Reports of Cases

JUDGMENT OF THE GENERAL COURT (Ninth Chamber)

8 September 2016 [1]

(Competition — Agreements, decisions and concerted practices — Market for antidepressant medicinal products containing the active pharmaceutical ingredient citalopram — Concept of restriction of competition 'by object' — Potential competition — Generic medicinal products — Barriers to market entry resulting from the existence of patents — Agreements concluded between a patent holder and generic undertakings — Article 101(1) and (3) TFEU — Errors of law and of assessment — Obligation to state reasons — Rights of defence — Legal certainty — Fines)

In Case T-472/13,

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

and

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

represented by R. Subiotto QC, and T. Kuhn, lawyer,

applicants,

supported by

European Federation of Pharmaceutical Industries and Associations (EFPIA), established in Geneva (Switzerland), represented by F. Carlin, Barrister, and M. Healy, Solicitor,

intervener,

v

European Commission, represented initially by J. Bourke, F. Castilla Contreras, B. Mongin, T. Vecchi and C. Vollrath, and subsequently by F. Castilla Contreras, B. Mongin, T. Vecchi, C. Vollrath and T. Christoforou, acting as Agents,

defendant,

APPLICATION for 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) and for reduction of the amount of the fine imposed on the applicants by that decision,

1 — Language of the case: English.

THE GENERAL COURT (Ninth Chamber),

composed of G. Berardis (Rapporteur), President, O. Czúcz and A. Popescu, Judges

Registrar: L. Grzegorczyk, Administrator,

having regard to the written procedure and further to the hearing on 26 November 2015,

gives the following

Judgment

Summary of the facts and background to the dispute

I – *The companies involved in the present case*

1 H. Lundbeck A/S ('Lundbeck') is a company governed by Danish law which controls a group of companies, 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 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 European Economic Area (EEA). Following a number of company restructurings, on 31 March 2008 Alpharma ApS became Axellia Pharmaceuticals ApS, renamed Xellia Pharmaceuticals ApS ('Xellia') 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, Lundbeck filed a patent application in Denmark for the citalopram API and two processes — a cyanation process and an alkylation process — to produce that API. Patents for that API and those two processes ('the original patents') were issued in Denmark and in a number of Western European countries between 1977 and 1985.

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

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

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

20 Secondly, on 13 March 2000 Lundbeck filed a patent application with the Danish authorities relating to a process for the production of citalopram which envisaged a method of purification of the salts used by means of crystallisation. Similar applications were filed in other EEA countries and also with the WIPO and the EPO. Lundbeck obtained patents protecting the crystallisation process in 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, Lundbeck had already obtained, on 6 November 2000, a utility model for that process ('Lundbeck's utility model'), that is to say, a patent valid for six years, granted without a genuine prior examination.

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

22 Lastly, 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 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, 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 generic undertakings').

A – *The agreements with Merck (GUK)*

24 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 Lundbeck A/S'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. Next, 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 Lundbeck failed to initiate legal proceedings against other generic undertakings which attempted to enter the market or on determination of the litigation between Lundbeck and Lagap Pharmaceuticals Ltd, another generic undertaking ('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 Lundbeck's intellectual property rights and could give rise to claims on the part of 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, 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 would constitute full and final settlement of any claim that Lundbeck might have against GUK for infringement of its intellectual property rights in connection with the 'Products' delivered by GUK up to that date (Article 2.4 of the UK agreement);

— Lundbeck undertook to sell its 'Finished Products' to GUK and GUK undertook to purchase those 'Finished Products' exclusively from Lundbeck for resale by GUK and its affiliates in the United Kingdom during the term and subject to the conditions of the agreement (Article 3.2 of the 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 [Lundbeck] to GUK pursuant to this Agreement';

— 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, Lundbeck transferred the equivalent of EUR 19.4 million to GUK.

30 A second agreement was concluded between 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 ('Natco') — the manufacturer of the citalopram API used by Merck (GUK) to market its version of generic citalopram ('the Natco API' or 'the Natco citalopram') — ceased to supply citalopram and products containing Citalopram in the EEA during the term of the agreement (Articles 1.1 and 1.2 of the GUK EEA agreement). 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, Lundbeck transferred the equivalent of EUR 12 million to GUK under that agreement.

B – *The agreements with Arrow*

32 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, 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 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 Lundbeck is the holder of the crystallisation and film distillation patents;

— 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 Lundbeck or with the consent of Lundbeck ("the said Citalopram", which definition shall for the avoidance of doubt comprise only citalopram for marketing and sale in the [United Kingdom] and shall exclude Citalopram for marketing and sale in other countries)';

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

— the seventh recital in the Arrow UK preamble states that Arrow UK does not consider that it has infringed those patents or that they are valid, but accepts that 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 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 Lundbeck alleges to infringe its [intellectual property] Rights and, to enable Lundbeck to ascertain if there may be an infringement, during the [term of the Arrow UK agreement] to provide Lundbeck with sufficient samples for analysis purposes at least one month prior to any threatened manufacture, importation, sale or offer for sale pending a final unappealable decision in [the 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 Lundbeck might ask the competent United Kingdom court to make;

— Article 2.1 of that agreement states that 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, Lundbeck would have had to deposit with the Court if it intended to seek an injunction in the infringement action against Arrow), 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 Lundbeck's intellectual property rights, the amount specified in Article 2.2 of that agreement would constitute the full and final compensation that Arrow UK could obtain from Lundbeck for loss sustained as a result of the obligations arising under Article 1.1 of the Arrow UK agreement;

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

36 It should be observed, moreover, that on 6 February 2002 Lundbeck obtained the order referred to in Article 1.2 of the Arrow UK agreement ('the Arrow consent order').

37 The second agreement, concerning Denmark, was concluded on 3 June 2002 between 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 ('the term of the Arrow Danish agreement').

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 Arrow consent order;

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

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

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

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

C – *The agreement with Alpharma*

40 Lundbeck signed an agreement with Alpharma on 22 February 2002 ('the Alpharma agreement'), to run from that date until 30 June 2003 ('the term of the Alpharma agreement').

41 Before concluding that agreement, in January 2002 Alpharma had bought from Alfred E. Tiefenbacher GmbH & Co. ('Tiefenbacher') 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 ('the Cipla citalopram' or 'the Cipla API') 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 '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 ('Appendix A');

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

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

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

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

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

— The ninth and tenth recitals state that Lundbeck:

  — 'has agreed to compensate Alpharma in order for Lundbeck to avoid patent litigation', the outcome of which cannot be predicted with absolute certainty and which would be costly and time-consuming;

  — 'in order to settle the dispute, [has] agreed to purchase all of 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 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 Lundbeck, Alpharma … will voluntarily submit to an interim injunction by any competent court in any applicable country in the Territory' and that Lundbeck is to be entitled to obtain such injunction without providing any kind of security;

— Article 1.3 states that, as compensation for the obligations set out in that agreement and in order to avoid the costs and time of litigation, Lundbeck is to pay to 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 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 contains a list of 28 intellectual property rights applications lodged by 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 and film distillation patents.

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 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 and film distillation patents granted by the United Kingdom authorities] or any equivalent patent granted or applied for in relation to the Relevant Territories … until 30 June 2003' ('the Alpharma consent order').

D – *The agreement with Ranbaxy*

46 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 ('the term of the Ranbaxy agreement').

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);

— Lundbeck performed laboratory analyses on that citalopram and concluded that the processes used infringed the amide patent and the iodo patent, the latter not having been granted yet (see paragraph 19 above), whereas Ranbaxy Laboratories disputed the existence of such infringements (fifth to eighth recitals in the preamble);

— Lundbeck and Ranbaxy Laboratories arrived at an agreement in order to avoid costly and time-consuming patent litigation, the outcome of which could not be predicted with absolute certainty (ninth recital in the 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 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 Lundbeck', Ranbaxy Laboratories and Ranbaxy (UK) would voluntarily submit to an interim injunction by any competent national court, without Lundbeck providing any kind of security or any undertaking other than the undertakings arising under that agreement (Article 1.2 of the Ranbaxy agreement);

— in consideration of the agreement arrived at between the parties, 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);

— 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);

— 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 KFST').

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 KFST would not pursue the matter.

51 Between 2003 and 2006, the Commission carried out inspections within the meaning of Article 20(4) of Council Regulation (EC) No 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles [101 TFEU] and [102 TFEU] (OJ 2003 L 1, p. 1) at the premises of Lundbeck and other companies active in the pharmaceutical sector. It also sent Lundbeck and another company requests for information within the meaning of Article 18(2) of that regulation.

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 Lundbeck.

55 In 2010 and the first half of 2011, the Commission sent requests for information to 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 Lundbeck, a statement of objections.

57 All the addressees of that statement of objections who had requested a hearing were heard at the hearings on 14 and 15 March 2013.

58 On 12 April 2013, the Commission sent a letter of facts to all the addressees of the statement of objections.

59 The hearing officer issued his final report on 17 June 2013.

60 On 19 June 2013, the Commission adopted Decision C(2013) 3803 final relating to a proceeding under Article 101 [TFEU] and Article 53 of the EEA Agreement (Case AT.39226 — Lundbeck) ('the contested decision').

V – *Contested decision*

61 By the contested decision, 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 EEA Agreement (Article 1(1) of the contested decision).

62 The two agreements between Merck (GUK) and 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 contested decision, the Commission relied, in particular, on the following factors in that respect:

— at the time of concluding those agreements, 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;

— 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 Natco's citalopram 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;

— 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 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 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 contested decision, relating to 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, Lundbeck and Arrow were at least potential competitors in the United Kingdom and in Denmark;

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

— that transfer of value was linked to Arrow's acceptance of the limitations on its entry to the citalopram market in the United Kingdom and in Denmark contained in those agreements, in particular Arrow's commitment not to sell generic citalopram, which 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;

— 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 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 contested decision, the Commission relied, in particular, on the following factors:

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

— 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;

— Lundbeck could not have obtained those limitations through the application of the crystallisation and film distillation patents, 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 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 contested decision, the Commission relied, in particular, on the following factors:

— at the time of concluding that agreement, Lundbeck and Ranbaxy were at least potential competitors in the EEA;

— 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;

— 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 Lundbeck to refrain from bringing infringement proceedings against Ranbaxy if the latter entered the market with its generic citalopram after the expiry of the agreement.

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

69 Thus, as regards the parties to the agreements at issue other than 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 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 contested decision).

70 As regards 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 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 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 No 2215 of the contested decision).

71 The Commission also imposed four separate fines on Lundbeck, since the six agreements at issue were regarded as giving rise to four separate infringements, in so far as the two agreements between Lundbeck and Merck (GUK) gave rise to a single and continuous infringement, as did the two agreements between 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 contested decision). That method resulted in a reduction of 15% for each infringement where overlaps were found (footnote No 2218 of the contested decision).

72 In the light of the gravity of the infringements found, which the Commission classified as 'serious', since they entailed market exclusion; 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 contested decision).

73 The Commission applied a multiplier to that amount to take account of the duration of the infringements (recitals 1334 to 1337 of the contested decision) 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 would be sufficiently deterrent (recital 1340 of the contested decision).

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 contested decision (recitals 1349 and 1380 of the contested decision).

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 Lundbeck A/S, of which EUR 5 306 000 jointly and severally with Lundbeck Ltd, composed as follows (recitals 1238 and 1358 and Article 2 of the contested decision):

— 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.

Procedure and forms of order sought

76 By application lodged at the Court Registry on 30 August 2013, the applicants, Lundbeck A/S and Lundbeck Ltd, brought the present action.

77 By order of the President of the Ninth Chamber of 20 May 2014, the European Federation of Pharmaceutical Industries and Associations ('EFPIA' or 'the intervener') was granted leave to intervene in the present proceedings, in support of the form of order sought by the applicants.

78 In the context of measures of organisation of procedure provided for in Article 64 of the Rules of Procedure of the General Court of 2 May 1991, the main parties were invited to comment in writing, in the context of their observations on EFPIA's statement in intervention, on the possible consequences for the present case of the judgment of 11 September 2014 in *CB* v *Commission* (C-67/13 P, ECR, EU:C:2014:2204).

79 The main parties submitted their observations within the prescribed period, by pleadings lodged at the Court Registry on 15 January 2015.

80 The written stage of the procedure was closed on the same day.

81 On a proposal from the Judge-Rapporteur, the Court (Ninth Chamber) decided to open the oral part of the procedure and, by way of measures of organisation of procedure provided for in Article 89 of its Rules of Procedure, put a number of questions to the parties, to be answered in writing.

82 The parties answered those questions within the prescribed period, by pleadings received at the Court Registry on 30 October 2015.

83 The parties presented oral argument and replied to the questions put by the Court at the hearing on 26 November 2015.

84 The applicants claim that the Court should:

— adopt a measure of inquiry requesting the Commission to produce unredacted versions of its correspondence with the KFST;

— annul the contested decision;

— in the alternative, annul the fines imposed on the applicants pursuant to that decision;

— in the further alternative, substantially reduce those fines;

— in any event, order the Commission to pay the costs incurred by the applicants;

— take any other measure that the Court may deem appropriate.

85 The Commission contends that the Court should:

— dismiss the action as unfounded;

— order the applicants to pay the costs, with the exception of those incurred by the intervener;

— order the intervener to bear its own costs.

86 The intervener claims that the Court should:

— annul the contested decision in so far as it concerns the applicants;

— order the Commission to pay the costs incurred by the intervener.

87 As regards the applicants' head of claim asking the Court to adopt a measure of inquiry requesting the Commission to produce unredacted versions of its correspondence with the KFST, it must be noted that, following the spontaneous communication of those documents in the present proceedings, the applicants confirmed at the hearing that they did not wish to maintain that head of claim.

Law

88 The applicants raise ten pleas in law in support of their action. It is appropriate to examine those pleas in the order in which they have been set out by the applicants.

I – *The first plea in law, alleging errors of law and of assessment in that the contested decision considered that the generic undertakings and Lundbeck were at least potential competitors at the time the agreements at issue were concluded*

89 The applicants submit that the contested decision misinterprets the relevant case-law on establishing whether an agreement restricts potential competition, which presupposes the existence of real concrete possibilities of entering the market in the absence of the agreement, and they maintain that the Commission disregarded essential facts in that respect.

90 Before examining the applicants' arguments, it is appropriate to give a brief summary of the relevant case-law and of the approach taken by the Commission in the contested decision as regards the potential competition between Lundbeck and the generic undertakings.

A – *Analysis relating to potential competition in the contested decision*

91 In recitals 615 to 620 of the contested decision, the Commission examined the specific characteristics of the pharmaceutical sector and identified two phases in which potential competition could occur in that sector.

92 The first phase may begin several years before the expiry of the patent on an API, when generic producers that want to launch a generic version of the medicinal product concerned begin developing viable production processes leading to a product that meets regulatory requirements. Next, in the second phase, in order to prepare for actual market entry, a generic undertaking must apply for marketing authorisations ('MAs') pursuant to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, p. 67), order tablets from one or more generic producers or produce them itself and find distributors or set up its own distribution network, that is to say, it must take a series of preliminary steps, without which there would never be any effective competition on the market.

93 The impending expiry of the patent on an API therefore generates a dynamic competitive process, during which the various undertakings producing generic medicinal products compete to be the first to enter the market. The first of those undertakings to enter the market can generate significant profits, before competition intensifies and prices fall drastically. That is why those undertakings are willing to make considerable investments and take significant risks in order to be the first to enter the market for the product concerned once the patent on the API concerned expires.

94 In those two phases of potential competition, undertakings which produce generic medicinal products or which intend to sell them are often confronted with issues concerning patent law and intellectual property law. Nevertheless, they generally find a way to avoid infringing existing patents, such as process patents. They have various options in that respect, such as seeking a declaration of non-infringement or 'clearing the way' by informing the originator undertaking of their intention to enter the market. They may also launch their products 'at risk', defending themselves against any allegations of infringement or bringing a counter-claim calling into question the validity of the patents relied on in support of an infringement action. Lastly, they may also work with their API supplier in order to alter the production process or reduce the risk of infringement, or they may switch to another API producer in order to avoid such risk.

95 In recitals 621 to 623 of the contested decision, the Commission noted that, in the present case, Lundbeck's original patents had expired by January 2002 in most EEA countries. That had generated a dynamic competitive process, in which several undertakings producing or selling generic medicinal products had taken steps in order to be the first to enter the market. Lundbeck had been aware of that threat since December 1999, when it wrote in a strategic plan for 2000 that 'by 2002 ... generics [were] expected to have captured a substantial share of Cipramil sales'. Likewise, in December 2001, Lundbeck wrote in its strategic plan for 2002 that it expected that the United Kingdom market in particular would be severely hit by generic competition. In the light of those factors, the Commission took the view that the generic undertakings were exerting competitive pressure on Lundbeck at the time the agreements at issue were concluded.

96 In addition, in recitals 624 to 633 of the contested decision, the Commission stated that challenging patents is an expression of potential competition in the pharmaceutical sector. It noted, in that respect, that in the EEA, undertakings that wish to sell generic medicinal products are not required to demonstrate that their products do not infringe any patents in order to obtain an MA or to begin marketing those products. It is for the originator undertaking to prove, at least in a prima facie fashion, that those products infringe one of its patents, in order to obtain a court injunction prohibiting any further sales of those products on the market. In the present case, the Commission considered, relying inter alia on the assessments of the parties to the agreements at issue, that the crystallisation patent, on which Lundbeck heavily relied in order to block the market entry of generics in the United Kingdom, had a 60% chance of being held invalid by a court and that it was not perceived as novel by the generic undertakings. In those circumstances, the Commission considered that the possibility for generic undertakings to enter the market 'at risk' and potentially face infringement actions brought by Lundbeck was an expression of potential competition. Accordingly, the Commission concluded that Lundbeck's process patents were not capable of blocking all possibilities of market entry open to the generic undertakings.

97 In recital 635 of the contested decision, the Commission identified eight possible routes to the market in the present case, namely:

— first, launching the product 'at risk' and facing possible infringement actions brought by Lundbeck;

— secondly, making efforts to 'clear the way' with the originator undertaking before entering the market, especially in the United Kingdom;

— thirdly, requesting a declaration of non-infringement from a national court before entering the market;

— fourthly, claiming patent invalidity before the national courts, as a counter-claim to a claim of patent infringement made by the originator undertaking;

— fifthly, opposing a patent before the competent national authorities or the EPO and requesting that the patent be revoked or narrowed;

— sixthly, working with the current API producer or its supplier — in the case of Merck (GUK), Schweizerhall Pharma International GmbH ('Schweizerhall') — to change the API producers' process in such a way as to eliminate or reduce the risk of infringement of the originator undertaking's process patents;

— seventhly, switching to another API producer within the existing supply contract;

— eighthly, switching to another API producer outside of the existing supply contract, either because the existing supply contract permits it or possibly because an exclusive supply contract could be invalidated if the supplied API were found to infringe Lundbeck's process patents.

B – *Applicable principles and case-law*

1. The concept of potential competition

98 It must be noted, first of all, that, having regard to the requirements set out in Article 101(1) TFEU regarding effect on trade between Member States and repercussions on competition, that provision applies only to sectors open to competition (see judgment of 29 June 2012 in *E.ON Ruhrgas and E.ON* v *Commission*, T-360/09, ECR, EU:T:2012:332, paragraph 84 and the case-law cited).

99 According to the case-law, the examination of conditions of competition on a given market must be based not only on existing competition between undertakings already present on the relevant market but also on potential competition, in order to ascertain whether, in the light of the structure of the market and the economic and legal context within which it functions, there are real concrete possibilities for the undertakings concerned to compete among themselves or for a new competitor to enter the relevant market and compete with established undertakings (judgments of 15 September 1998 in *European Night Services and Others* v *Commission*, T-374/94, T-375/94, T-384/94 and T-388/94, ECR, EU:T:1998:198, paragraph 137; 14 April 2011 in *Visa Europe and Visa International Service* v *Commission*, T-461/07, ECR, EU:T:2011:181, paragraph 68, and *E.ON Ruhrgas and E.ON* v *Commission*, cited in paragraph 98 above, EU:T:2012:332, paragraph 85).

100 In order to determine whether an undertaking is a potential competitor in a market, the Commission is required to determine whether, if the agreement in question had not been concluded, there would have been real concrete possibilities for it to enter that market and to compete with established undertakings. Such a demonstration must not be based on a mere hypothesis, but must be supported by factual evidence or an analysis of the structures of the relevant market. Accordingly, an undertaking cannot be described as a potential competitor if its entry into a market is not an economically viable strategy (see judgment in *E.ON Ruhrgas and E.ON* v *Commission*, cited in paragraph 98 above, EU:T:2012:332, paragraph 86 and the case-law cited).

101 It necessarily follows that, while the intention of an undertaking to enter a market may be of relevance in order to determine whether it can be considered to be a potential competitor in that market, nonetheless the essential factor on which such a description must be based is whether it has the ability to enter that market (see judgment in *E.ON Ruhrgas and E.ON* v *Commission*, cited in paragraph 98 above, EU:T:2012:332, paragraph 87 and the case-law cited).

102 It should, in that regard, be recalled that whether potential competition — which may be no more than the existence of an undertaking outside that market — is restricted cannot depend on whether it can be demonstrated that that undertaking intends to enter that market in the near future. The mere fact of its existence may give rise to competitive pressure on the undertakings currently operating in that market, a pressure represented by the likelihood that a new competitor will enter the market if the market becomes more attractive (judgment in *Visa Europe and Visa International Service* v *Commission*, cited in paragraph 99 above, EU:T:2011:181, paragraph 169).

103 Moreover, it also follows from the case-law that the very fact that an undertaking already present on the market seeks to conclude agreements or to establish information exchange mechanisms with other undertakings which are not present on the market provides a strong indication that the market in question is not impenetrable (see, to that effect, judgments of 12 July 2011 in *Hitachi and Others* v *Commission*, T-112/07, ECR, EU:T:2011:342, paragraph 226, and 21 May 2014 in *Toshiba* v *Commission*, T-519/09, EU:T:2014:263, paragraph 231).

104 Although it follows from that case-law that the Commission may rely inter alia on the perception of the undertaking present on the market in order to assess whether other undertakings are potential competitors, nevertheless, the purely theoretical possibility of market entry is not sufficient to

establish the existence of potential competition. The Commission must therefore demonstrate, by factual evidence or an analysis of the structures of the relevant market, that the market entry could have taken place sufficiently quickly for the threat of a potential entry to influence the conduct of the participants in the market, on the basis of costs which would have been economically viable (see, to that effect, judgment in *E.ON Ruhrgas and E.ON* v *Commission*, cited in paragraph 98 above, EU:T:2012:332, paragraphs 106 and 114).

2. The burden of proof

105 It follows from settled case-law, and from Article 2 of Regulation No 1/2003, that it is for the party or the authority alleging an infringement of the competition rules to prove its existence. Thus, where there is a dispute as to the existence of an infringement, it is incumbent on the Commission to prove the infringements which it has found and to adduce evidence capable of demonstrating to the requisite legal standard the existence of circumstances constituting an infringement (see judgment of 12 April 2013 in *CISAC* v *Commission*, T-442/08, ECR, EU:T:2013:188, paragraph 91 and the case-law cited).

106 In that context, any doubt on the part of the Court must operate to the advantage of the undertaking to which the decision finding an infringement was addressed. The Court cannot therefore conclude that the Commission has established the infringement in question to the requisite legal standard if it still entertains any doubts on that point, in particular in proceedings for annulment of a decision imposing a fine (see judgment in *CISAC* v *Commission*, cited in paragraph 105 above, EU:T:2013:188, paragraph 92 and the case-law cited).

107 It is necessary to take into account the principle of the presumption of innocence resulting in particular from Article 48 of the Charter of Fundamental Rights of the European Union. Given the nature of the infringements in question and the nature and degree of severity of the penalties which may ensue, the presumption of innocence applies, inter alia, to the procedures relating to infringements of the competition rules applicable to undertakings that may result in the imposition of fines or periodic penalty payments (see, to that effect, judgment in *CISAC* v *Commission*, cited in paragraph 105 above, EU:T:2013:188, paragraph 93 and the case-law cited).

108 In addition, account must be taken of the non-negligible stigma attached to a finding of involvement in an infringement of the competition rules for a natural or legal person (see judgment in *CISAC* v *Commission*, cited in paragraph 105 above, EU:T:2013:188, paragraph 95 and the case-law cited).

109 Thus, the Commission must show precise and consistent evidence in order to establish the existence of the infringement and to support the firm conviction that the alleged infringement constitutes a restriction of competition within the meaning of Article 101(1) TFEU (see judgment in *CISAC* v *Commission*, cited in paragraph 105 above, EU:T:2013:188, paragraph 96 and the case-law cited).

110 However, it is important to emphasise that it is not necessary for every item of evidence produced by the Commission to satisfy those criteria in relation to every aspect of the infringement. It is sufficient if the set of indicia relied on by the institution, viewed as a whole, meets that requirement (see judgment in *CISAC* v *Commission*, cited in paragraph 105 above, EU:T:2013:188, paragraph 97 and the case-law cited).

111 Lastly, it must be pointed out that, when the Commission establishes that the undertaking in question has participated in an anticompetitive measure, it is for that undertaking to provide, using not only documents that were not disclosed but also all the means at its disposal, a different explanation for its conduct (see, to that effect, judgment of 7 January 2004 in *Aalborg Portland and Others* v *Commission*, C-204/00 P, C-205/00 P, C-211/00 P, C-213/00 P, C-217/00 P and C-219/00 P, ECR, EU:C:2004:6, paragraphs 79 and 132).

112 Nevertheless, where the Commission has documentary evidence of an anticompetitive practice, it is not sufficient for the undertakings concerned to prove circumstances which cast the facts established by the Commission in a different light and thus allow another explanation of the facts to be substituted for the one adopted by the Commission. In the presence of documentary evidence, the burden is on those undertakings not merely to submit another explanation for the facts found by the Commission but to challenge the existence of those facts established on the basis of the documents produced by the Commission (see, to that effect, judgment in *CISAC* v *Commission*, cited in paragraph 105 above, EU:T:2013:188, paragraphs 99 and 102 and the case-law cited).

3. The extent of the Court's review

113 It must be borne in mind that Article 263 TFEU involves review by the EU judicature, in respect of both the law and the facts, of the arguments relied on by applicants against the contested decision, which means that it has the power to assess the evidence and annul that decision. Accordingly, whilst, in areas giving rise to complex economic assessments, the Commission has a margin of discretion, that does not mean that the Court must refrain from reviewing the Commission's interpretation of information of an economic nature. The Court must not only establish whether the evidence put forward is factually accurate, reliable and consistent but must also determine whether that evidence contains all the relevant data that must be taken into consideration in appraising a complex situation and whether it is capable of substantiating the conclusions drawn from it (see, to that effect, judgment of 10 July 2014 in *Telefónica and Telefónica de España* v *Commission*, C-295/12 P, ECR, EU:C:2014:2062, paragraphs 53 and 54 and the case-law cited).

114 The applicants' arguments concerning the absence of potential competition between them and the generic undertakings at the time the agreements were concluded must be examined in the light of those considerations.

C – *The first part, alleging that the launch of medicinal products that infringe third parties' intellectual property rights is not the expression of potential competition under Article 101 TFEU*

115 The applicants submit that the contested decision is vitiated by an error in law in that it takes the view that the launch of medicinal products that infringe third parties' intellectual property rights is the expression of potential competition under Article 101 TFEU. Basing the existence of potential competition on the hypothesis of the launch of generic medicinal products on the market, with the risk of facing infringement proceedings on the basis of those third parties' patents, is incompatible with the protection conferred on patents and the exclusive rights to which they give rise. Article 101 TFEU protects only lawful competition, which cannot exist where an exclusive right, like a patent, precludes market entry, in law or in fact.

116 The Commission disputes those arguments.

117 The Court notes that the specific purpose of industrial property is, inter alia, to ensure that the patentee, in order to reward the creative effort of the inventor, has the exclusive right to use an invention with a view to manufacturing industrial products and putting them into circulation for the first time, either directly or by the grant of licences to third parties, as well as the right to oppose infringements (judgment of 31 October 1974 in *Centrafarm and de Peijper*, 15/74, ECR, EU:C:1974:114, paragraph 9).

118 However, the case-law in no way excludes the application of Article 101(1) TFEU to settlement agreements that may be concluded in relation to patents. On the contrary, if follows from the case-law that, although the existence of rights recognised under the industrial property legislation of a Member State is not affected by Article 101(1) TFEU, the conditions under which those rights may be exercised may nevertheless fall within the prohibitions contained in that article. This may be the case

whenever the exercise of such a right appears to be the object, the means or the consequence of an agreement, decision or concerted practice (see, to that effect, judgment in *Centrafarm and de Peijper*, cited in paragraph 117 above, EU:C:1974:114, paragraphs 39 and 40).

119 Likewise, according to the case-law, although the Commission is not competent to determine the scope of a patent, it may not refrain from all action when the scope of the patent is relevant for the purposes of determining whether there has been an infringement of Articles 101 TFEU and 102 TFEU (judgment of 25 February 1986 in *Windsurfing International* v *Commission*, 193/83, ECR, 'the *Windsurfing* judgment', EU:C:1986:75, paragraph 26). The Court of Justice has also held that the specific subject matter of the patent cannot be interpreted as also affording protection against actions brought in order to challenge the patent's validity, in view of the fact that it is in the public interest to eliminate any obstacle to economic activity which may arise where a patent was granted in error (the *Windsurfing* judgment, EU:C:1986:75, paragraph 92).

120 In the present case, the applicants' argument is based on the erroneous premiss that, first, the generic undertakings undoubtedly infringed the applicants' patents and, secondly, those patents would certainly have withstood the claims of invalidity that would have been raised by the generic undertakings in infringement actions.

121 Whilst patents are indeed presumed valid until they are expressly revoked or invalidated by a competent authority or court, that presumption of validity cannot be equated with a presumption of illegality of generic products validly placed on the market which the patent holder deems to be infringing the patent.

122 As the Commission rightly points out, without this being called into question by the applicants, in the present case it was for the applicants to prove before the national courts, in the event that generics entered the market, that those generics infringed one of their process patents, since an 'at risk' entry is not unlawful in itself. Moreover, in the context of an infringement action brought by Lundbeck against the generic undertakings, those undertakings could have contested the validity of the patent on which Lundbeck relied by raising a counter-claim. Such claims occur frequently in patent litigation and lead, in numerous cases, to a declaration of invalidity of the process patent relied on by the patent holder (see recitals 75 and 76 of the contested decision). Thus, it can be seen from the evidence set out in recitals 157 and 745 of the contested decision that Lundbeck itself estimated the probability that its crystallisation patent would be held invalid at 50 to 60%.

123 In addition, it is clear from the contested decision that, in order to establish the existence of potential competition in the present case, the Commission relied on the case-law established in the judgments in *European Night Services and Others* v *Commission*, cited in paragraph 99 above (EU:T:1998:198), and *Visa Europe and Visa International Service* v *Commission*, cited in paragraph 99 above (EU:T:2011:181), according to which it must be examined whether, given the structure of the market and the economic and legal context within which it functions, there are real concrete possibilities for the undertakings concerned to compete among themselves or for a new competitor to enter the relevant market and compete with established undertakings (recitals 610 and 611 of the contested decision).

124 In that respect, in view of the factors recalled in paragraph 122 above, it must be found that the Commission did not commit an error in considering that Lundbeck's process patents did not necessarily constitute insurmountable barriers for the generic undertakings (see, to that effect, judgment in *Toshiba* v *Commission*, cited in paragraph 103 above, EU:T:2014:263, paragraph 230), which were 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.

125 It is indeed possible that, in certain cases, the applicants might have been successful before the competent courts and obtained injunctions or damages against the generic undertakings. However, it can be seen from the evidence in the contested decision as regards each of the generic undertakings that that possibility was not perceived at the time as a sufficiently credible threat to them. Thus Merck (GUK) had taken the view, for example, following the publication of the crystallisation patent, that the Natco citalopram was 'non-infringing', that 'none of the published patent applications ... constitute a problem' and that, in the light of expert statements, it did 'not have a patent problem at all' (recitals 237, 248 and 334 of the contested decision).

126 In addition, it was not at all certain that the applicants would have actually initiated litigation in the event that generics entered the market. The contested decision indeed acknowledges that the applicants had put in place a general strategy consisting in threatening infringement actions or bringing such actions on the basis of their process patents. Nevertheless, any decision to bring an action depended on the applicants' assessment of the probability that an action would be successful and that a marketed generic product would be held to be infringing. Yet they were aware that 'generic [manufacturers] could have produced citalopram by using the process described in [the applicants'] original compound patent ... or they could have invested to invent an entirely new process' (recital 150 of the contested decision). Furthermore, faced with possible counter-claims, Lundbeck knew that the crystallisation patent was 'not the strongest of all patents' and that it was considered by some of its rivals to be 'high school chemistry' (recital 149 of the contested decision).

127 Lastly, it must be observed that, in the present case, Lundbeck's original patents had already expired when the agreements at issue were concluded, and that the crystallisation patent had not yet been definitively granted in the United Kingdom, for the purpose of Article 25 of the UK Patents Act 1977, when the GUK United Kingdom agreement and the Arrow UK agreement were concluded. The grant of interim measures in favour of Lundbeck in the United Kingdom against Merck (GUK) and Arrow would therefore have been, if not impossible, at the very least unlikely in the event that those undertakings entered the United Kingdom market before that patent was granted. Consequently, it is unlikely that Lundbeck could have obtained injunctions against all of the generic undertakings, even if it had systematically brought actions against them. Likewise, the iodo patent was not granted until 26 March 2003.

128 It must therefore be found, as the Commission did in recital 635 of the contested decision, that in general the generic undertakings had several routes — constituting real concrete possibilities — to enter the market at the time the agreements at issue were concluded (paragraph 97 above). Those possible routes included, inter alia, launching the generic product 'at risk', with the possibility of having to face proceedings brought by Lundbeck.

129 That possibility represents the expression of potential competition, in a situation such as that in the present case where Lundbeck's original patents, concerning both the citalopram API and the cyanation and alkylation processes, had expired and where there were other processes allowing the production of generic citalopram that had not been found to infringe other Lundbeck patents, which the applicants themselves acknowledged in their reply to the statement of objections. In addition, the steps taken and investments made by the generic undertakings in order to enter the citalopram market before concluding the agreements at issue, as set out by the Commission in the contested decision as regards each of the generic undertakings (see recitals 738 to 743 and 827 to 832 as regards Merck (GUK), recitals 877 to 883 and 965 to 969 as regards Arrow, recitals 1016 to 1018 as regards Alpharma and recitals 1090 to 1102 as regards Ranbaxy) — the existence of which has not been contested by the applicants — show that they were ready to enter the market and to accept the risks involved in such an entry.

