking, first, annulment in part of Commission Decision C(2013) 3803 final of 19 June 2013 relating to a proceeding under Article 101 [TFEU] and Article 53 of the EEA Agreement (Case AT/39226 – Lundbeck) (the decision at issue') and, second, reduction of the amount of the fines imposed on them by that decision.

Legal context

Regulation (EC) No 1/2003

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

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

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

The 2006 Guidelines on the method of setting fines

3 Points 6, 13 and 22 of the Guidelines on the method of setting fines imposed pursuant to Article 23(2)(a) of Regulation No 1/2003 (OJ 2006 C 210, p. 2; 'the 2006 Guidelines'), state as follows:

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

…

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

…

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

The 2014 Guidelines on technology transfer agreements

4 Point 29 of the Guidelines on the application of Article 101 [TFEU] to technology transfer agreements (OJ 2014 C 89, p. 3; 'the 2014 Guidelines') reads as follows:

'In principle, the parties to an agreement are not considered competitors if they are in a one-way or two-way blocking position. A one-way blocking position exists where a technology right cannot be exploited without infringing upon another valid technology right, or where one party cannot be active in a commercially viable

way on the relevant market without infringing the other party's valid technology right. This is, for instance, the case where one technology right covers an improvement of another technology right and the improvement cannot be legally used without a licence of the basic technology right. A two-way blocking position exists where neither technology right can be exploited without infringing upon the other valid technology right or where neither party can be active in a commercially viable way on the relevant market without infringing the other party's valid technology right and where the parties thus need to obtain a licence or a waiver from each other. However, in practice there will be cases where there is no certainty whether a particular technology right is valid and infringed.'

Background to the dispute and the decision at issue

5 The present appeal is one of six related appeals brought against six judgments of the General Court that were delivered following actions for annulment brought against the decision at issue, namely, in addition to the present appeal: the appeal lodged in Case C−586/16 P (*Sun Pharmaceutical Industries and Ranbaxy (UK)* v *Commission*) against the judgment of 8 September 2016, *Sun Pharmaceutical Industries and Ranbaxy (UK)* v *Commission* (T−460/13, not published, EU:T:2016:453); the appeal lodged in Case C−588/16 P (*Generics (UK)* v *Commission*) against the judgment of 8 September 2016, *Generics (UK)* v *Commission* (T−469/13, not published, EU:T:2016:454); the appeal lodged in Case C−601/16 P (*Arrow Group and Arrow Generics* v *Commission*) against the judgment of 8 September 2016, *Arrow Group and Arrow Generics* v *Commission* (T−467/13, not published, EU:T:2016:450); the appeal lodged in Case C−611/16 P (*Xellia Pharmaceuticals and Alpharma* v *Commission*) against the judgment of 8 September 2016, *Xellia Pharmaceuticals and Alpharma* v *Commission* (T−471/13, not published, EU:T:2016:460), and the appeal lodged in Case C−614/16 P (*Merck* v *Commission*) against the judgment of 8 September 2016, *Merck* v *Commission* (T−470/13, not published, EU:T:2016:452).

6 The background to the dispute was set out in paragraphs 1 to 75 of the judgment under appeal as follows:

'*I – The companies involved in the present case*

1. H. Lundbeck A/S … is a company governed by Danish law which controls a group of companies, including Lundbeck Ltd, established in the United Kingdom, 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. [H. Lundbeck] is an "originator" undertaking, namely an undertaking whose activities are focused on researching new medicinal products and bringing them to the market.

3. Merck KGaA ("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.

4. The Commission regarded Merck and GUK as constituting a single undertaking for the purpose of competition law at the time of the infringements ("Merck (GUK)").

5. Arrow Group A/S, which was renamed Arrow Group ApS in August 2003 (hereinafter referred to without distinction as "Arrow Group"), is a company governed by Danish law at the head of a group of companies, present in several Member States, which since 2001 has been active in the development and sales of generic medicinal products.

6. Arrow Generics Ltd is a company incorporated in the United Kingdom, a subsidiary owned at first as to 100% and then, from February 2002, as to 76% by Arrow Group.

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

controlled by Arrow Group.

8. The Commission regarded Arrow Group, Arrow Generics Ltd and Resolution Chemicals Ltd as constituting a single undertaking ("Arrow") at the time of the infringements.

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

10. Alpharma ApS was a company governed by Danish law indirectly controlled as to 100% by Alpharma Inc. It had a number of subsidiaries in the [EEA]. Following a number of company restructurings, on 31 March 2008 Alpharma ApS became Axellia Pharmaceuticals ApS, renamed Xellia Pharmaceuticals ApS … in 2010.

11. The Commission regarded Alpharma Inc., A.L. Industrier AS and Alpharma ApS as constituting a single undertaking ("Alpharma") at the time of the infringements.

12. Ranbaxy Laboratories Ltd is a company governed by Indian law specialising in the development and production of APIs and generic medicinal products.

13. Ranbaxy (UK) Ltd is a company governed by English law and a subsidiary of Ranbaxy Laboratories and is responsible for the sale of the latter's products in the United Kingdom.

14. The Commission regarded Ranbaxy Laboratories Ltd and Ranbaxy (UK) Ltd as constituting a single undertaking ("Ranbaxy") at the time of the infringements.

II – The relevant product and the applicable patents

15. The relevant product for the purposes of the present case is the antidepressant medicinal product containing the API known as citalopram.

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

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

18. Over time, [H. 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) [("Lundbeck's new process patents")].

19. In particular, first, in 1998 and in 1999 [H. Lundbeck] applied to the EPO for two patents relating to the production of citalopram by processes using iodo and amide, respectively. The EPO granted [H. Lundbeck] a patent protecting the process using amide … on 19 September 2001 and a patent protecting the process using the iodo … on 26 March 2003.

20. Secondly, on 13 March 2000 [H. 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. [H. Lundbeck] obtained patents protecting the crystallisation process in a number of Member States during the first half of 2002: 30 January 2002 in the case of the United Kingdom ("the crystallisation patent"). The EPO granted a crystallisation patent on 4 September 2002. In addition, in the Netherlands, [H. Lundbeck] had already obtained, on 6 November 2000, a utility model for that process …, that is to say, a patent valid for six years, granted without a genuine prior examination.

21. Thirdly, on 12 March 2001, [H. Lundbeck] filed a patent application with the United Kingdom authorities for a citalopram production process using a salt purification method by film distillation. The [authorities of the United Kingdom of Great Britain and Northern Ireland] granted [H. Lundbeck] a patent for that film distillation method on 3 October 2001 ("the film distillation patent"). However, that patent was revoked on 23 June 2004 for lack of novelty by comparison with another [H. Lundbeck] patent. [H. Lundbeck] obtained a similar patent in Denmark on 29 June 2002.

22. Lastly, [H. Lundbeck] planned to launch a new antidepressant medicinal product, Cipralex, based on the API known as escitalopram (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 [H. 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

23. In 2002, [H. Lundbeck] entered into six agreements concerning citalopram ("the agreements at issue") with four undertakings active in the production and/or sale of generic medicinal products, namely Merck (GUK), Alpharma, Arrow and Ranbaxy ("the [manufacturers of generic medicinal products]").

A – The agreements with Merck (GUK)

24. [H. Lundbeck] entered into two agreements with Merck (GUK).

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

26 Under that agreement, the parties agreed, in particular, that:

– there was a risk that certain actions envisaged by GUK in respect of the marketing, distribution and sale of the "Products" might constitute an infringement of [H. Lundbeck's] intellectual property rights and could give rise to claims on the part of [H. Lundbeck] (Article 2.1 of the GUK United Kingdom agreement), the "Products" being defined in Article 1.1 of the GUK United Kingdom 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";

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

– the payments made and the delivery of the “Products” by GUK pursuant to Articles 2.2 and 2.3 of the GUK United Kingdom [agreement] would constitute full and final settlement of any claim that [H. 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);

– [H. Lundbeck] undertook to sell its “Finished Products” to GUK and GUK undertook to purchase those “Finished Products” exclusively from [H. 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 GUK United Kingdom agreement), those “Finished Products” being defined in paragraph 1.1 of the agreement as “products containing citalopram in finished pack form to be supplied by [H. Lundbeck] to GUK pursuant to this Agreement”;

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

27. The first extension of the GUK United Kingdom 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”.

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

29. The GUK United Kingdom agreement expired on 1 November 2003, following the settlement of the Lagap litigation. In total, over the entire term of the agreement, [H. Lundbeck] transferred the equivalent of EUR 19.4 million to GUK.

30. A second agreement was concluded between [H. Lundbeck] and GUK on 22 October 2002, covering the EEA excluding the United Kingdom (“the GUK 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 … – the manufacturer of the citalopram API used by Merck (GUK) to market its version of generic 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 GUK EEA agreement). [H. Lundbeck] undertook not to bring legal proceedings against GUK, on condition that GUK complied with its obligations under Article 1.1 of the GUK EEA agreement (Article 1.3 of the GUK EEA agreement).

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

B – The agreements with Arrow

32. [H. Lundbeck] signed two agreements with Arrow.

33. The first of those agreements, relating to the territory of the United Kingdom, was concluded on 24 January 2002 between, on the one hand, [H. Lundbeck] and, on the other, Arrow Generics and Resolution Chemicals (together “Arrow UK”) (“the Arrow UK agreement”).

34. The initial term of the Arrow UK agreement was until 31 December 2002 or, if it had been earlier, until the date on which a definitive decision had been delivered in the action which [H. Lundbeck] intended to bring against Arrow UK before the United Kingdom courts concerning Arrow UK’s alleged infringement of its patents (“the infringement action against Arrow”) (Article 4.1 of the Arrow UK agreement). That agreement was extended, on two occasions, by the signing of addenda. The first extension covered the period from 1 January

until 1 March 2003 (Article 3.1 of the first addendum to the Arrow UK agreement), while the second extension provided that the agreement was to end either on 31 January 2004 or seven days after signature of the court decision determining the Lagap litigation (Article 4.1 of the second addendum to the Arrow UK agreement). As that litigation was settled on 13 October 2003, the Arrow UK agreement ended on 20 October 2003. It follows that the overall duration of that agreement was from 24 January 2002 until 20 October 2003 ("the term of the Arrow UK agreement").

35. As regards the content of the Arrow United Kingdom agreement, it should be observed that:

– the first recital in the preamble to that agreement ("the Arrow UK preamble") refers, inter alia, to the fact that [H. Lundbeck] is the holder of the crystallisation [patent] and film distillation [patent];

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

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

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

– the eighth recital in the preamble to that agreement observes that [H. Lundbeck] has threatened to seek an interim injunction and that it intends to bring infringement proceedings against Arrow;

– Article 1.1 of that agreement provides that "Arrow [UK] on its own behalf and on behalf of all associated and related entities undertakes during the [term of the Arrow UK agreement] not in the United Kingdom to make, dispose of, offer to dispose of, use or, after the second delivery date, import or keep for disposal or otherwise (1) the said Citalopram or (2) any other Citalopram which [H. Lundbeck] alleges to infringe its [intellectual property] Rights and, to enable [H. Lundbeck] to ascertain if there may be an infringement, during the [term of the Arrow UK agreement] to provide [H. Lundbeck] with sufficient samples for analysis purposes at least one month prior to any threatened manufacture, importation, sale or offer for sale pending a final unappealable decision in [the infringement action against Arrow] …";

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

– Article 2.1 of that agreement states that [H. Lundbeck] will commence the infringement action against Arrow as soon as possible and in any event no later than 31 March 2002;

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

– Article 2.3 of that agreement establishes that, in the event that the final decision in the infringement action against Arrow should find that Arrow UK had not infringed [H. Lundbeck's] intellectual property rights, the

amount specified in Article 2.2 of that agreement would constitute the full and final compensation that Arrow UK could obtain from [H. Lundbeck] for loss sustained as a result of the obligations arising under Article 1.1 of the Arrow UK agreement;

– Article 3.4 of the agreement provides that Arrow UK is to deliver to [H. Lundbeck] its stock "of said Citalopram" in two stages, the first of which, covering approximately 3 975 million packed tablets, by no later than 6 February 2002 and the second, covering around 1.1 million bulk tablets, by no later than 15 February 2002.

36. It should be observed, moreover, that on 6 February 2002 [H. Lundbeck] obtained the order referred to in Article 1.2 of the Arrow UK agreement …

37. The second agreement, concerning Denmark, was concluded on 3 June 2002 between [H. Lundbeck] and Arrow Group ("the Arrow Danish agreement").