130 Lastly, the applicants' argument that an 'at risk' entry of the generic undertakings would have been unlawful, with the result that it cannot be regarded as the lawful exercise of actual or potential competition, must also be rejected.

131 The case-law requires only that it be demonstrated that the generic undertakings had real concrete possibilities and the capacity to enter the market, which is certainly the case when those undertakings had made significant investments in order to enter the market and when they had already obtained MAs or had taken the necessary steps to obtain them within a reasonable period. In that respect, it must be borne in mind that some of them even entered the market, at their own risk, before or after the conclusion of the agreements at issue. Thus, NM Pharma, Merck (GUK)'s distributor in Sweden, had made 'encouraging' sales for almost five months on the Swedish market, before the conclusion of the EEA agreement, without being worried by Lundbeck (recital 837 of the contested decision). Merck (GUK) had also been able to sell generic citalopram tablets for a value of GBP 3.3 million in the United Kingdom in August 2003, before obtaining a second, more lucrative, extension of the GUK United Kingdom agreement. To accept the applicants' argument would amount to accepting that such an effective entry to the market does not constitute the expression of potential competition, simply because the applicants were convinced of the unlawful nature of that entry and they could potentially have tried to prevent it by relying on their process patents in infringement actions. For the reasons set out in paragraphs 120 to 122 above, that line of argument must be rejected.

132 Accordingly, the applicants are not correct in their submission that the Commission disregarded the presumption of validity of their patents and the related intellectual property rights by characterising the 'at risk' entry of generic undertakings to the market as the expression of potential competition between Lundbeck and those undertakings in the present case.

133 The first part must therefore be rejected.

D – *The second part, alleging that the Commission relied on subjective assessments in concluding that the generic undertakings were actual or potential competitors of Lundbeck*

134 The applicants maintain that the contested decision errs in relying on the subjective assessment of the parties to the agreements at issue as to whether a patent is valid and whether a product is infringing or non-infringing in order to determine whether those parties were potential competitors.

135 In the first place, they maintain that the contested decision does not prove to the requisite standard that the generic undertakings' subjective assessment was that they considered that there was a realistic prospect that a court would find that Lundbeck's patents were invalid and/or that they were not infringed. Under Article 2 of Regulation No 1/2003, it is for the Commission to prove that a non-infringing market entry was possible during the periods covered by the agreements at issue. Such an assessment is based, moreover, on insufficient information which did not remain constant and could not therefore be used to demonstrate the existence of potential competition between the parties to the agreements at issue.

136 In the second place, they argue that the contested decision is flawed and fails to take account of the objective elements which confirm the difficulty which the generic undertakings encountered in entering the market, such as the scientific evidence supplied by Lundbeck proving the existence of a patent infringement, the confirmation, by both the EPO Appeal Board and the Netherlands Patent Office, of the validity of the crystallisation patent on all relevant aspects, or the fact that Lundbeck had been granted preliminary injunctions or other forms of interim relief in more than 50% of the proceedings which it had initiated in 2002-2003. The contested decision therefore fails to establish to the requisite standard the ability of the generic undertakings to enter the market and does not resolve the question whether Lundbeck's patents were valid and had been infringed at the time of the conclusion of the agreements at issue, which is an objective question.

137 The Commission disputes those arguments.

138 As a preliminary point, the Court confirms the Commission's approach, as it can be seen from the contested decision as a whole, which consisted in principally taking into account evidence prior to or contemporaneous with the date on which the agreements at issue were concluded (see, by analogy, judgment of 11 July 2014, *Esso and Others* v *Commission*, T-540/08, ECR, EU:T:2014:630, paragraph 75 and the case-law cited).

139 First, the Commission cannot reconstruct the past by imagining the events that would have occurred and which did not in fact occur as a result of those agreements. Secondly, the parties to those agreements now have every interest in arguing that they had no realistic perspective of entering the market or that they thought that their products infringed one of Lundbeck's patents. Nevertheless, it is solely on the basis of the information available to them at the time and their perception of the market at that time that they decided to adopt a particular course of conduct and concluded the agreements at issue.

140 Moreover, that approach is consistent with the *Windsurfing* judgment, cited in paragraph 119 above (EU:C:1986:75, paragraph 26), where the Court of Justice held that the Commission was not competent to determine the scope of a patent, but that it could not refrain from all action when the scope of a patent was relevant for the purpose of determining whether there had been an infringement of Articles 101 TFEU and 102 TFEU.

141 The Commission therefore did not err in relying on objective documents reflecting the perception that the parties to the agreements at issue had of the strength of Lundbeck's process patents at the time those agreements were concluded (see inter alia recital 669 of the contested decision) in order to evaluate the competitive situation between those parties, it being noted that subsequent evidence may also be taken into account provided that it is capable of clarifying those parties' positions at the time, confirming or challenging their arguments in that respect as well as allowing a better understanding of the market concerned. In any event, that subsequent evidence cannot be decisive in the examination of the potential competition between the parties to the agreements at issue.

142 In addition, the applicants wrongly submit that the Commission relied 'almost exclusively' on such subjective assessments in order to establish the existence of potential competition between them and the generic undertakings in the contested decision. The Commission in fact carried out a careful examination, as regards each of the generic undertakings concerned, of the real concrete possibilities they had of entering the market, relying on objective evidence 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. Those various pieces of evidence have also been expressly contested by the applicants, as regards each generic undertaking, and will be examined in the sixth to ninth parts below.

143 Similarly, the applicants cannot succeed in their argument that the Commission did not take sufficient account of the evidence which they supplied, showing that their patents were infringed by the generic undertakings and that the crystallisation patent was valid, which was confirmed, inter alia, by the EPO on all relevant aspects in 2009.

144 First, although other statements contemporaneous with the conclusion of the agreements at issue might suggest that the generic undertakings had doubts concerning the non-infringing nature of their products, or that Lundbeck was convinced of the validity of its patents, those statements are not enough to call into question the conclusion that the generic undertakings were perceived as a potential threat for Lundbeck and were liable, by their very existence, to exert competitive pressure on Lundbeck and on the undertakings operating in the same market (see, to that effect, judgment in *Visa Europe and Visa International Service* v *Commission*, cited in paragraph 99 above, EU:T:2011:181, paragraph 169). The strongest evidence in that respect is the very fact that Lundbeck concluded agreements with generic undertakings in order to delay their entry to the market (see, to that effect, judgment in *Toshiba* v *Commission*, cited in paragraph 103 above, EU:T:2014:263, paragraph 231).

145 Secondly, the evidence invoked by the applicants which dates from after the conclusion of the agreements at issue cannot be decisive in evaluating the existence of potential competition at the time those agreements were concluded. Even if the EPO had confirmed the crystallisation patent on all relevant aspects in 2009 (see recital 166 of the contested decision), it is nevertheless the case that, at the time the agreements at issue were concluded, the generic undertakings as well as Lundbeck itself doubted the validity of that patent and it was possible that a national court might declare it invalid, as had initially occurred at the EPO (recitals 151 and 166 of the contested decision).

146 Furthermore, as the Commission rightly submits, at the time the agreements at issue were concluded, no interim measure had been obtained by Lundbeck, whether against generic undertakings using the Natco citalopram, such as Merck (GUK), against generic undertakings using the Cipla citalopram or the generic citalopram developed from the API produced by the Indian company Matrix ('the Matrix citalopram' or 'the Matrix API'), such as Arrow and Alpharma, or against generic undertakings using the generic citalopram developed from the citalopram API produced by Ranbaxy ('the Ranbaxy citalopram' or 'the Ranbaxy API'), and no court in the EEA had found an infringement of the crystallisation, amide or iodo patents.

147 The applicants are therefore incorrect in their submission that the Commission relied mainly on subjective assessments in order to find that Lundbeck and the generic undertakings were potential competitors at that time the agreements at issue were concluded.

148 Accordingly, the second part must also be rejected.

E – *The third part, alleging that challenging a valid patent does not constitute a real concrete possibility of entering the market*

149 The applicants submit that the Commission erred in law in taking the view that challenging a valid patent constitutes a real concrete possibility of entering the market. They deny, in particular, that seeking a declaration of non-infringement, or claiming that a patent is invalid, or opposing a patent before the national patent authorities, or before the EPO, could constitute appropriate routes whereby the generic undertakings could enter the market, notwithstanding Lundbeck's processing patents.

150 In the first place, they maintain that the contested decision confuses market entry with the investments that allow market entry, and that it unduly stretches the boundaries of potential competition. The case-law requires that real concrete possibilities of entering the market be established and that market entry be sufficiently rapid for the threat of potential entry to constitute a constraint on the conduct of market participants. Establishing that there were real concrete possibilities of making investments that, if successful, could allow market entry fails to satisfy that test.

151 In the second place, the presumption of validity enjoyed by patents means that the possibility of challenging the validity of that patent cannot be regarded as constituting a real concrete possibility of entering the market. The approach taken by the Commission in that regard contradicts the judgment of 15 September 1998 in *European Night Services and Others* v *Commission*, cited in paragraph 99 above (EU:T:1998:198, paragraph 139).

152 In the third place, even if patent challenges could have constituted a real concrete possibility of entering the market, those challenges would not have made it possible to enter the market sufficiently quickly. As the Commission stated in its pharmaceutical sector inquiry, challenging a patent takes on average almost three years and would therefore not have enabled the generic undertakings to enter the market sufficient quickly. The contested decision is vague on that point, whereas, if the generic undertakings could not have lawfully entered the market during the term of the agreements at issue, the agreements could not have had any impact on competition.

153 In the fourth place, the applicants maintain that, even if the Commission's view is accepted, the contested decision should at least have demonstrated that, in the absence of the agreements at issue, the generic undertakings would have initiated legal actions and would probably have been successful before the national courts or at least that they had prospects of being successful if they challenged the patents.

154 Lastly, the applicants submit that the Commission's position is based on an unjustified bias against process patents as opposed to compound patents.

155 The intervener also argues that, in the contested decision, the Commission errs in taking the view that Lundbeck and the generic undertakings were potential competitors. Such a finding fails to take sufficient account of the presumption that Lundbeck's patents were valid or of the fact that interim injunctions would have represented an insurmountable barrier for the generic undertakings if they had attempted to enter the market. The intervener also rejects the argument that challenging the validity of patents is an inherent part of the competitive process.

156 The Commission disputes those arguments.

157 It must be noted that, contrary to the applicants' arguments, the Commission did not take the view, in the contested decision, that the mere possibility of challenging the validity of a patent before a court or before the competent authorities suffices to establish the existence of potential competition. In order to establish the existence of potential competition between the generic undertakings and Lundbeck in the present case, the Commission took several factors into consideration, such as the significant investments and efforts already made by the generic undertakings in order to prepare their entry to the market, the fact that they had already obtained MAs or had taken the necessary steps to obtain one within a reasonable period, the fact that the applicants had acknowledged that there were a certain number of processes available to produce citalopram without infringing their patents, the fact that, at the time the agreements at issue were concluded, no court had found the generic products to be infringing and the fact that there was a non-negligible possibility that some of Lundbeck's process patents might be declared invalid. In addition, a generic undertaking, namely Merck (GUK), even succeeded in entering the market before and during the term of the agreements at issue. Lastly, the fact that the applicants decided to pay significant amounts to the generic undertakings in order to keep them out of the market during the period of the agreements at issue also shows that those generic undertakings were potential competitors, since they were perceived by the applicants as a threat exerting competitive pressure on their position on the market (paragraphs 103 and 144 above).

158 None of the arguments put forward by the applicants is capable of undermining that conclusion.

159 As regards, first, the investments made by the generic undertakings in order to prepare their entry to the market, it suffices to note that the Commission never considered that such investments sufficed by themselves to demonstrate the existence of potential competition between those undertakings and the applicants. The Commission, on the contrary, relied on a set of relevant factors, relating to each generic undertaking, in that respect (see paragraph 157 above). Moreover, as the Commission rightly submitted, in order to establish the existence of potential competition, it is not necessary to demonstrate with certainty that the generic undertakings would have entered the market and that that entry would inevitably have been successful, but only that they had real concrete possibilities in that respect. To assert the contrary would amount to denying any distinction between actual and potential competition.

160 The case-law indeed indicates that the purely theoretical possibility of market entry is not sufficient to establish the existence of potential competition and that the Commission must demonstrate, by factual evidence or an analysis of the structures of the relevant market, that the market entry could have taken place sufficiently quickly for the threat of a potential entry to influence the conduct of the participants in the market, on the basis of costs which would have been economically viable (paragraph 104 above).

161 It does not appear, however, that the Commission disregarded that case-law in the present case, since the analysis of the pharmaceutical sector carried out by the Commission in the contested decision, as well as the particular situation of each generic undertaking at the time the agreements at issue were concluded (paragraph 129 above), adequately demonstrate that the entry of those generic undertakings to the citalopram market was not a mere theoretical possibility, but that they had real concrete possibilities in that respect, as can be seen from the examination of the sixth and ninth parts of the first plea in law below. Moreover, it would be surprising if an undertaking as experienced as Lundbeck would have decided to pay several million euros to the generic undertakings in exchange for their commitment not to enter the market during a certain period if the possibility that those generic undertakings could enter the market was purely theoretical.

162 Secondly, the judgment in *European Night Services and Others* v *Commission*, cited in paragraph 99 above (EU:T:1998:198, paragraph 139), relied on by the applicants, does not oppose the approach taken by the Commission in the present case. Although, in that judgment, the Court referred to the existence of exclusive rights precluding, *de jure* or *de facto*, in most Member States, both the provision of international passenger services and access to the infrastructure, before the adoption of Council Directive 91/440/EEC of 29 July 1991 on the development of the Community's railways (OJ 1991 L 237, p. 25), that situation cannot be transposed to the present case, since Lundbeck's process patents are in no way comparable to the exclusive rights enjoyed by railway undertakings before the adoption of that directive and there are significant differences between the markets concerned. In addition, as the Commission rightly submits, in the case that gave rise to that judgment, the Court had criticised the Commission for failing to carry out a detailed analysis of the market in order to establish the existence of potential competition and for having relied on hypothesises unsupported by any evidence or any analysis of the structures of the relevant market. In the present case, however, the applicants cannot legitimately argue that all of the relevant circumstances, summarised in paragraph 157 above and set out in detail in the contested decision, for each generic undertaking, are purely theoretical speculations unsupported by a detailed analysis of the characteristics of the relevant market.

163 Thirdly, it must be recalled that, in order to establish the existence of potential competition, the case-law requires only that the entry to the market take place within a reasonable period, without fixing a specific limit in that respect. The Commission therefore does not need to demonstrate with certainty that the entry of the generic undertakings to the market would have taken place before the expiry of the agreements at issue in order to be able to establish the existence of potential competition in the present case, particularly since, as the Court of Justice has already held, potential competition may be exerted long before the expiry of a patent (see, to that effect, judgment of 6 December 2012 in *AstraZeneca* v *Commission*, C-457/10 P, ECR, EU:C:2012:770, paragraph 108).

164 In that respect, it should be noted that the remark of the Court of Justice concerning the fact that potential competition may be exerted before the expiry of a patent is independent of the fact that the SPCs at issue in that judgment had been obtained fraudulently or irregularly. The case that gave rise to the judgment in *AstraZeneca* v *Commission*, cited in paragraph 163 above (EU:C:2012:770, paragraph 108) concerned, inter alia, an abuse of a dominant position committed by an undertaking which had submitted misleading representations in order to obtain, from the competent national authorities, SPCs allowing it to prevent the entry to the market of generic versions of its medicinal product, even after the future expiry of the patents protecting that product. In that context, the Court of Justice considered, in essence, that the anticompetitive character of those representations was not called into question by the fact that those SPCs had been requested between five and six years before their entry into force and that, until that time, the appellants' rights had been protected by regular patents. According to the Court of Justice, not only did such unlawful SPCs lead to a significant exclusionary effect after the expiry of the basic patents, but they were also liable to alter the structure of the market by adversely affecting potential competition even before that expiry. Accordingly, that

case-law confirms that potential competition already exists before the expiry of patents protecting a medicinal product and that the steps taken before that expiry are relevant in assessing whether that competition was restricted.

165 Fourthly, the applicants wrongly argue that the Commission should have demonstrated that the generic undertakings would have brought legal proceedings and that they would have been successful before the competent national courts. It can be seen from recital 624 et seq. of the contested decision that the generic undertakings were not required to demonstrate that their generic products did not infringe any patent in order to obtain an MA and sell their products in the market, which, moreover, is not called into question by the applicants. Thus, Merck (GUK) was able to enter the market through its distributor NM Pharma in Sweden in May 2002, without having obtained a declaration of non-infringement and without having had legal actions brought against it by Lundbeck. It was for the originator undertaking, namely, in the present case, Lundbeck, to prove that those products infringed one of its patents, which, according to its own estimates, was particularly difficult to establish, as regards process patents (see recital 629 of the contested decision). In addition, as the Commission submits, it is not certain that Lundbeck would have necessarily brought legal proceedings against the generic undertakings if they had entered the market (see paragraph 126 above). It is even less certain that Lundbeck would have been successful, if it had decided to bring such proceedings (see paragraph 122 above and recitals 75 and 76 of the contested decision).

166 Lastly, it must be recalled that the Commission did not disregard the presumption of validity enjoyed by Lundbeck's process patents (paragraphs 121 to 132 above). The applicants therefore cannot argue that the contested decision is based on a negative bias against such patents. The Commission took account of the existence of those patents but considered, without committing an error of assessment in that respect, that those patents were not capable of blocking any entry of generic undertakings to the market at the time the agreements at issue were concluded.

167 The third part must therefore be rejected.

F – *The fourth part, alleging that the lack of an MA prevents the existence of actual or potential competition*

168 The applicants submit that the Commission wrongly concluded that there was potential competition despite the fact that some of the generic undertakings did not have an MA, simply because they had tried to obtain one before the agreements at issue were concluded (recital 620 of the contested decision). That finding is inconsistent with certain passages in the contested decision (recital 85 in particular) and also with the findings of the pharmaceutical sector inquiry and the individual observations of the parties concerned on the time taken to obtain an MA, which was at least 14 months and could take as long as 25 months in certain EEA countries. It would have been better, in the applicants' submission, if the contested decision had assessed *in concreto* whether each generic undertaking had real concrete possibilities of obtaining an MA during the term of the agreements at issue, and to do so in each of the countries concerned, since each country constituted a separate geographic market and certain agreements related to individual countries. In any event, an MA would not make it possible to enter the market immediately, since additional preparatory stages are necessary in that respect.

169 The Commission disputes those arguments.

170 In that respect, it must be noted, first of all, contrary to the applicants' arguments, that the Commission evaluated, as regards each generic undertaking, whether it had an MA at the time the agreements at issue were concluded or whether it could have obtained an MA in a sufficiently near future.

171 It must also be observed that potential competition includes inter alia the activities of generic undertakings seeking to obtain the necessary MAs, as well as all the administrative and commercial steps required in order to prepare for entry to the market (see paragraphs 91 to 94 above). That potential competition is protected by Article 101 TFEU. If it were possible, without infringing competition law, to pay undertakings taking the necessary steps to prepare for the launch of a generic medicinal product, including obtaining an MA, and which have made significant investments to that end, to cease or merely slow that process, effective competition would never take place, or would suffer significant delays, at the expense of consumers, that is to say, in the present case, patients or national health insurance schemes.

172 Thus, the Commission found that Merck (GUK) had obtained an MA in the United Kingdom on 9 January 2002, and that its distributor NM Pharma also had an MA in Sweden since May 2002. Merck (GUK) and NM Pharma intended to use the 90-day mutual recognition period laid down in Article 18 of Directive 2001/83 in order to obtain MAs in other countries in the EEA (recital 326 of the contested decision).

173 As regards Arrow's position in the United Kingdom, in recitals 878 to 881 of the contested decision, the Commission noted that that undertaking had entered into an agreement with Tiefenbacher, in order to use the MA that Tiefenbacher had requested in the United Kingdom, on the basis of an MA which the latter already possessed in the Netherlands. The Commission also noted that, in the phase immediately preceding the conclusion of the Arrow UK agreement, it was expected that the United Kingdom authorities would issue that MA in the very near future and that the delay which subsequently occurred was due to the applicants' challenging the MA granted in the Netherlands.

174 As regards Arrow's position in Denmark, in recitals 967 and 968 of the contested decision, the Commission emphasised that the preamble to the Danish Arrow agreement mentioned that Arrow was about to obtain a 'licence' from a third party and that a copy of the MA granted to that third party was annexed to the agreement. As the Commission rightly submits, the fact that Arrow ultimately did not purchase that MA does not mean that it did not have a real concrete possibility of entering the market at the time that agreement was concluded.

175 As regards Alpharma, it can be seen from recitals 476, 485, 520 and 530 of the contested decision that it could use the MAs granted to Tiefenbacher, pursuant to its supply contract with the latter, at least as regards the Netherlands and Germany, and could either itself request an MA for the other EEA Member States or ask Tiefenbacher to extend the mutual recognition procedure to those other countries.

176 In addition, in October 2001 Alpharma intended to obtain MAs and launch generic citalopram, on various dates in 2002, in Austria, Denmark, Finland, Germany, the Netherlands, Norway, Sweden and the United Kingdom. Similarly, when the Alpharma agreement was concluded, four MAs had been granted (in Denmark, Finland, the Netherlands and in Sweden), and the MA for the United Kingdom was expected to be issued in the very near future (see paragraph 281 below). Moreover, during the term of that agreement, Alpharma received MAs for four other countries in the EEA (Norway, Germany, Austria and the United Kingdom).

177 As regards Ranbaxy, in recital 1094 of the contested decision, the Commission noted, in essence, that that undertaking had filed a Drug Master File ('DMF') for its citalopram API with the competent United Kingdom authority in June 2002. That step, although not necessary in order to obtain an MA, facilitated the procedure allowing a generic undertaking that already held an MA on generic citalopram tablets produced on the basis of a different API than that of Ranbaxy to request a variation of its MA so that it also included the Ranbaxy citalopram. The filing of a DMF with the competent authorities allows the API manufacturer not to disclose confidential information to the generic undertakings that purchase its API and wish to lodge an MA application in respect of the medicinal products that they produce using that API.

178 In addition, in recital 1095 of the contested decision, the Commission relied on the fact that, at a meeting held in April 2002, Ranbaxy had informed Lundbeck that it could obtain an MA within eight months and that it was in discussions with a potential purchaser of its citalopram, a purchaser which could enter the market with that citalopram within three to four months, following a variation of the MA that it already held. The applicants' argument that such statements were merely 'bluffing' will be examined in more detail below, in the ninth part of the present plea in law.

179 Those elements show that the generic undertakings concerned had either already obtained an MA at the time the agreements at issue were concluded, were taking the necessary steps to obtain one in the short or medium term, or were able to have their products covered by other MAs. Although, in certain cases, obtaining an MA might ultimately have taken more time than foreseen, it is nevertheless the case that, at the time the agreements at issue were concluded, the generic undertakings had real concrete possibilities of obtaining those MAs within a sufficiently short period and of entering the citalopram market in several EEA countries, by using the mutual recognition procedure laid down in Article 18 of Directive 2001/83, thereby exerting competitive pressure on Lundbeck. In addition, it must be recalled that in the present case, the generic undertakings had begun making preparations to enter the citalopram market one to three years before the expiry of Lundbeck's original patents (see recitals 219, 373, 476 and 549 of the contested decision), and that they were engaged in an intense race to be the first to enter the market after the expiry of those patents (see recitals 622 of the contested decision).

180 The Commission therefore did not err in finding, in recital 620 of the contested decision, that the absence of an MA did not mean that the generic medicinal products were not capable of entering the market in the near future, while the generic undertakings continued to take steps to obtain the necessary authorisations in that respect before concluding the agreements at issue with Lundbeck.

181 It must be recalled, moreover, that, even if it is an important factor in that respect, the Commission did not rely solely on the possibility of generic undertakings obtaining an MA in order to establish the existence of potential competition between them and Lundbeck in the contested decision, but rather on a set of factors taking account of the specific situation of each generic undertaking at the time the agreements at issue were concluded as well as the specific characteristics of the pharmaceutical sector (see paragraphs 91 to 96 and 157 above). In addition, it must be recalled that the very fact that Lundbeck decided to conclude agreements with the generic undertakings is a strong indication that it perceived those undertakings as a potential threat at the time the agreements at issue were concluded (see, to that effect, judgment in *Toshiba* v *Commission*, cited in paragraph 103 above, EU:T:2014:263, paragraph 231).

182 The fourth part must therefore also be rejected.

G – *The fifth part, alleging that the generic undertakings could not have had recourse to other processes and/or other API producers during the term of the agreements at issue*

183 The applicants dispute the finding in the contested decision that the possible routes to the market (recital 635 of the contested decision) included, in particular, a generic undertaking working with its API producer to alter that producer's process or switching to another API producer. They argue that those are theoretical alternative options because, first, there was no other commercially viable method of producing citalopram that would have permitted a lawful entry to the EEA market in 2002 and 2003 and, secondly, the generic undertakings would not have had sufficient time to switch to another API producer before the expiry of the agreements at issue.

184 First, according to the applicants, there is no serious evidence to rebut Lundbeck's evidence that no commercially viable and non-infringing process would have allowed market entry in 2002 and 2003. None of the evidence put forward in relation to Merck (GUK), Alpharma, Arrow and Ranbaxy is sufficient to prove the contrary.

185 Furthermore, the contested decision is wrong to rely on Lundbeck's statements to show that other non-infringing processes were available at the time of the conclusion of the agreements at issue (recital 634 of the contested decision). The Commission wrongly presumed that all the processes listed by Lundbeck in one of its statements were non-infringing, commercially viable and compliant with EEA regulatory requirements, when none of them could have allowed market entry in 2002-2003 with reliable and non-infringing medicinal products. In the applicants' submission, the contested decision ignores the extensive evidence showing that the original cyanation and alkylation processes could not be used to produce citalopram viably.

186 Secondly, in any event, according to the applicants, even if generic citalopram produced using a non-infringing and commercially viable process had been available during the term of the agreements at issue (which was not the case), the generic undertakings could not have switched to that process during the months covered by the agreements at issue, or at the very least they could not have done so 'sufficiently quickly' for the threat of potential entry to represent an effective competitive constraint while those agreements were in force.

187 Such a change would have entailed requesting a major variation, known as 'type II', within the meaning of Article 3 of Commission Regulation (EC) No 541/95 of 10 March 1995 concerning the examination of variations to the terms of a marketing authorisation granted by a competent authority of a Member State (OJ 1995 L 55, p. 7), which is the procedure used for the variation of an existing MA, as a result of a change of API producer. A type II variation is the most laborious to obtain, necessitating the use of a procedure equivalent to that applicable to a new MA application. The total duration of that procedure can be up to 19 months. Furthermore, in addition to the time necessary to obtain such a variation, there is the time needed to research and develop the new process, to register the medicinal product for reimbursement, to obtain reimbursement approval, and to produce and start selling the medicinal product.

188 The Commission disputes those arguments.

189 In the first place, the applicants wrongly assert that no commercially viable and non-infringing procedure would have allowed market entry during the term of the agreements at issue.

190 As indicated in recital 150 of the contested decision, Lundbeck itself initially stated, in response to the Commission's requests for information preceding the statement of objections, that the generic undertakings could have produced generic citalopram by using the procedures described in its original patents (that is to say, the cyanation and alkylation processes) or by inventing a new type of process, with the result that its patents were not capable of preventing all competition by the generic undertakings.

191 In addition, Lundbeck itself confirmed that its new process patents were not capable of blocking all possibilities of entering the market, even though the crystallisation-based process seemed to be the most effective. Thus, by way of example, the Commission noted, in recital 163 of the contested decision, that Niche Generics Ltd had entered the market by obtaining a declaration of non-infringement for the generic citalopram supplied by another Indian API producer, Sekhsaria. It can also be seen from the evidence referred to in recital 634 of the contested decision that, in March 2002, Lundbeck's patent experts declared that 'it [was] possible to make an [API] that very probably does not require crystallisation of the free base', i.e. which was not based on Lundbeck's crystallisation

patent. Lundbeck's Vice-President also stated in a press release of 9 November 2002 that 'it would be naive to think that it is not possible for producers of generic copies to produce Cipramil without breaking our patent' (recital 634 of the contested decision).

192 The applicants submit, nevertheless, that they have never acknowledged that other processes could be used to enter the citalopram market without infringing their patents or with safe medicinal products produced on an industrial scale.

193 However, it must be recalled, first, that at the time the agreements at issue were concluded, no court in the EEA had ruled on the infringing nature of products developed by the generic undertakings (see paragraph 146 above). The applicants cannot validly argue, therefore, that the generic medicinal products developed by the generic undertakings infringed its process patents, when they were, at most, potentially infringing at the time the agreements at issue were concluded.

194 Secondly, as the Commission submits, the assertion that there was no non-infringing version of generic citalopram capable of being developed on an industrial scale is not supported by the facts. It must be borne in mind that any API producer could have used the original cyanation and alkylation processes as published with the patent on Lundbeck's citalopram API, which had expired (paragraph 16 above). Thus, it can be seen from recital 158 of the contested decision that, in the context of the Lagap litigation, which concerned the Matrix citalopram, Lundbeck's counsel acknowledged that it was possible that the processes set out in its original patents could be developed economically, without specifying any period in that respect, that it would depend on the manner in which the cyanation was carried out and that Matrix '[did] the cyanation more efficiently that we [had] believed that they could do it', which shows that it was possible to produce generic citalopram on an industrial scale using Lundbeck's original patents.

195 In any event, the contested decision sufficiently establishes that each generic undertaking 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' patents at the time the agreement were concluded.

196 Thus, Natco citalopram, used by Merck (GUK), was based on processes covered by Lundbeck's original patents, which had expired, or on other processes covered by patents which had also expired (recitals 228 and 281 of the contested decision). The supply contract concluded between Merck (GUK) and Schweizerhall expressly provided that the Natco API was, to their knowledge, non-infringing (recital 235 of the contested decision). In addition, it must be noted that, at the time the GUK United Kingdom agreement was concluded, on 24 January 2002, the crystallisation patent had not yet been issued, either in the United Kingdom or throughout the EEA (see paragraph 20 above). The question whether the Natco process potentially infringed the crystallisation patent was therefore only a hypothetical question at the time that agreement was concluded. It is true that, when the GUK EEA agreement was concluded, Lundbeck's crystallisation patent had already been granted by the EPO, but it was in no way certain that the Natco API was infringing or that the validity of that patent would have been upheld in the event of litigation (see paragraph 122 above).

197 Moreover, even if Lundbeck had brought infringement actions against Merck (GUK) and the latter's products had been found to be infringing, Merck (GUK) would nevertheless have been able to obtain citalopram which had not been held to be infringing from other sources within a reasonable period. Although Merck (GUK) had concluded a supply agreement with Schweizerhall for a period of eight years, that agreement was based on the assumption that Natco's product was non-infringing (recital 235 of the contested decision), with the result that Merck (GUK) would probably have been able to terminate that agreement in the event of infringement, whether on the basis of the express provisions of that agreement or pursuant to German law, the law applicable to that contract. It can be seen, inter alia, from recitals 248 and 351 of the contested that there were other sources of generic citalopram on the market, of which Merck (GUK) was aware, through, inter alia, Merck dura GmbH, Merck's

subsidiary in Germany. In any event, even if Merck (GUK) had been bound, under the Schweizerhall agreement, to use Natco as its exclusive supplier and the generic citalopram produced by the latter infringed the crystallisation patent, it is possible that Natco could have produced the citalopram API using other non-infringing processes, as the Commission rightly pointed out in recital 746 of the contested decision.

198 As regards the generic citalopram supplied by Tiefenbacher to Arrow and to Alpharma, it must be noted that, although that generic citalopram was initially produced using Cipla's initial process ('the Cipla I process'), in respect of which there was a risk of infringement, Tiefenbacher could have easily switched to Matrix citalopram, produced initially in accordance with Matrix's initial process ('the Matrix I process') and subsequently in accordance with the new process used by Matrix ('the Matrix II process'). It must be recalled that the Cipla I and Matrix I processes had not been held to be infringing by any EEA court at the time the agreements at issue were concluded (paragraph 146 above).

199 As regards the Matrix II process, which was used to produce the generic citalopram to which Arrow and Alpharma could also have had access through Tiefenbacher, it follows from recitals 154, 155, 421 and 674 as well as footnote No 1828 of the contested decision that that process had already been developed in May 2002, in order to subsequently reduce the risk that the Matrix citalopram infringed the crystallisation patent. In the context of the Lagap litigation, following an inspection at Matrix's premises in India, Lundbeck acknowledged that the Matrix II process did not infringe its patents. Accordingly, as the Commission rightly points out, it is immaterial that, before that admission, some national courts had granted Lundbeck's requests for interim measures concerning that process. Likewise, no conclusion can be drawn from the fact that, in order to ensure that its MA also covers the Matrix II process, Tiefenbacher was able merely to file an application for a minor variation (type 1), within the meaning of Article 3 of Regulation No 541/95 ('the type I variation'), which is the procedure used inter alia for the variation of an existing MA as a result of a modification of the process used by the same API producer. That circumstance does not call into question Lundbeck's admission, in the Lagap litigation, of the non-infringing nature of that process which, moreover, was subsequently used by several generic undertakings without Lundbeck reacting.

200 Similar remarks can be made as regards the new process used by Cipla in order to produce the generic citalopram ('the Cipla II process'), which was also, in principle, accessible through Tiefenbacher. The Commission showed, particularly in recital 898 of the contested decision, that that process, which was developed during the period covered by the agreements at issue, was potentially non-infringing and had been the subject matter of an application for a type I variation of an MA in September 2002. Thus, Arrow and Alpharma could have sought to sell citalopram produced using that process, as Neolab did, without Lundbeck being able effectively to oppose them, as the Commission indicated in footnote No 1671 of the contested decision.

201 As regards, lastly, the process used by Ranbaxy, it should be noted that Lundbeck, even after having examined Ranbaxy's reaction schemes, wished to conclude an agreement with it providing for reverse payments, instead of applying to national courts for injunctions. It follows that Lundbeck was uncertain as to whether the API produced using that process was infringing, as can be seen from recitals 564 and 1109 of the contested decision. In addition, Ranbaxy claimed, both as regards Lundbeck and the generic undertakings potentially interested in purchasing its API, that the latter was not infringing, as the Commission noted, inter alia, in recital 1105 of the contested decision.

202 Furthermore, it must be recalled that, even if the products sold by the generic undertakings had infringed one of Lundbeck's patents, which was not established at the time of the conclusion of the agreements at issue in the present case, the generic undertakings would also have been able to challenge the validity of those patents before the competent courts (see paragraph 122 above).

203 In the second place, it is necessary to reject the applicants' argument that the Commission should have demonstrated that moving to another process or to another API producer would have taken place during the duration of the agreements at issue. In order to establish the existence of potential competition between the generic undertakings and Lundbeck, the Commission was only required to show that they had real concrete possibilities of entering the market within a sufficiently short period to exert effective competitive pressure on Lundbeck at the time the agreements at issue were concluded. The Commission was not required to demonstrate that the generic undertakings would undoubtedly have been able to obtain a commercially viable and non-infringing process during the term of the agreements at issue, but only that they had real concrete possibilities in that respect, at the time of concluding those agreements, and that those possibilities were not purely theoretical.

204 The applicants do not deny that it was possible, for the generic undertakings, to vary an existing MA or to switch to another API producer in the event of an increased risk of infringement, but submit that this could have taken several months, or even longer than the term of the agreements at issue. They cannot, however, require the Commission to show what would have happened in the absence of the agreements at issue, in a context where numerous options were open to the generic undertakings in order to enter the market, at the time those agreements were concluded. The possibility of altering an existing MA or of obtaining the API from another supplier was not a purely theoretical possibility, as shown by the evidence set out in the contested decision, as regards each generic undertaking, in that respect (see the sixth to ninth parts below). The applicants themselves have acknowledged, for example, that Tiefenbacher, acting as an intermediary for Arrow and Alpharma, had obtained a type I variation of its MA issued for the Matrix citalopram in only two and a half months in the Netherlands (recital 418 of the contested decision).

205 In any event, that possibility was probably not even necessary for most generic undertakings in order to be able to enter the market, and even less so in order to be able to exert a competitive pressure on Lundbeck, since they were taking the necessary steps and had even, in certain cases, already obtained an MA in order to enter the market with the generic citalopram of their supplier (or their own generic citalopram in Ranbaxy's case), which had not been declared infringing by any court at the time the agreements at issue were concluded. Moreover, as was already noted in paragraph 181 above, the very fact that Lundbeck concluded the agreements at issue with the generic undertakings constitutes an important indication that it perceived them as a potential threat exerting a competitive pressure on its position on the market.

206 The fifth plea in law must therefore be rejected.

H – *The sixth part, alleging the absence of potential competition between Lundbeck and Merck (GUK) at the time the agreements at issue were concluded*

207 The applicants claim that the contested decision was wrong to find that Merck (GUK) was a potential competitor of Lundbeck in the United Kingdom and, *mutatis mutandis*, in the EEA at the time of the alleged infringement.

208 They maintain that, while GUK's intention to enter the market may be relevant, the key test is whether it was actually able to enter the market. The contested decision obscures the fact that Merck (GUK) had access only to Natco's citalopram, which infringed Lundbeck's crystallisation patent, which means that it was not able to enter the market lawfully.

209 In addition, the contested decision is wrong to have found, in recital 754, on the basis of contemporaneous documents, that Merck (GUK) was very sure of its patent position. The applicants maintain that the Commission quoted those documents selectively and took them out of context.

210 Furthermore, in the applicants' submission, Merck (GUK) was not a potential competitor of Lundbeck, since it could not have switched to other APIs produced using non-infringing processes during the term of the agreements at issue. In 2003, no other commercially viable non-infringing generic product existed. In any event, on the assumption that Merck (GUK) could have switched to other producers of non-infringing API, if Merck (GUK) had acquired citalopram from third parties it would have been in breach of Article 1.3 of its agreement with Schweizerhall, which provided that Merck (GUK) was to cover 100% of its annual demand for citalopram API with Schweizerhall (recital 235 of the contested decision).

211 Lastly, the applicants maintain that the contested decision does not state the reasons for its finding that Merck (GUK) was a potential competitor of Lundbeck in the EEA (excluding the United Kingdom) at the time of the alleged infringement. Since the Commission, in the contested decision, calculated the fine imposed on Lundbeck on the basis of sales of citalopram throughout the EEA, that factor alone is sufficient to render the contested decision invalid.

212 As regards sales of citalopram in Sweden via NM Pharma (recitals 836 to 838 of the contested decision), which led the Commission to find that Merck (GUK) was a serious potential competitor, including on other EEA markets (recital 840), the applicants claim that the fact that they chose to litigate selectively in Sweden, without initiating proceedings against NM Pharma, does not prove that Merck (GUK) had the ability to enter other markets in the EEA or real concrete possibilities of doing so. The contested decision does not show to the requisite standard that Merck (GUK) was an actual or potential competitor of Lundbeck in all EEA countries, since the only country in which it had an MA before the conclusion of the GUK EEA agreement was Sweden. Merck (GUK) obtained an MA in Germany, Italy, the Netherlands and Spain only after the expiry of the GUK EEA agreement, and did so elsewhere while that agreement was in force.

213 The Commission disputes those arguments.

214 It is appropriate, before examining the applicants' arguments, to briefly recall the examination of the potential competition between Merck (GUK) and Lundbeck carried out by the Commission in the contested decision. The Commission made a distinction, in that respect, between the prevailing situation in the United Kingdom at the time the GUK United Kingdom agreement was concluded, on the one hand, and the prevailing situation in the EEA at the time the GUK EEA agreement was concluded, on the other.

1. The situation in the United Kingdom

215 As regards, first of all, the competitive situation in the United Kingdom, the Commission found that in the period preceding 24 January 2002, the date on which the GUK United Kingdom agreement was signed, Lundbeck was the only undertaking selling citalopram in the United Kingdom. On 5 January 2002, Lundbeck's original patents expired in the United Kingdom. From that date, the citalopram market in the United Kingdom was therefore in principle open to generic products, provided that they complied with the legal requirement in relation to quality, safety and efficacy, as confirmed by an MA. Accordingly, undertakings manufacturing or intending to sell genetic citalopram products in the United Kingdom which had a realistic prospect of obtaining supplies of generic citalopram and acquiring an MA in the near future could be regarded as potential competitors of Lundbeck. The market entry of generics, in particular by several generic undertakings simultaneously, would in all probability have generated an intense process of price competition that would have reduced citalopram prices quickly and steeply (recital 738 of the contested decision).

216 Merck (GUK), after informing Lundbeck of its intention to enter the citalopram market, was the first generic undertaking to obtain an MA for the United Kingdom market, on 9 January 2002. During that period, Merck (GUK) had assembled a stock of 8 million citalopram tablets made from Natco API, ready for sale in the United Kingdom (recital 741 of the contested decision).

217 Following the conclusion of the GUK United Kingdom agreement with Lundbeck on 24 January 2002, Merck (GUK) abstained from launching generic citalopram on the market until the end of the term of the agreement, which was initially planned for July 2003. Nevertheless, between 1 and 4 August 2003, before the agreement was extended for a second time on 6 August 2003, Merck (GUK) indeed sold generic citalopram in the United Kingdom corresponding to GBP 3.3 million (recital 742 of the contested decision).

218 The Commission concluded, in recital 743 of the contested decision, that those facts sufficiently demonstrated that Merck (GUK) had real concrete possibilities of entering the citalopram market in the United Kingdom at the time the GUK United Kingdom agreement was concluded. In addition, according to the Commission, the fact that Merck (GUK) actually briefly entered the market in August 2003 sufficiently demonstrated that Merck (GUK) and Lundbeck were potential competitors at the time the agreements at issue were concluded in January 2002. Furthermore, the very fact that Lundbeck agreed to transfer considerable value to Merck (GUK) under those agreements sufficiently demonstrated that Lundbeck perceived Merck (GUK) as a potential competitor, the market entry of which was plausible, and which constituted a threat to its position on the market at the time the agreements at issue were concluded.

219 The applicants nevertheless dispute that those factors are sufficient to establish the existence of potential competition between them and Merck (GUK) and argue that the Commission should have demonstrated, above all, Merck (GUK)'s capacity to enter the market instead of taking account of its intentions in that respect. They also call into question various statements used by the Commission in the contested decision which, in their view, were taken out of context and which were not capable of proving that the Natco API did not infringe any of Lundbeck's patents and, in particular, the crystallisation patent.

220 It suffices to note, however, that the Commission did not rely solely on the subjective assessments of Merck (GUK) and Lundbeck in order to establish the existence of potential competition between them, but rather on objective elements, such as the fact that Merck (GUK) had, at the time of concluding the GUK United Kingdom agreement, concluded a supply agreement with Schweizerhall, in order to obtain the Natco citalopram, that it had already assembled a large stock of generic citalopram and that it had obtained an MA in the United Kingdom on 9 January 2002.

221 In the first place, the applicants nevertheless argue that Merck (GUK) would not have been able to launch its generic products on the market without infringing their patents. However, that is again their subjective assessment, since, at the time the GUK United Kingdom agreement was concluded, no court in the EEA had declared that the Natco API, used by Merck (GUK) to produce its generic citalopram, infringed any of Lundbeck's patents. Moreover, at the time that agreement was concluded, Lundbeck's crystallisation patent had not yet been granted in the United Kingdom. Lastly, it must be recalled that Merck (GUK) did not have to prove that its products were non-infringing in order to be able to market them in the United Kingdom (see paragraph 122 above). It risked, at most, having to face applications for injunctions or infringement actions brought by Lundbeck, without it being in any way certain, however, that the latter would succeed, since, according to Lundbeck's own estimations, the infringement of process patents was particularly difficult to establish (recital 629 of the contested decision). In addition, it could, in the event of litigation, have challenged the validity of Lundbeck's patents, by raising a counter-claim (see paragraph 122 above).

222 Contrary to the applicants' assertion, the Commission was not required to establish with certainty that Merck (GUK) would have entered the market, during the term of the agreements, using an API that did not infringe any of Lundbeck's patents. The Commission was only required to prove that Merck (GUK) had real concrete possibilities of entering the market, at the time the agreements at issue were concluded, and that those possibilities were not purely theoretical but showed a real capacity to enter the market within a sufficiently short period to exert competitive pressure on Lundbeck.

223 In view of the factors set out in recital 738 et seq. of the contested decision, as summarised in paragraphs 215 to 218 above, the applicants cannot validly argue that the Commission did not accomplish that task. The fact that Merck (GUK) was able to enter the market with its generics briefly, on August 2003, when it considered that the conditions of its agreement with Lundbeck were no longer good enough (recital 755 of the contested decision), shows in a striking manner that Merck (GUK) was at the very least a potential competitor of Lundbeck at the time the GUK United Kingdom agreement was concluded. If the applicants' argument were accepted, it would mean that, even at that time, Merck (GUK) could not be considered a potential competitor of Lundbeck, since it had not been established that its products did not infringe any of Lundbeck's patents, even though it had sold tablets corresponding to a value of GBP 3.3 million in the United Kingdom. Such arguments clearly cannot be upheld. Lastly, the fact that Lundbeck preferred to conclude an agreement with Merck (GUK) in order to delay the latter's market entry also shows that it considered Merck (GUK) to be a threat capable of exerting competitive pressure on the citalopram market, at the time that agreement was concluded (see paragraph 103 above).

224 In the second place, as regards the applicants' arguments that Merck (GUK) would not have been able to switch to another API producer during the term of the agreements at issue, it must be pointed out that such an argument is ineffective, in view of the foregoing, since the Commission was not required to establish with certainty that Merck (GUK) would have entered the market with a non-infringing API in order to be able to regard it as a potential competitor of Lundbeck at the time those agreements were concluded. In any event, as the Commission rightly points out, the supply contract that Merck (GUK) had concluded with Schweizerhall was based on the premiss that the Natco API did not infringe any of Lundbeck's patents after the expiry of its original patents. In the event that Merck (GUK)'s products, based on the Natco API, were held to be infringing, it is very likely, therefore, that Merck (GUK) would have been able either to terminate that contract and seek to obtain generic citalopram from a supplier other than Schweizerhall, or to work with Schweizerhall in order to procure generic citalopram, obtained using non-infringing processes (paragraph 197 above).

225 Accordingly, the Commission did not err in concluding in the contested decision that Merck (GUK) had real concrete possibilities of entering the citalopram market in the United Kingdom at the time the GUK United Kingdom was signed, and that consequently it was at the very least a potential competitor of Lundbeck at that time.

2. The situation in the EEA

226 As regards, next, the competitive situation in the EEA, the Commission set out, in recitals 827 et seq., the reasons why it considered that Merck (GUK) could be regarded as a potential competitor of Lundbeck in most of the EEA States. At the time the agreements were signed, Merck (GUK) had concluded an exclusive distribution agreement with Schweizerhall covering the Natco API. Under that agreement Schweizerhall became the preferred supplier of Natco for a number of EEA States (namely Belgium, Germany, Spain, France, Italy, the Netherlands, Finland, Sweden and Norway) and Merck (GUK) became its 'preferred customer', meaning that its citalopram supply needs would be given priority (recital 235 of the contested decision).

227 In May 2002, NM Pharma, Merck (GUK)'s distributor for Sweden, obtained an MA and entered the Swedish market. NM Pharma also had a strong distribution network in Norway and intended to use its Swedish MA to obtain MAs in Belgium, Denmark, Spain, the Netherlands, Finland and Norway through the mutual recognition procedure laid down in Directive 2001/83. Merck (GUK), for its part, intended to obtain similar MAs for Germany, Ireland, Greece, France, Italy, Austria and Portugal by using its MA obtained in the United Kingdom (recitals 829 and 830 of the contested decision). In addition, point D of the preamble to the GUK EEA agreement recognised Merck (GUK)'s role as a potential competitor in the EEA (recital 831 of the contested decision).

228 Those factors allowed the Commission to conclude that Merck (GUK) and Lundbeck were at the very least potential competitors at the time the GUK EEA agreement was signed in October 2002. Merck (GUK) was even an actual competitor of Lundbeck in Sweden for several months preceding the signing of the agreement, through its distributor NM Pharma. Moreover, the very fact that Lundbeck agreed to transfer considerable value to Merck (GUK) under that agreement sufficiently demonstrated that Lundbeck perceived Merck (GUK) as a potential competitor, the market entry of which was plausible, and which constituted a threat to its position on the market at the time the GUK EEA agreement was signed (recital 832 of the contested decision).

229 The applicants submit, however, that the product markets for the supply of pharmaceutical products such as citalopram are national in scope and that the Commission ought therefore to have ascertained whether Merck (GUK) and Lundbeck were potential competitors in each Member State of the EEA, instead of making a single assessment for the whole of the EEA.

230 It must be pointed out, however, that the analysis carried out by the Commission in recitals 827 to 840 of the contested decision (see paragraphs 226 to 228 above) shows in a sufficiently convincing manner that Merck (GUK) and Lundbeck could be regarded as potential competitors in the whole of the EEA at the time the GUK EEA agreement was concluded. The fact that Merck (GUK) had not obtained an MA in all the EEA States at the time the GUK EEA agreement was concluded, nor during the term of that agreement, does not mean that it did not have real concrete possibilities to enter the markets of various EEA States, at the time that agreement was concluded.

231 As the Commission demonstrated in recitals 827 et seq. of the contested decision, Merck (GUK) had intended to use the mutual recognition procedure laid down in Directive 2001/83 in order to obtain MAs in other Member States by using the MA it had already obtained in the United Kingdom and the MA of its distributor, NM Pharma, in Sweden (see paragraph 227 above).

232 Furthermore, the fact that the GUK EEA agreement covered the whole EEA territory (with the exception of the United Kingdom), sufficiently demonstrates that Lundbeck perceived Merck (GUK) as a potential threat in the whole of that territory and that the latter had real concrete possibilities of entering the citalopram market, if not in all the EEA States, then at least in a large majority of them (see recitals 827 et seq. of the contested decision). As the Commission indicated in footnote No 1540 of the contested decision, it was not required to prove that, in the absence of the GUK EEA agreement, Merck (GUK) would undoubtedly have entered the market in each EEA Member State during the term of that agreement. It is not possible to reconstruct, *ex post*, the date on which Merck (GUK) would have entered the market in each EEA Member State, when the purpose and effect of the GUK EEA agreement was precisely to interrupt the efforts made by Merck (GUK) in that respect.

233 In addition, that argument once again disregards the distinction between actual and potential competition; the latter does not require the demonstration of certain market entry, but merely the existence of real concrete possibilities in that respect. It can be seen from recitals 328 and 347 of the contested decision, inter alia, that Merck (GUK) had the intention and capacity to sell citalopram in the EEA within a sufficiently short period to exert competitive pressure on Lundbeck, at the time the GUK EEA agreement was concluded.

234 In any event, it can be seen from the contested decision that the Commission took into account the differences between the EEA Member States when those differences were relevant for the purpose of examining the existence of potential competition in that territory. Thus, the Commission mentioned, in recital 827 of the contested decision, inter alia, that Lundbeck's API patent expired only in April 2003 in Austria, unlike in the other Member States. It also examined the situation as regards the MAs in various EEA States in recitals 326, 347 and 827 to 830 of the contested decision.

235 As regards the applicants' argument that NM Pharma would have inevitably faced litigation brought by the applicants, it suffices to note that that assertion is not supported by the facts, since NM Pharma actually entered the Swedish market for almost five months, making 'very encouraging' sales (recital 325 of the contested decision), without facing any litigation from Lundbeck.

236 The sixth part must therefore be rejected.

I – *The seventh part, alleging the absence of potential competition between Lundbeck and Arrow at the time the agreements at issue were concluded*

237 The applicants maintain that at the time of the conclusion of the Arrow UK and Arrow Danish agreements, Arrow was not in a situation in which there was potential competition between it and the applicants.

238 As regards the United Kingdom, the applicants argue, first, that Arrow did not have an MA until July 2002, and, moreover, that MA related to the APIs of Cipla and Matrix, obtained using their original production processes, the Cipla I process and the Matrix I process, which, according to them, infringed the crystallisation patent. There is no proof that Arrow had a reasonable prospect of having that patent declared invalid. Furthermore, Arrow could not rely on Cipla's cooperation to prove that there was no infringement.

239 Nor, secondly, did Arrow have real concrete possibilities of switching to APIs produced using the Cipla II and Matrix II processes, which in any event were also infringing, or to Ranbaxy's citalopram, which, in addition to infringing the amide and iodo patents, was not covered by an MA.

240 Thirdly, the applicants invoke the judgment of the High Court of England and Wales, Chancery Division, of 23 October 2001 in *Smithkline Beecham Plc* v *Generics (UK) Ltd* ([2002] 25(1) I.P.D. 25005; 'the *Paroxetine* judgment'), from which it follows, according to them, that a generic undertaking cannot enter the market before it has proved that its product does not constitute an infringement, which Arrow was unable to do.

241 Fourthly, the fact that the applicants agreed to conclude agreements with Arrow under which they were required to make payments to Arrow does not mean that they perceived Arrow as a potential competitor, but that they feared that it would infringe their patents.

242 As regards Denmark, the applicants refer to most of the arguments raised in respect of the United Kingdom, while adding that Arrow entered the Danish market only in 2005 and that during the term of the Arrow Danish agreement a number of generic undertakings were the subject of injunctions when they attempted to sell generic citalopram in that Member State.

243 The Commission contests all those arguments.

1. The situation in the United Kingdom

244 It is appropriate to examine, in the first place, the applicants' arguments concerning the alleged lack of potential competition between them and Arrow at the time the Arrow UK agreement was concluded.

245 As regards the applicants' arguments relating to the alleged impossibility for Arrow to enter the market with the Cipla citalopram or the Matrix citalopram, it is necessary to note the following.

246 First, in recitals 375 and 878 of the contested decision, the Commission found that, on 22 May 2001, Arrow had concluded an agreement with Tiefenbacher in order to purchase, on the one hand, the MAs that Tiefenbacher had requested in several EEA countries concerning generic citalopram and, on the other hand, tablets of that medicinal product produced using the Cipla or Matrix API.

247 Secondly, in recitals 379 and 878 of the contested decision, the Commission noted that, on 10 September 2001, Arrow had ordered 2.8 million German marks (DM) worth of citalopram tablets from Tiefenbacher, which it received in part in November 2001 and in part during the second week of January 2002. Those tablets had been developed using the Cipla API, produced in accordance with the Cipla I process.

248 Thirdly, it can be seen from recital 382 of the contested decision that, on 14 December 2001, a meeting was held between Arrow and Tiefenbacher. According to the notes on that meeting, which the applicants produced before the Court, Tiefenbacher considered that the citalopram produced in accordance with the Cipla I process could infringe the crystallisation patent, if it was granted in the United Kingdom, although Cipla argued that its process was one of those referred to in the original patents. Those notes also show that Arrow wanted to prepare a defence strategy as regards the applications for injunctions that Lundbeck was going to make before the competent courts in order to oppose Arrow's entry to the United Kingdom market. In addition, the email accompanying those notes mentions the fact that an Arrow employee had examined the Cipla I and Matrix I processes and had concluded that they did not seem to infringe the crystallisation patent.

249 Fourthly, according to recital 383 of the contested decision, on 21 December 2001, Arrow purchased from Tiefenbacher the MA application that Tiefenbacher had previously lodged with the competent authorities in the United Kingdom. That application, which was based, in accordance with the mutual recognition procedure referred to in Article 18 of Directive 2001/83, on the MA that Tiefenbacher had already obtained in the Netherlands, was granted in July 2002, after the action that Lundbeck had brought in the Netherlands against that MA had failed. In that respect, it must be noted that, as the Commission mentioned in recital 882 of the contested decision, potential competition begins before the issue of an MA (paragraphs 92 to 94 above) and that, in any event, that MA was issued during the term of the Arrow UK agreement.

250 Fifthly, in recital 387 of the contested decision, the Commission emphasised the fact that, in an email sent to Arrow on 15 January 2002, Cipla stated that it was ready to support Arrow in any litigation with Lundbeck, although it wished to provide the necessary information concerning its process directly to the competent authorities, and not first to Arrow or to Tiefenbacher. Thus, it is irrelevant that, according to an email of 11 January 2002, mentioned in recital 385 of the contested decision, Cipla did not wish to provide further information on its process.

251 Sixthly, it can be seen from recital 389 of the contested decision that, in an email of 22 January 2002, in response to a warning received from the applicants the day before, Arrow informed the applicants that it did not believe that it was infringing their new patents.

252 Seventhly, in an email of 23 January 2002, cited in recitals 390, 880 and 887 of the contested decision and sent to another producer of the citalopram API, a subsidiary of Arrow, Resolution Chemicals stated that it would 'launch [its product] in [the] UK [the following] week'. In that email, Resolution Chemicals also expressed an interest in the API of that supplier, as a second API source.

253 Eighthly, it must be recalled that, in the seventh recital in the Arrow UK preamble, Arrow did not state that it had infringed Lundbeck's new patents, but merely observed that it could not disprove that accusation by 'any demonstrable inconvertible' evidence.

254 Ninthly, it can be seen inter alia from recitals 157, 627, 669 and 745 and footnote No 322 of the contested decision that the other generic undertakings and even Lundbeck itself had doubts regarding the validity of the crystallisation patent. In particular, Lundbeck estimated the probability that that patent would be invalidated at 50 to 60%. It is true that the evidence concerning that estimation dates from the period after the conclusion of the agreements at issue. However, the applicants have not provided any evidence capable of explaining how, hitherto, their assessment of that question would have been different. Furthermore, account must also be taken of the considerations set out in paragraph 122 above concerning the invalidation of the process patents. If the crystallisation patent had been declared invalid, any violation of that patent by Arrow would have been without consequences.

255 Those pieces of evidence are sufficient to support a finding that, when the Arrow UK agreement was concluded, Arrow was in a situation of potential competition with Lundbeck as a result of Arrow's real concrete possibilities of entering the market with the Cipla citalopram, produced in accordance with the Cipla I process.

256 As regards the possibility for Arrow to switch API producer and use the Matrix API, produced in accordance with the Matrix I process, which Tiefenbacher could have provided to it, it must be observed that, according to the email accompanying the notes on the meeting of 14 December 2001 (see paragraph 248 above), Arrow believed that the process used by Matrix to produce that API probably did not infringe the crystallisation patent. Those notes also mention the possibility for Arrow to switch to the Matrix API, while presuming that it would not be possible to make such a switch at that stage. In that respect, it must be noted, as the Commission rightly observes in recitals 885, 886, 889 and 895 and in footnote No 1636 of the contested decision, that Arrow's agreement with Tiefenbacher allowed such a switch, so the fact that that option may have been a less advantageous solution for Arrow than concluding an agreement with Lundbeck does not alter the conclusion that Arrow had a real concrete possibility of entering the market with the citalopram produced on the basis of that API.

257 As regards the applicants' argument concerning the Matrix II and Cipla II processes, reference should be made to paragraphs 198 to 200 above).

258 As regards the applicants' argument based on the *Paroxetine* judgment, cited in paragraph 240 above, it must be borne in mind that a question relating to the interpretation of the national law of a Member State is a question of fact (see, to that effect and by analogy, judgments of 21 December 2011 in *A2A* v *Commission*, C-318/09 P, EU:C:2011:856, paragraph 125 and the case-law cited, and of 16 July 2014 in *Zweckverband Tierkörperbeseitigung* v *Commission*, T-309/12, EU:T:2014:676, paragraph 222 and the case-law cited) in respect of which the General Court is required, in principle, to carry out a comprehensive review (paragraph 113 above).

259 In the case that gave rise to the *Paroxetine* judgment, cited in paragraph 240 above, the court concerned applied the principles governing the grant of interim injunctions in English law and found that the balance of interests weighed in favour of the originator undertaking in view of the particular circumstances of the case and in particular the fact that the generic undertaking in question had not 'cleared the way' by informing the originator undertaking of its firm intention to launch its generic product on the market, even though it had been preparing for that entry for four years and despite the fact that it knew that the originator undertaking held patents allowing it to bring an infringement action against the generic undertaking.

260 Nevertheless, without it being necessary to rule on the interpretation and the exact scope to be given to the *Paroxetine* judgment, cited in paragraph 240 above, it must be noted that there are several differences between the present case and the case which gave rise to that judgment.

261 First, it can be seen from recital 374 of the contested decision that the applicants and Arrow had already been in contact on 15 December 2000 in order to discuss the issue of generic citalopram. In addition, in recital 389 of the contested decision, the Commission noted that, in January 2002, Arrow had confirmed to the applicants that it was preparing to enter the market in the United Kingdom.

262 In addition, whereas in the case that gave rise to the *Paroxetine* judgment, cited in paragraph 240 above, the patent allegedly infringed by the generic undertaking in question already existed throughout the period in which that undertaking was preparing to enter the market, in the present case, Lundbeck filed its application for the crystallisation patent in the United Kingdom only on 12 March 2001 and that application was not published until 4 July 2001, the patent itself being definitively issued, for the purpose of Article 25 of the UK Patents Act, only on 30 January 2002, after the Arrow UK agreement had been concluded.

263 Furthermore, the applicants have given no explanation, other than the imperfect nature of the patents system in Europe and the resulting asymmetry of risk, as to why the undertaking of which they form part — which is an experienced undertaking, advised by specialist lawyers — preferred to conclude a costly agreement such as the Arrow UK agreement, which merely allowed it delay Arrow's entry to the United Kingdom market. If their interpretation of the *Paroxetine* judgment, cited in paragraph 240 above, and their belief that they would be able to block the entry of generics by enforcing their patents, were correct, interim measures would surely have been granted against Arrow in the United Kingdom if Arrow attempted to enter that market with its generic medicinal products, thus allowing them to block that entry pending a favourable judgment on the substance.

264 In so far as the applicants invoke, in essence, the asymmetry of risks between themselves and Arrow, it must be noted that such an argument is not capable, by itself, of calling into question the conclusion that they perceived Arrow as a threat on the citalopram market at the time the Arrow UK agreement was concluded.

265 As regards the applicants' arguments relating to the fact that they did not perceive Arrow as a potential competitor but rather as an undertaking that might infringe their patents, it must be pointed out that the very fact that they concluded an agreement with Arrow is a very strong indication that they perceived Arrow as a potential competitor (see paragraph 181 above). In addition, it must be borne in mind that Lundbeck's belief that its patents had been infringed was not shared by Arrow (see the seventh recital in the preamble to the Arrow UK agreement and paragraph 35 above) and had not been confirmed by any court at the time the Arrow UK agreement was concluded.

266 Accordingly, it must be concluded that the Commission did not commit any error of assessment in treating Arrow as a potential competitor of Lundbeck in the United Kingdom in the contested decision.

2. The situation in Denmark

267 In the second place, as regards the potential competition in Denmark, it is appropriate first to reject the applicants' argument concerning the fact that Arrow did not enter the market upon the expiry of the Arrow Danish agreement, in April 2003, but only in 2005. In that respect, it must be pointed out, first of all, that that argument concerns *ex post* evidence and that it relates to actual competition, and not potential competition. Moreover, it must be noted that the situation which existed after the expiry of that agreement was not comparable to that which preceded it, since the conditions on that market had changed in the meantime.

268 Secondly, as regards the fact that the applicants obtained several injunctions in Denmark, it must be pointed out that those injunctions were granted after the Arrow Danish agreement had been concluded, with the result that the Commission was not required to take them into account in

evaluating whether Arrow had real concrete possibilities of entering the market at the time that agreement was concluded. Even if those injunctions could be taken into account, that would also be the case for the decisions on appeal which withdrew several injunctions granted at first instance, as the Commission observed at recital 185 of the contested decision.

269 Thirdly, while it is true that, when the Arrow Danish agreement was concluded, Arrow knew that the Cipla I process was probably infringing, it is nevertheless the case that it could have sought to have the crystallisation patent declared invalid and, moreover, that it could have sought to obtain first the Matrix citalopram, produced in accordance with the Matrix I process, and then the citalopram produced in accordance with the Cipla II or Matrix II processes or even that of Ranbaxy (see paragraphs 198 to 201 and 256 above). In that respect, it must be noted that, even after Lundbeck had obtained the crystallisation patent in Denmark, Arrow continued to take steps to obtain an MA within a reasonable period, in order to be able to sell generic citalopram supplied by Tiefenbacher, produced using the Cipla API or the Matrix API, on the Danish market (see recitals 450, 454, 967 and 968 of the contested decision as well as the third recital in the preamble to the Arrow Danish agreement).

270 It follows that the Commission rightly considered that Arrow was also a potential competitor of Lundbeck in Denmark.

271 Consequently, the seventh part of the plea must be rejected.

J – *The eighth part, alleging the absence of potential competition between Lundbeck and Alpharma at the time the agreements at issue were concluded*

272 The applicants maintain that, at the time of the conclusion of the Alpharma agreement, Alpharma was not a potential competitor of the applicants.

273 They argue, first, that Alpharma did not have access to any citalopram that did not infringe their patents, since it was obliged to buy its products from Tiefenbacher. Tiefenbacher supplied Alpharma with citalopram obtained using the Cipla I process, which was clearly infringing, and could have supplied it only with other infringing products obtained using the Matrix I process or, later, using the Cipla II and Matrix II processes. Furthermore, the fact that Alpharma had doubts as to the validity of the crystallisation patent does not mean that it was a potential competitor, particularly as those doubts were based on subjective assessments.

274 Secondly, the applicants observe that Alpharma had an MA for only eight EEA countries, including the MA for the United Kingdom, which was not granted until July 2002.

275 The Commission disputes those arguments.

276 In that respect, it must be recalled that, in recital 1035 of the contested decision, the Commission pointed out that, according to an email of 19 February 2002 from the managing director of Alpharma responsible for the dossier in question, instead of concluding the Alpharma agreement, the Alpharma group could have entered the market with the citalopram tablets it had already received or ordered, produced in accordance with the Cipla I process, and could have claimed that the crystallisation patent infringed by that process was invalid, according to the information available to the Alpharma group and Lundbeck at that time.

277 In the first place, it must be observed that the fact that Alpharma in no way excluded the possibility of entering the market with the tablets that it had already received or ordered can also be seen from the internal email of 14 February 2002, from the same managing director, cited in recital 516 of the contested decision. In that email, the managing director explained to one of his colleagues that, at that time, Alpharma was employing a dual strategy, as shown by the expression ‘we are riding two horses’,

consisting, on the one hand, of planning the launch of citalopram in several EEA countries and, on the other hand, of negotiating with Lundbeck, and that, the following week, it would probably be necessary to make a decision. In that respect, he stated that, in order to take the best possible decision, he needed a description of the legal situation in each of those countries and of the risks to which Alpharma was exposed.

278 It therefore follows from the emails of 14 and 19 February 2002 that Alpharma, while aware of the risks that market entry might entail, would not have abandoned its plans if it had not concluded a sufficiently advantageous agreement with Lundbeck. Since those emails were internal, it is not credible that the positions expressed therein were intended to 'bluff' Lundbeck. Furthermore, Lundbeck was an experienced undertaking which had for a long time been monitoring the steps taken by Alpharma, as demonstrated, in particular, by the letters mentioned in recitals 477 and 496 of the contested decision. Those letters referred, amongst other things, to Lundbeck's utility model as well as the crystallisation patent, with the result that it cannot be considered that the positions set out in those internal emails were expressed without knowledge of the risks relating to those intellectual property rights.

279 Moreover, the considerations set out in paragraphs 122 and 254 above in relation to the potential invalidity of the crystallisation patent must be borne in mind.

280 The declarations contained in the abovementioned emails must be read in the light of the steps that Alpharma had taken until then in order to prepare for its entry to the market.

281 In that regard, it can be seen, inter alia, from recitals 476, 486, 490, 516 and 1017 of the contested decision that, at the time the Alpharma agreement was concluded, Alpharma:

— had already concluded a contract with Tiefenbacher, dated 25 June 2001, for the supply of generic citalopram produced using the Cipla API or the Matrix API;

— could, pursuant to that contract and to a previous contract between the same parties, of 31 July 2000, obtain an MA in the Netherlands, on the basis of the MA issued to Tiefenbacher on 31 August 2001 by the authorities of that Member State, and could, pursuant to the mutual recognition procedure laid down in Directive 2001/83, obtain MAs in other EEA countries;

— had already a stock of 9.4 million citalopram tablets and had ordered 16 million more;

— had already obtained MAs in the Netherlands, in Finland, in Denmark and in Sweden and had received, on 9 January 2002, assurances that it would obtain one in the United Kingdom in the very near future;

— had already published a list of prices for its citalopram in the United Kingdom.

282 In the second place, it must be observed that, as the Commission noted in recital 1035 of the contested decision, according to the email of 19 February 2002, instead of concluding the Alpharma agreement, Alpharma could also have delayed its entry to the market until spring or summer of that year and switched to the Matrix citalopram, which was not considered to be problematic as regards the crystallisation patent.

283 It is indeed true that, according to the email of 19 February 2002, the switch to the Matrix citalopram presented serious drawbacks. However, it must be noted, first, that the contract between Tiefenbacher and Alpharma allowed the latter to obtain both the Cipla citalopram and the Matrix citalopram (see recital 480 of the contested decision).