38. The Arrow Danish agreement was intended to run from the date of signature, 3 June 2002, until 1 April 2003 or until such earlier date of a definitive decision in the infringement action against Arrow. As no such decision was delivered, the agreement was in force from 3 June 2002 until 1 April 2003 …

39. As regards the content of the Arrow Danish agreement, it should be observed that:

– the first, third and fifth to ninth recitals in the preamble thereto correspond, in essence, to the first, fourth and sixth to eighth recitals in the Arrow UK preamble, it being noted that the ninth recital in the Arrow Danish preamble refers to the [order referred to in Article 1.2 of the Arrow UK agreement];

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

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

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

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

C – The agreement with Alpharma

40. [H. Lundbeck] signed an agreement with Alpharma on 22 February 2002 ("the Alpharma agreement"), to run from that date until 30 June 2003 …

41. Before concluding that agreement, in January 2002 Alpharma had bought from Alfred E. Tiefenbacher GmbH & Co. … a stock of generic citalopram tablets developed on the basis of the citalopram API produced by the Indian company Cipla according to its own processes … and had ordered further supplies.

42. As concerns the preamble to the Alpharma agreement, it should be observed, in particular, that:

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

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

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

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

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

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

– The ninth and tenth recitals state that [H. Lundbeck]:

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

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

43. As regards the body of the Alpharma agreement, it should be observed, in particular, that:

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

– that same article specifies that it is not to apply to escitalopram;

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

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

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

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

45 Furthermore, it should be noted that on 2 May 2002 a United Kingdom court granted a consent order staying all proceedings in the infringement action against Alpharma because of the conclusion of the agreement between [H. Lundbeck] and, among others, Alpharma, according to which Alpharma and its affiliates agreed to

"cancel, cease and desist from all importation … production … or sale, in [the Member States], Norway and Switzerland ('the Relevant Territories') of pharmaceutical products containing citalopram manufactured using processes claimed in [the crystallisation patent and film distillation patent granted by the United Kingdom authorities] or any equivalent patent granted or applied for in relation to the Relevant Territories … until 30 June 2003" …

D – The agreement with Ranbaxy

46. [H. Lundbeck] signed an agreement with Ranbaxy Laboratories on 16 June 2002 ("the Ranbaxy agreement"), for a term of 360 days. Under an addendum signed on 19 February 2003 ("the Ranbaxy addendum"), that agreement was extended until 31 December 2003. The total duration of the agreement is therefore from 16 June 2002 until 31 December 2003 …

47. According to the preamble to the Ranbaxy agreement ("the Ranbaxy preamble"):

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

– [H. Lundbeck] performed laboratory analyses on that citalopram and concluded that the processes used infringed the amide patent and the iodo patent [referred to in paragraph 19 of the judgment under appeal], the latter [patent] not having been granted yet (see paragraph 19 [of the judgment under appeal]), whereas Ranbaxy Laboratories disputed the existence of such infringements (fifth to eighth recitals in the preamble);

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

48 According to the Ranbaxy agreement, in particular:

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

– "In the event of any breach of the obligation set forth in Article 1.1 or at the request of [H. Lundbeck]", Ranbaxy Laboratories and Ranbaxy (UK) would voluntarily submit to an interim injunction by any competent national court, without [H. Lundbeck] providing any kind of security or any undertaking other than the undertakings arising under that agreement (Article 1.2 of the Ranbaxy agreement);

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

– [H. Lundbeck] was to sell citalopram tablets to Ranbaxy Laboratories or Ranbaxy (UK), with a discount of 40% on the ex-factory price, so that they could sell those tablets on the United Kingdom market (Article 1.3 of, and Appendix B to, the Ranbaxy agreement);

– [H. Lundbeck] and Ranbaxy Laboratories undertook not to initiate legal proceedings against each other on the basis of any of the patents referred to earlier in the agreement itself (Article 1.4 of the Ranbaxy agreement).

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

49. In October 2003, the Commission of the European Communities 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"]).

50. Since most of those agreements concerned the whole of the EEA or, at 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.

51 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 [H. Lundbeck] and other companies active in the pharmaceutical sector. It also sent [H. Lundbeck] and another company requests for information within the meaning of Article 18(2) of that regulation.

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

53 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.

54 On 7 January 2010, the Commission opened formal proceedings against [H. Lundbeck].

55 In 2010 and the first half of 2011, the Commission sent requests for information to [H. Lundbeck] and to the other companies which were parties to the agreements at issue.

56 On 24 July 2012, the Commission opened proceedings against the companies which were parties to the agreements at issue and sent them, and [H. Lundbeck], a statement of objections.

…

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

V – [The decision at issue]

61 By the [decision at issue], the Commission considered that the agreements at issue constituted restrictions of competition "by object" within the meaning of Article 101(1) TFEU and Article 53(1) of the [Agreement on the European Economic Area of 2 May 1992 (OJ 1994 L 1, p. 3)] (Article 1(1) of the [decision at issue]).

62 The two agreements between Merck (GUK) and [H. Lundbeck] were considered to have constituted a single and continuous infringement lasting from 24 January 2002 until 1 November 2003.

63 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 in that respect:

– at the time of concluding those agreements, [H. 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 GUK United Kingdom agreement;

– [H. Lundbeck] transferred significant value to Merck (GUK) pursuant to those agreements;

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

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

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

– those agreements contained no commitment from [H. Lundbeck] to refrain from bringing infringement proceedings against Merck (GUK) if the latter entered the market with generic citalopram after the expiry of the agreements.

64 The two agreements between Arrow and [H. Lundbeck] were considered to have constituted a single and continuous infringement lasting from 24 January 2002 until 20 October 2003.

65 As is apparent from the summaries in recitals 962 and 1013 of the [decision at issue], relating to [the] Arrow UK agreement and the Arrow Danish agreement respectively, the Commission relied, in particular, on the following factors:

– at the time those agreements were concluded, [H. Lundbeck] and Arrow were at least potential competitors in the United Kingdom and in Denmark;

– [H. Lundbeck] transferred significant value to Arrow pursuant to those agreements;

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

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

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

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

66 As regards the Alpharma agreement, as stated in the summary set out in recital 1087 of the [decision at issue], the Commission relied, in particular, on the following factors:

– at the time when they concluded that agreement, [H. Lundbeck] and Alpharma were at least potential competitors in a number of EEA countries;

– [H. Lundbeck] transferred significant value to Alpharma pursuant to that agreement;

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

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

– [H. Lundbeck] could not have obtained those limitations through the application of the crystallisation [patent] and film distillation [patent], since the obligations placed on Alpharma under that agreement went beyond the rights granted to holders of process patents;

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

67 As regards the Ranbaxy agreement, as is apparent from the summary set out in recital 1174 of the [decision at issue], the Commission relied, in particular, on the following factors:

– at the time of concluding that agreement, [H. Lundbeck] and Ranbaxy were at least potential competitors in the EEA;

– [H. Lundbeck] transferred significant value to Ranbaxy pursuant to that agreement;

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

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

– [H. Lundbeck] could not have obtained those limitations by enforcing its process patents, since the obligations on Ranbaxy under that agreement went beyond the rights granted to holders of process patents;

– that agreement contained no commitment from [H. Lundbeck] to refrain from bringing infringement proceedings against Ranbaxy if the latter entered the market with its generic citalopram after the expiry of [that agreement].

68 The Commission also imposed fines on all the parties to the agreements at issue. To that end, it applied [the 2006 Guidelines]. In [H. Lundbeck's] case, the Commission followed the general methodology described in the 2006 Guidelines, based on the value of sales of the relevant product made by each participant in an infringement (recitals 1316 to 1358 of the [decision at issue]). In the case of the other parties to those agreements however, namely the [manufacturers of generic medicinal products], 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]).

69 Thus, as regards the parties to the agreements at issue other than [H. Lundbeck], 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 [H. Lundbeck] pursuant to those agreements, without differentiating between the infringements on the basis of their nature or geographic scope, or on the basis of the market share of the undertakings concerned, those factors being addressed only for the sake of completeness (recital 1361 of the [decision at issue]).

70 As regards [H. Lundbeck], the Commission applied the general method described in the 2006 Guidelines, taking as a basis the value of sales on the relevant market. Since [H. Lundbeck's] sales of citalopram had significantly decreased during the course of the agreements, and since the agreements did not cover a full business year, the Commission calculated an average annual value of sales. For that purpose, it first calculated the monthly average value of [H. Lundbeck's] sales of citalopram during the term of each of the agreements at issue, then multiplied that value by 12 (recital 1326 and footnote [2215] of the [decision at issue]).

71 The Commission also imposed four separate fines on [H. Lundbeck], since the six agreements at issue were regarded as giving rise to four separate infringements, in so far as the two agreements between [H. Lundbeck] and Merck (GUK) gave rise to a single and continuous infringement, as did the two agreements between [H. Lundbeck] and Arrow. In order to avoid arriving at a disproportionate fine, the Commission nevertheless applied a negative weighting in the light of the circumstances of the case, based on a method reflecting the geographic and temporal overlaps between the various infringements (recital 1329 of the [decision

at issue]). That method resulted in a reduction of 15% for each infringement where overlaps were found (footnote [2218] of the [decision at issue]).

72 In the light of the gravity of the infringements found, which the Commission classified as "serious", since [the agreements at issue] entailed market exclusion; [H. Lundbeck's] high market share of the product to which the infringements related; the wide geographic scope of the agreements at issue; and the fact that all the agreements had been implemented, the Commission considered that the proportion of the value of sales to be applied should be set at 11% for the infringements where the geographic scope was the entire EEA and 10% for the other infringements (recitals 1331 and 1332 of the [decision at issue]).

73 The Commission applied a multiplier to that amount to take account of the duration of the infringements (recitals 1334 to 1337 of the [decision at issue]) and an additional amount of 10% for the first infringement committed, that is to say, the infringement concerning the agreements with Arrow, in application of point 25 of the 2006 Guidelines, in order to ensure that the fines [imposed on H. Lundbeck and Lundbeck Ltd] would be sufficiently deterrent (recital 1340 of the [decision at issue]).

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

75 On the basis of those considerations, and taking into account the fact that the GUK United Kingdom agreement had been signed by Lundbeck Ltd, the Commission imposed a total fine of EUR 93 766 000 on [H. Lundbeck], of which EUR 5 306 000 jointly and severally with Lundbeck Ltd, composed as follows (recitals 1238 and 1358 and Article 2 of the [decision at issue]):

– EUR 19 893 000 for the agreements concluded with Merck (GUK), of which EUR 5 306 000 jointly and severally with Lundbeck Ltd;

– EUR 12 951 000 for the agreements concluded with Arrow;

– EUR 31 968 000 for the agreement concluded with Alpharma; and

– EUR 28 954 000 for the agreement concluded with Ranbaxy.'

The procedure before the General Court and the judgment under appeal

7 By document lodged at the Registry of the General Court on 30 August 2013, H. Lundbeck and Lundbeck Ltd (together 'Lundbeck') brought an action for annulment in part of the decision at issue and reduction of the fines imposed on them by the Commission.

8 In support of its action, Lundbeck relied on 10 pleas in law; in the present appeal, Lundbeck challenges the rejection of only the first to sixth, ninth and tenth of those pleas. By its first plea in law, Lundbeck contested the assertion in the decision at issue that the manufacturers of generic medicinal products ('generic medicines') and Lundbeck were at least potential competitors at the time the agreements at issue were concluded. The second to sixth pleas in law were essentially based on an infringement of Article 101(1) TFEU in so far as the Commission characterised the agreements at issue as 'restrictions of competition by object'. By its ninth and tenth pleas in law, Lundbeck contested, in the alternative, the fact that fines had been imposed on it and, in the further alternative, the calculation of the amount of those fines.

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

Procedure before the Court of Justice

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

11 By document lodged at the Registry of the Court of Justice on 24 November 2016, Lundbeck asked the Court to treat as confidential in relation to the European Federation of Pharmaceutical Industries and Associations (EFPIA), intervener at first instance, the confidential version of the decision at issue, just as the General Court had done in respect of that same decision in the context of Case T−472/13 (*Lundbeck* v *Commission*). By order of 13 December 2016, *Lundbeck* v *Commission* (C−591/16 P, not published, EU:C:2016:967), the President of the Court granted that application. Thus only a non-confidential version of the decision at issue was served on EFPIA.

12 By document lodged at the Registry of the Court of Justice on 10 March 2017, the United Kingdom sought leave to intervene in the present case in support of the form of order sought by the Commission. By order of 5 July 2017, *Lundbeck* v *Commission* (C−591/16 P, not published, EU:C:2017:532), the President of the Court granted that application. However, at Lundbeck's request, the President of the Court ordered that, in relation to the United Kingdom, the confidential version of the decision at issue was to be treated as confidential, and only a non-confidential version of that decision was served on the United Kingdom

13 Following Lundbeck's application of 17 March 2017, the President of the Court granted Lundbeck leave to file a reply.

14 By document lodged at the Registry of the Court of Justice on 16 May 2017, the Commission applied for an extension of the time limit for submitting its rejoinder. By decision of 17 May 2017, the President of the Court granted that application.