284 Secondly, although the email of 19 February 2002 states that the switch to the Matrix API would involve market entry being delayed, which would reduce the expected profits, that disadvantage must be weighed against the advantage of reducing the risk of infringement of the crystallisation patent. In any event, that email does not change the fact that, despite that delay and its consequences, the switch to the Matrix API constituted a viable economic option. It was simply a factor making it financially preferable to conclude an advantageous agreement with Lundbeck. That issue is irrelevant to the assessment of whether Alpharma had real concrete possibilities of entering the market.

285 Thirdly, the fact that, subsequent to the conclusion of the Alpharma agreement, Matrix altered the process that it used to produce the citalopram API, as can be seen from footnote No 155 of the contested decision, does not demonstrate that the process available hitherto infringed the crystallisation patent, but merely shows the efforts subsequently made by Matrix to avoid all risk of infringement. Moreover, that alteration took place during the term of that agreement, with the result that Alpharma could have used the new Matrix API, produced in accordance with the Matrix II process, if it had not been paid to stay out of the market. In any event, on 19 February 2002, the Alpharma group took the view that the Matrix API, based on the Matrix I process that Matrix used at the time, could allow it to enter the market without infringing the crystallisation patent.

286 It follows that, when the Alpharma agreement was concluded, that undertaking had real concrete possibilities to enter the market with generic citalopram produced in accordance with the Cipla I or Matrix I processes. Moreover, as examined in paragraphs 198 and 200 above, during the term of that agreement, generic citalopram produced in accordance with the Matrix II and Cipla II processes also became available.

287 The finding that Alpharma was a potential competitor of the applicants is not called into question by the reference that they make to a press release issued by Alpharma on 28 February 2002. By that press release, Alpharma announced, in essence, that it would postpone the launch of citalopram until at least the end of the summer holiday and that it might, if necessary, abandon that planned launch, on the ground that there was a problem with its stock in view of the applicants' patents. It added that it had to seek a new API producer and obtain the necessary authorisations.

288 In that respect, it must be observed that, as the Commission pointed out in recital 1055 of the contested decision, that press release presents the alteration of Alpharma's plans as result of a unilateral decision of Alpharma. It contains no reference to the Alpharma agreement, in accordance with the confidential nature of that agreement, as laid down in point 3.1 thereof. Moreover, account must be taken of the fact that that press release was intended to provide an explanation to Alpharma's potential customers.

289 Accordingly, that press release does not undermine the Commission's thesis — based, inter alia, on the emails of 14 and 19 February 2002 and on the steps that Alpharma had taken until then — that, if Alpharma had not concluded the Alpharma agreement, it would have had a real concrete possibility of entering the market.

290 As regards the applicants' argument relating to the fact that Alpharma did not have an MA in all the EEA countries, it suffices to note that it already had several MAs and that it had real concrete possibilities of obtaining others through the mutual recognition procedure referred to in Article 18 of Directive 2001/83. Moreover, in view of the considerations set out in paragraphs 163 and 171 above, such possibilities indeed constitute potential competition.

291 In the light of the foregoing, the eighth part of the plea must be rejected.

K – *The ninth part, alleging the absence of potential competition between Lundbeck and Ranbaxy at the time the agreements at issue were concluded*

292 The applicants maintain that, at the time the Ranbaxy agreement was concluded, Ranbaxy was not in potential competition with the applicants.

293 First, the applicants submit that, although Ranbaxy informed them, at a meeting held on 17 April 2002, that it had a process that did not infringe any patent, that it intended to obtain an MA within eight months and that it was about to enter into an agreement with another generic undertaking which could purchase its API and enter the market with citalopram produced on the basis of that API within no more than four months, it was merely 'bluffing' in order to persuade them to enter into an agreement favourable to Ranbaxy. Nor does the fact that Ranbaxy made statements to the same effect to other generic undertakings who were potential buyers of its API have any evidential value. In particular, Ranbaxy's statement to Alpharma preceded Lundbeck's examination of Ranbaxy's reaction schemes, which showed that Ranbaxy's process infringed the amide and iodo patents.

294 Secondly, the applicants submit that Ranbaxy had no real concrete possibility of obtaining an MA during the term of the Ranbaxy agreement. During the administrative procedure, Ranbaxy acknowledged all the problems associated with the mutual recognition procedure referred to in Article 18 of Directive 2001/83.

295 Thirdly, the applicants emphasise that, in October 2002, Ranbaxy stated that it had not sold any citalopram after June 2002, not only in Europe but in the entire world, which proves that it could not do so, independently of the Ranbaxy agreement, which related only to the EEA.

296 Fourthly, the applicants observe that after the expiry of the agreement concerning it, Ranbaxy requested them to grant a licence for the iodo patent, instead of simply using its process, which confirms that that process infringed that patent.

297 Fifthly, the contested decision adduces no evidence that the applicants or Ranbaxy had any doubts as to the validity of the amide and iodo patents, as the statements mentioned relate only to the crystallisation patent.

298 The Commission disputes those arguments.

299 In the first place, as regards the applicants' argument concerning Ranbaxy's alleged 'bluffing', it must be noted that, as the Commission emphasised, inter alia, in recitals 1095 and 1096 of the contested decision, it can be seen from the minutes of the meeting of 17 April 2002 between them and Ranbaxy, that, on that occasion, the latter had indicated the following:

— it used a process which did not infringe Lundbeck's patents;

— Lundbeck knew of that process;

— it intended to file MA applications for the United Kingdom and Germany, where it had its own subsidiaries, and it expected to receive those MAs within eight months;

— it was nearing conclusion of an agreement with another generic undertaking — which it did not identify, but which Lundbeck believed to be Tiefenbacher or a company in the Merck group — on the basis of which it would be able to bring its API to the Northern Europe market within three to four months;

— its production capacity was 4.5 tonnes of API per year worldwide;

— it was ready to conclude an agreement with Lundbeck.

300 Likewise, it must be pointed out that, according to those minutes, Lundbeck knew that such an agreement could be costly and difficult, in particular from a competition law perspective (see recitals 188 and 1095 of the contested decision).

301 Nevertheless, Lundbeck decided to conclude the Ranbaxy agreement, which shows that it took seriously the threat posed by Ranbaxy.

302 In that context, it must be noted that, in accordance with the case-law (see paragraphs 101 and 104 above), the perception that Lundbeck had of Ranbaxy is a factor that may be taken into consideration, although it does not suffice, by itself, to demonstrate the existence of potential competition.

303 As regards the possibility that the applicants' perception was affected by 'bluffing' on Ranbaxy's part, it must be noted, first of all, that the applicants are an experienced undertaking, which had for a long time monitored the steps taken by generic undertakings in relation to citalopram (see, inter alia, recitals 172 to 183 of the contested decision).

304 The applicants had monitored Ranbaxy, in particular, especially closely, since, between January and July 2001, they had had frequent contacts, with the stated aim of exploring the possibility of using Ranbaxy's citalopram, whereas it was in reality a delaying tactic on their part (see recitals 549 to 552 of the contested decision). In addition, in May 2002, the applicants learned that Ranbaxy had filed two patent applications in India and, after analysing Ranbaxy's reaction schemes, they considered that those application could be in conflict with the amide and iodo patents (see recitals 560 to 564 of the contested decision).

305 Even after the Ranbaxy agreement had been signed, the applicants never complained that they had been the victims of a bluff; rather, as can be seen from recital 206 of the contested decision, they were delighted, in December 2002, that they had delayed the launch of generic citalopram, expected for the first quarter of 2002, which would have a positive effect on the sales development of their new medicinal product, Cipralex (see paragraph 22 above). They even wanted to extend that agreement until 31 December 2003 by signing an addendum, on 19 February 2003. In the absence of any evidence to that effect, it is not credible that Ranbaxy could have deceived Lundbeck twice, over such a long period.

306 In addition, it can be seen, inter alia, from recital 1105 of the contested decision, that before and after the conclusion of the Ranbaxy agreement, Ranbaxy stated to third parties that its processes did not infringe Lundbeck's new patents. In particular, in recitals 554, 557 and 1093 of the contested decision, the Commission noted that Ranbaxy had had contacts with Arrow, first in January, then in April 2002, which ended with a concrete offer to the latter in relation to the sale of 500 to 1000 kg of API. It is not credible that Ranbaxy would have deliberately given false information to its potential customers with the aim of convincing them to purchase its API. Such conduct would have exposed it to actions for damages brought by those customers. Moreover, one of those customers had received from Ranbaxy all the documentation necessary to support the fact that its processes were not infringing.

307 That Ranbaxy was not 'bluffing' the applicants is also confirmed by other evidence which the Commission adduced in the contested decision.

308 Thus, first, it must be recalled that, as the Commission noted in recital 1091 of the contested decision, Ranbaxy had already begun to develop a process to produce citalopram in January 2001. It can be seen from the document cited in recitals 552 and 1091 of the contested decision that, when, in July 2001, Lundbeck informed Ranbaxy that it did not wish to purchase the 400 kg of API that Ranbaxy had

proposed, Ranbaxy was particularly disappointed because, throughout the previous period, in the course of which Lundbeck had led it to believe that it had an interest in Ranbaxy's API, Ranbaxy had deliberately waived other opportunities.

309 Secondly, in recitals 566 and 1092 of the contested decision, the Commission found, first of all, that Ranbaxy had sent technical data concerning its API to a potential customer in Italy in December 2001, followed, in the first semester of 2002, by 16 kg of API. Next, in January 2002, a potential customer in France had also received technical data. Subsequently in 2002, Ranbaxy had sent a small quantity of API to a potential Swedish customer.

310 Thirdly, it must be observed that, as the Commission pointed out in recital 584 of the contested decision, in July 2002, Ranbaxy sold a small quantity of its API to the Italian customer with whom it had been in contact a few months earlier. If Ranbaxy was able to sell a small quantity of API just after the conclusion of the Ranbaxy agreement, it must at the very least have had real concrete possibilities to do so before then.

311 Lastly, it must be noted that, even after the applicants had examined its reaction schemes, Ranbaxy decided to file its DMF with the competent United Kingdom authorities and then applied for an MA. Those steps would not have been taken if, following that examination, it had been concluded that the process used by Ranbaxy to produce its API infringed the amide and iodo patents.

312 In the second place, as regards the applicants' argument relating to the period necessary to obtain an MA, it is necessary to recall the considerations set out in paragraphs 171, 177 and 178 above as well as the evidence relating to the periods stated by Ranbaxy at the meeting of 17 April 2002 (see paragraph 299, third and fourth indents, above).

313 Since the steps taken by a generic undertaking such as Ranbaxy in order to prepare its entry to the market with generic citalopram, including as regards the procedures necessary to obtain MAs, are relevant for the assessment of potential competition and, moreover, those steps were taken seriously by Lundbeck, it is irrelevant whether the procedures necessary in order to obtain those MAs could succeed within the periods envisaged by Ranbaxy, or later.

314 It must be noted that, although the success of the procedure to obtain an MA is indispensable in order for effective competition to exist, the path to obtaining such an MA, when it is taken by an undertaking which has for a long time been seriously preparing its market entry, constitutes potential competition, even though it may in fact take longer than envisaged by the interested parties.

315 In that respect, even if Ranbaxy underestimated the period necessary in order to obtain an MA, it must be noted, first, that Lundbeck nevertheless felt competitive pressure, to the point that it believed it to be in its interest to pay Ranbaxy in order to limit, or even exclude, its access to the market during the term of the Ranbaxy agreement.

316 Secondly, that payment necessarily made Ranbaxy's need to accelerate as much as possible the procedure for obtaining an MA less pressing, since, by concluding the Ranbaxy agreement, it was ensured significant profits, given its scale, in consideration for that limitation or exclusion. The fact that, as a result of a 'reformatting' of the dossier, it filed its MA request in August 2002, even though, according to the Commission's findings in footnote 1887 of the contested decision, all the relevant test results had been sent from India in June, confirms that it was not in any particular hurry to obtain an MA, after the conclusion of the agreement concluded with Lundbeck.

317 In any event, it must be noted, first of all, that according to Article 17(1) of Directive 2001/83, the Member States are to take all appropriate measures to ensure that the procedure for granting a marketing authorisation for medicinal products is completed within a maximum of 210 days after the

submission of a valid application. Thus, if Ranbaxy had made a request containing all the necessary information, the competent authorities would have treated it in a period even briefer than the eight months mentioned in the minutes of the meeting of 17 April 2002.

318 It is true that that period of 210 days laid down by Article 17(1) of Directive 2001/83 is suspended if the competent authority considers that an application is not valid and asks the undertaking concerned to provide it with further information.

319 However, when it drafted the minutes of the meeting of 17 April 2002, Lundbeck did not insert a remark to indicate that the period of eight months envisaged by Ranbaxy was unrealistic, but only noted that an agreement could cost USD 10 to 20 million or more (recital 1095 of the contested decision).

320 It follows that Ranbaxy had a real concrete possibility of obtaining an MA during the term of the Ranbaxy agreement, which was sufficient, in the circumstances of the present case, to exert a competitive pressure on Lundbeck.

321 Next, it must be recalled that according to the minutes of the meeting of 17 April 2002, Ranbaxy had the possibility of purchasing an existing MA or of selling its API to a generic undertaking which already held an MA. Those two options required, however, that those MAs be subject to a Type II variation.

322 It must be noted that, as was pointed out in paragraphs 306 and 309 above, before concluding the agreement with Lundbeck, Ranbaxy had taken several steps to sell its API, and not to sell finished products made from that API. The fact that the sale of finished products may have been more profitable does not prevent the sale of its API being considered as a real concrete possibility for Ranbaxy to compete with Lundbeck, as was mentioned in the minutes of the meeting of 17 April 2002.

323 Lastly, as the Commission mentioned in footnote No 1885 of the contested decision, the period of three to four months mentioned in the minutes of the meeting of 17 April 2002 is compatible with the statistics of the competent United Kingdom authority concerning the period of the procedures relating to Type II variations that the Commission produced before the Court, from which it follows that, between March 2001 and February 2002, most of those procedures were completed within a period of 90 days.

324 In that respect, it is true that, as can be seen from the introductory explanations to those statistics, that period was calculated on the basis of the filing of a complete application, without taking into account suspensions due to requests for further information. However, as the Commission stated in its reply to a question from the Court, the competent United Kingdom authority confirmed that, during the period referred to by the statistics at issue, 50% of applications for Type II variations submitted were determined within a maximum period of 90 days. In 40% of cases, no request for further information was made and, in 10% of cases, the sending of such a request did not extend the procedure beyond that period of 90 days.

325 Those statistics therefore confirm that there was a real concrete possibility of varying an existing MA so that it referred to the citalopram produced in accordance with the Ranbaxy processes within a period of the order of that mentioned in the minutes of the meeting of 17 April 2002, since the application for a variation could fall within one of the cases referred to in paragraph 324 above.

326 Moreover, it must be noted that, although the explanations provided by the competent United Kingdom authority date from after the conclusion of the Ranbaxy agreement and even after the adoption of the contested decision, given that they were provided for the purposes of the proceedings before the Court, they refer to the prevailing situation at the time the Ranbaxy agreement was being

negotiated and provide details for the interpretation of the factors set out in the contested decision. Thus, those explanations may be taken into account under the conditions referred to in paragraphs 138 to 141 above.

327 In the third place, as regards the fact that Ranbaxy stated that, during the term of the Ranbaxy agreement, it had not sold any citalopram in Europe, or in the entire world after June 2002 (see recital 577 of the contested decision), it must be pointed out that it is not relevant to the assessment of potential competition in the EEA at the time that agreement was concluded. The fact that Ranbaxy also made no sales outside the EEA demonstrates, at most, that that undertaking was not in actual competition with Lundbeck outside the EEA, but has no impact on the existence of a relationship of potential competition, whether within the EEA or outside that territory. Moreover, it must be noted that the Commission was in no way required to examine potential competition outside the EEA.

328 In the fourth place, as regards the applicants' argument relating to the fact that, in January 2004, Ranbaxy asked them for a licence covering the iodo patent, granted on 23 March 2003, it must be pointed out that this does not mean that it did not have real concrete possibilities of entering the market with its products before 2004. A licence request may be motivated by several different reasons, such as avoiding any infringement action. Ranbaxy may have believed that the applicants would grant it a licence at a reduced price, which would have allowed it to protect itself, at a low cost, from any risk of potentially infringing the iodo patent. Accordingly, the licence agreement invoked by the applicants is not decisive to the issue whether they were potential competitors of Ranbaxy at the time the Ranbaxy agreement was concluded.

329 In the fifth place, it must be noted, as the applicants submit, that the contested decision does not appear to contain any reference to the existence of doubts as to the validity of the amide and iodo patents. However, apart from the fact that the iodo patent had not been granted when the Ranbaxy agreement was concluded, with the result that it could not be used as a basis for an infringement action, it must be noted that the assessment of the potential competition between Lundbeck and Ranbaxy carried out in the contested decision is based on the evidence showing that Ranbaxy was preparing to enter the market because it considered that its process was not infringing, rather that the possibility of obtaining the cancellation of those of Lundbeck's patents which were liable to be infringed.

330 In the light of the foregoing, the ninth part of the first plea in law must be rejected, as must the first plea in law in its entirety.

II – *The second, third, fourth, fifth and sixth pleas in law, alleging, in essence, infringement of Article 101(1) TFEU*

331 Before examining the applicants' arguments relating to the content, the purpose and the context of the agreements at issue, it is appropriate to summarise briefly the approach taken by the Commission in the contested decision in finding that the agreements at issue in the present case were a restriction of competition 'by object', and the relevant case-law.

A – *Analysis relating to the existence of a restriction of competition 'by object' in the contested decision*

332 The Commission considered, in the contested decision, that the agreements at issue constituted a restriction of competition 'by object', for the purpose of Article 101(1) TFEU by relying, in that respect, on a series of factors relating to the content, the context and the purpose of those agreements (paragraphs 61 to 67 above).

333 It therefore found that the fact that Lundbeck's original patents had expired before the conclusion of the agreements at issue, but that it had obtained — or was about to obtain — several process patents at the time those agreements were concluded, including the crystallisation patent, was a significant element of the economic and legal context in which the agreements at issue were concluded. The Commission took the view, however, that a patent did not grant the right to limit the commercial autonomy of parties by going beyond the rights granted by that patent (recital 638 of the contested decision).

334 It thus considered that although all patent settlements were not necessarily problematic from a competition law perspective, such agreements were problematic where they provided for the exclusion from the market of one of the parties, which was at the very least a potential competitor of the other party, for a certain period, and where they were accompanied by a transfer of value from the patent holder to the generic undertaking liable to infringe that patent ('reverse payments') (recitals 639 and 640 of the contested decision).

335 It can also be seen from the contested decision that, even if the restrictions set out in the agreements at issue fell within the scope of the Lundbeck patents — that is to say that the agreements prevented only the market entry of generic citalopram deemed to potentially infringe those patents by the parties to the agreements and not that of every type of generic citalopram — they would nevertheless constitute restrictions on competition 'by object', since, inter alia, they prevented or rendered pointless any type of challenge to Lundbeck's patents before the national courts, whereas, according to the Commission, that type of challenge is part of normal competition in relation to patents (recitals 603 to 605, 625, 641 and 674 of the contested decision).

336 In other words, according to the Commission, the agreements at issue transformed the uncertainty in relation to the outcome of such litigation into the certainty that the generics would not enter the market, which may also constitute a restriction on competition by object when such limits do not result from an assessment, by the parties, of the merits of the exclusive right at issue, but rather from the size of the reverse payment which, in such a case, overshadows that assessment and induces the generic undertaking not to pursue its independent efforts to enter the market (recital 641 of the contested decision).

337 The applicants' arguments seeking to call into question the existence of a restriction by object in the present case must be examined in the light of those considerations.

B – *Applicable principles and case-law*

338 It must be recalled that Article 101(1) TFEU provides that 'the following shall be prohibited as incompatible with the internal market: all agreements between undertakings, decisions by associations of undertakings and concerted practices ... which have as their object or effect the prevention, restriction or distortion of competition within the internal market, and in particular those which:

(a) directly or indirectly fix purchase or selling prices or any other trading conditions;

(b) limit or control production, markets, technical development, or investment;

(c) share markets or sources of supply;

(d) apply dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage;

(e) make the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts.'

339 In that regard, it is apparent from the case-law that certain types of coordination between undertakings reveal a sufficient degree of harm to competition for the examination of their effects to be considered unnecessary (judgment in *CB* v *Commission*, cited in paragraph 78 above, EU:C:2014:2204, paragraph 49; see also, to that effect, judgments of 30 June 1966 in *LTM*, 56/65, ECR, EU:C:1966:38, pp. 359 and 360, and 14 March 2013 in *Allianz Hungária Biztosító and Others*, C-32/11, ECR, EU:C:2013:160, paragraph 34).

340 That case-law arises from the fact that certain forms of coordination between undertakings can be regarded, by their very nature, as being injurious to the proper functioning of normal competition (judgment in *CB* v *Commission*, cited in paragraph 78 above, EU:C:2014:2204, paragraph 50; see also, to that effect, judgment in *Allianz Hungária Biztosító and Others*, cited in paragraph 339 above, EU:C:2013:160, paragraph 35 and the case-law cited).

341 Consequently, it is established that certain collusive behaviour, such as that leading to horizontal price-fixing by cartels or consisting in the exclusion of some competitors from the market, may be considered so likely to have negative effects, in particular on the price, quantity or quality of the goods and services, that it may be considered redundant, for the purposes of applying Article 101(1) TFEU, to prove that they have actual effects on the market. Experience shows that such behaviour leads to falls in production and price increases, resulting in poor allocation of resources to the detriment, in particular, of consumers (see judgment in *CB* v *Commission*, cited in paragraph 78 above, EU:C:2014:2204, paragraph 51 and the case-law cited; see also, to that effect, judgment of 20 November 2008 in *Beef Industry Development Society and Barry Brothers*, C-209/07, ECR, 'the *BIDS* judgment', EU:C:2008:643, paragraphs 33 and 34).

342 Where the analysis of a type of coordination between undertakings does not reveal a sufficient degree of harm to competition, the effects of the coordination should, on the other hand, be considered and, for it to be caught by the prohibition, it is necessary to find that factors are present which show that competition has in fact been prevented, restricted or distorted to an appreciable extent (judgments in *Allianz Hungária Biztosító and Others*, cited in paragraph 339 above, EU:C:2013:160, paragraph 34, and *CB* v *Commission*, cited in paragraph 78 above, EU:C:2014:2204, paragraph 52).

343 In order to establish the anticompetitive nature of an agreement and assess whether it reveals a sufficient degree of harm to competition that it may be considered a restriction of competition by object for the purpose of Article 101(1) TFEU, regard must be had to the content of its provisions, its objectives and the economic and legal context of which it forms a part. When determining that context, it is also necessary to take into consideration the nature of the goods or services affected, as well as the real conditions of the functioning and structure of the market or markets in question (judgments in *Allianz Hungária Biztosító and Others*, cited in paragraph 339 above, EU:C:2013:160, paragraph 36 and in *CB* v *Commission*, cited in paragraph 78 above, EU:C:2014:2204, paragraph 53).

344 In addition, although the parties' intention is not a necessary factor in determining whether an agreement between undertakings is restrictive, there is nothing prohibiting the competition authorities, the national courts or the Courts of the European Union from taking that factor into account (judgments in *Allianz Hungária Biztosító and Others*, cited in paragraph 339 above, EU:C:2013:160, paragraph 37, and *CB* v *Commission*, cited in paragraph 78 above, EU:C:2014:2204, paragraph 54 and the case-law cited).

C – *The second plea in law, alleging a manifest error of law and of fact and a failure to state reasons in assessing the role of value transfers in the agreements at issue*

345 According to the applicants, the decision errs where it takes the view that the fact that the agreements at issue provide for payments by Lundbeck means that those agreements had an anticompetitive object, on the ground that those payments showed that the restrictions in each of the agreements did not correspond to the parties' assessments of the strength of the relevant patents and their infringement (first part). In addition, the decision errs when it concludes that the restrictions in the agreements at issue reduced or eliminated the generic undertakings' incentives to pursue independently their efforts to enter the market even if those restrictions did not exceed the restrictions inherent in Lundbeck's patents. The decision does not establish that the payments made by Lundbeck had that effect or that the restrictions in question did not correspond to the parties' assessment (second part). The argument employed by the Commission in the contested decision in that respect is inconsistent and unrealistic and applies an unworkable legal test (third part).

1. The first part

346 The applicants maintain that the decision is incorrect in law and in fact when it concludes that the agreements at issue did not reflect the parties' assessment of the strength of the patents.

347 They observe that the contested decision states that a settlement agreement is probably lawful if it 'has been reached on [the basis of] each party's competing assessment of the patent situation' (recital 604) but that the restrictions provided for in a settlement 'are likely to breach Article 101 [TFEU] when those limitations cannot be justified and do not result from the parties' assessment of the merits of the exclusive right itself' (recital 641). However, the contested decision's finding that the agreements at issue did not reflect the parties' assessment of the strength of the patents (i) is not supported by any written evidence showing the parties' lack of confidence in the strength of the patents and (ii) is based on an unfounded presumption that the value transfers meant that the restrictions in those agreements did not match the parties' assessment of the strength of the patents.

348 The Commission disputes those arguments.

349 It must be recalled that the Commission considered, in the contested decision, that the fact that the restrictions contained in the agreements at issue had been obtained through significant reverse payments was decisive for the legal assessment of those agreements (recital 660 of the contested decision).

350 The contested decision nevertheless acknowledges that the existence of a reverse payment in the context of a patent settlement is not always problematic, particularly when (i) that payment is linked to the strength of the patent, as perceived by each of the parties, (ii) it is necessary in order to find an acceptable and legitimate solution in the eyes of the two parties and (iii) it is not accompanied by restrictions intended to delay the market entry of generics (recitals 638 and 639 of the contested decision). It thus took as an example the company Neolab, with which Lundbeck had also concluded a settlement agreement, which was not considered to be problematic — even though it involved a reverse payment — since that payment to Neolab had been made in exchange for a commitment on Neolab's part not to seek damages before the competent courts and Lundbeck had agreed to not bring any claims under its patents during a certain period (recitals 164 and 639 of the contested decision). In that case, the actual object of the reverse payment was to settle a dispute between the parties, without, however, delaying the market entry of generics.

351 Although it is true that, as the applicants submit, in Neolab's case, there was also a first settlement agreement between the parties which provided that Neolab's entry to the market would be delayed, pending the outcome of the Lagap litigation, that settlement agreement was not accompanied by a

transfer of value and was conditional upon Lundbeck paying damages to Neolab in the event of an unfavourable judgment in that litigation. After Lundbeck ultimately decided to settle its dispute with Lagap amicably, Neolab still had an interest in obtaining damages by having Lundbeck's patent declared invalid. In that context, Lundbeck deemed it preferable to settle its dispute with Neolab also, by accepting to pay it the damages incurred in respect of the year when it withdrew from the market, and by committing not to make any patent claims in the event that Neolab entered the market (recital 164 of the contested decision). That latter commitment is therefore crucial, since, contrary to the agreements at issue in the present case, the payment made by Lundbeck was not made in exchange for an exclusion from the market, but was accompanied, on the contrary, by an acceptance of non-infringement and a commitment not to hinder the market entry of Neolab with its generics.

352 However, where a reverse payment is combined with an exclusion of competitors from the market or a limitation of the incentives to seek market entry, the Commission rightly took the view that it was possible to consider that such a limitation did not arise exclusively from the parties' assessments of the strength of the patents but rather was obtained by means of that payment (recital 604 of the contested decision), constituting, therefore, a buying-off of competition.

353 The size of a reverse payment may constitute an indicator of the strength or weakness of a patent, as perceived by the parties to the agreements at the time they were concluded, and of the fact that originator undertaking was not initially convinced of its chances of succeeding in the event of litigation. Similarly, the Supreme Court of the United States has also held that the presence of a significant reverse payment in a patent settlement agreement can provide a workable surrogate for the weakness of a patent, without a court having to carry out a detailed analysis of the validity of that patent (judgment of the Supreme Court of the United States of 17 June 2013 in *Federal Trade Commission v. Actavis*, 570 U.S. (2013), 'the *Actavis* judgment'). Moreover, the applicants, citing recital 640 of the contested decision in their written pleadings, seem to acknowledge that, the higher the originator undertaking estimates the chances of its patent being found invalid or not infringed, and the higher the damage to the originator undertaking resulting from successful generic entry, the more money it will be willing to pay the generic undertakings to avoid that risk.

354 It must be noted, in that respect, that the Commission did not find, in the contested decision, that all patent settlement agreements containing reverse payments were contrary to Article 101(1) TFEU; it found only that the disproportionate nature of such payments, combined with several other factors — such as the fact that the amounts of those payments seemed to correspond at least to the profit anticipated by the generic undertakings if they had entered the market, the absence of provisions allowing the generic undertakings to launch their product on the market upon the expiry of the agreement without having to fear infringement actions brought by Lundbeck, or the presence, in those agreements, of restrictions going beyond the scope of Lundbeck's patents — led to the conclusion that the agreements at issue had as their object the restriction of competition, within the meaning of Article 101(1) TFEU, in the present case (see recitals 661 and 662 of the contested decision).

355 It must be found, therefore, that the Commission did not err in considering, in the contested decision, that the very existence of reverse payments and the disproportionate nature of those payments were relevant factors in establishing whether the agreements at issue constituted restrictions of competition 'by object' for the purpose of Article 101 TFEU in that, by those payments, the originator undertaking provided an incentive to the generic undertakings not to continue their independent efforts to enter the market.

356 None of the applicants' arguments is such as to call that conclusion into question.

357 In the first place, the applicants submit that the contested decision does not establish that the agreements at issue did not reflect the parties' assessment of the strength of the patents. The contested decision refers to a literal reading of specific clauses of the agreements at issue and to isolated statements of Lundbeck and of the generic undertakings concerning the possible invalidity or

the possible non-infringement of the crystallisation patent, and concludes that the parties did not reach an agreement on the basis of the strength of the patents. However, those clauses and those statements, which constitute the only documentary evidence in the decision, do not show that the parties were in any doubt as to the strength of Lundbeck's patents.

358 The applicants do not dispute, however, that the payments provided for in the agreements at issue represented 'consideration for' and were 'related to' the generic undertakings' commitments to refrain from launching citalopram that infringed Lundbeck's patents. Nor do they deny that the payments may have represented an additional incentive for the generic undertakings to find a settlement. Nonetheless, in their submission, a mere 'consideration' or 'relation' does not prove that the payments 'overshadowed' the parties' assessment of the merits of the patents in such a way that 'the result of market exclusion [was] achieved not by the strength of the patent, but by the amount of the value transfer' (recitals 604 and 641 of the contested decision).

359 It suffices to note that that argument is ineffective, since it is based on an erroneous reading of the contested decision.

360 The Commission did not consider, in the contested decision, that only settlements based 'exclusively' on the parties' assessment of the strength of the patents were outside the scope of Article 101(1) TFEU. Rather, it took the view, taking into account a series of factors in that respect (see paragraph 354 above), that where such agreements contain significant reverse payments, which reduce or eliminate any incentive for the generic undertakings to enter the market for a certain period, without, however, resolving the underlying patent dispute, those agreements fall within the scope of Article 101(1) TFEU (recital 604 of the contested decision). In such cases, the transfer of value replaces the autonomous assessment, by the parties, of the strength of the originator undertaking's patents and the assessment of their chances of succeeding in potential litigation based on those patents or concerning their validity (see paragraph 353 above).

361 First, in the present case, it must be recalled, as the Commission submits, that the parties to the agreements at issue were in dispute over whether Lundbeck's patents were sufficiently strong to prevent the market entry of generic citalopram and that those patents cannot have constituted the decisive basis of the generic undertakings' commitment not to enter the market. The payments thus served as a 'deal clincher' and were decisive in convincing the generic undertakings to abandon their efforts to enter the market.

362 Secondly, the applicants do not dispute that the amounts which they paid to the generic undertakings may have been calculated by taking into consideration the profit or turnover which those undertakings expected to make during the term of the agreements at issue if they had entered the market, which is a significant factor in that respect. At the hearing, the applicants submitted that such a calculation could only have been made by the generic undertakings, and not by themselves, which in no way changes that finding.

363 Thirdly, the evidence relating to the period preceding the conclusion of the agreements at issue shows that the generic undertakings 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 patents. It is true that there was uncertainty as to whether their products would have eventually been declared infringing by a competent court. The contested decision demonstrates, however, that the generic undertakings had a real chance of succeeding in the event of litigation (see paragraph 122 above and recitals 75 and 76 of the contested decision). Accordingly, by concluding the agreements at issue, the applicants exchanged that uncertainty for the certainty that the generic undertakings would not enter the market, by means of significant reverse payments (recital 604 of the contested decision), thus eliminating all competition, even potential, on the market, during the term of those agreements.

364 In the second place, the applicants maintain that the contested decision fails to show how the existence of a value transfer indicates that the restrictions did not match the parties' assessment of the strength of the patents at issue. In their submission, the contested decision relies on the fact that the applicants made payments to the generic undertakings as a basis for the presumption that the parties had doubts as to the validity or the infringement of the relevant patents. It is incorrect to assert that 'the higher the originator undertaking estimates the chance of its patent being found invalid or not infringed ..., the more money it will be willing to pay the generic undertaking to avoid that risk' (recital 640 of the contested decision). The contested decision therefore breaches the applicable evidential rules, under which the Commission is required to rebut all explanations for the value transfers other than anticompetitive collusion.

365 The applicants claim that an economic presumption, such as that on which the Commission relies in the contested decision, can be accepted only if it is based on robust empirical and theoretical foundations, and that the Commission can rely on an insufficiently clear presumption only if it has proved that that was the only plausible explanation. This standard must apply by analogy to the inference that a reverse payment in a settlement implies that the parties lack confidence in the strength of the relevant patent.

366 It must be pointed out, in that respect, that, in accordance with the case-law cited in paragraphs 105 to 112 above, in the present case, the Commission relied on a body of evidence in the contested decision to demonstrate that it is principally the size of the reverse payments to the generic undertakings which induced those undertakings to accept the limitations governing their behaviour and not the existence of Lundbeck's process patents or even the desire to avoid the expenses linked to potential litigation (see inter alia recitals 255 and 748 of the contested decision and paragraphs 354 and 363 above). As regards Merck (GUK), for example, the contested decision shows that those amounts corresponded to the profits that it expected to make by entering the market, without it having to continue its efforts and bear the risks of such an entry (recitals 350, 809 and 862 of the contested decision). Similar considerations are set out in recitals 398, 460, 1071 and 1157 of the contested decision as regards Arrow, Alpharma and Ranbaxy.

367 In addition, in their pleadings the applicants themselves quote recital 640 of the contested decision (paragraph 353 above), where the Commission found that the size of a reverse payment is often linked to the risk, as perceived by the originator undertaking, of a judgment finding its patent invalid or the generic products non-infringing, as well as the damage to the originator undertaking resulting from the market entry of those products. The applicants also do not dispute that the reverse payments represent consideration for the commitments made by the generic undertakings to abstain from entering the market with generic citalopram which the applicants considered to infringe their patents, nor that those payments could have represented an additional incentive to conclude the agreements at issue.

368 In addition, the evidence contemporaneous to the agreements at issue shows that the applicants intended to use 'a large pile of [USD]' to exclude generics from the market (recital 131 of the contested decision) whereas they doubted the validity of their patents and their chances of succeeding in proceedings before a court (recital 149 of the contested decision and paragraph 126 above).

369 In any event, the Commission was not required to demonstrate irrefutably that the applicants doubted the validity of their patents in order to establish the existence of an infringement by object in the present case, since the evidence set out in the contested decision shows that the generic undertakings were confident of their chances of being able to enter the market within a sufficiently short period, either by overcoming the applicants' infringement allegations, or by challenging the validity of their patents, in the event of a dispute (see the first plea in law above). What matters, therefore, is that there was uncertainty, at the time the agreements at issue were concluded, as to the possibility, for the generic undertakings, of entering the market without being subject to injunctions or infringement actions, or of successfully challenging the validity of the applicants' patents, and that those agreements

had replaced that uncertainty, by means of significant reverse payments, with the certainty that the generic undertakings would not enter the market during the term of the agreements at issue (paragraphs 336 and 363 above).

370 In the third place, the applicants contend that the contested decision does not rebut the alternative explanations for the value transfers, and point out that in their reply to the statement of objections they claimed that the payments at issue demonstrated the pressure applied by the generic undertakings because of the asymmetry of the risks borne by the applicants and those borne by the generic undertakings. The applicants were at risk of sustaining considerable and irreversible damage as a result of the infringement by the generic undertakings, whereas the latter undertakings faced little or no risk. That asymmetry explains why the applicants agreed to make the reverse payments specified in the agreements at issue. That 'hold-up' problem is apparent in each of the agreements identified in the statement of objections.

371 According to the applicants, the contested decision, particularly in recital 644, recognises that asymmetry of risks, when it states that the profit that a generic undertaking could make from entering the market would be lower, indeed considerably lower, than the losses which the originator undertaking would be likely to make if generic medicinal products entered the market. In addition, the damages which the generic undertakings might be ordered to pay would represent only a fraction of the potential damage that would probably be caused to the originator undertaking by the unlawful entry of the generic undertakings. In some cases the generic undertakings would not have to pay compensation for any of the irreversible damage caused by their unlawful entry. Furthermore, the price levels or reimbursement levels, set by the public authorities, might be automatically lowered upon the entry of generic versions to the market, independently of whether or not those versions infringe valid patents. The costs incurred in litigating multiple patent disputes would also be extremely high.

372 It is therefore, according to the applicants, that asymmetry of risks which the generic undertakings exploited by giving the misleading impression that they were about to sell their infringing products, and which gave them the necessary power to extract payments from Lundbeck. Both the economic literature and the contested decision, in particular in recital 640, also recognise that the greater the damage the originator undertaking estimates it will suffer as a result of market entry by generic undertakings, the more money it may be willing to pay those undertakings in order to avoid such a risk.

373 Accordingly, in the applicants' submission, the Commission, in the contested decision, errs when it presumes that a generic undertaking's assessment of the strength of a patent is the sole factor that determines its incentive to launch a medicinal product, whereas such an assessment is only one of a number of criteria of relevance to the decision to launch and may not be relevant when the generic undertakings expect to make a profit from an infringement.

374 Consequently, in the absence of a link between the payments and the subjective perceptions of the parties to the agreements at issue of their respective patent claims, the contested decision cannot substantiate the finding that the payment induced the generic undertakings to accept limitations that they would not have accepted on the sole basis of their assessment of the strength of the patents. According to the applicants therefore, the first causal link on which the contested decision bases its theory falls, and the conclusion that the agreements at issue infringe Article 101(1) TFEU is baseless.

375 The intervener also maintains that the Commission ought to have shown that there was no other lawful explanation for the value transfer, taking into account, first, the risk of irreparable damage for the patent-holder in the event of the generics' unlawful entry to the market; secondly, the likelihood of being able to obtain adequate compensation by way of damages or being able to obtain interim relief; thirdly, the costs associated with bringing proceedings before multiple courts, including the risk

of different courts arriving at different outcomes. The Commission is therefore required to show why the existence of a value transfer transforms a lawful settlement agreement into an anticompetitive horizontal agreement.

376 It must be pointed out that, contrary to the applicants' assertions, the Commission refuted, in the contested decision, the other explanations put forward by the applicants concerning the existence of reverse payments in the agreements at issue, in particular those relating to the 'bluff theory' and the asymmetry of risks.

377 The Commission thus recognised, in the contested decision, that it could make sense, from a commercial perspective, for the originator undertaking to pay the generic undertakings in order to prevent their market entry, in view of the amounts that it could lose in the event of such entry. In addition, those amounts would probably exceed the profits that the generic undertakings would have made in the event of such entry, if their products were not considered to be infringing or if they succeeded in having the patents concerned invalidated. In such a case, however, the Commission considered that consumers would be worse off, since they would be deprived of the possibility of paying lower prices due to the market entry of generics (recital 640 of the contested decision).

378 The applicants submit in that respect that, in certain cases, the risks relating to market entry, if any, are very small for generic undertakings, which could avoid injunctions precluding that market entry or orders to pay damages in the event of unlawful entry, in particular by means of artificial arrangements such as the transfer of profits between various legal entities. Moreover, the contested decision acknowledges that the damages that they could be ordered to pay will often be substantially lower than the damage suffered by the originator undertaking in the event of unlawful market entry, because of the downward spiral of prices caused by such entry (recitals 93 and 645 of the contested decision).

379 It is true that the asymmetry of the risks faced by the generic undertakings and the originator undertaking can partly explain why the latter may decide to grant significant reverse payments in order to avoid any risk, even small, that the generics might enter the market. That is particularly so where the patented medicinal product, like Cipramil in the present case, is the flagship product of the originator undertaking, representing most of its turnover (recitals 26 and 120 of the contested decision).

380 It must be recalled, however, that the fact that the adoption of anticompetitive behaviour may be the most cost-effective or least risky course of action for an undertaking in no way excludes the application of Article 101 TFEU (see, to that effect, judgments of 8 July 2004 in *Corus UK* v *Commission*, T-48/00, ECR, EU:T:2004:219, paragraph 73, and 8 July 2004 in *Dalmine* v *Commission*, T-50/00, ECR, EU:T:2004:220, paragraph 211), particularly if that behaviour consists in paying actual or potential competitors not to enter the market and sharing with those competitors the profits resulting from the absence of generic medicinal products on that market, to the detriment of consumers, as in the present case.

381 According to the applicants, the asymmetry of risks allowed the generic undertakings to 'bluff' the applicants in order to obtain significant amounts of money, by pretending that they were preparing to enter the market with non-infringing products.

382 However, that merely confirms the Commission's theory that there was significant uncertainty, at the time the agreements at issue were concluded, as regards the outcome of the potential patent litigation, and that that uncertainty was eliminated and replaced by the certainty that the generic undertakings would not enter the market during the term of those agreements.

383 Furthermore, the fact that a reverse payment may constitute the only means of reaching an agreement by 'bridging the gap' between the parties to that agreement, does not mean that such a payment constitutes a legitimate means of reaching such an agreement or that that agreement is exempt from the application of competition law, in particular in circumstances where (i) the amount of that payment appears to be linked to the profits expected by those generic undertakings if they had entered the market, (ii) the agreement does not enable the resolution of the underlying patent dispute and (iii) the agreement contains restrictions going beyond the scope of the originator undertaking's patents (see paragraph 354 above and recitals 661 and 662 of the contested decision).

384 In addition, if the applicants were so convinced of the validity of their patents, and of the fact that the products that the generic undertakings intended to sell infringed them, they could have obtained orders to prevent market entry before the competent national courts, or, in the event that the generic undertakings unlawfully entered the market, obtained damages from them. They could also, as in Neolab's case (paragraph 350 above), reach a settlement with the genuine purpose of resolving the underlying patent dispute, without the limitations on the commercial autonomy of the generic undertakings potentially obtained under such an agreement being motivated by a reverse payment.

385 Although it is possible, as the Commission acknowledges, that the originator undertaking may have suffered irreparable harm in the event of unlawful entry of the generic undertakings to the market, as a result of the irreversible price falls that such entry would have brought about, regulatory price cuts following the expiry of an API patent are a characteristic of pharmaceutical markets known to the applicants and therefore constitute a normal commercial risk which cannot justify the conclusion of anticompetitive agreements. Furthermore, such price cuts resulting from a regulatory intervention, in a context where the API patent has already expired, illustrate the balance which the Member States have struck between the protection afforded to the patent of the originator undertaking, on the one hand, and the savings for State budgets and for consumers achieved by the entry of generics to the market and the effects of competition, on the other.

386 Accordingly, to accept the applicants' argument concerning the asymmetry of risks would amount, ultimately, to considering that they could — by concluding agreements such as the agreements at issue with the generic undertakings — protect themselves against an irreversible price fall which, according to their own assertions, could not have been avoided even if they had been successful in infringement actions brought before the national courts. They could therefore, by concluding such agreements, maintain higher prices for their products, to the detriment of consumers and the healthcare budgets of States, even though such an outcome could not have been obtained if the national courts had confirmed the validity of their patents and the products of the generic undertakings had been held to be infringing. Such an outcome would be manifestly contrary to the objectives of the treaty provisions on competition, which are intended inter alia to protect consumers from unjustified price increases resulting from collusion between competitors (see, to that effect, judgments of 19 March 2015 in *Dole Food and Dole Fresh Fruit Europe* v *Commission*, C-286/13 P, ECR, EU:C:2015:184, paragraph 115 and the case-law cited, and 9 July 2015 in *InnoLux* v *Commission*, C-231/14 P, ECR, EU:C:2015:451, paragraph 61). There is no reason to suppose that such collusion would be lawful in the present case, under the pretext that certain process patents were in dispute, when the defence of those patents before the national courts could not, even in the most favourable scenario for the applicants, have led to the same negative consequences for competition and, in particular, for consumers.

387 It should be recalled that it is indeed 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 (see judgment of 27 July 2005 in *Brasserie nationale and Others* v *Commission*, T-49/02 to T-51/02, ECR, EU:T:2005:298, paragraph 81 and the case-law cited).

388 Lastly, inasmuch as the applicants, supported by the intervener, argue that the agreements at issue would have allowed the avoidance of significant costs linked to litigation in various Member States, as well as the risk of conflicting decisions resulting from such litigation before multiple courts, it must be pointed out, first of all, that most of the agreements at issue contain no specific reference to the costs of the litigation that would be avoided, nor the least estimate of those costs. Furthermore, the applicants have not provided any explanation regarding the manner in which the amounts of the reverse payments were calculated, except that they resulted from their negotiations with the generic undertakings, whereas the contested decision contains numerous pieces of evidence showing that those amounts broadly corresponded to the profits expected by the generic undertakings if they had entered the market or to the damages that they might have obtained if they had succeeded in litigation against Lundbeck (see, inter alia, recitals 398, 460, 809, 862, 1071 and 1157 of the contested decision).

389 In any event, contrary to the applicants' assertions, it is unlikely that the costs relating to any litigation in the various EEA countries would have been greater than the payments obtained by the generic undertakings under the agreements at issue in the present case, which amounted to several million euros. Pharmaceutical undertakings do not often initiate litigation in all the Member States simultaneously. Usually, as the Lagap case in the United Kingdom shows (recital 63 of the contested decision), they decide to focus on a few test cases, rather than bringing multiple actions before different courts when the same issues are in question. In the Lagap case, however, the applicants ultimately decided to settle in order to avoid a defeat that would be used against them in other jurisdictions (recital 160 of the contested decision).

390 Moreover, the contested decision acknowledges that there are ways of resolving a dispute amicably, which are acceptable from a competition law perspective, other than those consisting in delaying the market entry of potential competitors through reverse payments, as in the present case (paragraph 354 above). According to the case-law, the specific subject matter of the patent cannot be interpreted as also affording protection against actions brought in order to challenge the patent's validity, in view of the fact that it is in the public interest to eliminate any obstacle to economic activity, which may arise where a patent was granted in error (see, to that effect, the *Windsurfing* judgment, cited in paragraph 119 above, EU:C:1986:75, paragraph 92). Although the applicants were entitled to enter into settlements with the generic undertakings in order to avoid the costs of potential litigation, they could not, on that ground, substitute their own assessment of the validity of their patents and the infringing nature of the generic undertakings' products for that of an independent judge while paying the generic undertakings to comply with that assessment and refrain from entering the market for a certain period.

391 Accordingly, the contested decision rightly concluded that the reverse payments had induced the generic undertakings to accept the limitations on their autonomy laid down in the agreements at issue, and the alternative explanations put forward by the applicants in order to justify those payments are not such as to call that conclusion into question.

392 The first part must therefore be rejected.

2. The second part

393 The applicants maintain that the contested decision wrongly finds that the contractual limitations imposed in the agreements at issue removed the other incentives to enter the market.

394 They submit, in the first place, that the limitations falling within the scope of the patents do not reduce or eliminate incentives to sustain independent efforts to enter the market. Thus, the generic undertakings which agree to refrain from entering the market with infringing medicinal products in exchange for a value transfer might still want to obtain a judgment finding that their medicinal

products are non-infringing or that the patent which is alleged to be infringed is invalid. Nor is there any reason to conclude that a payment for refraining to launch infringing medicinal products will reduce a generic undertaking's incentive to maintain its efforts to enter the market with non-infringing medicinal products. The fact that a generic undertaking is satisfied with the value transferred by the originator undertaking and does not seek to challenge the relevant patent, in spite of the absence of a no-challenge clause, suggests only that that undertaking lacks confidence in its chances of having the patent declared invalid.

395 The applicants therefore maintain that a legal presumption that market exclusion in exchange for a payment constitutes a restriction by object by reducing or eliminating the generic undertakings' incentive to pursue independent efforts to enter the market can arise only if the contractual restrictions fall outside the scope of the relevant patent.

396 In the second place, the applicants maintain that the contested decision does not state sufficient reasons for its finding that the value transfers indisputably reduce the generic undertakings' incentive to litigate. The contested decision acknowledges that the prospect of entering into a settlement agreement specifying a reverse payment some time after initiating proceedings against the originator undertaking may provide an incentive for the generic undertakings to bring such an action (recital 711). That recognition contradicts the contested decision's reasoning that reverse payments would in all likelihood only deter generic undertakings from initiating proceedings (recital 966). That internal inconsistency shows that the contested decision lacks a rigorous economic foundation and undermines the finding that 'considerable' reverse payments must be bad for consumers (recital 646).

397 The Commission disputes those arguments.

398 As regards the applicants' argument that the agreements at issue did not contain any provision preventing the generic undertakings from contesting the validity of their patents, with the result that those agreements did not remove all incentive for those undertakings to enter the market, it must be pointed out, first of all, that that argument is ineffective, since the contested decision states only that the reverse payments provided for in the agreements at issue encouraged or induced the generic undertakings 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 (recitals 604 and 659 to 661 of the contested decision).

399 In any case, even though the agreements at issue did not contain any no-challenge clause, the generic undertakings had no incentive to challenge Lundbeck's patents after concluding the agreements at issue, since the reverse payments broadly correspond to the profits that the generic undertakings expected to make if they had entered the market or to the damages that they would have obtained if they had succeeded in litigation against Lundbeck (see paragraph 388 above). Even if those payments were less than the expected profits, they nevertheless constituted a certain and immediate profit, without necessitating the risks that market entry would have entailed. Moreover, the events in the present case support that interpretation, since no generic undertakings contested Lundbeck's patents or entered the market during the term of the agreements at issue. Although Merck (GUK) indeed entered the citalopram market in the United Kingdom for a few days, after the expiry of the GUK United Kingdom agreement, it did so because it considered that the conditions offered by Lundbeck in order to extend that agreement were not good enough and it wanted more lucrative remuneration in exchange for a second extension of that agreement (recital 299 of the contested decision).

400 Next, inasmuch as the applicants claim that the generic undertakings could have entered the market using non-infringing generic products, reference must be made to the examination below of the sixth plea in law, relating to the assessment of the content and scope of the agreements at issue.

401 In any event, even if the restrictions contained in the agreements at issue potentially fell within the scope of Lundbeck's patents, in that they could also have been obtained through litigation, the contested decision rightly finds that this was merely a possibility at the time the agreements at issue were concluded. Replacing that uncertainty in relation to whether or not the generic undertakings were infringing and to the validity of the applicants' patents with the certainty that the generic undertakings would not enter the market during the term of the agreements at issue constitutes, as such, a restriction on competition by object in the present case, since that result was obtained through a reverse payment (see paragraphs 336 and 363 above).

402 Lastly, the applicants cannot succeed in their argument that the contested decision fails to state sufficient reasons in that respect. The numerous passages in the contested decision relating to the reverse payments, referred to by the applicants themselves, show that they understood the Commission's view in that respect, even if they did not share it. In addition, there is no contradiction, in the contested decision, in the fact that it acknowledges, on the one hand, that the possibility of obtaining reverse payments from the originator undertaking may encourage the generic undertakings to bring legal actions, whereas, on the other hand, the reverse payments obtained under the agreements at issue would have dissuaded the generic undertakings from bringing such actions in the present case. As the Commission indicates, in essence, in recitals 639 and 660 of the contested decision, inter alia, settlements providing for payments — even reverse payments — are not always problematic from a competition law perspective, particularly when they are not accompanied by any restriction on the market entry of generics but are intended, on the contrary, to offer compensation to the generic undertakings for their lost profits, once the originator undertaking acknowledges that their generic products do not infringe any patent.

403 Consequently, it must be concluded that the Commission did not commit any error of assessment in finding, in the contested decision, that the restrictions set out in the agreements at issue — obtained in exchange for significant reverse payments — had reduced the incentives for the generic undertakings to enter the market.

404 Accordingly, the second part must also be rejected.

3. The third part

405 The applicants maintain that the standard applied in the decision, namely that patent settlement agreements induced by a value transfer constitute restrictions of competition by object, is unworkable.

406 First, they claim that that standard is intrinsically inconsistent and has a dissuasive effect on the conclusion of agreements providing for early market entry, which benefit consumers, since it leads to different results depending on whether the value transfer takes the form of a cash payment or a rapid entry to the market.

407 Secondly, they maintain that an agreement cannot be based 'purely' on the parties' assessment of the strength of the patent and that the standard applied by the Commission prohibits, in practice, all reverse payments. No settlement agreement can be based 'purely' on the parties' assessment of the strength of the patent, for the simple reason that the 'strength' of a patent is not a clear-cut concept. If settlement agreements had to be based 'purely' on the parties' assessment of the strength of the patent, that would amount to requiring the parties to litigate. The decision leaves no discretion to the parties to use a reverse payment in order to deter a generic undertaking from infringing an originator undertaking's patents.

408 Thirdly, the applicants submit that the legal test based on the amount of the payment is unworkable in practice, since the contested decision established no clear threshold for the purpose of determining whether a payment is acceptable or anticompetitive.

409 The Commission disputes those arguments.

410 First, the Court finds that the applicants' argument that the contested decision will have a dissuasive effect on the conclusion of settlement agreements providing for the rapid market entry of generics is manifestly unfounded, since the Commission, on the contrary, considered that the agreements at issue were problematic from a competition law perspective because their object was to delay the market entry of generics and not to facilitate such entry. Moreover, it must be recalled that the Commission also took account of the fact that the agreements at issue did not contain any commitment from Lundbeck to refrain from bringing infringement proceedings against the generic undertakings if the latter entered the market with generic citalopram after the expiry of the agreements (recital 662 of the contested decision).

411 Furthermore, the decision acknowledges that, in certain cases, settlements are not problematic, even when they provide for reverse payments, if they also provide for the immediate market entry of generics (see the example of Neolab, cited in paragraph 350 above). The Commission's treatment of the agreements accompanied by a reverse payment differently from those which did not provide for a reverse payment is entirely justifiable, in view of the incentive that such a payment provides to the generic undertakings to accept restrictions that they would not have accepted in the absence of that incentive (see paragraph 349 et seq. above). In addition, an agreement allowing quicker market entry is clearly not problematic as regards competition law, with the result that the provision of such consideration for other commitments contained in a settlement is not comparable to a reverse payment intended to delay such entry.

412 Secondly, it must be recalled that the contested decision does not establish that an agreement must be based exclusively on the assessment of the parties to that agreement of the strength of a patent in order for Article 101(1) TFEU not to apply (paragraph 360 above). The applicants are therefore wrong in their submission that the contested decision removes all incentive to conclude patent settlements, thus leading to an avalanche of litigation throughout the EEA. The Commission criticised only the agreements concluded in the form of settlements, as in the present case, the real purpose of which is not to resolve the underlying patent dispute between the parties to that agreement and which provide for reverse payments in exchange for the generic undertakings' commitment not to enter the market. In addition, while it is true that the Commission considered that such agreements were anticompetitive, there is no obligation on the originator undertaking to initiate litigation in every EEA jurisdiction in order to protect its patents, since it is still possible, for example, to conclude settlements which do not contain any reverse payment or to conclude settlements which, although they provide for such payments, are not accompanied by any restriction on the market entry of generics (see the example of Neolab, cited in paragraph 350 above).

413 Lastly, the applicants' argument that the contested decision did not allow them any discretion to use reverse payments in order to dissuade the generic undertakings from infringing their patents is again based on the erroneous premiss that the products of the generic undertakings infringed their patents, whereas this had not been established at the time the agreements at issue were concluded.

414 Thirdly, the Commission explained, in the contested decision, that the reverse payments were particularly problematic, in the present case, since the amounts provided for in the agreements at issue broadly corresponded to the profits expected by the generic undertakings if they had entered the market or to the damages that they would have obtained if they had succeeded in litigation against Lundbeck (paragraph 388 above). In such a case, any incentive for the generic undertakings to enter the market is considerably reduced, if not eliminated. What is important, therefore, is that in the present case the amounts of the reverse payments provided for in each of the agreements at issue were sufficiently high to allow the generic undertakings to accept the limitations on their autonomy and to reduce their incentives to enter the market with their generic products (see inter alia recital 644 of the contested decision).

415 It is true that the Commission relied on a series of factors in order to establish the existence of a restriction by object in the present case (see paragraph 354 above and recitals 661 and 662 of the contested decision). However, the applicants cannot succeed in their submission that the Commission did not sufficiently clarify, in the contested decision, the significance that it attached to the fact that the reverse payments corresponded to the profits expected by the generic undertakings. In any event, as the Commission emphasises, it is not required, in its decisions, to lay down generally applicable legal rules, but only to determine, in each specific case, whether the agreements that it examines are compatible with the treaty provisions on competition, giving sufficiently clear and convincing reasons in that respect. In view of the foregoing, it must be held that the Commission satisfied those requirements in the present case.

416 Accordingly, the third part of the plea must be rejected, as must the second plea in law in its entirety.

D – *The third plea in law, alleging a manifest error of law in the application of the principles relating to the notion of restriction of competition by object*

417 The applicants maintain that the contested decision is vitiated by an error of law since it concludes that the agreements at issue constitute restrictions of competition by object by applying the established principles applicable to the interpretation of Article 101(1) TFEU. In particular, the contested decision errs, first, by treating the agreements at issue in the present case as comparable to the agreements at issue in the case that gave rise to the *BIDS* judgment, cited in paragraph 341 above (EU:C:2008:643), and in other classic market-sharing cases which did not involve patent enforcement; secondly, by finding that a value transfer could in itself make a patent settlement agreement restrictive by object; thirdly, by not recognising that the objective pursued by the agreements at issue in the present case, namely compliance with Lundbeck's patents, precluded the finding of a restriction by object; and, fourthly, by failing to recognise that the situation that would have prevailed in the absence of the agreements at issue ('the counterfactual scenario') precluded the existence of any restriction of competition by object in the present case.

1. The first part

418 The applicants submit that the Commission, in the contested decision, errs when it treats the agreements at issue as being equivalent to market-sharing agreements such as those at issue in the *BIDS* judgment, cited in paragraph 341 above (EU:C:2008:643).

419 In that regard, first, the applicants claim that, unlike the situation in the present case, the agreements at issue in the *BIDS* judgment, cited in paragraph 341 above (EU:C:2008:643), were not intended to preserve a patent which conferred on its holder the right to prevent the market entry of infringing products and the irreparable damage that would have followed from such an entry.

420 Secondly, unlike the situation in the present case, the undertakings leaving the relevant market under the agreements at issue in the case that gave rise to the *BIDS* judgment, cited in paragraph 341 above (EU:C:2008:643), would certainly have competed with the undertakings remaining on the market if those agreements had not been concluded.

421 Thirdly, unlike the reasoning used in the present case, the agreements at issue in the *BIDS* judgment, cited in paragraph 341 above (EU:C:2008:643), would have been deemed to be restrictive of competition even in the absence of any payment. The fact that in that case compensatory payments were involved was not decisive for the conclusion that those agreements had as their object the restriction of competition.

422 The Commission disputes those arguments.

423 First, it must be pointed out that the analogy made by the Commission in recitals 657 and 658 of the contested decision, between the agreements at issue in the case that gave rise to the *BIDS* judgment, cited in paragraph 341 above (EU:C:2008:643), and the agreements at issue in the present case, is not vitiated by any error of law.

424 As can be seen from, inter alia, paragraph 8 of that judgment, in that case, the undertakings active in the beef processing market in Ireland had created a mechanism by which some undertakings agreed to stay out of that market for two years in exchange for payments from the undertakings that stayed in the market. A similar dynamic arose in the present case through the conclusion of the agreements at issue, pursuant to which Lundbeck, which was the principal, or even the only, undertaking on the market in the countries concerned by those agreements, paid the generic undertakings, which were potential competitors, so that they would stay out of the market for a certain period.

425 It follows that both the case that gave rise to the *BIDS* judgment, cited in paragraph 341 above (EU:C:2008:643), and the present case concern agreements that limited the ability of competing economic operators to determine independently the policy that they intended to adopt on the market, by preventing the normal operation of the competitive process (see, to that effect, the *BIDS* judgment, cited in paragraph 341 above, EU:C:2008:643, paragraphs 33 to 35).

426 As regards the applicants' argument that, unlike in the case that gave rise to the *BIDS* judgment, cited in paragraph 341 above (EU:C:2008:643), the agreements at issue in the present case were concluded in a context in which they held patents allowing them to prevent the market entry of infringing products, it must be pointed out, first of all, that in the present case, the existence of Lundbeck's new process patents did not mean that the generic undertakings could not be regarded as potential competitors of Lundbeck, as can be seen from the analysis of the first plea in law. Article 101 TFEU protects potential competition as well as actual competition (see paragraph 99 above).

427 In addition, it must be recalled that, according to the case-law, an agreement is not exempt from competition law merely because it concerns a patent or is intended to settle a patent dispute (see, to that effect, judgment of 27 September 1988 in *Bayer and Maschinenfabrik Hennecke*, 65/86, ECR, EU:C:1988:448, paragraph 15). Furthermore, an agreement may be regarded as having a restrictive object even if it does not have the restriction of competition as its sole aim but also pursues other legitimate objectives (see the *BIDS* judgment, cited in paragraph 341 above, EU:C:2008:643, paragraph 21 and the case-law cited).

428 Secondly, although it is true that, in the case that gave rise to the *BIDS* judgment, cited in paragraph 341 above (EU:C:2008:643), the undertakings at issue were actual competitors, since the agreements in that case were intended to remove from the market undertakings which were already present on that market, whereas, in the present case, Lundbeck and the generic undertakings were merely potential competitors, it is nevertheless the case that, in the *BIDS* judgment, the Court of Justice did not require the Commission to demonstrate that, in the absence of those agreements, the undertakings would have stayed on the market. In the context of a restriction of competition by object, it is unnecessary to examine the effects of the agreements (see paragraph 341 above). The Court merely found, in that case, that the agreements in question were intended to implement a common policy which had as its object the encouragement of some of them to withdraw from the market and the reduction, as a consequence, of the overcapacity which affected their profitability by preventing them from achieving economies of scale. It therefore held that that type of agreement conflicted patently with the concept inherent in the treaty provisions relating to competition, according to which each economic operator must determine independently the policy which it intends to adopt on the common market, noting that Article 101(1) TFEU is intended to prohibit any form of coordination which deliberately substitutes practical cooperation between undertakings for the risks of competition (see the *BIDS* judgment, cited in paragraph 341 above, EU:C:2008:643, paragraphs 33 and 34).

429 In the present case, the parties to the agreements at issue preferred to replace the risks inherent in the normal competitive process and the state of uncertainty surrounding the validity of Lundbeck's process patents and whether or not the products that the generic undertakings intended to market infringed those patents, with the certainty that those undertakings would not enter the market during the term of those agreements, in return for significant reverse payments which corresponded approximately to the profits that those undertakings would have made if they had entered the market. It is therefore irrelevant whether the undertakings would undoubtedly have entered the market during the term of the agreements at issue, since those agreements eliminated that very possibility, replacing it with the certainty that those undertakings would not enter the market with their products during that period. By doing so, the parties to the agreements at issue were able to share a part of the profits that Lundbeck continued to enjoy, to the detriment of consumers who continued to pay higher prices than those they would have paid if the generics had entered the market (see recitals 644 to 646 of the contested decision).

430 Thirdly, the Court must also reject the applicants' argument that, unlike the agreements at issue in the present case, the agreements at issue in the case that gave rise to the *BIDS* judgment, cited in paragraph 341 above (EU:C:2008:643), would have been anticompetitive even in the absence of the payments provided for in those agreements. As the Commission submitted, in both cases, the payments played a decisive role in that they induced the undertakings to withdraw from the market. Thus, in the case that gave rise to the *BIDS* judgment, cited in paragraph 341 above (EU:C:2008:643), it is unlikely that the 'going' undertakings would have agreed to withdraw from the market in the absence of payments from the 'staying' undertakings. Likewise, in the present case, it can be seen from the file that the generic undertakings would not have agreed to stay out of the market unilaterally, after having taken significant steps and having made significant investments, in the absence of reverse payments.

431 The Commission indeed acknowledged that, in certain cases, the conclusion of a patent settlement is not anticompetitive, particularly where it is based on the assessment of the strength of the patents made by each of the parties to the agreement, or where it provides for a reverse payment, without however delaying the market entry of generics (recitals 638 and 639 of the contested decision). In the present case, however, the Commission rightly considered that the reverse payments had played a decisive role, in that they had allowed Lundbeck to obtain commitments from the generic undertakings which they would not have been able to obtain in the absence of those payments, thereby delaying the market entry of those undertakings.

432 In answer to a question from the Court concerning the implications of the judgment in *CB* v *Commission*, cited in paragraph 78 above (EU:C:2014:2204), the applicants claimed that that judgment supported their view that the Commission had erred in classifying the agreements at issue as restrictions by object. First, the Court of Justice held that the concept of restriction by object had to be interpreted restrictively. Secondly, a restriction by object could be found only if the agreement revealed, in itself, a sufficient degree of harm. According to the contested decision, however, the question whether a settlement agreement may be deemed compatible with competition law requires a thorough analysis of the individual agreement, in the light of its factual, economic and legal context. It also follows from an internal KFST memorandum that the Commission had not considered that the size of the payments in the Lundbeck case constituted a clear example of a company paying its competitors to stay out of the market. The applicants maintain, therefore, that by its approach the Commission seeks in reality to avoid the factual analysis and the burden of proof which it bears when it has to establish a restriction of competition based on the effects of an agreement. Thirdly, the context in which the agreements at issue were concluded, namely, in particular, the existence of valid process patents, the limited duration of the agreements, the specific regulatory framework in the EEA and the absence of non-infringing products available within a sufficiently brief period, cannot be ignored. Fourthly, past experience is important for establishing whether conduct has the object of

restricting competition. Past experience must be understood to mean what can traditionally be seen to follow from economic analysis, as confirmed by the competition authorities and supported, if necessary, by case-law. In fact, no experience of that type existed in the present case.

433 The Commission explained that it applied the settled case-law in the area, as noted by the Court of Justice in the judgment in *CB* v *Commission*, cited in paragraph 78 above (EU:C:2014:2204).

434 It must be observed that, by the judgment in *CB* v *Commission*, cited in paragraph 78 above (EU:C:2014:2204), the Court of Justice did not call into question the basic principles concerning the concept of a restriction 'by object' set out in the previous case-law. It is true that, in its judgment, the Court of Justice rejected the General Court's analysis in the judgment of 29 November 2012 in *CB* v *Commission* (T-491/07, EU:T:2012:633), according to which the concept of restriction of competition 'by object' should not be interpreted in a restrictive manner. The Court of Justice noted that the concept of restriction of competition 'by object' could be applied only to certain types of coordination between undertakings which revealed a sufficient degree of harm to competition that it could be found that there was no need to examine their effects, otherwise the Commission would be exempted from the obligation to prove the actual effects on the market of agreements which were in no way established to be, by their very nature, harmful to the proper functioning of normal competition (judgment in *CB* v *Commission*, cited in paragraph 78 above, EU:C:2014:2204, paragraph 58).

435 It follows from the general scheme of the contested decision and from recitals 802 and 1338 in particular, that the agreements at issue were comparable to market exclusion agreements, which are among the most serious restrictions of competition. The exclusion of competitors from the market constitutes an extreme form of market sharing and of limitation of production. The applicants cannot claim that the Commission did not take account of the existence of their process patents or of the specific legislative context of the EEA in the present case as relevant background factors in that respect. It can be seen from recitals 666 to 671 of the contested decision that the Commission took account of the applicants' process patents, but took the view that, even if those patents were presumed to be valid, they did not allow the exclusion of all competition in relation to the citalopram API. In addition, the Commission also took account of the fact that there was uncertainty, at the time the agreements at issue were concluded, regarding the validity of the applicants' patents, in particular the crystallisation patent, and that no court in the EEA had ruled on that issue at the time the agreements at issue were concluded.

436 Accordingly, it must be held that the Commission correctly applied the case-law referred to in paragraphs 338 to 344 above, which consists in determining whether an agreement may, by its very nature, be regarded as restricting competition in a sufficiently serious manner as to be classified as a restriction 'by object' in the case at hand (see, inter alia, recital 651 of the contested decision).

437 Accordingly, the Commission was not required also to examine the specific effects of the agreements at issue on competition and, in particular, whether, in the absence of those agreements, the generic undertakings would have entered the market without infringing one of Lundbeck's patents, in order to be able to establish the existence of a restriction of competition by object, within the meaning of Article 101(1) TFEU, since those generic undertakings had real concrete possibilities in that respect and were potential competitors of Lundbeck at the time the agreements at issue were concluded (see the first plea in law above).