15 By document lodged at the Registry of the Court of Justice on 24 July 2017, the United Kingdom applied for an extension of the time limit for submitting its statement in intervention. By decision of the President of the Court of 26 July 2017, that application was granted.

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

17 Following the lodging of the rejoinders of EFPIA and the Commission and the lodging by Lundbeck, EFPIA and the Commission of their responses to the statement in intervention submitted by the United Kingdom, the written part of the procedure in the present case was closed on 13 November 2017.

18 On 27 November 2018, the Court of Justice decided that the present case would be assigned to the Fourth Chamber, which was to give judgment following a joint hearing in respect of the present case and Cases C−586/16 P (*Sun Pharmaceutical Industries and Ranbaxy (UK)* v *Commission*), C−588/16 P (*Generics (UK)* v *Commission*), C−601/16 P (*Arrow Group and Arrow Generics* v *Commission*), C−611/16 P (*Xellia Pharmaceuticals and Alpharma* v *Commission*) and C−614/16 P (*Merck* v *Commission*) and having heard an Opinion of the Advocate General.

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

20 The hearing in this case and in the cases referred to in paragraph 18 of the present judgment was held on 24 January 2019.

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

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

22 By its appeal, Lundbeck claims that the Court of Justice should:

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

– annul the decision at issue in so far as it applies to Lundbeck or, in the alternative, annul the fines imposed on Lundbeck pursuant to the decision at issue or, in the further alternative, substantially reduce the amount of those fines;

– order the Commission to pay Lundbeck's legal and other costs incurred in the context of the present appeal and of the proceedings before the General Court;

– if necessary, remand the case to the General Court for reconsideration in accordance with the judgment of the Court of Justice;

– take any other measures that the Court of Justice considers appropriate.

23 The Commission contends that the Court of Justice should:

– dismiss the appeal in its entirety;

– order Lundbeck to pay the costs.

24 EFPIA contends that the Court of Justice should:

– allow the appeal, in whole or in part;

– if necessary, refer the case back to the General Court for reconsideration in accordance with the judgment of the Court of Justice;

– order the Commission to bear the costs of EFPIA incurred in the context of the present appeal and of the proceedings before the General Court.

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

The appeal

26 In support of its appeal, Lundbeck relies on six grounds.

27 By its first ground of appeal, Lundbeck complains that the General Court erred in law in upholding the Commission's characterisation of the agreements at issue as 'restrictions of competition by object', even if they fall within the scope of Lundbeck's new process patents.

28 By its second ground of appeal, Lundbeck alleges that the General Court erred in law by failing to apply the correct legal test to determine whether five of the six agreements at issue – namely the GUK EEA Agreement, the Arrow UK Agreement, the Arrow Danish Agreement, the Alpharma Agreement and the Ranbaxy Agreement – contained restrictions falling outside the scope of the Lundbeck's new process patents, as no 'meeting of minds' between the contracting parties to those agreements had been established.

29 By its third ground of appeal, Lundbeck submits that, even if the General Court was entitled to find that at least five of the six agreements at issue fell outside the scope of Lundbeck's new process patents, it nevertheless erred in concluding that those agreements constituted restrictions of competition by object.

30 By its fourth ground of appeal, Lundbeck claims that the General Court erred in law, manifestly disregarded the evidence and contradicted itself by upholding the Commission's finding that Lundbeck and the manufacturers of generic medicines were actual or potential competitors at the time the agreements at issue were concluded, irrespective of whether the products made by the manufacturers of generic medicines infringed Lundbeck's new process patents.

31 By its fifth ground of appeal, Lundbeck complains that the General Court erred in upholding the fines imposed on it by the Commission.

32 By its sixth ground of appeal, Lundbeck submits, in the alternative, that the General Court erred in law in its decision to uphold Commission's method for calculating the fines imposed on it and failed to state sufficient reasons for that decision.

33 It is appropriate to start by examining the fourth ground, then to move on to the first, second and third grounds together, and, finally, in turn, the fifth and sixth grounds.

The fourth ground of appeal

The relevant paragraphs of the judgment under appeal

34 By its first plea in law in its action for annulment, Lundbeck argued that the Commission had made several errors of law and of assessment in finding that the manufacturers of generic medicines which had concluded the agreements at issue were at least potential competitors of Lundbeck at the time when those agreements were concluded.

35 That plea was divided into nine parts, all of which the General Court rejected as being unfounded.

36 First, as regards the first to fifth parts of the first plea in law, the General Court, in paragraphs 117 to 133 and 157 to 167 of the judgment under appeal respectively, refused to accept Lundbeck's argument that, first, the launch of generic medicines that infringe third parties' intellectual property rights is not the expression of potential competition under Article 101 TFEU and, second, that challenging a valid patent does not constitute a real and concrete possibility of entering the market.

37 The General Court noted that, in the light of the various factors taken into account by the Commission and Lundbeck's decision to pay significant amounts to the manufacturers of generic medicines in order to keep them out of the market during the term of the agreements at issue, the finding that Lundbeck and those manufacturers were potential competitors was established, since the latter had both real and concrete possibilities and the capacity to enter the market.

38 In that regard, the General Court held, inter alia, in paragraphs 124 and 195 of the judgment under appeal respectively, that the Commission had not made an error in finding that Lundbeck's new process patents did not necessarily constitute insurmountable barriers for the manufacturers of generic medicines and that each of those manufacturers had, or could have obtained within a sufficiently short time, a generic version of citalopram based on processes which had not been held to infringe any of Lundbeck's new patents at the time the agreements at issue were concluded. In paragraph 171 of that judgment, the General Court also held that potential competition includes, inter alia, the activities of manufacturers of generic medicines by which they seek to obtain the necessary marketing authorisations ('MAs') required in order to prepare for their entry to the market.

39 In its assessment of the evidence, the General Court took into account, inter alia, in paragraphs 126 and 254 of the judgment under appeal, the fact that Lundbeck knew that the crystallisation patent was, in essence, weak and liable to be declared invalid, and did not accept, in paragraphs 142 and 147 of that judgment, that the finding that the manufacturers of generic medicines and Lundbeck were potential competitors was based mainly on subjective assessments.

40 The General Court also agreed, in paragraphs 134 to 148 of that judgment, to take into account evidence subsequent to the agreements at issue and took into account, in paragraph 254 of that judgment, evidence establishing that certain manufacturers of generic medicines and Lundbeck itself had doubts regarding the validity of the crystallisation patent when those agreements were concluded. However, in paragraph 145 of the judgment under appeal, the General Court refused to consider as decisive, in evaluating the existence of potential competition between Lundbeck and the manufacturers of generic medicines at the time when those agreements were concluded, the fact, in particular, that the EPO had confirmed that patent on all its relevant aspects in 2009.

41 Second, in the context of its reply to the sixth to ninth parts of the first plea in law in the action for annulment, the General Court assessed, in respect of each of the agreements at issue, whether the evidence adduced by the Commission did indeed make it possible to establish the existence of potential competition between each of the manufacturers of generic medicines and Lundbeck, and found, inter alia, in paragraph 181 of the judgment under appeal, that the conclusion reached by the Commission was based on a set of factors taking account of the specific situation of each of those manufacturers at the time the agreements at issue were concluded as well as the specific characteristics of the pharmaceutical sector.

Arguments of the parties

42 By its fourth ground of appeal, consisting of seven parts, Lundbeck submits that the General Court erred in law, made a manifest error in its assessment of the evidence and contradicted itself by upholding the Commission's finding that Lundbeck and the manufacturers of generic medicines were at least potential competitors.

43 By the first part of that ground, Lundbeck submits that, by limiting itself to verifying whether the manufacturers of generic medicines could physically enter the market, the General Court erred in law by disregarding the existence of legal barriers, namely Lundbeck's new process patents, which prevented the legal entry of those manufacturers to the market, as confirmed by point 29 of the 2014 Guidelines. According to Lundbeck, which is supported by EFPIA, where exclusive rights such as patents exist and the Commission finds that there is potential competition on the market, the Commission is required to determine whether, if the agreement in question had not been concluded, there would have been real and concrete possibilities for the undertaking lawfully to enter the market and to compete with established undertakings on that market. Consequently, the General Court could not, without incorrectly apportioning the burden of proof and thus making an error of law, find, in paragraph 195 of the judgment under appeal, that the Commission was not required to show that the processes of the manufacturers of generic medicines did not infringe Lundbeck's new process patents. Similarly, the General Court could not, without disregarding the presumption of validity which Lundbeck's new process patents enjoy and, therefore, without making an error of law, find, in paragraphs 115 to 132 and 149 to 167 of the judgment under appeal, that, even if the manufacturers of generic medicines had only citalopram covered by Lundbeck's new process patents, they were nevertheless its potential competitors by virtue of the possibility of challenging the validity of Lundbeck's patents.

44 By the second part of the fourth ground, Lundbeck submits that the finding of the General Court in paragraph 145 of the judgment under appeal that Lundbeck itself doubted the validity of the crystallisation patent is based on 'a manifest error of assessment of the evidence', since it is based on only two documents dated 22 November 2002 and 29 September 2003, which were subsequent to the agreements at issue; this runs counter to the assertion in paragraph 141 of the judgment under appeal that evidence subsequent to the conclusion of those agreements cannot be decisive in the examination of the existence of potential competition. Furthermore, in paragraph 254 of the judgment under appeal, the General Court reversed the burden of proof to the detriment of Lundbeck by requiring the latter to adduce evidence explaining how, prior to the conclusion of those agreements, its assessment of the likelihood that the crystallisation patent would be declared invalid would have been different.

45 By the third part of the fourth ground, Lundbeck submits that the General Court erred in law by holding, in paragraphs 134 to 148 of the judgment under appeal, that evidence subsequent to the agreements at issue, even if it was objective, could not be decisive in the examination of the potential competition between Lundbeck and each of the manufacturers of generic medicines.

46 By the fourth to seventh parts of the fourth ground, Lundbeck submits that the General Court erred in law in concluding, in paragraphs 225, 230, 255, 270, 286 and 330 of the judgment under appeal, that Merck (GUK) was at least a potential competitor of Lundbeck in the United Kingdom and the other EEA countries, that Arrow was a potential competitor of Lundbeck in the United Kingdom and Denmark and, finally, that Alpharma and Ranbaxy were potential competitors of Lundbeck in the EEA, on the ground, inter alia, that those manufacturers of generic medicines did not have an MA or equivalent authorisation for the marketing of their generic medicine in the territory of the States concerned at the time the agreements at issue were concluded. Moreover, in the case of Arrow and Alpharma, that error of law also constituted a manifest disregard for the evidence.

47 The Commission submits that the fourth ground is inadmissible and is, in any event, unfounded.

Findings of the Court

48 As a preliminary point, it should be noted that, under the second subparagraph of Article 256(1) TFEU and the first paragraph of Article 58 of the Statute of the Court of Justice of the European Union, an appeal lies on points of law only. The General Court has exclusive jurisdiction to find and appraise the relevant facts and to assess the evidence. The appraisal of those facts and the assessment of that evidence therefore do not, save where the facts and evidence are distorted, constitute a point of law which is subject, as such, to review by the Court of Justice on appeal.

49 However, it should be noted that Lundbeck's argument in the second part of the present ground that the General Court made a manifest error of assessment in finding that Lundbeck had doubts about the validity of its new process patents and the argument in the fourth to seventh parts of that ground that the General Court disregarded evidence in concluding that Merck (GUK) was at least a potential competitor of Lundbeck and that Arrow, Alpharma and Ranbaxy were potential competitors of Lundbeck in the relevant territories seek to challenge the Court's finding or assessment of the facts or evidence without Lundbeck alleging or, a fortiori, demonstrating any distortion of those facts or evidence by the General Court.

50 Accordingly, the arguments set out in the second and fourth to seventh parts of the fourth ground are inadmissible.

51 However, contrary to what is claimed by the Commission, the other parts of that ground and the remainder of its second and fourth to seventh parts constitute points of law subject to review by the Court of Justice in the context of an appeal.

52 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).

53 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).

54 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).