438 Moreover, contrary to what is claimed by the applicants, it is not necessary that the same type of agreement have already been censured by the Commission in order for them to constitute a restriction of competition by object. The role of experience, mentioned by the Court of Justice in paragraph 51 of the judgment in *CB* v *Commission* (cited in paragraph 78 above, EU:C:2014:2204), does not concern the specific category of an agreement in a particular sector, but rather refers to the fact that it is established that certain forms of collusion are, in general and in view of the experience gained, so likely to have negative effects on competition that it is not necessary to demonstrate that

they had such effects in the particular case at hand. The fact that the Commission has not, in the past, considered that a certain type of agreement was, by its very object, restrictive of competition is therefore not, in itself, such as to prevent it from doing so in the future following an individual and detailed examination of the measures in question having regard to their content, purpose and context (see, to that effect, judgment in *CB* v *Commission*, cited in paragraph 78 above, EU:C:2014:2204, paragraph 51; the Opinion of Advocate General Wahl in *CB* v *Commission*, C-67/13 P, ECR, EU:C:2014:1958, point 142, and the Opinion of Advocate General Wathelet in *Toshiba Corporation* v *Commission*, C-373/14 P, ECR, EU:C:2015:427, point 74).

439 The applicants are therefore wrong in their submission that the Commission did not sufficiently establish that the agreements at issue could be regarded, by their content and their objectives, viewed in their economic and legal context, as sufficiently harmful to competition (see paragraph 343 above).

440 The first part must therefore be rejected.

2. The second part

441 The applicants maintain that the Commission errs in law when it finds in the contested decision that a value transfer is in itself sufficient to make a patent settlement agreement restrictive by object.

442 They observe that the contested decision states that the 'means used by patent holders to defend their rights matter' (recital 641), which means that the 'means' can in themselves render an agreement anticompetitive by object. However, there is no precedent that would indicate that an extraneous inducement, whether in the form of economic benefits or of physical or psychological pressure, can by itself make anticompetitive an agreement that would otherwise be lawful. Furthermore, if the existence of an extraneous inducement cannot justify what would otherwise be an anticompetitive agreement, it is similarly incapable of making an otherwise lawful agreement anticompetitive. Last, the case-law of the Court of Justice confirms that the anticompetitive object of an agreement must be established independently of any consideration of the parties' financial incentives. The contested decision errs in that it attaches decisive importance to the payment, whereas the payment is neutral under competition law.

443 The Commission disputes those arguments.

444 In so far as, by this part, the applicants call into question the Commission's assessment of the reverse payments in the contested decision, reference must be made, in that respect, to the considerations concerning that issue in the context of the second plea in law (see paragraphs 345 to 416 above).

445 In addition, it must be added that the case-law relied on by the applicants, according to which it does not matter, as far as the existence of the infringement is concerned, whether or not the conclusion of the agreement was in the commercial interests of the parties concluding that agreement (see, to that effect, judgment of 25 January 2007 in *Sumitomo Metal Industries and Nippon Steel* v *Commission*, C-403/04 P and C-405/04 P, ECR, EU:C:2007:52, paragraphs 44 and 45 and the case-law cited), means only that the parties to an agreement cannot maintain that that agreement was the most cost-effective option in order to circumvent the prohibition laid down in Article 101 TFEU (see paragraph 380 above). It does not, however, prevent the Commission from taking account of the content of an agreement, as well as its purpose and the context in which it was concluded — such as, in the present case, the presence of significant reverse payments — in order to establish the existence of a restriction by object.

446 Accordingly, the second part must also be rejected.

3. The third part

447 The applicants submit that the decision is vitiated by an error of law, first, in that it fails to recognise that the agreements at issue were necessary in order to achieve a legitimate objective, namely to protect and enforce a patent, and, secondly, in that it misapplies the case-law on 'other legitimate objectives' in the present case.

448 In the first place, the applicants rely on a consistent line of decisions of the Courts of the European Union in which it has been held that a restriction of the parties' freedom of action does not automatically restrict competition, particularly if that restriction is necessary in order to pursue a primary object which is neutral as regards competition or promotes competition. The protection of the investment made by the holder of an intellectual property right may in the applicants' submission constitute such a legitimate objective.

449 In the present case, the agreements at issue pursued the legitimate objective of protecting and enforcing Lundbeck's process patents and thus safeguarding Lundbeck's investment by preventing the irreparable harm resulting from the launch of generic medicinal products. The agreements also gave the generic undertakings the necessary time to determine whether Lundbeck's patents were infringed, without being obliged to incur the costs or other burdens or suffer the delays inherent in litigation. In addition, the scope and duration of the agreements at issue were proportionate, since the agreements were intended solely to prevent the generic undertakings from marketing citalopram that infringed Lundbeck's patents, and their duration was ultimately linked to the outcome of the Lagap litigation in the United Kingdom, which was intended to address the underlying disputes and to establish whether Lundbeck would still have a reason to enforce its process patents.

450 The Commission disputes those arguments.

451 It must be recalled that, according to the case-law, if a given operation or activity is not covered by the prohibition rule laid down in Article 101(1) TFEU, owing to its neutrality or positive effect in terms of competition, a restriction of the commercial autonomy of one or more of the participants in that operation or activity is not covered by that prohibition rule either if that restriction is objectively necessary to the implementation of that operation or that activity and proportionate to the objectives of one or the other (see judgment of 11 September 2014 in *MasterCard and Others* v *Commission*, C-382/12 P, ECR, EU:C:2014:2201, paragraph 89 and the case-law cited).

452 Where it is not possible to dissociate such a restriction from the main operation or activity without jeopardising its existence and aims, it is necessary to examine the compatibility of that restriction with Article 101 TFEU in conjunction with the compatibility of the main operation or activity to which it is ancillary, even though, taken in isolation, such a restriction may appear on the face of it to be covered by the prohibition rule in Article 101(1) TFEU (judgment in *MasterCard and Others* v *Commission*, cited in paragraph 451 above, EU:C:2014:2201, paragraph 90).

453 Where it is a matter of determining whether an anticompetitive restriction can escape the prohibition laid down in Article 101(1) TFEU because it is ancillary to a main operation that is not anticompetitive in nature, it is necessary to inquire whether that operation would be impossible to carry out in the absence of the restriction in question. The fact that that operation is simply more difficult to implement or even less profitable without the restriction concerned cannot be deemed to give that restriction the 'objective necessity' required in order for it to be classified as ancillary. Such an interpretation would effectively extend that concept to restrictions which are not strictly indispensable to the implementation of the main operation. Such an outcome would undermine the effectiveness of the prohibition laid down in Article 101(1) TFEU (judgment in *MasterCard and Others* v *Commission*, cited in paragraph 451 above, EU:C:2014:2201, paragraph 91).

454 The condition that a restriction be necessary therefore implies a two-fold examination. It is necessary to establish, first, whether the restriction is objectively necessary for the implementation of the main operation and, secondly, whether it is proportionate to it (see judgment in *E.ON Ruhrgas and E.ON* v *Commission*, cited in paragraph 98 above, EU:T:2012:332, paragraph 64 and the case-law cited).

455 Moreover, it must be emphasised that inasmuch as the existence of a rule of reason in EU competition law cannot be upheld, it would be wrong, when classifying ancillary restrictions, to interpret the requirement for objective necessity as implying a need to weigh the pro and anticompetitive effects of an agreement (see, to that effect, judgment in *E.ON Ruhrgas and E.ON* v *Commission*, cited in paragraph 98 above, EU:T:2012:332, paragraph 65 and the case-law cited).

456 In the present case, the applicants submit that the restrictions on the generic undertakings' commercial autonomy were ancillary to the achievement of the main object, which was the protection of their intellectual property rights.

457 That argument cannot be upheld.

458 First, the applicants have not demonstrated that the restrictions set out in the agreements at issue were objectively necessary in order to protect their intellectual property rights, within the meaning of the abovementioned case-law. They could have protected those rights by bringing actions before the competent national courts in the event that their patents were infringed. Furthermore, as the Commission indicated in recital 638 et seq. of the contested decision, there are numerous ways of settling a patent dispute without agreeing to restrictions on the market entry of generic undertakings, by means of reverse payments corresponding approximately to the profits expected by those undertakings if they had entered the market (see paragraphs 334 and 411 above). The applicants have therefore failed to establish that those restrictions were objectively necessary for the achievement of the alleged objective, namely protecting their intellectual property rights.

459 Secondly, it must be recalled that, according to the case-law, an agreement is not exempt from competition law merely because it concerns a patent or is intended to settle a patent dispute, and it may be regarded as having a restrictive object even if it does not have the restriction of competition as its sole aim but also pursues other legitimate objectives (see paragraph 427 above and the case-law cited). The fact that it may have been the most cost-effective or least risky option from a commercial perspective in no way precludes the application of Article 101 TFEU (paragraph 380 above).

460 Thirdly, in any event, even if the restrictions agreed under the agreements at issue could be regarded as objectively necessary for the achievement of the main objective alleged by the applicants, namely protecting their intellectual property rights, they are nevertheless disproportionate to the achievement of that objective. Contrary to the applicants' assertions, the agreements at issue did not resolve any patent dispute, since they provided only that the generic undertakings would stay out of the citalopram market for a certain period, in return for payment, without even providing that at the end of that period they could enter that market without having to face infringement actions from Lundbeck. Moreover, the scope of the restrictions contained in those agreements often went beyond the scope of Lundbeck's patents (see the sixth plea in law below). Lastly, the applicants wrongly assert that the Lagap case in the United Kingdom was a key case enabling it to resolve the disputes with the generic undertakings, since, as the Commission points out in recital 683 et seq. of the contested decision, the GUK United Kingdom, Arrow UK, Arrow Danish, Alpharma and Ranbaxy agreements were all concluded before Lundbeck had brought an infringement action against Lagap in the United Kingdom, on 14 October 2002. As regards the only agreement concluded subsequently, namely the GUK EEA agreement, the litigation with Lagap was not really relevant, since the API at issue in the Lagap trial, based on the Matrix II process, was different from the Natco API, on the basis of which the generic citalopram that Merck (GUK) intended to sell was produced (recital 687 of the contested decision).

461 The applicants' assertion that the restrictions contained in the agreements at issue were objectively necessary and proportional in order to protect their intellectual property rights is therefore wrong.

462 In the second place, the applicants maintain that, in the contested decision, the Commission misapplies the case-law on 'other legitimate objectives' in the present case. The Commission asserts in the contested decision that the fact that an agreement may also have other, entirely legitimate objectives does not preclude the possibility of finding a restriction by object. However, according to the applicants, the cases cited by the Commission in support of that assertion relate to situations where the legitimate objective could have been achieved without restricting competition, whereas in the present case the agreements at issue were necessary in order to ensure compliance with Lundbeck's patents.

463 The intervener supports the applicants' arguments and also maintains that the Commission misapplied the legal test for the application of Article 101(1) TFEU. In its submission, the case-law of the Court of Justice is based on an 'objective necessity' test which is applied in order to determine whether Article 101 TFEU is applicable. The Commission ought therefore to have examined whether a settlement agreement had been concluded in good faith in order to resolve a genuine patent dispute and whether the restrictions agreed were necessary and proportionate to that legitimate objective.

464 It must be stated in that respect that, contrary to the assertions of the applicants and the intervener, the Commission did not commit an error of law in applying the case-law on other legitimate objectives in the present case (see paragraph 427 above and the case-law cited) and in rejecting the applicants' arguments in that respect, in recital 653 of the contested decision, since those arguments were also based on the erroneous premiss that the legitimate objective alleged by the applicants, namely protecting their intellectual property rights, could not have been achieved without restricting competition (see paragraphs 458 to 461 above).

465 Accordingly, the third part must be rejected.

4. The fourth part

466 The applicants maintain that the decision is vitiated by an error of law in that it does not recognise that the counterfactual scenario in the present case precludes the possibility of a finding of a restriction of competition by object.

467 They submit that the contested decision disregards the fact that, even without the agreements at issue, the generic undertakings would not have sold non-infringing citalopram. It has consistently been held that the general criterion for deciding whether an agreement has the object or the effect of restricting competition is how competition would have operated in the market in question in the absence of that agreement. If there is the slightest doubt that competition would have existed in the absence of the agreement that is enough to preclude any infringement of Article 101 TFEU. Furthermore, the removal of uncertainty is inherent in any settlement agreement and the contested decision recognises that settlement agreements which delay market entry may in certain cases not infringe Article 101 TFEU.

468 The realistic prospects referred to in the contested decision of entering one or more markets in the EEA during the period covered by the agreements at issue are unfounded and in any event are mere possibilities, which means at the very least that it was not certain that, in the absence of those agreements, the generic undertakings would have sold non-infringing citalopram. In fact, according to the applicants, the generic undertakings did not have an MA and, on the assumption that they could have launched their infringing generic products, they would have been faced with injunctions sought by the applicants. In addition, those undertakings could have chosen to stay out of the market or to exit the market in order to avoid litigation with Lundbeck. Furthermore, a number of generic

undertakings continued to prepare for their market entry, in particular by continuing their research into non-infringing citalopram, and the agreements at issue did not prevent them from challenging the validity of Lundbeck's patents either.

469 The Commission disputes those arguments.

470 First, inasmuch as, by their arguments, the applicants appear to seek to call into question the conclusion that the generic undertakings were potential competitors of Lundbeck at the time the agreements at issue were concluded, those arguments were already rejected in the context of the first plea in law above and reference must be made to the considerations set out in that respect.

471 Moreover, it must be recalled that Article 101 TFEU is intended to protect potential competition as well as actual competition between undertakings on the market (see paragraph 99 above). It is thus to no avail that the applicants again submit that there is no certainty that the undertakings would have actually entered the market during the term of the agreements at issue, since that argument disregards the distinction between actual competition and potential competition.

472 Secondly, inasmuch as the applicants submit that the Commission should have examined the counter factual scenario in the present case, it must be recalled that, as regards restrictions on 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 are intended to achieve and the economic and legal context of which they formed part, without being required, however, to examine their effects (paragraph 341 above).

473 The examination of a hypothetical counterfactual scenario — besides being impracticable since it requires the Commission to reconstruct the events that would have occurred in the absence of the agreements at issue, whereas the very purpose of those agreements was to delay the market entry of the generic undertakings (see paragraphs 138 and 139 above) — 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. Such an examination of effects is not required in the context of an analysis based on the existence of a restriction of competition by object (paragraph 341 above).

474 Accordingly, even if some generic undertakings would not have entered the market during the term of the agreements at issue, as a result of infringement actions brought by Lundbeck, or because it was impossible to obtain an MA within a sufficiently short period, what matters is that those undertakings had real concrete possibilities of entering the market at the time the agreements at issue were concluded with Lundbeck, with the result that they exerted competitive pressure on the latter. That competitive pressure was eliminated for the term of the agreements at issue, which constitutes, by itself, a restriction of competition by object, for the purpose of Article 101(1) TFEU.

475 Although it is true that settlements are often intended to reduce the uncertainty inherent in litigation, such settlements are not exempt from the application of competition law (see paragraph 427 above). In addition, as the Commission found in the contested decision, settlements are particularly problematic when they are intended to pay potential competitors to stay out of the market for a certain period, without, however, resolving the underlying patent dispute, as in the present case.

476 Accordingly, the Commission rightly considered that the agreements at issue were akin to market exclusion agreements between competitors and that they were liable to have negative effects on competition, without it being necessary, for the purpose of Article 101(1) TFEU, to demonstrate that they had had such effects.

477 Consequently, the fourth part must also be rejected, as, accordingly, must the third plea in law in its entirety.

E – *The fourth plea in law, alleging an error of law and a failure to state reasons in rejecting the scope-of-the-patent test as the key standard in assessing patent settlement agreements under Article 101(1) TFEU*

478 The applicants maintain that the Commission is wrong not to accept that agreements containing restrictions which correspond to those inherent in the exercise of the rights which a patent confers on its holder are not covered by Article 101(1) TFEU and is wrong to suggest that agreements imposing restrictions which go beyond the scope of the patent are likely to be caught by that provision. In their submission, first, the contested decision is vitiated by an error of law in that it rejects the 'scope of the patent' test as the relevant standard for assessing patent settlement agreements under Article 101(1) TFEU and, secondly, the argument used by the Commission in the contested decision in order to reject that test is unclear, illogical and contradicted by the key reasoning underlying the rest of the contested decision.

1. The first part

479 In the first place, the applicants claim 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, irrespective of whether the settlement agreement also involves a value transfer from the originator undertaking to the generic manufacturer.

480 Such a condition is consistent with the principle that patents are presumed valid until expressly declared invalid. In the *Windsurfing* judgment, cited in paragraph 119 above (EU:C:1986:75), the Court of Justice accepted that any clause relating to products covered by a patent was justified on the ground that it protected an intellectual property right. The scope of the patent is therefore relevant for the purposes of determining whether there has been an infringement of Article 101 TFEU.

481 In the second place, the applicants maintain that every settlement agreement must be linked to a 'bona fide' dispute between the parties to the agreement concerning the validity and/or the infringement of a patent. Such agreements are intrinsically lawful and useful and would be subject to antitrust scrutiny only if the underlying dispute were fictitious.

482 As regards settlement agreements concerning patents and generic medicinal products, a dispute must be classified as authentic where, first, it is not established that the patent-holder knew or was firmly persuaded that the patent was invalid and, secondly, the patent-holder had sufficient evidence to claim that the generic medicinal products infringed its patent. If a patent-holder merely had doubts as to the validity of the patent, those doubts, which reflect the uncertainty inherent in the outcome of any dispute, would not be sufficient to affect the genuine nature of the dispute and to render a settlement agreement unlawful. Accordingly, statements such as those repeatedly cited in the contested decision, made more than one and a half years after the conclusion of the agreements at issue, and suggesting that a Lundbeck employee had estimated at 60% the chances of the crystallisation patent being declared invalid by the United Kingdom courts, cannot be taken to indicate that Lundbeck believed that the crystallisation patent was invalid or that it had no chance of having it enforced before a court.

483 In the third place, the applicants argue, therefore, that the 'scope of the patent' test is the only appropriate standard. First of all, that test strikes a reasonable balance between competition law and patent law. Furthermore, it meets the Commission's concerns in relation to patent settlement agreements, since a generic undertaking concluding such an agreement is able, in particular, to enter the market in a way that does not infringe the material, temporal or territorial scope of the patent at issue. Lastly, it is not tainted by the flaws that vitiate the test applied in the contested decision.

484 In the fourth place, according to the applicants, none of the agreements at issue infringes Article 101 TFEU, because they all satisfy the 'scope of the patent' condition, since the contractual restrictions were limited to infringing medicinal products and did not exceed the territorial and temporal scope of Lundbeck's process patents, and also satisfy the 'genuine dispute' condition, since there is no evidence to suggest that Lundbeck considered that its patents were invalid and since, in addition, Lundbeck had scientific evidence that the generic undertakings infringed its process patents.

485 The Commission disputes those arguments.

486 It must be recalled, first of all, that, according to the case-law, Article 101(1) TFEU makes no distinction between agreements whose object is to put an end to litigation and those concluded with other aims in mind (judgment in *Bayer and Maschinenfabrik Hennecke*, cited in paragraph 427 above, EU:C:1988:448, paragraph 15). Although the rights recognized under the industrial property legislation of a Member State are not affected by Article 101 TFEU, the circumstances in which they are exercised may nevertheless fall within the scope of the prohibitions laid down in that article. This may be the case whenever the exercise of such a right appears to be the object, the means or the consequence of an agreement (judgment in *Centrafarm and de Peijper*, cited in paragraph 117 above, EU:C:1974:114, paragraphs 39 and 40).

487 Accordingly, whilst the specific subject matter of the industrial property is, in particular, the guarantee that the patentee, to reward the creative effort of the inventor, has the exclusive right to use an invention with a view to manufacturing industrial products and putting them into circulation for the first time, either directly or by the grant of licences to third parties, as well as the right to oppose infringements (judgment in *Centrafarm and de Peijper*, cited in paragraph 117 above, EU:C:1974:115, paragraph 9), that right cannot be interpreted as also affording protection against actions brought in order to challenge the patent's validity, in view of the fact that it is in the public interest to eliminate any obstacle to economic activity which may arise where a patent was granted in error (judgment in *Windsurfing*, cited in paragraph 119 above, EU:C:1986:75, paragraph 92).

488 It must be noted, in that respect, that, contrary to the applicants' submission, the considerations set out in paragraph 92 of the *Windsurfing* judgment, cited in paragraph 119 above (EU:C:1986:75), do not only apply to clauses which clearly fall outside the scope of the patent. In paragraph 46 of that judgment, the Court of Justice held that, even on the assumption that the German patent covered the complete sailboard, and therefore included the board, which would have meant that the clause in question fell within the scope of the patent, it could not be accepted that that clause was compatible with Article 101 TFEU.

489 In addition, according to the case-law, although the Commission may not refrain from all action when the scope of the patent is relevant for the purposes of determining whether there has been an infringement of Articles 101 TFEU and 102 TFEU, it is not competent to determine the scope of a patent (judgment in *Windsurfing International* v *Commission*, cited in paragraph 119 above, EU:C:1986:75, paragraph 26).

490 In the light of that case-law, and of the inherent objectives of Article 101 TFEU, which require, inter alia, that each economic operator must determine independently the policy which it intends to adopt on the market (see, to that effect, the *BIDS* judgment, cited in paragraph 341 above, EU:C:2008:643, paragraphs 33 and 34) in order to protect consumers from unjustified price increases resulting from collusion between competitors (see paragraph 386 above), the Commission was entitled to refuse to apply the 'scope of the patent' test in the present case in order to evaluate the agreements at issue in the light of Article 101(1) TFEU.

491 As the Commission rightly noted in recital 698 of the contested decision, that test is problematic from a competition law perspective in several respects. First, it leads to a presumption that a generic medicinal product infringes the originator undertaking's patent and thus allows the generic medicinal

product to be excluded on that basis, when the question whether it infringes any patents is an unresolved issue. Secondly, it is based on the premiss that any patent invoked in the context of a settlement agreement will be held valid if its validity is challenged, although there is no basis in law or in practice for that outcome (paragraph 122 above). The 'scope of the patent' test is therefore based on a subjective assessment, by the applicants, of the scope of their patents and of their validity, whereas a national court or competent authority may have taken a different view.

492 Moreover, the Supreme Court of the United States, concluding an intense debate on that issue, adopted the same approach by rejecting the 'scope of the patent' test applied by some lower courts in its *Actavis* judgment, cited in paragraph 353 above, in which it held that the fact that an agreement fell within the scope of a patent did not exempt it from an antitrust action.

493 Whether or not a restriction falls within the scope of a patent is a conclusion that follows from an examination of the scope and validity of that patent and not, as the applicants suggest, the starting point of such an examination (see paragraph 353 above as regards the *Actavis* judgment).

494 Thus, when the applicants argue that the products that the generic undertakings intended to market infringed their patents, or fell within the material, temporal or territorial scope of those patents, those arguments are merely speculations based on their own subjective assessments, since they do not dispute that, at the time the agreements at issue were concluded, no national court or competent authority had established that those products infringed one of their process patents (paragraph 145 above). In addition, as the Commission emphasises, the crystallisation patent had not even been issued when most of the agreements at issue were concluded (paragraph 127 above), with the result that the scope of the applicants' patents was uncertain, as was the scope of the restrictions contained in those agreements.

495 Moreover, 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 patents means only that the applicants could have obtained comparable restrictions through court rulings enforcing their patents, assuming that they succeeded in actions brought before the competent national courts. In that respect, even if the agreements at issue also contained restrictions potentially falling within the scope of the applicants' 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 (see paragraph 487 above and recital 698 of the contested decision).

496 The applicants nevertheless submit that there were real patent disputes between the parties to the agreements at issue in the present case, with the result that they could settle those disputes without infringing Article 101 TFEU.

497 It is doubtful, however, that the agreements at issue really resolved the underlying patent disputes between the applicants and the generic undertakings, since those agreements do not provide for any immediate market entry for the generics upon the expiration of the agreement, accompanied by a commitment from the applicants to refrain from bringing patent infringement proceedings (see paragraph 354 above and recital 662 of the contested decision).

498 In addition, even if the agreements at issue had settled a dispute between the parties, it must be recalled that Article 101(1) TFEU makes no distinction between agreements whose purpose is to put an end to litigation and those concluded with other aims in mind (see, to that effect, judgment in *Bayer and Maschinenfabrik Hennecke*, cited in paragraph 427 above, EU:C:1988:448, paragraph 15). The anticompetitive object of those agreements being sufficiently established — since they amount to agreements excluding potential competitors from the market in exchange for payment — even if they might also have benefited competition and consumers, those effects must be demonstrated by the applicants and examined in the light of Article 101(3) TFEU (see the examination of the seventh plea

in law below), and not evaluated by the Commission in the context of the first paragraph of that article (see, to that effect, judgment of 27 July 2005 in *Brasserie nationale and Others* v *Commission*, cited in paragraph 387 above, EU:T:2005:298, paragraph 85).

499 Accordingly, the applicants are wrong in their assertion that the legal test applied by the Commission was not based on the case-law and that the exercise of intellectual property rights falls within the prohibition laid down in Article 101(1) TFEU only in exceptional circumstances. The Commission did not commit any error of law in rejecting the 'scope of the patent' test as the relevant test for the purpose of examining the agreements at issue in the light of Article 101(1) TFEU. As the Commission points out, the relevant test in the present case was the concept of restriction by object, as developed by the case-law of the European Union courts (paragraphs 338 to 344 above).

500 Consequently, the Commission was entitled, in the present case, to rely on a series of factors as contextual elements — such as the existence of a reverse payment, the size of that payment and the fact that it appeared to correspond to the profits expected by the generic undertakings if they had entered the market, as well as the absence of a clause enabling the generic undertakings to enter the market upon the expiry of the agreements at issue and the presence of restrictions going beyond the scope of the applicants' patents — in order to find that those agreements had the object of restricting competition within the meaning of Article 101 TFEU (see recitals 661 and 662 of the contested decision).

501 The first part of the fourth plea must therefore be rejected.

2. The second part

502 The applicants argue, in the first place, that the reasons for rejecting the 'scope of the patent' test are stated only in recital 698 of the contested decision, which, moreover, is vitiated by illogical reasoning, since, in their submission, that test does not encourage generic undertakings to abandon their efforts to enter the markets, but only their efforts to sell infringing products.

503 In addition, the right to oppose infringements also implies that the patent-holder can oppose infringements by entering into a settlement agreement. Such a right also flows from the specific subject matter of a patent, contrary to what the contested decision suggests. The *Windsurfing* judgment, cited in paragraph 119 above (EU:C:1986:75), cited in the contested decision, can be relied on only to support the assertion that Lundbeck is not entitled to decide on a conflict between the products of two third party manufacturers, which is not the issue in this case. Furthermore, the argument raised by the contested decision, that settlement agreements are permissible only if they are based on the parties' subjective assessment of the strength of the patent, contradicts the assertion that patent-holders should not be able to assess for themselves whether the generic medicinal products infringe their patent. Nor does the contested decision explain how the 'scope of the patent' test, which exists in the law of the United States of America, is not transposable to EU law.

504 The applicants maintain, in the second place, that the Commission's rejection of the 'scope of the patent' test is inconsistent with the key reasoning in the contested decision, in which the Commission focused its assessment of the agreements at issue. The Commission based its finding that the agreements had as their object the restriction of competition on the assertion that they contained restrictions going beyond the scope of Lundbeck's patents, since they were intended to prevent the market entry of any generic citalopram, irrespective of whether it was infringing. Elsewhere, however, the Commission stated that the reverse payments as such indicated that the agreements at issue had the object of committing the generic undertakings to stay out of the generic citalopram market for the duration of the agreements, irrespective of whether or not the medicinal products which those undertakings might have been able to sell were infringing.

505 That shows that the 'scope of the patent' test played a crucial role in the Commission's analysis, which is at odds with its assertion that the question whether the agreements at issue remained within the scope of Lundbeck's patents would not have fundamentally changed the Commission's legal analysis of those restrictions.

506 The Commission disputes those arguments.

507 First, it should be borne in mind that the statement of reasons required by Article 296 TFEU must be appropriate to the measure at issue and must disclose in a clear and unequivocal fashion the reasoning followed by the institution which adopted that measure in such a way as to enable the persons concerned to ascertain the reasons for it and to enable the competent court to exercise its power of review (see judgment of 29 September 2011 in *Elf Aquitaine* v *Commission*, C-521/09 P, ECR, EU:C:2011:620, paragraph 147 and the case-law cited).

508 Thus, it is settled case-law that the purpose of the obligation to state the reasons on which an individual decision is based is, in addition to permitting review by the Courts, to provide the person concerned with sufficient information to know whether the decision may be vitiated by an error enabling its validity to be challenged. It should be borne in mind, however, that the obligation laid down in Article 296 TFEU to state adequate reasons is an essential procedural requirement that must be distinguished from the question whether the reasoning is well founded, which goes to the substantive legality of the measure at issue (judgment in *Elf Aquitaine* v *Commission*, cited in paragraph 507 above, EU:C:2011:620, paragraph 146 and 148 and the case-law cited).

509 In the present case, as regards the statement of reasons, in the contested decision, for the rejection of the 'scope of the patent' test, it must be noted that the Commission expressly responded to the applicants' arguments on that point in recital 698 of the contested decision. In particular, the Commission explained in that recital the reasons why that test did not respond to the concerns posed by the agreements at issue from a competition law perspective (see paragraph 491 above). In addition, it is apparent from the broad logic of the contested decision that the Commission applied the concept of restriction by object, pursuant to Article 101(1) TFEU, to the agreements at issue, taking into account the economic and legal context in which they were concluded, and taking account of a series of factors in that respect (see paragraph 354 above), thereby necessarily ruling out the 'scope of the patent' test as the relevant legal test in order to evaluate those agreements from the perspective of Article 101(1) TFEU.

510 The applicants cannot therefore claim that the Commission did not provide sufficient reasons, in the contested decision, for the rejection of the 'scope of the patent' test, or on whether patent holders are entitled to oppose infringements by settling their disputes, an issue concerning the substance of the contested decision, which has been examined in the context of the second and third pleas above.

511 In addition, the applicants cannot succeed in their assertions that the Commission should have provided reasons for the contested decision by referring to the legal tests applicable in United States law. It has already been held that a legal position adopted by the law of a third country cannot take precedence over that adopted by EU law and that an infringement of that law does not constitute as such a defect resulting in the illegality of a decision adopted under EU law (see, to that effect, judgment of 30 September 2003, *Atlantic Container Line and Others* v *Commission*, T-191/98 and T-212/98 to T-214/98, ECR, EU:T:2003:245, paragraphs 1406 and 1407 and the case-law cited).

512 In any event, it suffices to note that the judgment containing the majority opinion of the Supreme Court of the United States in the case that gave rise to the *Actavis* judgment, cited in paragraph 353 above — and not the dissenting opinion of Chief Justice Roberts — clearly established that the fact that an agreement falls within the scope of a patent does not make that agreement exempt from an

antitrust action, thus rejecting the 'scope of the patent' test as the relevant rule for the purpose of examining the anticompetitive nature of patent settlement agreements containing reverse payments (known as 'pay for delay' settlements) such as the agreements at issue in the present case.

513 It is true that, as the applicants noted at the hearing, the prevailing regulatory context in the United States is different from that in the various EU Member States. The Commission was therefore right not to examine further the applicants' arguments concerning the application of the 'scope of the patent' test, which had been applied by some lower courts in the United States before the *Actavis* judgment, cited in paragraph 353 above, in order to examine the agreements at issue in the light of Article 101 TFEU.

514 Secondly, the applicants wrongly submit that the contested decision is contradictory, since it indicates, on the one hand, that the agreements at issue were anticompetitive, whether or not they contained restrictions going beyond the scope of the applicants' patents and, on the other hand, that those agreements contained restrictions going beyond the applicants' patents, since they were intended to prevent the sale of all types of generic citalopram by the generic undertakings.

515 The Commission explained, in recitals 661 and 662 of the contested decision inter alia, that the fact that Lundbeck could not have obtained the same limitations on the market entry of generics through the enforcement of its patents was an important indication, amongst others, that the agreements at issue were contrary to Article 101(1) TFEU. In other words, the issue whether the restrictions contained in the agreements at issue fell outside the scope of the applicants' patents was considered as a relevant, but not decisive, factor in establishing the existence of a restriction of competition by object for the purpose of that provision, which is also apparent from recital 641 of the contested decision (paragraphs 335, 336 and 354 above). There is therefore no contradiction in the contested decision on that point.

516 The fourth plea must therefore be rejected.

F – *The fifth plea in law, alleging a manifest error of assessment of the facts, breach of the duty of care and failure to state reasons in characterising Lundbeck's actions as an overall strategy against the entry of generics to the market relevant for the assessment of the agreements at issue under Article 101(1) TFEU*

517 According to the applicants, the contested decision is insufficiently reasoned, is vitiated by manifest errors of assessment of the facts and breaches the Commission's duty of care, in that it focused on a few selected statements and disregarded key facts when concluding that the applicants pursued an 'overall strategy' against generic versions of citalopram and relied on that alleged strategy when assessing the agreements at issue under Article 101(1) TFEU.

518 In the first place, the applicants claim that their overall strategy consisted of unilateral actions which were unrelated to the agreements at issue and in any event were not illegal. They maintain that the Commission made a number of serious errors in maintaining in the contested decision that they had pursued several policies forming part of an alleged overall strategy against generic entry to the citalopram market, namely (i) creating a window of opportunity for the launch of escitalopram; (ii) filing process patents for the manufacture of citalopram; (iii) intervening in MA procedures for the generic versions of citalopram; (iv) eliminating the competitive threat of future manufacturers of citalopram API; and (v) inciting generic undertakings to abandon their efforts to enter the citalopram market.

519 In the second place, the applicants submit that the contested decision does not explain how their actions are relevant to a finding of an infringement of Article 101(1) TFEU. They maintain that the parties' intention cannot make what are otherwise lawful agreements incompatible with competition

law. The parties' subjective intention is ancillary to the main issue, namely whether a restriction of competition is apparent from the objective aims pursued by those agreements, in the light of their context. The contested decision wrongly focuses on Lundbeck's unilateral conduct and fails to explain how the generic undertakings shared Lundbeck's alleged intention or whether they were aware of that intention. Consequently, the Commission cannot rely on that conduct to establish the existence of a concurrence of wills between Lundbeck and the generic undertakings with the aim of containing competition from the generic version of citalopram.

520 In the third place, the applicants maintain that the Commission breached its duty of care, which requires that it examine all the relevant aspects of the case carefully and impartially, by failing to take account of all the other facts indicating that their actions were intended to implement legitimate objectives, such as enforcing a valid patent against infringing entry, launching an innovative product for the benefit of consumers, informing the health authorities of potential safety risks or obtaining additional production capacity.

521 In the fourth place, the applicants contend that the contested decision errs in characterising some of their actions as illegal, such as the switching of their commercial efforts to a new, more effective product, Cipralex, the filing of several patent applications covering processes for the manufacture of citalopram, their interventions in MA procedures, or their dealings with API producers. The applicants also maintain that the contested decision is wrong to suggest that, in the course of the Lagap trial, they accepted that the generic products based on the process used by Matrix were not infringing, when the MA based on the Matrix II process, including a 'washing step', was not granted in the United Kingdom until 4 June 2003. Moreover, Lundbeck never accepted that Matrix had employed a process used on a commercial scale that was both commercially viable and non-infringing.

522 The Commission disputes those arguments.

523 It must be recalled, first of all, that the Commission was fully entitled to take into account the applicants' intention at the time the agreements at issue were concluded, since the case-law recognises that the parties' intention may be a relevant factor for the purpose of establishing the existence of a restriction by object within the meaning of Article 101(1) TFEU (paragraph 344 above).

524 Next, inasmuch as the applicants submit that their strategy was not unlawful, in that it consisted, inter alia, in developing a new patented product, escitalopram, in registering process patents for citalopram, or in defending those process patents by intervening in the MA procedures of generic undertakings, it must be found that the contested decision does not establish that such actions were, in themselves, unlawful. The Commission solely took into account the factors, as relevant factual evidence, that allowed the agreements at issue to be placed in their wider context and demonstrated that the applicants sought to delay the market entry of generics in order to find a suitable window for the launch of escitalopram (recitals 123 et seq. of the contested decision), by all possible means, whether lawful or unlawful. Those arguments are therefore largely ineffective.

525 Nevertheless, inasmuch as the applicants' arguments may also be interpreted as challenging the factual assessments carried out by the Commission in the contested decision, by alleging a distortion of the evidence in that respect, the following must be noted.

526 First, as regards the applicants' allegations that their process patents enjoyed a presumption of validity and that no court had found the absence of infringement by the generic undertakings at the time the agreements at issue were infringed, it must be recalled that the Commission never found, in the contested decision, that the applicants' process patents were not valid or that they had no chance of opposing the market entry of generic undertakings if the latter had entered the market 'at risk', but that there was uncertainty in that respect, which was considerably reduced or eliminated by the agreements at issue (paragraphs 336, 363 and 429 above).

527 In addition, Lundbeck's internal estimates concerning the chances of the crystallisation patent being invalidated were used principally by the Commission in the contested decision in order to establish that Lundbeck and the generic undertakings were potential competitors at the time of concluding the agreements at issue (see paragraph 96 above and recital 627 and the contested decision). Regardless of the context in which that statement was made, or the identity of its author, it is apparent from it, as the Commission noted in the contested decision, that there was uncertainty as to whether Lundbeck's patents would have enabled it to block the market entry of all the generic undertakings, and that those generic undertakings had real concrete possibilities to enter the market at the time the agreements at issue were concluded. The applicants also acknowledge that the invalidity proceedings at the national level were characterised by significant unknowns.

528 Secondly, the applicants wrongly submit that the contested decision does not rely on any specific document in order to establish a link between the agreements at issue and the launch of escitalopram. The contested decision is based, inter alia, in that respect, on Lundbeck's strategic plan for 1993 (recital 135), on a document prepared for a Lundbeck A/S board meeting of 24 April 1998 (recital 136), on a Lundbeck document of 24 September 1999 (recital 138), on Lundbeck's Budget and Activity Plan for 1999 (recital 137), 2001 (recital 139), and 2002 (recital 140), and on handwritten notes taken at a Lundbeck strategic meeting at the beginning of 2003 (recital 141). That latter document, for example, shows that Lundbeck was considering fighting the generics in order to create a window of opportunity to switch to escitalopram. In addition, in Lundbeck's Budget and Activity Plan for 2003, Lundbeck had concluded that the market entry of generics, initially expected for the first quarter of 2002, had been very effectively postponed until October 2002, and that it was obvious that the absence of generics had had a positive effect on the development of Cipralex sales (escitalopram) in 2003 (recital 206 of the contested decision).

529 Thirdly, the applicants' allegation of a distortion, in the contested decision, of the details of the Lagap trial in the United Kingdom also cannot succeed. It can be seen from the evidence put forward by the Commission, which, moreover, is not called into question by the applicants, that, although, in the context of that trial, the applicants indeed claimed that the citalopram produced by Matrix infringed the crystallisation patent, this was again their subjective assessment, since that allegation was never confirmed by the court adjudicating on the case, the applicants having preferred to reach a settlement with Lagap in order to avoid a defeat which, in their own words, would have been 'humiliating' and would have been 'used against [them] in other jurisdictions' (recital 160 of the contested decision). The applicants have not established how the Commission distorted the evidence set out in the contested decision in that respect.

530 The applicants nevertheless maintain that the MA relating to the additional 'washing step' (that is to say the Matrix II process) was not granted until 3 December 2003 in the United Kingdom, with the result that the generic citalopram sold before that date in the United Kingdom was based on the Matrix I process, which, according to the applicants, infringed their patents since it was based on falsified data. However, that has never been established; rather, on the contrary, it can be seen from recital 155 of the contested decision that, in an interim ruling of 14 February 2003, the United Kingdom judge ruling on the action against Lagap stated that 'Lundbeck now had to admit ... that their firm and unshakeable confidence that it was impossible for Lagap and its suppliers to be operating a non-infringing process was unfounded', with the result that the applicants cannot allege distortion of the evidence in that respect.

531 Fourthly, as regards the applicants' allegation that the sole purpose of their dealings with the API producers was to find a solution to the capacity problems with which they were faced, it must be pointed out that this explanation is unlikely, in view of the evidence adduced by the Commission in recitals 172 et seq. of the contested decision. In particular, it is difficult to understand why it was essential or even useful for Lundbeck to take over the Italian business VIS Farmaceutici S.p.A ('VIS') and to withdraw its DMF from Tiefenbacher's MA, which was pending before the Netherlands authorities (recital 176 of the contested decision), in order to resolve such capacity problems.

532 Lastly, the applicants' submission that the contested decision found that their infringement actions had failed is incorrect. On the contrary, the contested decision acknowledges that, initially, the applicants were able to obtain injunctions in certain courts or seizure orders in certain States, but that, after numerous generic undertakings switched to the Matrix II process, those injunctions or seizure orders were either lifted or denied, or resulted in settlements. The contested decision merely concludes that at the time the agreements at issue were concluded, no court in the EEA had found that the crystallisation patent was both valid and infringed (recital 185 of the contested decision), which, moreover, the applicants do not dispute (paragraph 145 above).

533 In view of all the foregoing, it is necessary to reject the fifth plea as ineffective or, in any event, unfounded.

G – *The sixth plea in law, alleging a manifest error of assessment of the facts in that the contested decision finds that the agreements at issue contained restrictions going beyond those inherent in the exercise of the rights conferred by Lundbeck's patents*

534 The applicants claim that the contested decision is vitiated by a manifest error of assessment in that it fails to examine all the circumstances of the agreements at issue and incorrectly finds that those agreements contained restrictions going beyond those inherent in the exercise of the rights which their patents confer on them. They maintain that each of the agreements at issue remained within the scope of their patents and prevented only the sale of infringing citalopram.

535 In the first place, the applicants maintain that the contested decision wrongly concludes that the agreements at issue prevented the generic undertakings from selling citalopram, including non-infringing citalopram, and therefore went beyond the rights which the applicants derived from their patents.

536 They claim that, if they had intended to prevent the generic undertakings from selling all citalopram, they would have had to enter into agreements with all potential entrants, when at the time there were more than 300 generic undertakings selling antidepressants in the EEA. Lundbeck had no plausible reason to prevent the sale of non-infringing medicinal products by only four generic undertakings.

537 In the second place, the applicants claim that, for each of the agreements at issue, the contested decision fails to take account of all the relevant circumstances and fails to examine the faithful expression of the parties' intention, which may result both from the clauses of a contract and from the conduct of the undertakings concerned, in finding that those agreements went beyond the scope of the applicants' patents.

538 The Commission disputes those arguments.

539 As a preliminary point, it must be noted that, as the Commission submits, even if the agreements at issue had not gone beyond the scope of the applicants' 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 generic undertakings, in exchange for significant reverse payments (see the second, third and fourth pleas in law above), 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 (paragraph 363 above).

540 The present plea in law is therefore ineffective.

541 It is appropriate, nevertheless, to examine the applicants' arguments in that respect, as a secondary point, inasmuch as the Commission maintains that the applicants do not meet the conditions that they themselves established, since the contractual restrictions contained in the agreements at issue are not limited to potentially infringing products and exceed the scope of the patents in question.

1. The GUK United Kingdom agreement

542 According to the applicants, the contested decision errs when it considers, first, that Merck (GUK)'s obligation not to launch citalopram based on only Natco's API applied irrespective of whether Natco's API was infringing and, secondly, that the exclusive purchase obligation in that agreement prevented Merck (GUK) from selling any other generic version of citalopram.

543 The Commission disputes those arguments.

544 In the first place, the applicants argue that the contested decision was wrong to find that the GUK United Kingdom agreement prevented sales of Natco's citalopram, irrespective of whether it was infringing. They submit that the GUK United Kingdom agreement applied to only one product, namely the Natco citalopram, which Lundbeck had tested and found to infringe its patents.

545 The contested decision incorrectly relies on statements in two Merck (GUK) internal emails for its finding that Lundbeck's patents, in point of fact the crystallisation patent, were neither valid nor infringed, and that none of the published patent applications constituted a problem. Furthermore, the contested decision fails to have regard to other Merck (GUK) documents contemporaneous with the facts which show that Merck (GUK) had serious concerns that Natco's API infringed Lundbeck's patents, or to the fact that during the administrative procedure Merck (GUK) admitted that it was not confident that Natco's process did not infringe Lundbeck's process patents.

546 In addition, the applicants contend that the GUK United Kingdom agreement could not in any event encompass citalopram produced according to different and non-infringing processes, since Natco and Merck (GUK) would have been unable to switch to a new medicinal product during the brief term of that agreement.

547 It must be borne in mind, in that respect, that it is clear from point C of the preamble to the GUK United Kingdom agreement that Merck (GUK) did not accept that its product was infringing, but that it acknowledged that there was a risk of patent litigation, which could give rise to delays and disadvantages.

548 In addition, it must be pointed out, as the Commission noted in recital 768 of the contested decision, that the GUK United Kingdom agreement did not even specify which of the applicants' patents had allegedly been infringed.

549 The applicants are therefore wrong to assert, again, that the generic products of Merck (GUK) were infringing, an assertion based only on their own subjective assessment (paragraph 221 above). The fact that Merck (GUK) may have had doubts as to whether its products were infringing merely confirms the state of uncertainty which the applicants and the generic undertakings were in at the time the agreements at issue were concluded, but in no way establishes that Natco's API was infringing. In addition, the objective evidence on which the Commission relied in the contested decision shows rather that Merck (GUK) was confident about its chances of succeeding in the event of litigation with Lundbeck (paragraph 125 above).

550 Since the applicants' other arguments have already been rejected in the context of the examination of the first plea in law concerning potential competition, reference must be made to the examination of that plea and to paragraphs 207 to 236 above as regards the situation of Merck (GUK) in particular.

551 Accordingly, the applicants' argument that the Commission wrongly concluded that the GUK United Kingdom agreement had limited the sales of Natco citalopram, irrespective of whether it was infringing, must be rejected.

552 In the second place, the applicants argue that the contested decision is wrong to find that the exclusivity clause in Article 3.2 of the United Kingdom agreement prevented Merck (GUK) from entering the market with another generic version of citalopram, whether in the form of a finished product or in the form of an API. In their submission, Article 3.2 merely required Merck (GUK) to purchase blisterpacks containing 28 Cipramil 20 mg tablets exclusively from Lundbeck, and did not restrict GUK's freedom to buy either non-Lundbeck finished medicinal products containing citalopram or citalopram in any other form, for example citalopram API, from any third party.

553 Contrary to the Commission's assertion in the contested decision, such an interpretation is logical, since, in the absence of such a clause, Merck (GUK) would have been able to buy Lundbeck's Cipramil from third parties, such as wholesalers, which would have defeated Lundbeck's objective of increasing the overall sales of that medicinal product in the United Kingdom.

554 In addition, the contested decision acknowledges that, 'based on a literal interpretation of the wording used in these provisions, Merck (GUK) may indeed have not been restrained in Article 3.2 from buying citalopram API from third parties' (recital 781). However, the contested decision wrongly finds that Merck (GUK) was prevented from buying citalopram API from third parties in that it had no incentive to do so. In fact, Merck (GUK) was free to sell non-Lundbeck citalopram in finished product form, with the exception of Natco's infringing citalopram, and, moreover, if by buying citalopram API from third parties Merck (GUK) had breached Article 1.3 of its agreement with Schweizerhall, under which Merck (GUK) undertook to cover all of its annual demand for citalopram with Schweizerhall (recital 783), Lundbeck was not aware of that provision and could not therefore be aware that Merck (GUK) had no incentive to buy API from third parties. In any event, such a lack of incentive was not a consequence of the GUK United Kingdom agreement and it cannot therefore be used to define the scope of that agreement.

555 The Commission disputes those arguments and submits that Article 3.2 of the GUK United Kingdom agreement states that 'GUK agrees to exclusively purchase the Finished Products from [Lundbeck] for resale by GUK and its Affiliates'. That provision means, in its ordinary sense, that Merck (GUK) could acquire finished products only from Lundbeck, to the exclusion of other suppliers. That interpretation is confirmed by recital D in the preamble, which provides that the 'parties have further agreed that GUK shall purchase its requirements of the Finished Products from [Lundbeck]'. The applicants even acknowledged during the administrative procedure that Merck (GUK) had 'agreed to exclusively purchase its requirements of citalopram from Lundbeck for resale in the [United Kingdom]'. Those commitments clearly go beyond the scope of Lundbeck's patents.

556 The Commission rejects the interpretation, proposed by the applicants, that 'finished product' refers only to Lundbeck's Cipramil. In fact, the expression is defined in Article 1.1 of the agreement as 'products containing citalopram in finished pack form to be supplied by [Lundbeck] to GUK pursuant to this Agreement'. The interpretation proposed by the applicants makes the word 'exclusively' redundant, since Merck (GUK) could clearly buy Lundbeck's Cipramil only from Lundbeck. The word 'exclusively' therefore means that Merck (GUK) was to cover all of its requirements of finished product citalopram by buying it from Lundbeck. Furthermore, that provision should be interpreted in the light of the parties' intention, which was to avoid an independent presence of generic undertakings on the market.

557 As regards purchases of citalopram API from third parties, the contested decision acknowledged that a literal interpretation of Article 3.2 of the GUK United Kingdom agreement clearly did not prevent Merck (GUK) from purchasing API from third parties. However, the contested decision concluded that, given the supply contract concluded between Merck (GUK) and Schweizerhall in May 2011, the

terms of which reinforced those of the GUK United Kingdom agreement, Merck (GUK) had no incentive to purchase citalopram API from third parties. Even if Merck (GUK) had purchased non-Natco API in order to produce and sell a finished product itself, it would have been at risk of breaching its obligation under the GUK United Kingdom agreement to purchase 'its requirements' of finished product citalopram exclusively from Lundbeck.

558 In that respect, it must be pointed out that, as the applicants submit, the Commission's interpretation of Article 3.2 of the GUK United Kingdom agreement in the contested decision, according to which Merck (GUK) undertook to purchase citalopram exclusively in the form of finished products from Lundbeck in order to sell them in the United Kingdom, to the exclusion of all other citalopram, cannot be accepted.

559 It is clear from the definition of 'Finished Products' in Article 1.1 of the GUK United Kingdom agreement (paragraph 26 above) that they refer to finished products from Lundbeck, namely Cipramil. By that article, Merck (GUK) therefore only undertook to purchase Cipramil tablets from Lundbeck, with a view to their resale in the United Kingdom, under a distribution agreement. The term 'exclusively' used in that provision does not mean, contrary to the Commission's assertion, that Merck (GUK) undertook to purchase and sell citalopram exclusively in the form of finished products from Lundbeck, excluding any other citalopram, but rather that it undertook to purchase Cipramil, for resale in the United Kingdom, from Lundbeck only, excluding other suppliers. Contrary to the Commission's assertion in recital 779 of the contested decision, that interpretation is not absurd, since the purpose of the term 'exclusively' in Article 3.2 could thus have been to preclude Merck (GUK) from acquiring Cipramil from wholesalers or suppliers other than Lundbeck, in accordance with Lundbeck's objective of increasing the volume of sales of Cipramil.

560 Furthermore, the Commission wrongly relied on point D of the preamble to the GUK United Kingdom agreement, the wording of which is essentially identical to Article 3.2 of the agreement, in order to support its interpretation, since reference is also made in that article to 'Finished Products' — with upper case initial letters — which are clearly defined in Article 1.1 of that agreement.

561 In addition, as the Commission itself acknowledges in recital 781 of the contested decision, a literal interpretation of Article 3.2 of the GUK United Kingdom agreement leads to the conclusion that that provision did not prevent Merck (GUK) from acquiring citalopram in the form of API from third parties.

562 It must be noted that Article 2.2 of the GUK United Kingdom agreement provides only that Merck (GUK) undertakes to deliver to Lundbeck all of its 'Products', which are defined in Article 1.1 of the agreement as 'the citalopram products … 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 [of the agreement]. Attached to Schedule 2.' That schedule actually refers to the Natco API. That means that Merck (GUK) was solely required, under that provision, to deliver its existing citalopram stock, which already existed at the time the agreement was signed, and not any other type of generic citalopram, from producers other than Natco, that Merck (GUK) could have acquired subsequently. The Commission also acknowledges, in recital 763 of the contested decision inter alia, that that obligation concerned only the Natco API.

563 In recital 783 of the contested decision, the Commission nevertheless considered that, if Merck (GUK) had purchased citalopram in the form of API from third parties, it would have breached Article 1.3 of its supply contract with Schweizerhall, which provided that Merck (GUK) would cover 100% of its annual demand for generic citalopram with Schweizerhall (see paragraph 210 above). The Commission therefore took the view, in footnote No 1435 of the contested decision, that, even if it were formally possible for Merck (GUK) to enter the market with generic citalopram acquired from

sources other than Natco under the GUK United Kingdom agreement, it could not do so because of the Schweizerhall agreement. According to the Commission, those two agreements reinforced each other and must therefore be read together.

564 It must be pointed out, however, as the applicants submit, that, even if they had been aware of Merck (GUK)'s obligation to acquire generic citalopram from Natco exclusively, pursuant to a supply contract concluded with Schweizerhall, that obligation does not arise from the provisions of the GUK United Kingdom agreement but from the Schweizerhall agreement.

565 The Commission cannot rely on the provisions of another agreement which does not concern the same parties in order to determine the content of articles of the GUK United Kingdom agreement and, in particular, in order to establish whether or not those articles contain restrictions going beyond the scope of Lundbeck's patents. Such an interpretation would lead to the conclusion that any type of agreement concluded by Merck (GUK) containing restrictions concerning the Natco API, which was nevertheless identified as potentially infringing by the parties to the GUK United Kingdom agreement, went beyond the scope of Lundbeck's patents, due to the exclusive supply obligation under the Schweizerhall agreement, which was concluded previously and between different parties.

566 Accordingly, even though Lundbeck may have been aware of the existence of the Schweizerhall agreement, the Commission cannot rely on that fact in order to conclude that Article 3.2 of the GUK United Kingdom agreement was intended, in itself, to prevent Merck (GUK) from entering the market with any type of citalopram, whether or not it came from Natco, and whether or not it was deemed to be infringing by the parties.

567 It is true that, as the Commission submits, in interpreting the agreements at issue, it is necessary to take into account not only their wording, but also their context and objectives. That method of interpretation cannot, however, lead the Commission to ignore the wording of the provisions of an agreement, where that wording is sufficiently clear.

568 Moreover, it must be noted, in that respect, that the Commission itself stated, in recital 635 and footnote No 1562 of the contested decision, and in reply to a question put to it by the Court, that the Schweizerhall agreement could have been terminated in the event of infringement of Lundbeck's patents (see paragraph 224 above). It is difficult to reconcile that interpretation of the Schweizerhall agreement with the interpretation of the GUK United Kingdom agreement proposed by the Commission in the contested decision, according to which the restrictions went beyond the scope of Lundbeck's patents due to Merck (GUK)'s obligation, under the Schweizerhall agreement, to purchase generic citalopram exclusively from Schweizerhall. The fact that Merck (GUK) may not have intended to purchase citalopram that was not produced by Natco does not mean that the GUK United Kingdom agreement contains such restrictions going beyond the scope of Lundbeck's patents.

569 Accordingly, it must be found that the Commission, which bears the burden of proof in that respect (paragraphs 105 to 112 above), did not establish to the requisite legal standard, in the contested decision, that the restrictions contained in the GUK United Kingdom agreement went beyond the scope of Lundbeck's patents, that is to say that such restrictions could not have been obtained by Lundbeck before a court with jurisdiction to rule on patent-related matters if the generic products based on the Natco API that Merck (GUK) intended to bring to the market had been held to be infringing and if those patents had survived any counter-claims challenging their validity.

570 However, that finding is not capable of affecting the examination of the lawfulness of the contested decision, since the complaint put forward by the applicants is ineffective, for the reasons set out below.

571 First, it must be noted that the applicants do not dispute that, under Article 1.1 of the GUK United Kingdom agreement, Merck (GUK) undertook not to enter the market with its generic products based on the Natco API and that, under Articles 2.2 and 2.3 of the same agreement, Merck (GUK) undertook to deliver the entirety of its stock of citalopram to the applicants (recitals 771 and 772 of the contested decision), nor the fact that they paid GBP 3 million to Merck (GUK) in exchange for that commitment (paragraph 26 above). Similarly, the applicants do not dispute that, under Article 2.7 of the GUK United Kingdom agreement, Merck (GUK) undertook not to grant or license, during the term of that agreement, a copy of the MAs it had already obtained in the United Kingdom.

572 As the Commission submits, such commitments are, in any event, anticompetitive by their very object, whether or not they went beyond the scope of Lundbeck's patents, since, far from resolving any patent dispute between the parties to the GUK United Kingdom agreement, they were obtained in exchange for significant reverse payments and they were intended to prevent Merck (GUK) — and any undertaking that wished to use its MA — from entering the market during the term of the agreement with its generic products, based on the Natco API, on which it had hitherto based its entire strategy for entering the market.

573 As the Commission emphasised in recitals 641 and 820 of the contested decision, what matters, in that respect, is that the GUK United Kingdom agreement transformed the uncertainty regarding the outcome of any infringement actions into the certainty that Merck (GUK) would not enter the market with its generic products during the term of that agreement, whereas the limitations on Merck (GUK)'s commercial autonomy did not arise exclusively from an evaluation, by the parties to the agreement, of Lundbeck's patents, but rather from the size of the reverse payment which, in such a case, overshadowed that evaluation and induced the generic undertaking not to pursue its efforts to enter the market.

574 Secondly, it should be pointed out, for the sake of completeness, that the Commission rightly found, in recital 784 of the contested decision inter alia, that, due to the provisions of the GUK United Kingdom Agreement, taken in context, Merck (GUK) no longer had any incentive to purchase citalopram in the form of API from a third party, or to sell citalopram in the form of finished products other than those of Lundbeck, even though it was in principle free to do so under that agreement.

575 It must be borne in mind, first of all, that Merck (GUK) undertook, under Article 3.2 of the GUK United Kingdom agreement, to sell Lundbeck's Cipramil in the United Kingdom during the term of the agreement and that, under Article 6.2 of that agreement, the payment of GBP 5 million, described as 'net profits', was conditional upon the sale of a certain volume of those medicinal products in the United Kingdom during the term of that agreement. It must also be noted that the sum in question was to be paid in several tranches, which allowed Lundbeck to ensure satisfactory performance of the agreement.

576 Accordingly, even though Merck (GUK) could, in theory, have purchased generic citalopram in the form of API from a third party and sold types of finished products other than those of Lundbeck, it had no incentive to do so, since it was able, without taking any risks, to obtain GBP 5 million as guaranteed profits for the sale of Cipramil under Article 6.2 of the GUK United Kingdom agreement, whereas any attempt to enter the market with other generic products could have exposed it to infringement actions and actions for damages brought by Lundbeck. Furthermore, as the Commission notes in recital 784 of the contested decision, there is no apparent reason why third parties would purchase generic citalopram in the form of API from Merck (GUK), in order to resell it in the United Kingdom in the form of finished products, if they could purchase it directly from the API producer or from its preferred supplier.

577 Accordingly, the applicants' argument that the Commission wrongly concluded that the GUK United Kingdom agreement had limited the sales of citalopram other than that produced on the basis of the Natco IPA must be rejected as ineffective.

2. The GUK EEA agreement

578 As regards the GUK EEA agreement, the applicants maintain that the contested decision was wrong to find that the scope of that agreement included non-infringing citalopram and that it was intended to eliminate Natco as an API supplier.

579 In the first place, the applicants maintain that the contested decision was wrong to find that the GUK EEA agreement applied to any type of citalopram. The contested decision wrongly makes a literal interpretation of Article 1.1 of the GUK EEA agreement, which states that GUK is to 'cease the sale and supply of pharmaceutical products containing Citalopram', when in Danish law, which is the law applicable to that agreement, the interpretation of agreements must be based on the common intention of the parties. In fact the parties' intention, as confirmed by recitals D, F and G in the preamble to the agreement, was that the agreement was to apply only to citalopram based on Natco's API. In addition, that agreement should be interpreted in conjunction with and consistently with the GUK United Kingdom agreement, since according to the Commission those two agreements constitute a single and continuous infringement.

580 Nor does the Commission's interpretation of Article 1.1 of the GUK EEA agreement take account of the fact that Merck dura, a German subsidiary of Merck, continued to sell Tiefenbacher's citalopram in Germany from 15 April 2002 and throughout the period covered by the GUK EEA agreement, and that Lundbeck initiated infringement proceedings against Merck dura rather than enforcing that agreement. Under Article 1.1 of the agreement, under which Merck (GUK) is prohibited from selling or supplying products containing citalopram, Merck dura was an 'affiliate' of Merck (GUK) for the purposes of that provision, which means that the expression 'products containing citalopram' could refer only to Natco's citalopram and not to any type of citalopram.

581 Lastly, the applicants take issue with the Commission's finding at recital 845 of the contested decision that it does not follow logically that, simply because Merck (GUK) had a contract to buy all its requirements from Natco until 2008, its commitment to refrain from selling citalopram during the term of the GUK EEA agreement should also be limited to citalopram from Natco. Such a finding clearly contradicts the reasoning in the contested decision concerning the GUK United Kingdom agreement, according to which Merck (GUK)'s contractual commitment to cover all its supply requirements from Natco shows that Merck (GUK) had no incentive to sell API or finished products obtained from third parties on this basis.

582 In the second place, the applicants maintain that the contested decision was wrong to find that the GUK EEA agreement was intended to eliminate Natco as a supplier of API.

583 The applicants deny that Article 1.1 of the GUK EEA agreement, according to which Merck (GUK) was to 'use all reasonable efforts to ensure that Natco cease[ed] to supply Citalopram and products containing Citalopram in the Territory', was intended to eliminate Natco as a supplier of API. That provision was merely a tool designed to ensure that Merck (GUK) could not circumvent the agreement and sell infringing citalopram based on Natco's API through, for example, a different company. It is based on the fact that Lundbeck believed — wrongly — at least until June 2002 that Merck (GUK) was Natco's exclusive distributor. Furthermore, if the Commission acknowledges, as regards the GUK United Kingdom agreement, that the limitations placed on Natco's API were not outside the scope of Lundbeck's patents, the same conclusion must apply to the contractual limitations in the GUK EEA agreement.

584 The Commission disputes those arguments.

585 It must be pointed out, in that respect, that the wording of the first sentence of Article 1.1 of the GUK EEA agreement provides that Merck (GUK) 'shall cease the sale and supply of pharmaceutical products containing Citalopram in the [EEA] ... (including, without limitation, ceasing to sell and supply NM Pharma AB) during the term of this Agreement', without further details.

586 Points D and E in the preamble to that agreement indeed refer to the fact that Merck (GUK) was the distributor of products containing citalopram manufactured or delivered by Natco, and to the fact that the sale and supply of products containing citalopram in the United Kingdom by Merck (GUK) had been carried out without a licence from Lundbeck.

587 However, that does not confirm the applicants' interpretation that Article 1.1 of the GUK EEA agreement referred solely to the Natco citalopram.

588 If the parties to the GUK EEA agreement wished to refer only to the Natco citalopram, they would have referred expressly to that citalopram in Article 1.1, and in the preamble to that agreement, and not to 'pharmaceutical products containing citalopram' in general, as the Commission rightly points out. They could also have defined the term 'citalopram' so as to specify that that term covered only certain types of citalopram, produced using certain methods, as in the United Kingdom agreement (see paragraph 562 above).

589 In addition, the interpretation proposed by the applicants is implausible, when it is compared with the wording of Article 1.3 of the GUK EEA agreement, pursuant to which Lundbeck undertakes not to initiate legal proceedings against Merck (GUK), provided that the latter observes Article 1.1 of the agreement. If the applicants' interpretation were accepted, that would mean that Lundbeck undertook not to bring any infringement action against Merck (GUK), provided that the latter refrained from selling or supplying Natco citalopram within the EEA, even if it sold another version of citalopram from another producer. That is hard to reconcile with the context in which the agreements at issue were concluded, which demonstrates, inter alia, that Lundbeck had the firm intention to prevent any entry of generics to the market.

590 The applicants nevertheless submit that Merck dura, a German subsidiary of Merck (GUK), was able to enter the citalopram market in Germany, even though it was an affiliate within the meaning of Article 1.1 of the GUK EEA agreement, which implies that the expression 'products containing citalopram' in that article could refer only to Natco citalopram, and not to any type of citalopram.

591 It must be noted, however, as the Commission submits, that Article 1.1 of the GUK EEA agreement applies only to Merck (GUK), as does the rest of the agreement, by virtue of the principle of privity of contract, with the result that the obligation for Merck (GUK) not to sell generic citalopram to its affiliates does not mean that those affiliated companies, such as Merck dura, could not procure generic citalopram from another source and sell it themselves, as Merck dura did in the present case by purchasing generic citalopram from Tiefenbacher. It therefore cannot be inferred from the fact that Merck dura entered the German market during the term of the GUK EEA agreement, nor from the fact that the applicants brought infringement actions against it, that the terms 'products containing Citalopram' in Article 1.1 of that agreement did not refer to any type of citalopram but only to Natco citalopram.

592 Accordingly, by imposing an obligation on Merck (GUK) to refrain from selling or supplying products containing citalopram to those affiliates or to any other third party (including NM Pharma which had begun to sell citalopram in Sweden) during the term of the GUK EEA agreement, Article 1.1 of that agreement contained restrictions going beyond the scope of Lundbeck's patents, since that obligation was not limited to the citalopram deemed potentially infringing by the parties to that agreement.

593 Furthermore, it must be recalled that Article 1.1 of the GUK United Kingdom agreement not only imposed an obligation on Merck (GUK) to refrain from selling or supplying products containing citalopram for the term of the agreement, but also to use all reasonable efforts to ensure that Natco ceased to supply citalopram and products containing citalopram in the EEA during the term of the agreement.

594 Nothing indicates that that obligation was merely an insignificant, or even non-existent, commitment or that it was based on the applicants' erroneous belief that Merck (GUK) was Natco's exclusive distributor. As the Commission submits, that clause was deemed sufficiently important by the parties to the agreement to be a condition for the payment of EUR 12 million. Moreover, Article 1.2 of the GUK EEA agreement expressly provides that Lundbeck is not to be required to make any payment not yet due in the event that Natco supplies Citalopram or products containing citalopram in the EEA during the term of the agreement.

595 Accordingly, even if Merck (GUK) did not have the power to prevent Natco from supplying citalopram in the EEA, as the applicants maintain, it is nevertheless the case that Article 1.1 of the GUK EEA agreement provided a strong incentive for Merck (GUK) to take all the necessary steps and use 'all reasonable efforts' in that respect, or risk losing a substantial part of the payments promised by Lundbeck under that agreement.

596 That shows, as the Commission rightly found in recital 848 of the contested decision, that the objective goal of the GUK EEA agreement was not only to eliminate Merck (GUK) from the EEA markets, as a seller of generic products based on the Natco citalopram, but also to eliminate Natco as a producer of generic citalopram in that territory.

597 It must be held, therefore, that it is sufficiently clear from the content of the GUK EEA agreement, read in context, that Merck (GUK) had, under the clauses of that agreement, abandoned all possibility of selling its generic version of citalopram, whether or not it came from Natco, and whether or not it potentially infringed Lundbeck's patent.

598 Accordingly, the Commission did not err in finding, in recital 846 of the contested decision, that the GUK EEA agreement and, in particular, Article 1.1 of that agreement, had to be interpreted as obliging Merck (GUK) to cease selling and supplying all types of citalopram in the EEA during the term of the agreement, which went beyond the scope of Lundbeck's patents.

599 In any event, whatever the interpretation given to that agreement, and whether or not the restrictions imposed on Merck (GUK) fall within the scope of Lundbeck's patents, those restrictions were nevertheless anticompetitive by object, since it was not established that the citalopram produced by Natco infringed one of those patents, Merck (GUK) had expressly disputed that its generic products were infringing (see point C of the preamble to the UK agreement and point G of the preamble to the GUK EEA agreement) and the restrictions on its commercial autonomy were induced by significant reverse payments, which constituted the consideration for those restrictions (see paragraphs 572 and 573 above).

600 In addition, as the Commission found in recital 847 of the contested decision, the agreements at issue did not provide any consideration for the restrictions in question — such as the possibility for Merck (GUK) to enter the market immediately upon the expiry of the agreements without having to fear infringement actions from Lundbeck — other than the reverse payments promised by Lundbeck, with the result that those agreements were not intended to resolve any patent dispute.

601 Accordingly, the applicants' submission that the GUK EEA agreement did not contain any restriction going beyond the scope of Lundbeck's patents must be rejected as ineffective and, in any event, unfounded.

3. The Arrow UK agreement

602 The applicants maintain that the Commission made a manifest error of assessment in interpreting the Arrow UK agreement as preventing Arrow from selling any form of generic citalopram during the term of that agreement, which applied only to citalopram infringing the applicants' patents. That is shown by the wording of that agreement and by the circumstances surrounding its conclusion, including, in particular, a patent dispute with Arrow and the Lagap litigation.

603 The Commission disputes those arguments.

604 In the first place, the applicants deny that the expression 'the said Citalopram', defined in the fourth recital in the Arrow UK preamble and used in Article 1.1 of the Arrow UK agreement (see the second and sixth indents of paragraph 35 above), refers to any type of citalopram that Arrow could buy from Tiefenbacher. According to the applicants, that expression refers only to citalopram which Arrow had already bought or ordered from Tiefenbacher and which infringed their patents.