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

56 Specifically, with regard to such agreements occurring in the context of the opening of the market, for a medicine containing an active ingredient that has recently entered the public domain, to the manufacturers of generic medicines, it should be established, by taking due account of the regulatory constraints that are characteristic of the medicine sector and of the intellectual property rights and, in particular, the patents held by the manufacturers of originator medicines relating to one or more processes for the manufacture of an active ingredient that is in the public domain (see, to that effect, judgment of 30 January 2020, *Generics (UK) and Others*, C−307/18, EU:C:2020:52, paragraphs 40 and 41), whether the manufacturer of generic medicines has in fact a firm intention and an inherent ability to enter the market, and does not meet barriers to entry that are insurmountable (see, to that effect, judgment of 30 January 2020, *Generics (UK) and Others*, C−307/18, EU:C:2020:52, paragraph 58).

57 In order to do so, it is necessary to assess, first, whether, at the time when those agreements were concluded, that manufacturer had taken sufficient preparatory steps to enable it to enter the market concerned within such a period of time as would impose competitive pressure on the manufacturer of originator medicines. Second, it must be determined that the market entry of such a manufacturer of generic medicines does not meet barriers to entry that are insurmountable (see, to that effect, judgment of 30 January 2020, *Generics (UK) and Others*, C−307/18, EU:C:2020:52, paragraphs 43 and 45). Furthermore, a finding of potential competition between a manufacturer of generic medicines and a manufacturer of originator medicines can be confirmed by additional factors, such as the conclusion of an agreement between them at a time when the former was not present on the market concerned (see, to that effect, judgment of 30 January 2020, *Generics (UK) and Others*, C−307/18, EU:C:2020:52, paragraphs 54 to 56).

58 Specifically, with regard to the assessment of whether there are barriers to entry into the market concerned which are insurmountable, the Court has held that the existence of a patent which protects the manufacturing process of an active ingredient that is in the public domain cannot, as such, be regarded as such an insurmountable barrier, regardless of the presumption of validity attached to that patent, since that presumption sheds no light, for the purposes of applying Articles 101 and 102 TFEU, on the outcome of any dispute in relation to the validity of that patent (see, to that effect, judgment of 30 January 2020, *Generics (UK) and Others*, C−307/18, EU:C:2020:52, paragraphs 46 to 51).

59 Consequently, the existence of such a patent does not, as such, mean that a manufacturer of generic medicines who has in fact a firm intention and an inherent ability to enter the market, and who, by the steps taken, shows a readiness to challenge the validity of that patent and to take the risk, upon entering the market, of being subject to infringement proceedings brought by the patent holder, cannot be characterised as a ‘potential

competitor' of the manufacturer of originator medicines concerned (judgment of 30 January 2020, *Generics (UK) and Others*, C−307/18, EU:C:2020:52, paragraph 46).

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

61 It follows that, in the present case, and contrary to what Lundbeck maintains, the General Court did not make any error of law and, in particular, did not infringe either the presumption of validity attached, inter alia, to Lundbeck's new process patents or the rules applicable to the burden of proof in respect of the practices referred to in Article 101 TFEU, when it ruled, in essence, in paragraphs 117 to 132, 157 to 167 and 195 of the judgment under appeal that it was not for the Commission to provide definite proof that the citalopram which the manufacturers of generic medicines intended to market did not infringe Lundbeck's new process patents, and that the fact that Lundbeck held such patents did not preclude a finding that there was potential competition between Lundbeck and those manufacturers.

62 The General Court, taking due account, in paragraphs 117, 119 and 129 of the judgment under appeal, of the fundamental characteristics both of the patents and of the competitive relationships specific to the relevant market as well as the situation in the present case in which, first, Lundbeck's original patents, relating to both the citalopram API and the alkylation and cyanation production processes, had expired and, second, there were other processes for the production of generic citalopram which were not found to infringe other Lundbeck patents, held, in paragraph 124 of that judgment, that the Commission had not erred in considering that Lundbeck's new process patents did not necessarily constitute insurmountable barriers for the manufacturers of generic medicines, which were both willing and 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.

63 In addition, in paragraph 159 of the same judgment, the General Court was fully entitled to find that, unless it were to be held that there is no distinction between actual and potential competition, it is not necessary to demonstrate with certainty that the manufacturers of generic medicines would have entered the market and that that entry would inevitably have been successful, but only that those manufacturers had real and concrete possibilities in that respect.

64 Furthermore, the conclusion that the General Court did not err in finding that the manufacturers of generic medicines were potential competitors of Lundbeck is not called into question by the 2014 Guidelines, in particular point 29 thereof. First, that point applies exclusively to technology transfer agreements, to which the agreements at issue cannot be compared. Second, it is clear from that point that the Commission's finding that there is no competitive relationship between undertakings that find themselves in a blocking position arising from an exclusive technology right is valid only 'in principle' and is therefore subject to exceptions, which is also alluded to in that same point when it mentions situations in which 'there is no certainty whether a particular technology right is valid and infringed'.

65 Therefore, the first part of the fourth ground of appeal must be rejected as being unfounded.

66 As regards the evidence that may be taken into consideration in order to establish the existence of at least potential competition between Lundbeck and the manufacturers of generic medicines, it has already been pointed out in paragraph 57 of the present judgment that, in the case of agreements such as the agreements at issue, the existence of potential competition between a manufacturer of originator medicines and a manufacturer of generic medicines must be assessed at the time when the settlement agreement in respect of the process patent dispute between them was concluded (judgment of 30 January 2020, *Generics (UK) and Others*, C−307/18, EU:C:2020:52, paragraph 43), taking into account the fact that that agreement comes at a time when each of the parties to the agreement is uncertain as to the validity of the process patent of the manufacturer of originator medicines and as to the infringing nature of the generic medicine which the manufacturer of that generic medicine intends to place on the market (see, to that effect, judgment of 30 January 2020, *Generics (UK) and Others*, C−307/18, EU:C:2020:52, paragraph 52).

67 It follows that, 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), any evidence prior to, contemporaneous with or even subsequent to the conclusion of the agreement at issue may be taken into consideration if it is of such a nature as to throw light on the existence or absence of a competitive relationship between the undertakings concerned at the time when that agreement was concluded, as the General Court states, in essence, in paragraph 141 of the judgment under appeal.

68 However, as the Advocate General indicated in points 90 and 91 of her Opinion, such evidence relating to events subsequent to the conclusion of that agreement and, in particular, evidence relating to the subsequent outcome of the dispute which had justified the conclusion of that same agreement cannot be taken into consideration in order to assess and, where necessary, retrospectively to rebut the claim that the parties to that agreement were potential competitors at the time when it was concluded.

69 Such evidence which is unknown to the parties at the date of conclusion of the agreement at issue is not capable of having influenced their conduct on the market and, therefore, of shedding light on the existence or absence of a competitive relationship between the undertakings concerned at the time when that agreement was concluded.

70 Consequently, the General Court did not err in law or reverse the burden of proof when it found, in paragraphs 141 and 254 of the judgment under appeal, that evidence subsequent to the agreements at issue – in this instance, documents giving an indication of how the parties to those agreements perceived the strength of Lundbeck's new process patents when those agreements were concluded – could be taken into consideration, since it allows the positions of the parties to those agreements at the time when those agreements were concluded to be established.

71 Nor did the General Court contradict itself when it decided, in paragraphs 141 and 254 of the judgment under appeal, to accept that very evidence, which is subsequent to the agreements at issue, at the same time as it refused, in paragraphs 136 and 143 to 146 of that judgment, to take account of other evidence submitted by Lundbeck which is also subsequent to those agreements, that is to say, principally, the confirmation, by both the EPO Board of Appeal and the Netherlands Patent Office, of the validity of the crystallisation patent in all relevant aspects in 2009, as well as the fact that Lundbeck had been 'granted preliminary injunctions or other forms of interim relief' in more than 50% of the proceedings it had initiated in 2002-2003.

72 While the former evidence may help to establish what the position of the parties to the agreements at issue was at the time of their conclusion, as was stated in paragraph 70 of the present judgment, the latter evidence, relating to events subsequent to the conclusion of those agreements and, accordingly, unknown to the parties to those agreements are, as the General Court noted in substance in paragraphs 145 and 146 of the judgment under appeal, not capable of having influenced their conduct on the market and, therefore, of shedding light on the existence or absence of a competitive relationship between the undertakings concerned at the time when those agreements were concluded.

73 Furthermore, Lundbeck complains that the General Court concluded that there was potential competition between it and the manufacturers of generic medicines on the basis of subjective evidence taken into account in paragraphs 126 and 254 of the judgment under appeal.

74 In that regard, it should be noted that, although the existence of potential competition between two undertakings operating at the same level of a production chain must be assessed in the light of the objective factors recalled in paragraph 57 of the present judgment, the fact remains that that competition can be confirmed by additional factors (judgment of 30 January 2020, *Generics (UK) and Others*, C−307/18, EU:C:2020:52, paragraph 54), which include subjective factors (judgment of 30 January 2020, *Generics (UK) and Others*, C−307/18, EU:C:2020:52, paragraph 42), provided that they are not decisive for the purpose of the assessment carried out.

75 It follows that the taking into account of subjective factors in order to establish that two or more undertakings were potential competitors cannot be excluded provided that that competition is not established

exclusively or principally on the basis of those factors.

76 This applies in particular to the perception by the manufacturer of originator medicines of the risk that the manufacturer of generic medicines concerned presents to its commercial interests, that perception being relevant to the assessment of the existence of potential competition where that perception affects the conduct on the market of the manufacturer of originator medicines (judgment of 30 January 2020, *Generics (UK) and Others*, C−307/18, EU:C:2020:52, paragraphs 42 and 57).

77 As is clear from paragraphs 142 and 147 of the judgment under appeal – which have neither been alleged nor, a fortiori, found to be based on a distortion of the clear sense of the facts or evidence – the General Court definitively found that Lundbeck is wrong to submit that the Commission relied 'almost exclusively' on such subjective assessments in the decision at issue in order to establish the existence of potential competition between Lundbeck and the manufacturers of generic medicines.

78 In that regard, it is noted in paragraph 142 that the Commission carried out a careful examination, in respect of each of the relevant manufacturers of generic medicines, concerning the real and concrete possibilities they had of entering the market, relying on objective factors such as the investments already made, the steps taken in order to obtain an MA and the supply contracts concluded with, amongst others, their API suppliers. In addition, in paragraph 144 of that judgment, the General Court found that the strongest evidence is the very fact that Lundbeck concluded agreements with manufacturers of generic medicines in order to delay their entry to the market, as the Court of Justice found previously in the judgment of 30 January 2020, *Generics (UK) and Others* (C−307/18, EU:C:2020:52, paragraph 55 and the case-law cited).

79 Furthermore, contrary to what Lundbeck alleges in the second part of the present ground, the General Court did not reverse the burden of proof to the detriment of Lundbeck in paragraph 254 of the judgment under appeal. In that paragraph of the judgment under appeal, the General Court confined itself, in essence, to finding that Lundbeck had not provided sufficient evidence to call into question the conclusions arising from the evidence adduced by the Commission in the decision at issue. According to the settled case-law of the Court of Justice, in matters of liability for an infringement of the competition rules, the factual evidence on which a party relies may be of such a kind as to require the other party to provide an explanation or justification, failing which it is permissible to conclude that the burden of proof has been discharged (judgments of 1 July 2010, *Knauf Gips* v *Commission*, C−407/08 P, EU:C:2010:389, paragraph 80, and of 18 January 2017, *Toshiba* v *Commission*, C−623/15 P, not published, EU:C:2017:21, paragraph 52).

80 Accordingly, the second part, in so far as it is admissible, and third part of the fourth ground of appeal must be dismissed as being unfounded.

81 Finally, with regard to the fourth to seventh parts of the fourth ground, in which Lundbeck submits that the General Court wrongly held that it was at least a potential competitor of Merck (GUK) in the United Kingdom and other EEA countries, a potential competitor of Arrow in the United Kingdom and Denmark and a potential competitor of Alpharma and Ranbaxy in the EEA, it should be noted that those allegations are inadmissible in part, as was found in paragraphs 49 and 50 of the present judgment, since they seek to obtain a re-examination by the Court of Justice of all or part of the evidence assessed by the General Court.

82 To the extent that they do not seek to do so, those allegations by Lundbeck, first, repeat the criticisms of methodology which were held to be unfounded in the context of the first to third parts of the present ground, and, second, seek to criticise, in essence, the General Court for having found there to be potential competition, or at least potential competition, between Lundbeck and the manufacturers of generic medicines, even though the latter did not have an MA for their respective generic medicines when the agreements at issue were concluded.

83 In that respect, although it is indeed necessary for a manufacturer of generic medicines to hold a valid MA when it enters the market and it can, therefore, be found that there is currently competition between that manufacturer of generic medicines and a manufacturer of originator medicines that correspond to those generic medicines only if the manufacturer of generic medicines does hold a valid MA, it nevertheless remains the case that the fact that a manufacturer of generic medicines does not hold such an MA when it concludes an agreement

with a manufacturer of originator medicines cannot, as Lundbeck maintains, preclude, as such, all potential competition between those two manufacturers of medicines.

84 As was pointed out, in essence, in paragraph 57 of the present judgment, in the absence of an insurmountable barrier to market entry, the existence of potential competition between a manufacturer of generic medicines and a manufacturer of originator medicines presupposes only that the manufacturer of generic medicines has taken sufficient preparatory steps to enable it to enter the market concerned within a period of time capable of putting competitive pressure on the manufacturer of originator medicines, it being of no relevance whether those steps will in fact be finalised in due time or will be successful, as the General Court rightly points out in paragraphs 313 and 314 of the judgment under appeal.

85 Indeed, the Court has previously had the opportunity to find, to that effect, that, in the pharmaceutical sector, potential competition may be exerted before the expiry of a compound patent protecting an originator medicine, since the manufacturers of generic medicines want to be ready to enter the market as soon as that patent expires (judgment of 30 January 2020, *Generics (UK) and Others*, C−307/18, EU:C:2020:52, paragraph 51).

86 Such preparatory steps which make it possible to establish the firm intention and inherent ability of a manufacturer of generic medicines to enter the market for a medicine containing an active ingredient that is in the public domain include, inter alia, steps taken to put it in a position to obtain the MAs or equivalent authorisations necessary for the marketing of its generic medicine, which, the General Court established, in the present case, in paragraphs 171 to 179, 230, 231, 246, 249, 269, 290 and 312 to 326 of the judgment under appeal, had been taken by each of the manufacturers of generic medicines concerned and were sufficient to exert competitive pressure on Lundbeck (see, by analogy, judgment of 30 January 2020, *Generics (UK) and Others*, C−307/18, EU:C:2020:52, paragraph 134).

87 Consequently, the General Court did not err in law when it found, in paragraph 171 of the judgment under appeal, that the steps taken by each of the manufacturers of generic medicines concerned with a view to obtaining an MA for the medicines concerned constituted relevant indications in establishing the existence of potential competition between them and Lundbeck.

88 In addition, the findings that there was potential competition between Lundbeck and each of the manufacturers of generic medicines at issue are based on a consistent body of evidence (see, to that effect, judgment of 30 January 2020, *Generics (UK) and Others*, C−307/18, EU:C:2020:52, paragraph 44) which reflect the fact that the General Court took into consideration not only the real and concrete possibilities for each of those manufacturers to obtain MAs or equivalent authorisations but also, as is apparent from paragraph 181 of the judgment under appeal, a number of factors relating to the specific situation of each manufacturer of generic medicines at the time when the agreements at issue were concluded and the fact that Lundbeck entered into agreements with manufacturers of generic medicines that were not yet present on the market (see, to that effect, judgment of 30 January 2020, *Generics (UK) and Others*, C−307/18, EU:C:2020:52, paragraphs 55 to 57).

89 Consequently, nor did the General Court err in law in being able to conclude, in the judgment under appeal, that Lundbeck was at least a potential competitor of Merck (GUK) in the United Kingdom and in the other countries of the EEA, as is also apparent from the judgments delivered today in Case C−588/16 P, *Generics (UK)* v *Commission* (paragraph 36) and in Case C−614/16 P, *Merck* v *Commission* (paragraph 45), a potential competitor of Arrow in the United Kingdom and in Denmark, as is also apparent from paragraph 48 of the judgment delivered today in Case C−601/16 P, *Arrow Group and Arrow Generics* v *Commission* and a potential competitor of Alpharma and Ranbaxy in the EEA, as is also apparent from the judgments delivered today in Case C−611/16 P, *Xellia Pharmaceuticals and Alpharma* v *Commission* (paragraph 59), and in Case C−586/16 P, *Sun Pharmaceutical Industries and Ranbaxy (UK)* v *Commission* (paragraph 43).

90 Consequently, the fourth to seventh parts of the fourth ground of appeal must be rejected as being unfounded, in so far as they are admissible.

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

The first three grounds of appeal

92 By its first three grounds of appeal, Lundbeck challenges the characterisation of the agreements at issue as 'restrictions by object'. Those grounds should therefore be examined together.

The relevant paragraphs of the judgment under appeal

93 By the second to sixth pleas in law relied on in support of its action for annulment, alleging, in essence, infringement of Article 101(1) TFEU – the rejection of only the second, third, fourth and sixth of which is being challenged in the present appeal – Lundbeck submitted that the Commission had made several errors of law and of assessment in finding that the agreements at issue had to be characterised, in the decision at issue, as 'restrictions by object'.

94 After noting, in paragraphs 338 to 344 of the judgment under appeal, the applicable principles and case-law concerning the characterisation of 'restriction by object', the General Court rejected each of those pleas.

95 In rejecting the second plea seeking annulment, alleging an error of law and fact and a failure to state reasons with regard to the assessment of the role of transfers of value in the agreements at issue, the General Court noted, inter alia, in paragraphs 361 to 363 of the judgment under appeal, that the parties to those agreements were in dispute over whether Lundbeck's new process patents were sufficiently strong to prevent the market entry of generic citalopram, with the result that those patents cannot have constituted the decisive basis for the commitments, made by the manufacturers of generic medicines, not to enter the market.

96 It also stated, in paragraph 366 of that judgment, that, in the decision at issue, the Commission relied on a body of evidence to demonstrate that it is principally the size of the reverse payments made by Lundbeck to the manufacturers of generic medicines which induced the latter to accept the limitations governing their behaviour and not the existence of Lundbeck's new process patents or even the desire to avoid the expenses linked to potential litigation.

97 In addition, after setting out Lundbeck's arguments regarding the fact, inter alia, that the damages which the manufacturers of generic medicines could be ordered to pay were often much lower than the loss suffered by the manufacturer of originator medicines in the event of unlawful market entry, the General Court held, in paragraph 387 of that judgment, that it is unacceptable for undertakings to attempt to mitigate the effects of legal rules which they consider 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.

98 Finally, in paragraphs 398 and 399 of that same judgment, the General Court rejected Lundbeck's argument that the agreements at issue did not contain any provision preventing manufacturers of generic medicines from contesting the validity of Lundbeck's new process patents, with the result that those agreements did not remove all incentive for those manufacturers to enter the market. In that regard, it pointed out, first, that the decision at issue stated only that the reverse payments provided for in the agreements at issue encouraged or induced the manufacturers of generic medicines to accept limitations on their commercial autonomy that they would not have accepted in the absence of those payments, and not that they removed all incentives in that respect and, second, in any case, even though the agreements at issue did not contain any no-challenge clause, the manufacturers of generic medicines had no incentive to challenge Lundbeck's new process patents after concluding the agreements at issue, since the reverse payments approximately corresponded to the profits that they expected to make if they had entered the market or to the damages which could have been paid to them if they had ultimately succeeded in litigation against Lundbeck.

99 In rejecting the third plea seeking annulment, alleging an error of law made in the application of the principles relating to the notion of restriction of competition by object, the General Court held, inter alia, in paragraphs 435 and 438, of the judgment under appeal respectively, that the agreements at issue were

comparable to market exclusion agreements, which are among the most serious restrictions of competition, and that it is not necessary that the same type of agreement has already been censured by the Commission in order for them to constitute a restriction of competition by object. As regards the argument that the decision at issue is vitiated by an error of law in that it is not accepted in that decision that, in the present case, the 'counterfactual scenario' precluded the possibility of finding a restriction of competition by object, the General Court held, in paragraphs 472 and 473 of the judgment under appeal, that, as regards restrictions of competition by object, the Commission was only required to demonstrate that the agreements at issue revealed a sufficient degree of harm to competition, in view of the content of their provisions, the objectives that they were intended to achieve and the economic and legal context of which they formed part, but was not required, however, to examine their effects, since the examination of a hypothetical 'counterfactual scenario' is more an examination of the effects of agreements at issue on the market than an objective examination of whether they are sufficiently harmful to competition.

100 In order to reject the fourth plea seeking annulment, alleging an error of law and a failure to state reasons for rejecting the scope-of-the-patent test as the key standard in assessing patent settlement agreements under Article 101(1) TFEU, the General Court held, in particular, in paragraphs 491 and 495 of the judgment under appeal, that Lundbeck's argument that the contractual restrictions falling within the patent holder's temporal, territorial and material rights do not infringe competition law, because those restrictions are analogous to the restrictions inherent in the underlying patent, was problematic because, first, it leads to a presumption that a generic medicine infringes the patent of the manufacturer of originator medicines and thus allows the generic medicine to be excluded on that basis, while the question as to whether the generic medicine infringes any patents remains unresolved and, second, it is based on the presumption that any patent invoked in the context of a settlement agreement will be held valid if its validity is challenged, although there was no basis in law or in practice for that outcome, while adding that the fact that some restrictions contained in the agreements at issue were considered by the Commission as potentially falling within the scope of Lundbeck's new process patents means only that Lundbeck could have obtained comparable restrictions through court rulings enforcing those patents, assuming that it succeeded in actions brought before the national courts with jurisdiction. In paragraph 515 of the judgment under appeal, the General Court also noted that the issue whether the restrictions contained in the agreements at issue fell outside the scope of Lundbeck's new process patents was considered as a relevant, but not decisive, factor in establishing the existence of a restriction by object for the purpose of Article 101(1) TFEU.

101 In order to reject the sixth plea seeking annulment, alleging a manifest error of assessment of the facts, in that the decision at issue contains a finding that the agreements at issue contained restrictions going beyond those inherent in the exercise of the rights conferred by Lundbeck's new process patents, the General Court held, in particular, in paragraphs 539 and 572 of the judgment under appeal, that, even if those agreements had not gone beyond the scope of Lundbeck's new process patents, those agreements would nevertheless have constituted restrictions on competition by object for the purpose of Article 101(1) TFEU, since they consisted in agreements intended to delay the market entry of manufacturers of generic medicines, in exchange for significant reverse payments, which transformed the uncertainty in relation to that market entry into the certainty that it would not take place during the term of the agreements at issue.

Arguments of the parties

102 By its first ground of appeal, which is composed of four parts, concerning paragraphs 335, 491, 495, 515, 536, 539, 572 and 801 of the judgment under appeal, Lundbeck, supported by EFPIA, complains that the General Court erred in law in upholding the decision at issue in so far as it concluded that the agreements at issue constituted restrictions of competition by object, even if the restrictions set out in those agreements fell within the scope of Lundbeck's new process patents.

103 In essence, Lundbeck submits, first, that, because of the requirement to interpret strictly the concept of a 'restriction by object', the agreements at issue cannot be regarded as harmful to competition by their very nature, since they contain restrictions comparable to those which the holder of the patents concerned could have obtained by means of a court decision imposing compliance with its patents. Similarly, the General Court was

wrong to hold that the existence of reverse payments and their disproportionate nature were decisive in the characterisation of the agreements at issue as 'restrictions by object'.

104 Second, Lundbeck claims that the General Court did not properly assess the economic and legal context of the agreements at issue, which provides an explanation of why it made the relevant payments to the manufacturers of generic medicines. In that respect, Lundbeck states primarily that the settlement of patent disputes is a legitimate and commonplace method of avoiding litigation which does not in itself raise competition concerns and that the asymmetry of risks between the patent holder and the manufacturers of generic medicines, which leaves the former in a position in which it cannot obtain full compensation for the loss caused by unlawful entry into the market of generic medicines, justifies settlements even where the patents concerned are objectively strong and infringed.

105 Third, Lundbeck claims that the General Court erred in law by refusing, in paragraphs 466 to 477 of the judgment under appeal, to require the Commission to examine the 'counterfactual scenario' at issue, on the ground that such an examination was a necessary factor to be taken into account in any analysis of competition even where the agreement concerned is deemed to contain a restriction by object, in order to establish the causal link between the practice concerned and the restriction invoked and to ensure that the restriction is not caused by other factors, such as the existence of patents in the present case. In its reply to the question to be answered in writing of 6 February 2020, Lundbeck stated that that error of law is borne out by the significance which the Court of Justice attached to the examination of that scenario in paragraph 37 of the judgment of 30 January 2020, *Generics (UK) and Others* (C−307/18, EU:C:2020:52).

106 Fourth, Lundbeck argues that the General Court erred in law by equating, in paragraphs 435 and 470 to 476 of the judgment under appeal, the agreements at issue with naked market exclusion agreements on the ground that they were made between actual or potential competitors. Those agreements did pursue legitimate objectives. Moreover, at the time of the agreements at issue, no 'unequivocal experience and consensus' on characterisation as 'restrictions by object' existed, either in the case-law or in the decision-making practice of the European and national competition authorities. Furthermore, it is apparent from the Danish Competition Authority communications that, at that time, agreements such as the agreements at issue were in a grey area, and therefore did not reveal a sufficient degree of harmfulness to competition to allow them to be characterised as 'restrictions by object'.

107 Finally, in its reply to the question to be answered in writing of 6 February 2020, Lundbeck argued that the agreements at issue could not be characterised as 'restrictions by object' since, unlike those at issue in the case giving rise to the judgment of 30 January 2020, *Generics (UK) and Others* (C−307/18, EU:C:2020:52), they did not contain no-challenge clauses in respect of the patents concerned.

108 By its second ground of appeal, Lundbeck claims that the General Court erred in law and made a manifest error of assessment of the evidence by failing to apply the appropriate legal test in concluding that five of the six agreements at issue – namely the GUK EEA Agreement, the UK Arrow Agreement, the Danish Arrow Agreement, the Alpharma Agreement and the Ranbaxy Agreement – fell outside the scope of the Lundbeck's new process patents. Those agreements, in particular when read in the light of the applicable national law, did not indicate any meeting of minds in respect of bringing those agreements outside of the scope of Lundbeck's new process patents and, therefore, applying those same agreements to non-infringing citalopram.

109 By its third ground of appeal, raised in the alternative in the event that the Court of Justice rejects, in whole or in part, the second ground of appeal and therefore upholds the finding that five or fewer of the six agreements at issue fall outside the scope of Lundbeck's new process patents, Lundbeck submits that the General Court erred in law by characterising those agreements as 'restrictions by object' for the reasons set out in the second, third and fourth parts of the first ground of appeal.

Findings of the Court

110 As a preliminary point, it should be noted that Lundbeck's criticisms are of two kinds: the first, second and fourth parts of the first ground challenge the characterisation of the agreements at issue as 'restrictions by

object', and the third part of that ground challenges the methodology used to arrive at that conclusion and, specifically, the failure of the General Court to examine the 'counterfactual scenario'.

111 It is therefore appropriate to start by examining the first, second and fourth parts of the first ground, taken together, and then to move on to examine the third part of that ground.

112 As regards, in the first place, the first, second and fourth parts of the first ground, the Court of Justice has previously held, as the General Court pointed out in paragraph 343 of the judgment under appeal, that the concept of restriction of competition 'by object' must be interpreted strictly and can be applied only to some agreements between undertakings which reveal, in themselves and having regard to the content of their provisions, their objectives, and the economic and legal context of which they form part, a sufficient degree of harm to competition for the view to be taken that it is not necessary to assess their effects, since some forms of coordination between undertakings can be regarded, by their very nature, as being harmful to the proper functioning of normal competition (judgment of 30 January 2020, *Generics (UK) and Others*, C−307/18, EU:C:2020:52, paragraph 67 and the case-law cited).

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

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

115 For the purpose of that examination, it is appropriate to assess on a case-by-case basis whether the net gain of the transfers of value from the manufacturer of originator medicines to the manufacturer of generic medicines was sufficiently significant actually to act as an incentive to the manufacturer of generic medicines to refrain from entering the market concerned and, consequently, not to compete on the merits with the manufacturer of originator medicines; however, there is no requirement that the net gain should necessarily be greater than the profits which that manufacturer of generic medicines would have made if it had been successful in the patent proceedings (see, to that effect, judgment of 30 January 2020, *Generics (UK) and Others*, C−307/18, EU:C:2020:52, paragraphs 93 and 94).

116 In the present case, it is apparent from the judgment under appeal that the effects of the agreements at issue were to keep the manufacturers of generic medicines outside the markets concerned and to lead one of them – namely Merck (GUK) – to stop supplying a reseller operating on the Swedish market with the generic medicines concerned and to exit the UK market, as is apparent from paragraph 131 of the judgment under appeal.

117 In addition, paragraphs 361 to 363 and paragraph 366 of the judgment under appeal, which are not contested by Lundbeck in the context of its appeal, highlight, first, the fact that the parties to the agreements at issue were, prior to the conclusion of those agreements, in dispute over whether Lundbeck's new process patents were sufficiently strong to prevent the market entry of generic citalopram which means that those patents could not have constituted the decisive basis of the commitment by the manufacturers of generic medicines not to enter the market. Second, it is also apparent from those paragraphs that Lundbeck does not dispute that the amounts which it paid to those manufacturers could have been calculated by taking into consideration the profit or turnover which the latter expected to make during the term of the agreements at issue if they had entered the market. Third, those paragraphs also indicate that the evidence relating to the period preceding the conclusion of

the agreements at issue shows that the manufacturers of generic medicines had made considerable efforts to prepare for their market entry and that they did not intend to desist from those efforts on account of Lundbeck's new process patents and, consequently, that it is principally the size of the reverse payments to the manufacturers of generic medicines which had induced them to accept the limitations governing their behaviour.

118 In the light of those findings of fact, and there being no need to determine whether the General Court was entitled to treat the agreements at issue, in paragraphs 435 and 476 of the judgment under appeal, as market exclusion agreements or even as market-sharing agreements, it concluded, without committing any error of law, that the agreements at issue should be characterised as 'restrictions by object' for the purpose of Article 101(1) TFEU, especially since Lundbeck has not in any way argued, in particular in its reply to the question to be answered in writing of 6 February 2020, that the transfers of value which are associated with the agreements at issue could be justified by the existence of possible consideration or proven and legitimate commitments by one or other of the manufacturers of generic medicines to refrain from taking action.

119 That conclusion cannot be called into question by the arguments put forward by Lundbeck.

120 First, in order to establish that the agreements at issue should not be characterised as 'restrictions by object', Lundbeck cannot validly rely on the fact that those agreements were limited to the scope of Lundbeck's new process patents, compliance with which that party is entitled to obtain.

121 While the conclusion by the holder of a patent with a party allegedly infringing that patent of a settlement agreement that does not exceed the scope and duration of remaining validity of that patent does constitute an expression of the intellectual property right of that holder, which permits that holder, inter alia, to oppose any infringement, the fact remains that that patent does not permit its holder to enter into contracts that are contrary to Article 101 TFEU (judgment of 30 January 2020, *Generics (UK) and Others*, C−307/18, EU:C:2020:52, paragraph 97).

122 As the General Court rightly found in paragraph 495 of the judgment under appeal, even if the agreements at issue also contained restrictions potentially falling within the scope of Lundbeck's new process patents, 'those agreements went beyond the specific subject matter of their intellectual property rights, which indeed included the right to oppose infringements, but not the right to conclude agreements by which actual or potential competitors were paid not to enter the market', which is confirmed, in essence, by paragraphs 117 and 118 of the present judgment.

123 Consequently, there is no basis for Lundbeck's attempt to rely on the fact that the agreements at issue are a legitimate expression of its intellectual property rights. In any event, such an allegation is based on the twofold assumption – which was not established at the time the agreements were concluded – that the validity of Lundbeck's new process patents cannot be called into question and that the manufacturers of generic medicines are infringing them (see, to that effect, judgment of 30 January 2020, *Generics (UK) and Others*, C−307/18, EU:C:2020:52, paragraph 88).

124 Second, nor can Lundbeck argue, in order to establish that the agreements at issue should not be characterised as 'restrictions by object', that those agreements pursued legitimate objectives since their purpose was to protect Lundbeck's new process patents by recourse to a legitimate and commonplace means of dispute resolution, or that they were responding to an asymmetry of risk between manufacturers of originator medicines and manufacturers of generic medicines.

125 As regards, in the first place, the argument that the purpose of those agreements was to protect Lundbeck's new process patents by recourse to a legitimate and commonplace means of dispute resolution, it is sufficient to note that, as was stated previously in paragraph 121 of the present judgment and was correctly pointed out, in essence, by the General Court in paragraph 495 of the judgment under appeal, a patent does not permit its holder to enter into contracts that are contrary to Article 101 TFEU.

126 As regards, in the second place, the argument that the agreements at issue reflect the fact, referred to by the General Court in paragraph 378 of the judgment under appeal, that the damages to which manufacturers of

originator medicines may be entitled in the event of the unlawful entry of generic medicines on the market are often substantially lower than the damage 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).

127 Thus, as the General Court rightly pointed out in paragraph 387 of the judgment under appeal, it is unacceptable for undertakings to attempt to mitigate the effects of legal rules which they consider 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.

128 Consequently, the circumstances referred to by Lundbeck cannot legitimise an infringement of Article 101 TFEU, let alone a concerted practice which has been found to be sufficiently harmful to competition to be characterised as a 'restriction by object'.

129 Third, nor can Lundbeck argue, in order to establish that the agreements at issue should not be characterised as 'restrictions by object', that, at the time when the agreements at issue were concluded, there were doubts as to whether agreements such as the agreements at issue could be characterised as such, in particular in view of the lack of decision-making practice in relation to those agreements and the doubts arising, according to Lundbeck, from certain statements made by the Danish Competition Authority and the Commission.

130 As the General Court rightly pointed out in paragraphs 438 and 774 of the judgment under appeal, it is in no way necessary that the same type of agreement has already been censured by the Commission in order for such agreements to be considered to be restrictive of competition by object, and that remains the case even if they occur in a specific context, such as that of intellectual property rights.

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

132 Similarly, the adoption of contradictory positions – some of which are merely noted in reports – by the Commission and a national competition authority in respect of an agreement, such as those referred to in paragraphs 747 to 751 of the judgment under appeal, assuming that they are correct, cannot lead to the conclusion that that agreement cannot be characterised as a 'restriction by object' since it is in no way established that those positions are the result of an analysis such as that referred to in the previous paragraph.

133 Fourth, and finally, nor can Lundbeck rely, in order to establish that the agreements at issue should not be characterised as 'restrictions by object', on the fact that the agreements at issue did not contain any no-challenge clauses, unlike the agreements at issue in the case which gave rise to the judgment of 30 January 2020, *Generics (UK) and Others* (C−307/18, EU:C:2020:52), or the fact that that judgment stressed the importance of taking into account the pro-competitive effects of the agreements at issue when deciding whether to characterise them as 'restrictions by object'.

134 In that regard, it was pointed out previously in paragraph 114 of the present judgment that, in the case of agreements such as the agreements at issue, it is necessary to determine whether, by those agreements, competitors deliberately substitute practical cooperation between them for the risks of competition, by assessing, in essence, whether the net gain of the transfers of value for which they provide can be explained only by 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.

135 In paragraph 399 of the judgment under appeal, the General Court definitively found, first, that, even though the agreements at issue did not contain any no-challenge clause, the manufacturers of generic medicines had no incentive to challenge Lundbeck's new process patents after concluding the agreements at issue, since the

reverse payments broadly correspond to the profits that those manufacturers expected to make if they had entered the market or to the damages which could have been paid to them if they had succeeded in litigation against Lundbeck, and, second, that even if those payments were of an amount less than the expected profits, they nevertheless constituted a certain and immediate profit, without those manufacturers having to take the risks that market entry would have entailed.

136 In the present case, such a finding is sufficient to establish that the agreements at issue are restrictive of competition by object, especially given that, in any event, Lundbeck does not in the appeal make mention of any pro-competitive effect associated with those agreements, and therefore does not satisfy the standard of proof required by the judgment of 30 January 2020, *Generics (UK) and Others* (C−307/18, EU:C:2020:52), in particular in paragraph 107 of that judgment, in order to rebut characterisation of those agreements as 'restrictions by object' on the basis of reasonable doubts as to whether they caused a sufficient degree of harm to competition.

137 A mere unsubstantiated assertion concerning the pro-competitive effects of the agreements at issue is insufficient to rebut their characterisation as 'restrictions by object' (see, to that effect, judgment of 30 January 2020, *Generics (UK) and Others*, C−307/18, EU:C:2020:52, paragraph 110).

138 Although, in its action for annulment and, specifically, in the seventh plea in law relied on in support of that action, Lundbeck did indeed submit that the Commission made a manifest error of assessment by incorrectly assessing the efficiency gains of the agreements at issue in the context of the application of Article 101(3) TFEU, the fact remains that paragraphs 708 to 720 of the judgment under appeal, by which the General Court rejected that plea, have not been challenged in the present appeal, and that no reference has been made to the reasoning set out in those paragraphs in an effort to call into question the characterisation of those agreements as 'restrictions by object', particularly in the context of Lundbeck's reply to the question to be answered in writing of 6 February 2020.

139 In the second place, as regards the third part of the first ground of appeal directed against paragraphs 472 and 473 of the judgment under appeal, by which the General Court held, in essence, that it was not necessary to examine the 'counterfactual scenario' in order to characterise conduct as a 'restriction by object', it should be noted that that examination allows the effects of a concerted practice with regard to Article 101 TFEU to be assessed when the analysis of that practice does not reveal a sufficient degree of harm to competition to enable it to be characterised as a 'restriction by object' (judgment of 30 January 2020, *Generics (UK) and Others*, C−307/18, EU:C:2020:52, paragraphs 115 and 118 and the case-law cited).

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

141 Therefore, and as the General Court rightly held in paragraph 472 of the judgment under appeal, in order to characterise such a practice as a 'restriction by object' it was only necessary to establish that that practice revealed a sufficient degree of harm to competition, in view of the content of the provisions involved in that practice, the objectives that that practice is intended to achieve and the economic and legal context of which it formed part; the Commission was not required, however, to examine the effects thereof.

142 Furthermore, contrary to what Lundbeck argued in its reply to the question to be answered in writing of 6 February 2020, the examination of the 'counterfactual scenario' is not required by paragraph 37 of the judgment of 30 January 2020, *Generics (UK) and Others* (C−307/18, EU:C:2020:52).

143 Although, in that paragraph, the Court of Justice did indeed specify that, when the agreement at issue is one which has the effect of temporarily keeping an undertaking outside a market, it must be determined whether there would have existed, in the absence of that agreement, real and concrete possibilities for that undertaking to enter that market, it should be noted that that specific clarification concerned the assessment of the existence of a

potential competitive relationship between the parties to an agreement such as those at issue in the case which gave rise to that judgment and not the characterisation of those agreements as a ‘restriction by object’.

144 The third part of the first ground of appeal must therefore be rejected as being unfounded.

145 As regards the second ground of appeal, there being no need to rule on the admissibility of that ground, which is contested by the Commission, it should be recalled that, in paragraph 539 of the judgment under appeal, the General Court noted, without erring in law, as is apparent from paragraph 121 of the present judgment, that even if the agreements at issue had not gone beyond the scope of Lundbeck’s new process patents, those agreements would nevertheless have constituted restrictions on competition by object for the purpose of Article 101(1) TFEU. As is apparent from paragraph 541 of the judgment under appeal, the examination of Lundbeck’s arguments, which is criticised in the second ground of appeal, was carried out by the General Court only for the sake of completeness. Consequently, since it was aimed at reasoning set out in the judgment under appeal for the sake of completeness, the second ground of appeal must be rejected as being ineffective (see, to that effect, judgment of 14 December 2016, *SV Capital* v *ABE*, C−577/15 P, EU:C:2016:947, paragraph 65).

146 Finally, it should be noted that, in its third ground of appeal, Lundbeck refers to the arguments developed in support of its first ground of appeal. However, the solution reached in respect of the first ground of appeal concerning the characterisation of the agreements at issue as ‘restrictions by object’ in so far as they fall solely within the scope of Lundbeck’s new process patents applies a fortiori to the third ground of appeal concerning the characterisation of some of the agreements at issue as ‘restrictions by object’ to the extent that they go beyond the scope of those patents.

147 Accordingly, it follows from foregoing that the first, second and third grounds of appeal must be rejected.

The fifth ground of appeal

The relevant paragraphs of the judgment under appeal

148 By the first part of the ninth plea in law of its action for annulment, Lundbeck argued that, assuming that the Commission was entitled to conclude that the agreements at issue had infringed Article 101 TFEU, there were no valid grounds for imposing fines on Lundbeck in the present case, given the novelty and complexity of the factual and legal issues raised, and that to do so would infringe the principle of legal certainty and the principle that offences and penalties must have a proper legal basis (*nullum crimen, nulla poena sine lege*).

149 In order to reject that plea, the General Court held, in essence, in paragraph 777 of the judgment under appeal, that, far from being unforeseeable at the time, the restrictions on competition set out by the agreements by means of which a manufacturer of originator medicines managed to exclude potential competitors from a market for a given period through significant reverse payments could reasonably have been perceived by the parties to those agreements as being contrary to Article 101(1) TFEU, which means that the Commission was allowed to impose penalties on them without infringing the principle of legal certainty and the principle that offences and penalties must have a proper legal basis (*nullum crimen, nulla poena sine lege*).

150 In that regard, the General Court noted, inter alia, in paragraph 776 of the judgment under appeal, that certain manufacturers of generic medicines had been aware of the infringing nature of agreements similar to the agreements at issue and had refused to enter into such agreements precisely for that reason.

Arguments of the parties

151 By its fifth ground of appeal, which is composed of three parts, Lundbeck alleges that the General Court was wrong to uphold the fines imposed on it by the Commission.

152 In support of that ground, Lundbeck submits, in the first place, that, in paragraph 777 of the judgment under appeal, the General Court erred in law by misapplying the standard for culpability required to impose a

fine on the perpetrator of an anticompetitive practice, as such a fine can be imposed only if it is certain – and not merely possible – that the perpetrator was aware of the anticompetitive nature of the infringement.

153 In the second place, in view of the complexity of the agreements at issue, Lundbeck submits that the General Court erred in law by upholding the Commission's conclusion that Lundbeck could not be unaware of the anticompetitive nature of its conduct. Moreover, Lundbeck states that that conclusion could not be substantiated by the documents on which the General Court relied to that end, referred to in paragraph 776 of the judgment under appeal, at least in respect of all of the agreements at issue, without distorting the clear sense of those documents.

154 In the third place, Lundbeck criticises the General Court for having disregarded the principle of legal certainty and the principle that a new interpretation of a provision establishing an infringement should not have retroactive effect by upholding the imposition of penalties that went beyond nominal fines. A nominal amount should have been imposed on account of, first, the fact that the issues raised by the agreements at issue were complex and novel, second, the uncertainty existing at the material time as to the interpretation of Article 101 TFEU arising, inter alia, from the statements of the Danish Competition Authority and, third, of the absence of precedents in respect of such agreements.

155 The Commission submits that the fifth ground of appeal must be rejected as being unfounded.

Findings of the Court

156 As the General Court rightly pointed out in paragraph 762 of the judgment under appeal, a penalty may be imposed on an undertaking for conduct falling within the scope of Article 101(1) TFEU where that undertaking could not be unaware of the anticompetitive nature of its conduct, whether or not it is aware that it is infringing the competition rules of the Treaty (see, to that effect, judgment of 18 June 2013, *Schenker & Co. and Others*, C−681/11, EU:C:2013:404, paragraph 37).

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

158 Thus, all that matters is whether that undertaking was in a position to determine that its conduct was anticompetitive in nature and not, as Lundbeck submits, whether that undertaking had in fact established that it was anticompetitive.

159 In that regard, the General Court held, in paragraphs 764 and 777 of the judgment under appeal, that, far from being unforeseeable at the time the agreements at issue were concluded, the restrictions on competition set out in those agreements could reasonably have been perceived by the parties thereto as being contrary to Article 101(1) TFEU.

160 In support of that assessment, the General Court essentially held, in paragraphs 765 to 776 of that judgment, first, that neither the wording of Article 101(1) TFEU nor the case-law relating to that provision in relation to intellectual property rights, which Lundbeck does not claim to have been incorrectly interpreted by the General Court, left any room for doubt as to the incompatibility of the agreements at issue with Article 101(1) TFEU; second, that the Danish Competition Authority's adoption of a position with respect to those agreements, if it was vague, could not give rise to a legitimate expectation that those agreements would not be subject to a penalty; third, that the novelty of a penalty in respect of the agreements at issue could not justify fines limited to a nominal amount; and, fourth, that some manufacturers of generic medicines had been very much aware of the offending nature of agreements similar to the agreements at issue and had refused to enter into such agreements precisely for that reason.

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

162 Furthermore, Lundbeck cannot validly argue that the General Court distorted the clear sense of the facts or the evidence by finding that certain manufacturers of generic medicines had been very much aware of the offending nature of agreements similar to the agreements at issue and had refused to enter into such agreements precisely for that reason. In addition to the fact that that claim is directed against only one of the grounds on which the General Court's finding is based, as set out in paragraph 160 of the present judgment, it should be noted that, given the exceptional nature of a ground alleging that there has been a distortion of the clear sense of the facts or the evidence, Article 256 TFEU, the first paragraph of Article 58 of the Statute of the Court of Justice of the European Union, and Article 168(1)(d) of the Rules of Procedure provide, in particular, that an appellant must indicate precisely the evidence the sense of which is alleged to have been distorted by the General Court and show the errors of appraisal which, in its view, led to that distortion (judgment of 20 October 2011, *PepsiCo* v *Grupo Promer Mon Graphic*, C−281/10 P, EU:C:2011:679, paragraph 78 and the case-law cited).

163 Although Lundbeck relied on a distortion of the clear sense of the documents referred to in paragraph 776 of the judgment under appeal, it has not in any way set out the errors of appraisal allegedly made by the General Court which led it to distort the sense of those documents. Consequently, in so far as it is based on an alleged distortion of the clear sense of the facts and the evidence, the fifth ground must be dismissed as inadmissible.

164 Furthermore, the fact that certain manufacturers of generic medicines or members of Lundbeck's staff may have expressed doubts as to the legality of the agreements at issue or agreements similar to those agreements is a factor that is entirely capable of substantiating the finding that Lundbeck was in a position to determine that its conduct was or, at the very least, may have been anticompetitive in nature.

165 Finally, the fact that the General Court upheld the imposition on Lundbeck of fines exceeding a nominal level in no way infringed the principle of legal certainty, notwithstanding the novel and complex nature of the issues raised by the agreements at issue, the lack of precedent, and the existence of documents relating to those agreements published by the Danish Competition Authority, the content of which is referred to in paragraphs 749 to 752 of the judgment under appeal.

166 In the first place, with regard to the novelty of the penalties imposed with respect to the agreements at issue, as the General Court noted, in essence, in paragraph 763 of the judgment under appeal, the principle *nulla poena sine lege certa*, which is enshrined in Article 49 of the Charter of Fundamental Rights of the European Union, cannot be interpreted as prohibiting the gradual clarification of rules of criminal liability by means of interpretations in the case-law, provided that those interpretations are reasonably foreseeable (judgment of 28 March 2017, *Rosneft*, C−72/15, EU:C:2017:236, paragraph 167 and the case-law cited).

167 It follows from paragraph 114 of the present judgment that characterisation as a 'restriction by object' and, a fortiori, as a 'restriction of competition' within the meaning of Article 101(1) TFEU must be made where it is apparent from an analysis of the relevant settlement agreement that the transfers of value provided for therein are explained solely by the commercial interest of both the holder of the patent at issue and the alleged infringer in not competing on the merits, since agreements in which competitors deliberately substitute practical cooperation between themselves for the risks of competition are clearly to be characterised as a 'restriction by object'.

168 Furthermore, the General Court found, in paragraphs 764 and 777 of the judgment under appeal, that Lundbeck could have foreseen the imposition of a penalty in respect of the agreements at issue pursuant to Article 101 TFEU.

169 In the second place, with regard to the information contained in the documents issued by the Danish Competition Authority, it should be noted that the General Court, in its absolute discretion, found, in essence, in paragraphs 749 and 750 and then in paragraphs 834 and 835 of the judgment under appeal, either that those documents made it apparent that that authority took the view that the agreements at issue could influence competition if it appeared that Lundbeck had paid competitors to stay out of the market and, therefore, constituted very serious infringements of Article 101 TFEU, or that those documents were merely a report concerning the Commission's preliminary opinion.

170 Moreover, as the General Court rightly pointed out in paragraph 748 of the judgment under appeal, national competition authorities cannot cause undertakings to entertain a legitimate expectation that their conduct does not infringe Article 101 TFEU, since they do not have the power to adopt a negative decision, that is to say, a decision concluding that there is no infringement of Article 101 TFEU (see, to that effect, judgment of 18 June 2013, *Schenker & Co. and Others*, C-681/11, EU:C:2013:404, paragraph 42 and the case-law cited).

171 Furthermore, as regards Lundbeck's claim that the imposition of the relevant fines constituted an infringement of the principle of non-retroactivity of criminal law, it is sufficient to note that that allegation, which was made for the first time at the appeal stage, constitutes a new plea in law and is therefore inadmissible, in accordance with Articles 127 and 190, taken together, of the Rules of Procedure.

172 As is apparent from paragraph 757 of the judgment under appeal, in the first part of the ninth plea seeking annulment, Lundbeck merely relied on a breach of the principle of legal certainty and of the principle that offences and penalties must have a proper legal basis (*nullum crimen, nulla poena sine lege*).

173 Accordingly, the fifth ground of appeal must be rejected as being inadmissible in part and unfounded in part.

The sixth ground of appeal

The relevant paragraphs of the judgment under appeal

174 By the tenth plea in law in its action for annulment – the rejection of only the first and second parts of which is being disputed in the present appeal – Lundbeck submitted that the Commission had made several errors of law and of fact by adopting as the basic amount of the fines imposed on it an excessively high percentage of 10 and 11% of the value of the sales of the product concerned, according to the geographical scope of the agreements at issue, and by failing to limit the duration of the infringements in question solely to the period during which manufacturers of generic medicines were actually ready to enter the market, which presupposed that they had at least one MA in the relevant countries, which was not the case, for example, in Austria.

175 In dismissing the first part of the tenth plea in law, the General Court found, in paragraphs 806 and 812 of the judgment under appeal, that the Commission did not make an error of law or infringe the principle of proportionality when it determined the basic amount of the fines concerned in accordance with point 22 of the 2006 Guidelines.

176 In particular, it stated in paragraph 804 of the judgment under appeal that 'contrary to [Lundbeck's] claim in that regard, the Commission was not required to reduce the basic amount of the [fines] in order to take into account only the value of sales in the countries where the [manufacturers of generic medicines] were at a more advanced stage in their preparations for entering the market' and that 'as they were infringements by object, the Commission was entitled, in so far as the infringements constituted by the agreements at issue (with the exception of the agreements concluded with Arrow) had a geographic scope of the whole of the EEA, to rely on that geographic scope without carrying out a detailed examination of the specific entry prospects of [manufacturers of generic medicines] in each EEA [Member] State'. In that regard, the General Court stated that 'it is the parties to the agreements at issue who specified the geographic scope of those agreements, and accordingly of the infringements in question in the present case, by deciding to provide that they would cover the whole of the EEA (with the exception of the infringement with Arrow)'.

177 In rejecting the second part of the tenth plea in law, the General Court held, in paragraphs 815 and 816 of the judgment under appeal, that the Commission had established to the requisite legal standard in the decision at issue that competition had been restricted by virtue of the agreements at issue, during their entire term and that Lundbeck had failed to demonstrate that, in the absence of the agreements at issue, competition – even potential – between them and the manufacturers of generic medicines would have been impossible or non-existent or that those agreements placed no restriction on competition, unlike the situation in the case that gave rise to the judgment of 29 June 2012, *E.ON Ruhrgas and E.ON* v *Commission* (T-360/09, EU:T:2012:332). It

also noted that the opposite approach would amount to denying the distinction between ‘actual competition’ and ‘potential competition’.

178 Finally, in paragraph 842 of the judgment under appeal, the General Court held, in the exercise of its unlimited jurisdiction, that it was not necessary, in the present case, to grant the benefit of mitigating circumstances, and that the fine imposed on Lundbeck in the decision at issue must be upheld.

Arguments of the parties

179 By its sixth ground of appeal, which is submitted in the alternative and which is composed of three parts, Lundbeck submits that the General Court’s decision to uphold the calculation of the fines imposed on Lundbeck by the Commission is vitiated by an error in law and contains an inadequate statement of reasons.

180 In support of that ground, Lundbeck submits, in the first place, that the General Court erred in law by failing to find it necessary, in paragraph 804 of the judgment under appeal, to exclude, for the purpose of calculating the fines imposed on it, sales which were not able to have been affected by the agreements at issue, namely sales made by Lundbeck in certain EEA Member States whose markets were effectively closed to manufacturers of generic medicines on the ground that they were not granted an MA before the expiry of those agreements or, in the case of Austria, on the ground that the patent for Lundbeck’s citalopram API remained in force there for a large part of the duration of those agreements. In accordance with points 6 and 13 of the 2006 Guidelines, the Commission should have taken into account only those sales to which the infringement in question actually related.

181 In addition, the General Court misapplied the case-law, also in paragraph 804 of the judgment under appeal, first, by finding that the fact that the agreements at issue were ‘infringements by object’ by their very nature meant that the Commission did not need to carry out a specific examination, even though such an examination may be of some importance for the purpose of calculating the amount of the fines, as the Court of Justice stated in paragraph 31 of the judgment of 4 June 2009, *T-Mobile Netherlands and Others* (C−8/08, EU:C:2009:343). Second, by not excluding from the calculation of the fines sales corresponding to activities that were not capable of being in competition during the term of the agreements at issue – which were excluded in the case which gave rise to the judgment of 29 June 2012, *E.ON Ruhrgas and E.ON* v *Commission* (T−360/09, EU:T:2012:332) – the General Court failed to carry out the factual and legal analysis necessary in order to determine the value of sales directly or indirectly related to the infringements at issue, as required by the judgment of 28 June 2016, *Telefónica* v *Commission* (T−216/13, EU:T:2016:369, paragraph 309).

182 In the second place, Lundbeck criticises the General Court for having failed to give adequate reasons, in paragraph 816 of the judgment under appeal, for failing to apply the method accepted in the judgment of 29 June 2012, *E.ON Ruhrgas and E.ON* v *Commission* (T−360/09, EU:T:2012:332). In particular, the General Court failed to explain how manufacturers of generic medicines were not de facto prevented from entering the market of the EEA Member States concerned by the lack of an MA and the existence of the patent for Lundbeck’s citalopram API.

183 In the third place, Lundbeck submits that the General Court incorrectly assessed the circumstances of the case by finding, in paragraph 806 of the judgment under appeal, that the Commission was entitled to adopt, for the purpose of calculating the amount of the fines imposed on it in accordance with the 2006 Guidelines, a percentage of the value of sales to which the infringement relates of 10 and 11% depending on the geographical scope of the agreements at issue. In view of the limited geographical impact of those agreements and the Commission’s decision-making practice in similar cases and the fact that such agreements do not constitute cartels, those percentages should have been lower and set at the lowest level possible.

Findings of the Court

184 As regards, in the first place, the first and second parts of the sixth ground of appeal, which should be examined together, Lundbeck claims, in essence, that, in paragraphs 804 and 816 of the judgment under appeal, the General Court erred in law by finding, without responding to its arguments, that the Commission was not

required to reduce the basic amount of the fines in order to take into account only the value of sales in countries where the manufacturers of generic medicines were more advanced in their preparations for market entry.

185 With regard to the imposition by the Commission of a fine pursuant to Article 23(2) of Regulation No 1/2003, the Court has held previously that that institution must assess, in each specific case and having regard to both the context and the objectives pursued by the scheme of penalties created by that regulation, the intended impact on the undertaking concerned, in particular by taking into account a turnover which reflects the undertaking's real economic situation during the period in which the infringement was committed (judgment of 7 September 2016, *Pilkington Group and Others* v *Commission*, C−101/15 P, EU:C:2016:631, paragraph 16 and the case-law cited).

186 In that context, it is permissible, for the purpose of setting the amount of the fine, to have regard both to the overall turnover of the undertaking, which gives an indication, albeit approximate and imperfect, of its size and of its economic power, and to the proportion of that turnover accounted for by the goods in respect of which the infringement was committed, which gives an indication of the scale of the infringement (judgment of 7 September 2016, *Pilkington Group and Others* v *Commission*, C−101/15 P, EU:C:2016:631, paragraph 17 and the case-law cited).

187 Since the fines imposed by the decision at issue were set, by the Commission, in application of the 2006 Guidelines, it should be noted that, according to the case-law of the Court of Justice, while the concept of the 'value of sales' referred to in point 13 of those guidelines admittedly cannot extend to encompassing sales made by the undertaking in question which do not come within the scope of the alleged cartel, it would, however, be contrary to the goal pursued by that provision if that concept were to be understood as applying only to turnover achieved by the sales in respect of which it is established that they were actually affected by that cartel (judgment of 7 September 2016, *Pilkington Group and Others* v *Commission*, C−101/15 P, EU:C:2016:631, paragraph 19).

188 It is true that it follows from that finding that sales by the infringer on a market which is not open to competition, such as the market in question in the judgment of 29 June 2012, *E.ON Ruhrgas and E.ON* v *Commission* (T−360/09, EU:T:2012:332, paragraphs 105 and 155), must be excluded from the value of sales that are the subject of an infringement, as is argued by Lundbeck, to the extent that such a market cannot be affected by an anticompetitive practice under Article 101 TFEU, or sales made by one of the parties to a cartel on markets on which the other parties to that cartel are not present and cannot be regarded as potential competitors.

189 However, in the present case, none of the sales included by the Commission in the accepted value of the sales, the total amount of which was upheld by the General Court, falls within any of the categories of excluded sales referred to in the preceding paragraph.

190 As the Advocate General pointed out in points 222 and 223 of her Opinion, regardless of whether the sales were made in Austria, where the patent for Lundbeck's citalopram API expired, according to that party, only in April 2003, namely while the agreements at issue were in force, or in States in which the manufacturers of generic medicines obtained an MA only while those agreements were in force or even afterwards, all those sales were made on markets on which the manufacturers of the medicines concerned were at least in potential competition for the entire term of those agreements, which the General Court rightly noted, in paragraph 815 of the judgment under appeal, and which is confirmed by the rejection of the fourth ground of appeal.

191 It cannot therefore be validly argued that the sales referred to in the preceding paragraph were not at least indirectly linked to the infringements found and, therefore, should not be taken into account for the purpose of calculating the fines imposed on Lundbeck.

192 As the General Court noted in paragraph 804 of the judgment under appeal, it is the parties to the agreements at issue themselves which defined the geographical scope of those agreements, excluding those concluded between Lundbeck and Arrow, as extending to the whole of the EEA, which shows that they considered that they were, on each of the EEA markets, in competition that was, if not actual, then at the very

least potential, with the result that Lundbeck's sales in each of those markets must be considered as sales 'to which the infringement directly or indirectly relates' under point 13 of the 2006 Guidelines.

193 Accordingly, Lundbeck cannot criticise the General Court for having accepted, in paragraph 804 of the judgment under appeal, that, as regards the agreements at issue, with the exception of the agreements concluded between Lundbeck and Arrow, sales throughout the EEA were to be taken into account without carrying out a detailed examination of the specific entry prospects of manufacturers of generic medicines in the territory of each EEA Member State.

194 Finally, nor can Lundbeck validly complain that the General Court failed to state sufficient reasons, in paragraph 816 of the judgment under appeal, for not having applied, in the present case, the approach followed in the judgment of 29 June 2012, *E.ON Ruhrgas and E.ON* v *Commission* (T−360/09, EU:T:2012:332).

195 By stating, in that paragraph, that the case which gave rise to that judgment was of no help to Lundbeck because, in that instance, all competition was impossible, even in the absence of the anticompetitive agreement at issue in that case, for part of the period of the infringement, since the market was legally shielded from competition by the national legislation applicable during that period, which created a de facto monopoly, the General Court allowed the persons concerned to know why it has not upheld their arguments and provides the Court of Justice with sufficient material for it to exercise its power of review (judgment of 25 June 2020, *SatCen* v *KF*, C−14/19 P, EU:C:2020:492, paragraph 96 and the case-law cited).

196 It follows that the first and second parts of the present ground of appeal must be rejected as being unfounded.

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

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

199 It follows that, in so far as Lundbeck challenges, by the third part of the sixth ground of appeal, the assessment made by the General Court, in particular in paragraph 842 of the judgment under appeal, as to the amount of the fines imposed in the light of the circumstances of the case, without establishing or even alleging that that amount is not merely inappropriate but is also excessive to the point of being disproportionate, it is in fact seeking a new assessment of the appropriateness of the amount of the fines imposed on it. That part must therefore be rejected as being inadmissible.

200 Consequently, the sixth ground in the present appeal must be rejected as being inadmissible in part and unfounded in part.

201 Having regard to all the foregoing, the appeal must be dismissed.

Costs

202 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.

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

204 Under Article 184(4) of the Rules of Procedure, where the appeal has not been brought by an intervener at first instance, he or she may not be ordered to pay costs in the appeal proceedings unless he or she participated in the written or oral part of the proceedings before the Court of Justice. Where an intervener at first instance takes part in the proceedings, the Court of Justice may decide that he or she is to bear his or her own costs.

205 Since EFPIA participated in the proceedings before the Court of Justice, it must be held, in the circumstances of the present case, that it must bear its own costs.

206 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.

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

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

1. **Dismisses the appeal;**

2. **Orders H. Lundbeck A/S and Lundbeck Ltd to bear their own costs and to pay the costs incurred by European Commission;**

3. **Orders the European Federation of Pharmaceutical Industries and Associations (EFPIA) to bear its own costs;**

4. **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

* Language of the case: English.