605 According to the applicants, their proposed interpretation of that expression is confirmed by the fact, set out in the sixth recital in the Arrow UK preamble (see the third indent of paragraph 35 above) that laboratory tests had been performed on 'the said Citalopram', and their interpretation is not called into question by the reference, in Article 1.1 of the Arrow UK agreement, to a prohibition on importing, in particular, 'the said Citalopram' after the second date of delivery defined in Article 3.4 of the Arrow UK agreement (see the last indent of paragraph 35 above) ('the second delivery date'). That reference applies only to the expression 'other Citalopram', employed in Article 1.1 of the Arrow UK agreement. In any event, even after the second delivery date, Arrow was in possession of citalopram tablets ordered from Tiefenbacher which had not been delivered to the applicants.

606 It must be noted that Article 1.1 of the Arrow UK agreement provides as follows:

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

607 In order to interpret the meaning of the expression 'the said Citalopram' contained in Article 1.1 of the Arrow UK agreement, it must be noted that:

— that expression is a defined term used in the fourth recital of the Arrow UK preamble, which is worded as follows: 'Arrow [UK] has obtained a licence from a third party to import into the [United Kingdom] Citalopram not manufactured by Lundbeck or with the consent of Lundbeck ("the said Citalopram", which definition shall for the avoidance of doubt comprise only Citalopram for marketing and sale in the [United Kingdom] and shall exclude Citalopram for marketing and sale in other countries)';

— it is clear from Article 3.4 of the Arrow UK agreement that the 'Second Delivery date' referred to in Article 1.1 of the Arrow UK agreement is the date on which Arrow was to deliver to Lundbeck the second stage of its stock 'of the said Citalopram' and that that delivery was to take place no later than 15 February 2002.

608 In recitals 905, 910 to 913 and 916 of the contested decision, the Commission considered that the expression 'the said Citalopram' should be interpreted as covering not only the citalopram that Arrow had already purchased from Tiefenbacher but also any citalopram that it could buy from that undertaking subsequently, even if the API used was henceforth produced in accordance with the Cipla II or Matrix II processes. To that end, the Commission relied on the reference, in Article 1.1 of the Arrow UK agreement, to the period after the 'Second Delivery date', set out in Article 3.4 of the Arrow UK agreement, which, according to the Commission, prevents restriction of the concept of 'the said Citalopram' to the stock already held by Arrow and on the wording of the fourth recital in the Arrow UK preamble, from which it is apparent that 'the said Citalopram' is any citalopram produced by Tiefenbacher and covered by its MA.

609 In the light of the abovementioned factors, it must be observed that one of the obligations provided for in Article 1.1 of the Arrow UK agreement consists of prohibiting Arrow from importing or keeping 'the said Citalopram' after the second delivery date referred to in Article 3.4 of that agreement. That obligation only has meaning and effectiveness if that expression also relates to citalopram indeed originating from Tiefenbacher, but ordered by Arrow after that delivery. As regards that point, it must be noted that nothing in the wording of that clause allows the view that the abovementioned obligation does not concern 'the said Citalopram' but only relates to 'any other Citalopram which Lundbeck alleges to infringe its [intellectual property] Rights'.

610 Likewise, the definition of 'the said Citalopram' in the fourth recital in the Arrow UK preamble is worded so that it cannot be interpreted as referring only to the citalopram that Arrow had already purchased from Tiefenbacher. That recital means that any citalopram covered by Tiefenbacher's MA was included in the definition of 'the said Citalopram'. That MA applied to citalopram produced in accordance with the Cipla I and Matrix I processes, irrespective of the fact that the tablets that Arrow had in stock were produced only in accordance with the Cipla I process.

611 While it is true that the applicant for or holder of an MA may make a request to the authority which is to grant or has granted that MA for variations in order to extend its scope to other processes, the applicants are nevertheless justified in claiming that there is nothing in the recital in question which can establish that the parties to the Arrow UK agreement, when they defined 'the said Citalopram', also covered the citalopram API produced in accordance with the Cipla II and Matrix II processes, which were not included in the 'licence' referred to in that recital. Those processes could have been covered by Tiefenbacher's MA only after that MA was varied.

612 Finally, that interpretation is not called into question by the fact, relied on by the Commission, that, in the Arrow consent order (paragraph 36 above), the expression 'the said Citalopram' was replaced by the expression 'Citalopram not manufactured by Lundbeck or with the consent of Lundbeck'. The consent order, although it was adopted following the conclusion of the Arrow UK agreement, is a separate legal instrument from that agreement.

613 Consequently, 'the said Citalopram' must be understood to mean any generic citalopram produced by Tiefenbacher using the processes used by Cipla or Matrix that Arrow had already purchased on the date of signature of the Arrow UK agreement or that it could have purchased subsequently, which was covered by the Tiefenbacher MA.

614 In the second place, according to the applicants, the expression 'any other Citalopram which Lundbeck alleges to infringe its [intellectual property] Rights', used in Article 1.1 of the Arrow UK agreement, does not confer a right of veto on them, as they could not merely rely on the infringing nature of the citalopram that Arrow might seek to use, but would have had to prove that their patents were infringed, by means of the sampling mechanism provided for in that provision, which is consistent with the *Paroxetine* judgment, cited in paragraph 240 above. In that regard, the applicants emphasise

that the Arrow UK agreement did not prevent Arrow from challenging before the competent courts any allegations by the applicants that the citalopram that Arrow might have sought to use infringed their patents.

615 It must be recalled that, inter alia, in recitals 917 and 922 to 924 of the contested decision, the Commission considered that the expression in question allowed Lundbeck to veto the importation or sale by Arrow of citalopram produced using any process, in so far as Lundbeck needed only to declare that it believed that a given process infringed its intellectual property rights. The Commission also noted that the sampling mechanism provided for in Article 1.1 of the Arrow UK agreement had never been used, since Arrow had no interest in challenging Lundbeck's claims concerning the outcome of possible tests, or even in submitting APIs to it for testing as long as Lundbeck made the agreed payments.

616 In that regard, it must be stressed that, as the Commission correctly stated, Arrow, in reply to the Commission's request for information of 18 December 2008, produced by the applicants themselves in annex to the application and which was a subject of discussion at the hearing, acknowledged the following:

'The test established [in Article 1.1 of the Arrow UK agreement] is a subjective test of alleged infringement, not actual infringement. Therefore, citalopram products that have not been found by a court to be non-infringing [of Lundbeck's intellectual property rights] but do not actually infringe [those rights] could have been within the scope [of that article], but that is entirely usual in agreements of this nature'.

617 That statement confirms the Commission's view that Lundbeck had, in essence, a right of veto. Contrary to what the applicants claim, such a right may not be regarded as equivalent to the situation allegedly created by the judgment in *Paroxetine*, cited in paragraph 240 above. In addition to the considerations set out in paragraphs 258 to 263 above, it must be observed that the mechanism provided for in Article 1.1 of the Arrow UK agreement does not involve court intervention, while that is clearly the case in the scenario set out in that judgment, it being noted that is inconceivable that a court would adopt an interim measure on the basis of mere allegations made by the holder of a patent alleged to have been infringed.

618 Moreover, it should be noted that the existence of that right of veto does not render superfluous the part of Article 1.1 of the Arrow UK agreement referring to 'the said Citalopram', given that, with regard to that citalopram, Lundbeck did not even have to exercise its right of veto, since the prohibitions imposed on Arrow concerning that citalopram were applicable without Lundbeck having to do anything other than make the payments provided for.

619 That the test provided for in Article 1.1 of the Arrow UK agreement, by its subjective nature, served to confer a right of veto on Lundbeck, of which Arrow was aware, is corroborated by the fact that that test was not used at any time during the term of that agreement. Although, during the term of that agreement, Arrow continued to seek other sources of API, it never submitted samples to Lundbeck for examination.

620 As regards that point, first, it must be noted that Arrow's searches for that purpose can be explained by its intention to enter markets other than that of the United Kingdom. On the one hand, Arrow was preparing its entry to the Danish market up to the time of the conclusion of the Arrow Danish agreement, which took place several months after the Arrow UK agreement. On the other hand, as the Commission noted in recital 931 of the contested decision, Arrow was also interested in the Swedish market. Secondly, Arrow needed an alternative to Tiefenbacher in order to complete its plan to be able eventually to produce generic citalopram tablets itself, by purchasing the API directly from producers without using an intermediary such as Tiefenbacher which transformed that API into tablets (see footnote No 1935 of the contested decision).

621 Moreover, such research could relate to steps taken in preparation for the period after the expiry of the Arrow UK agreement, which was initially concluded for a term of under one year and which was subsequently extended twice. Those considerations also apply in respect of the fact that, during the term of the Arrow UK agreement, Arrow requested a variation of the MA concerning the Cipla and Matrix APIs so that it would also cover the Cipla II and Matrix II processes.

622 Those findings also make it possible to reject the applicants' argument that the fact that, even after concluding the Arrow UK agreement, Arrow UK continued to seek suppliers capable of supplying it with an API that did not infringe Lundbeck's patents confirms that that agreement related only to citalopram that did infringe those patents.

623 In the third place, the applicants note that, under English law, which governs the Arrow UK agreement, that agreement must be interpreted on the basis, in particular, of its commercial purpose, which was to serve as an alternative to an application for an interim injunction before the national court. Such an injunction could have related only to generic citalopram that infringed Lundbeck's patents.

624 It must be observed, however, that the reference made by the applicants to the principles of English law concerning the interpretation of contracts does not call into question the Commission's interpretation.

625 It is true that a question relating to the interpretation of the national law of a Member State is a question of fact concerning which the Court must, in principle, carry out a comprehensive review (paragraph 258 above).

626 However, Lundbeck's commercial objective, of which Arrow could not have failed to be aware, was to prevent Arrow from entering the market with generic citalopram. That is why Lundbeck paid Arrow amounts linked to the profits it hoped to obtain by entering the market. Under these circumstances, it is not surprising that the parties to the Arrow UK agreement agreed to grant Lundbeck a right of veto, which could also be used against citalopram produced in accordance with the Cipla II and Matrix II processes.

627 In fact, such a payment was hardly compatible with Arrow's retaining the freedom to begin selling citalopram other than 'the said Citalopram', namely that produced in accordance with the Cipla I or Matrix I processes. Had it been otherwise, Arrow could have enjoyed not only payments made by Lundbeck but also the benefits of market entry, for example with generic citalopram produced in accordance with the Cipla II or Matrix II processes, while Lundbeck would have had to bear both the payments and the losses arising from that entry.

628 In the fourth place, the applicants claim that the Commission cannot draw any conclusion, as regards the scope of the Arrow UK agreement, from Article 3 of the second addendum to that agreement, according to which, in the event that the Lagap litigation showed that the crystallisation patent was invalid, they would have to pay Arrow GBP 750 000 to deliver up its remaining stock of tablets. That payment was justified by the fact that the validity of the tablets in question expired in October 2003, so that it would not have been possible for Arrow to sell them on the market. Furthermore, the applicants claim that the Commission's objection is inadmissible, since it was not raised in either the contested decision or the statement of objections.

629 In that regard, it must be observed that that argument is ineffective, since the interpretation of the scope of the Arrow UK agreement adopted in the contested decision is in no way based on Article 3 of the second addendum to that agreement. It was only before the Court that the Commission relied on that article, which it merely referred to in recital 441 of the contested decision, without drawing any inferences from it.

630 It follows from the foregoing that the Commission did not err in interpreting Article 1.1 of the Arrow UK agreement as seeking to prevent Arrow from entering the United Kingdom market during the term of that agreement, not only with generic citalopram which it had already ordered or purchased from Tiefenbacher, but also with any other generic citalopram that it could have obtained subsequently, including generic citalopram produced in accordance with the Cipla II and Matrix II processes.

631 Accordingly, the present complaint must be rejected.

4. The Arrow Danish agreement

632 The applicants claim that the Commission made a manifest error of assessment in interpreting the Arrow Danish agreement as preventing Arrow from selling any form of generic citalopram during the term of that agreement, which applied only to citalopram infringing their patents.

633 First, Article 1.1 of the Arrow Danish agreement (see the second indent of paragraph 39 above), read in the light of the preamble to and the general context of that agreement, refers only to the citalopram that Arrow had already imported and which the applicants had subjected to laboratory tests. It therefore relates to citalopram originating from Tiefenbacher, which infringed their patents.

634 Secondly, the applicants submit that, under Danish law, which governs that agreement, particular importance must be placed on the common intention of the parties, which was to ensure compliance with the applicant's patents. The Commission's over-extensive interpretation is therefore contrary to Danish law.

635 Thirdly, the applicants put forward arguments similar to those referred to with respect to the Arrow UK agreement, particularly concerning the fact that Arrow had continued to seek other sources of API and could have sought a declaration from a national court that there was no infringement of the applicants' patents.

636 Fourthly, the applicants claim that if the Arrow Danish agreement and the Arrow UK agreement constitute a single and continuous infringement, as the contested decision alleges, it is inconceivable that the former should also apply to non-infringing citalopram, when the latter does not.

637 The Commission disputes those arguments.

638 It must be noted that Article 1.1 of the Arrow Danish agreement states as follows:

'Arrow [Group] consents to cancel, cease and desist from any importation, manufacture, production, sale or other marketing of products containing citalopram which Lundbeck alleges to infringe its intellectual property rights in the territory [of Denmark] for the term of [the Danish agreement]'.

639 The applicants maintain that the preamble to the Arrow Danish agreement shows that that point must be interpreted as meaning that it concerns only the citalopram that Arrow had already purchased from Tiefenbacher.

640 It should be noted that it is true that the third and fifth recitals in the preamble to the Arrow Danish agreement, read in the light of the clarifications concerning them in recital 986 of the contested decision, which were not called into question by the applicants, refer to the fact that Arrow was about to purchase an MA which would have allowed it to sell in Denmark generic citalopram produced from the Cipla or Matrix API and which had been subjected to laboratory tests by Lundbeck. The fourth recital in that preamble also refers to Arrow's intention to export bulk citalopram originating from Tiefenbacher from Germany to Denmark.

641 However, those references, while they explain the context in which the Arrow Danish agreement took place, are not sufficient to call into question the clear wording of Article 1.1, whose scope cannot be reduced to that proposed by the applicants.

642 If the parties to that agreement had wished to reduce the scope of the obligations covered by it to the citalopram that Arrow had in stock, they could have chosen wording suitable for that purpose, instead of choosing wording which was very broad, whose scope had to be restricted by an interpretation in the light of the recitals in the preamble, which, moreover, did not express the clear intention to introduce restrictions.

643 As regards, more particularly, the reference by the applicants to the importance of the shared intention of the parties under Danish law, which governs the agreement in question, it must be noted that the applicants have not provided any evidence that that intention differed from the intention that was clearly apparent from the text of the agreement and which was not called into question by the recitals in its preamble.

644 Moreover, the applicants' argument that, since both agreements that they concluded with Arrow constitute a single and continuous infringement, the Arrow Danish agreement should be recognised as having a restricted scope for reasons of consistency with the Arrow UK agreement, cannot succeed either. Indeed, that agreement does not have the restricted scope that the applicants attribute to it, as is clear from the examination carried out in paragraphs 604 to 629 above.

645 Accordingly, it must be concluded that the Commission made no error of assessment in considering that Article 1.1 of the Arrow Danish agreement should be interpreted as meaning that Arrow would not enter the Danish market during the term of that agreement with any generic citalopram.

646 In the light of the foregoing considerations, the fourth part must be rejected.

5. The Alpharma agreement

647 The applicants claim that the Commission made a manifest error of assessment in taking the view that the Alpharma agreement prohibited Alpharma from selling any form of generic citalopram during the term of that agreement, which related only to generic citalopram produced in breach of Lundbeck's patents, including those listed in Appendix A.

648 The Commission disputes those arguments.

649 It must be noted that, inter alia in recitals 1042, 1059 and 1061 of the contested decision, the Commission interpreted Article 1.1 of the Alpharma agreement as meaning that, by that agreement, Alpharma had agreed not to sell any citalopram during the relevant period, or, at least, had accepted restrictions on its ability to sell citalopram which greatly exceeded the restrictions that Lundbeck could have obtained by means of litigation on the basis of its new patents.

650 The applicants maintain, in the first place, that the wording of Article 1.1 of the Alpharma agreement must be interpreted in the light of its context and the available evidence, from which it may be concluded that the word 'Citalopram' contained therein refers only to citalopram infringing their patents. That interpretation follows from a reading of the preamble to the Alpharma agreement and of Appendix A, which show that such was the intention of the parties to that agreement.

651 Article 1.1 of the Alpharma agreement stipulates that Alpharma, and its '[a]ffiliates', 'shall cancel, cease and desist from any importation, … production, … or sale of pharmaceutical products containing Citalopram in the Territory … during [the relevant period]' and that Lundbeck is to withdraw the infringement action against Alpharma. It also states that that article does not apply to 'any product containing escitalopram'.

652 It must be noted that the Alpharma agreement, including in Article 1.1, always uses the term 'Citalopram' with an upper case 'C'. Likewise, that agreement uses words written with an initial upper case letter where it employs defined terms, as is the case with the words 'Territories' in the second recital in the preamble and 'Subsidiaries' in the abovementioned Article 1.1. However, those defined terms are set out explicitly, with a precise definition of their scope where they first appear. It is therefore clear that 'Territories' is a term used to refer to the group formed by the EU Member States, Norway and Switzerland, and the term 'Affiliates' refers to any company which, directly or indirectly, controls or is controlled or is under common control with Alpharma ApS.

653 By contrast, the Alpharma agreement contains no definition of the term 'Citalopram' which would enable a more restrictive meaning to be attributed to that term than that of its international non-proprietary name of citalopram, as an API recognised by the World Health Organisation (WHO), as the Commission notes.

654 Moreover, as the Commission stated correctly in recital 1050 of the contested decision, the fact that Article 1.1 of the Alpharma agreement, provides, at the very end, that it does not apply to escitalopram confirms that, where the parties to that agreement wished to restrict the scope of the obligations arising from that article, they did so explicitly.

655 In that regard, while the absence, highlighted by the applicants, of an upper case 'e' in the word 'escitalopram' reveals inconsistency in the spelling of words used in the Alpharma agreement to refer to APIs, it must be observed, however, that that fact is not sufficient to consider that the parties to that agreement wished to restrict the scope of the word 'Citalopram'.

656 Next, as regards the preamble to the Alpharma agreement, it should be noted that the first recital in that preamble states that 'Lundbeck owns intellectual property rights including, in particular, patent rights relating to the manufacture and production of the active chemical substance Citalopram, including the patents set out in Appendix A hereto'.

657 It follows from the seventh recital in the preamble to the Alpharma agreement that Lundbeck had lodged an action for infringement against Alpharma 'seeking an injunction against sales [by the Alpharma group] of products containing Citalopram for infringing Lundbeck's intellectual property rights'.

658 Finally, according to the eighth recital in the preamble, Alpharma acknowledged that the findings by Lundbeck in relation to the infringement of its patents were correct and that it undertook not to place 'such products' on the market.

659 It must be observed in that regard, as the Commission noted in essence in recital 1047 of the contested decision, that the mere reference, in the first recital in the preamble, to the fact that Lundbeck owned patents relating to 'Citalopram', which are listed in Appendix A, does not allow the conclusion that the parties to the Alpharma agreement intended, even if only implicitly, to include a definition of the word 'Citalopram' which would not coincide with that normally attributable to citalopram without an upper case 'c', namely the citalopram API, irrespective of the process used to produce it.

660 Furthermore, as the Commission observed in recitals 1047 to 1049 of the contested decision, the seventh and eighth recitals of the preamble do indeed recall the context in which the Alpharma agreement took place but are not decisive in terms of their ability to attribute restricted meaning to

the word 'Citalopram'. First, the seventh recital is not worded in terms defining that word, but refers to an application for an injunction prohibiting the sale of products containing 'Citalopram' on account of the infringement of patents belonging to Lundbeck. Secondly, even if, in the eighth recital, the expression 'such products' only covers products containing citalopram synthesised using processes covered by that application for an injunction whose infringing nature Alpharma acknowledged, that fact does not allow the conclusion that, within the entire Alpharma agreement, including Article 1.1 thereof, the word 'Citalopram' only included those products.

661 Accordingly, in the absence of clear restrictions in the meaning of the word 'Citalopram' arising from the preamble, it may not be considered that, by mere references to the background to the conclusion of the Alpharma agreement, the parties to that agreement intended to restrict the scope of the obligations assumed by Alpharma solely to the citalopram acknowledged to have been produced in breach of Lundbeck's new patents.

662 In the second place, the applicants rely on the fact that that agreement was intended to settle a dispute between them and Alpharma specifically relating to Alpharma's infringement of their patents. They also refer to the significance of the Lagap litigation.

663 In that regard, it must be observed, first, that the fact that the Alpharma agreement took place after the launch of the applicants' infringement action against Alpharma, which specifically concerned tablets that that undertaking had already received or ordered, does not mean that the obligations set out in Article 1.1 of that agreement, despite its broad wording, must be interpreted as being restricted to what the applicants could have obtained from that action. Secondly, the Alpharma agreement did not resolve that action, which was simply suspended for the term of the Alpharma agreement, with no guarantee that it would be withdrawn at the end of that period. The Alpharma agreement does not provide that Lundbeck should subsequently refrain from pursuing the Alpharma group for infringement of its patents. Moreover, it is clear from Lundbeck's statement cited in recital 80 of the contested decision that it did not consider that the agreements at issue, including the Alpharma agreement, resolved any disputes. Thirdly, the Lagap litigation, which began in October 2002, as is clear from recital 63 of the contested decision, can have no effect on the scope of the obligations arising from Article 1.1 of the Alpharma agreement.

664 In the third place, the applicants rely on a statement made to the press by the chief executive officer of Alpharma responsible for the relevant file on 28 February 2002 ('the statement of 28 February 2002'), which mentions that the launch of the generic citalopram had been postponed, but that it was not precluded from taking place after the summer holidays, if the problems arising from Lundbeck's new patents were resolved in the meantime. In view of the duration of the Alpharma agreement, the applicants maintain that that statement confirms that Article 1.1 of the Alpharma agreement did not refer to every type of citalopram.

665 It must be observed that, by the statement of 28 February 2002, Alpharma announced, in essence, that it would postpone the launch of sales of citalopram until at least the end of the summer holiday and that it might, if necessary, abandon that planned launch, on the ground that there was a problem with its stock in view of Lundbeck's patents. It added that it had to seek a new API producer and obtain the necessary authorisations.

666 It must be noted in that regard that, as the Commission stated in recital 1055 of the contested decision, that statement, which is dated after the conclusion of the Alpharma agreement, shows Alpharma's change of plans as being the consequence of a unilateral decision on its part, separate from the payments provided for in the Alpharma agreement. Accordingly, in the light of the considerations set out in paragraphs 138 and 139 above, such a press release cannot have significant evidential value, particularly since Alpharma, which had accepted in secret restrictions on its commercial independence arising from the Alpharma agreement against the payments provided for

therein, had to justify, if only to its potential customers, the changes to the plans it had announced previously. It follows that the statement of 28 February 2002 is not a significant contextual element in interpreting the scope of the Alpharma agreement.

667 In any event, it must be observed that, although Alpharma mentioned the possibility of entering the market after the summer, it also referred to the possibility of abandoning the project, a possibility which is in line with the Commission's interpretation of the Alpharma agreement.

668 Under those circumstances, that press release does not allow the conclusion that Article 1.1 of the Alpharma agreement concerned only citalopram produced in accordance with processes acknowledged to be infringing.

669 In the fourth place, the applicants refer to the Alpharma consent order (see paragraph 45 above), the terms of which are relevant for the purpose of interpreting Article 1.1 of the Alpharma agreement, in so far as that order was made in order to put an end to the Alpharma infringement proceedings. In that respect, the applicants maintain that that order states that the scope of the restrictions placed on Alpharma is limited to citalopram infringing their patents. Further, the applicants dispute the argument set out in the contested decision that the Alpharma consent order was drafted in more restrictive terms than those of Article 1.1 of the Alpharma agreement on the ground that it would otherwise have been difficult for a court to uphold it. They observe that it would also be difficult for a court to ensure compliance with that provision, as it was interpreted by the Commission.

670 In that regard, it is indeed true that the Alpharma consent order of 2 May 2002 is worded in the terms referred to by the applicants (paragraph 45 above) which clearly include restrictions on Alpharma's conduct which are less broad than those arising from Article 1.1 of the Alpharma agreement, as interpreted by the Commission in the contested decision.

671 It is also true that there is a connection between that order and the Alpharma agreement. That order was adopted in order to stay the infringement proceedings against Alpharma precisely because the Alpharma agreement had been concluded.

672 Nevertheless, those factors are not sufficient to interpret Article 1.1 of the Alpharma agreement as coinciding with the scope of the Alpharma consent order.

673 As the Commission noted in recital 1054 of the contested decision, the two are separate legal instruments. What matters in order for it to be possible for the Alpharma agreement to have constituted the reason for the Alpharma consent order is that the obligations agreed upon by Alpharma under the Alpharma agreement, should be sufficient that, throughout the term of that agreement, Lundbeck had no further interest in pursuing the infringement proceedings against Alpharma, which were limited to the question whether Alpharma was already infringing Lundbeck's new patents. That condition is fulfilled, even if the scope of the Alpharma agreement exceeds that of that order.

674 Moreover, since it was not necessary to disclose before the national court which adopted the Alpharma consent order the precise scope of the Alpharma agreement, it is entirely reasonable that the parties to that agreement merely restated, in the text of the order submitted to that court, the obligations arising from that agreement which were relevant for the purposes of the infringement proceedings against Alpharma. Furthermore, the lack of a direct correspondence between the Alpharma agreement and that order is confirmed by the fact that that order makes no reference to the fact that that agreement provided for a reverse payment to Alpharma, even though that was a fundamental element with regard to its conclusion.

675 It follows that the Alpharma consent order does not allow Article 1.1 of the Alpharma agreement to be interpreted in the sense suggested by the applicants.

676 In the fifth place, the applicants refer to the email of 12 March 2002 from one of their executives involved in the file ('the email of 12 March 2002'), which asserted that, although there was considerable uncertainty, he did not believe that Alpharma would enter the United Kingdom market in the foreseeable future. The applicants submit that there would have been no uncertainty if Article 1.1 of that agreement had the scope that the Commission attributed to it.

677 It must be noted, in that regard, that that email is a reply to another email containing a price list from Alpharma relating to citalopram and asking the recipient of that email to check the situation with Alpharma. According to the Commission, since, in his reply to that request, the author of the email of 12 March 2002 indicates that it is probably an old price list and specifies that he has not contacted Alpharma on that matter, there is nothing in that email which can call into question the interpretation of the scope of the Alpharma agreement contained in the contested decision.

678 If the scope of the Alpharma agreement was limited to citalopram produced in accordance with the Cipla I process, which Alpharma had already received or ordered, as the applicants claim, they ought to have been concerned about that price list, so that the author of the email of 12 March 2002 would have probably taken steps to determine whether Alpharma had already been able to obtain citalopram produced in accordance with other processes which were not covered by the obligations arising from the Alpharma agreement interpreted in that manner. Therefore, the fact that the author of that email did not follow up on the request he received from his colleague while stating that he did not think that Alpharma would enter the market in the foreseeable future implies that he considered that the Alpharma agreement did not concern only citalopram produced in accordance with the Cipla I process.

679 However, since these are mere hypotheses, it must be noted that the email of 12 March 2002 does not allow firm conclusions to be drawn as to the scope of the Alpharma agreement. In that regard, it must be noted that the Commission did not rely on that email to support its interpretation of the Alpharma agreement, but merely referred to it in the contested decision in order to reject one of the applicants' arguments in support of their interpretation of that agreement.

680 In the light of all the foregoing considerations, it must be held that the Commission has proved to a sufficient legal standard that a literal, contextual and teleological interpretation of the Alpharma agreement allowed the conclusion that the obligations assumed by Alpharma by virtue of Article 1.1 of that agreement were not limited to citalopram produced in accordance with processes which Alpharma and Lundbeck had acknowledged that they were infringing Lundbeck's new patents. Those obligations concerned not only the citalopram that Alpharma already had in stock, produced in accordance with the Cipla I process, but also citalopram that it had ordered or would order from Tiefenbacher, irrespective of the process used by the API producer which supplied Tiefenbacher.

681 That interpretation of Article 1.1 of the Alpharma agreement allows the conclusion that the obligations undertaken in that agreement by Alpharma exceeded those that Lundbeck could have obtained through enforcement of its new patents.

682 Since the applicants have not succeeded in rebutting the evidence by which the Commission proved that the Alpharma agreement included restrictions for that undertaking which went beyond those that they could have obtained by relying on their new patents and obtaining damages in the event of litigation in that regard, the present part must be rejected.

6. The Ranbaxy agreement

683 The applicants claim that the Commission made a manifest error of assessment in concluding that the Ranbaxy agreement prohibited that undertaking from selling not only citalopram produced in accordance with the process already in use, but also citalopram produced in accordance with the processes that it might develop during the term of that agreement.

684 The Commission disputes that interpretation.

685 In the first place, the applicants maintain, in that regard, that Article 1.1 of the Ranbaxy agreement (see the first indent of paragraph 48 above), where it mentions 'any production method used by [Ranbaxy]', does not refer to the methods that Ranbaxy might be able to develop after the conclusion of the Ranbaxy agreement and which could not infringe their patents, a possibility which, moreover, did not exist. The applicants submit that the Commission's interpretation is incompatible with the recitals in the Ranbaxy preamble and with the circumstances in which that agreement was concluded.

686 It must be recalled that the obligations undertaken by Ranbaxy by virtue of the Ranbaxy agreement are those set out in Article 1.1 of that agreement, which provides as follows:

'Subject to the terms and conditions of this Agreement and subject to payment of the Settlement Amount by Lundbeck, [Ranbaxy Laboratories] shall not … claim any rights on the [p]atent [a]pplication [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 …'.

687 It must be observed that the Commission took the view, inter alia in recitals 1131 to 1137 of the contested decision, that the expression 'any production method used by Ranbaxy' covered not only the process already used by Ranbaxy at the time of conclusion of the Ranbaxy agreement, but also those that it might develop subsequently, during the term of that agreement.

688 The applicants dispute that interpretation and claim that that expression covers only processes which Ranbaxy already had when the Ranbaxy agreement was concluded.

689 As regards the wording of that article, it must be noted that the use of the expression 'any ... method' permits, in itself, the view that it did not concern only the methods already used by Ranbaxy when it signed that agreement and that the methods that it might develop subsequently were also covered, as the Commission noted in the contested decision.

690 It is necessary, however, to confirm whether other factors arising from the Ranbaxy agreement itself or from the context in which it was concluded undermine that interpretation.

691 In that regard, first, the applicants submit that the fifth and sixth recitals in the Ranbaxy preamble refer to the patent applications filed by Ranbaxy in India (third recital) which, from their point of view, based on the results of laboratory analyses, related to processes which infringed its amide and iodo patents.

692 However, those are factors which explain the context in which the Ranbaxy agreement took place but do not suffice to call into question the fact that, in the light of its clear wording, Article 1.1 of the Ranbaxy agreement does not contain restrictions concerning the processes covered by the obligations undertaken by Ranbaxy. If the parties to that agreement had intended to restrict the scope of those obligations to the processes corresponding to Ranbaxy's patent applications, they could have chosen suitable wording for that purpose, instead of choosing very broad wording, whose scope has to be restricted by a constructive interpretation in the light of the preamble to that agreement.

693 Secondly, the context in which the Ranbaxy agreement was concluded confirms the interpretation of Article 1.1 of that agreement set out in paragraph 689 above. As the Commission noted in essence, inter alia in recitals 130 to 132, 140, 204 and 206 of the contested decision, Lundbeck wished to delay the entry of generic citalopram on the market, in order to create the best possible conditions for the launch of its new medicinal product Cipralex, which was protected by a patent (see paragraph 22 above).

694 In the light of that objective, it is inconceivable that the applicants agreed to pay Ranbaxy the amounts provided for in the Ranbaxy agreement, if that agreement had allowed it to produce and sell generic citalopram using processes other than those covered by its patent applications filed in India. In reality, it is unlikely that Lundbeck would have concluded a costly agreement if it had not brought certainty that Ranbaxy would keep out of the market with its generic citalopram during the term of that agreement, during which Lundbeck planned to begin to market Cipralex.

695 While it is true that Ranbaxy did not have the same objective as the applicants as regards Cipralex, it nevertheless could not have failed to have been aware of it, in particular, since it had a clear interest in obtaining specific sums rather than taking the risks that its market entry would have entailed.

696 Based on those considerations, the Court can also reject the applicants' argument that, under Swedish law, which governs the Ranbaxy agreement, the Commission should have taken further into account the common intention of the parties to that agreement.

697 It follows from the foregoing that the Commission did not err in concluding, inter alia in recitals 1137 and 1172 of the contested decision, that the obligations undertaken by Ranbaxy under Article 1.1 of the Ranbaxy agreement, read also in the light of their context, were not limited to citalopram produced in accordance with the processes that it was using at the time of signature of that agreement, with the result that those obligations went beyond the scope of Lundbeck's patents.

698 In the second place, the applicants submit that the Commission's interpretation cannot be reconciled with its acceptance of the fact that Ranbaxy remained free to sell citalopram infringing their patents, provided that the API came from a third party.

699 In that regard, as the Commission rightly points out, it is irrelevant that the Commission acknowledged in recital 694 of the contested decision that the Ranbaxy agreement did not prevent that company from selling pharmaceutical products containing citalopram, provided that the API came from a third party. The obligations undertaken by Ranbaxy in accordance with the Commission's interpretation of Article 1.1 of the Ranbaxy agreement, which concern the sale of citalopram produced by that undertaking itself, are not linked to the purely theoretical possibility that Ranbaxy might sell products containing citalopram from other API producers. In that regard, it must be noted that Ranbaxy was essentially an API producer and accordingly had no interest in obtaining the API from elsewhere in order to produce citalopram in the form of finished products.

700 In the third place, the applicants maintain that Article 1.4 of the Ranbaxy agreement (see the last indent of paragraph 48 above) did not prevent Ranbaxy from challenging the validity of their patents. A legal action to have a patent declared invalid is not 'based' on the patent, whereas that article refers to the commitment not to initiate proceedings 'based' on the patents set out in the Ranbaxy agreement. All that Ranbaxy was prevented from doing was initiating proceedings against the applicants for infringement of the patents for which it had applied in India.

701 In that regard, it must be observed, first of all, that those arguments are ineffective because, as is clear from paragraphs 398 and 399 above, the classification of the agreements at issue as restrictions by object does not rely on the presence in the agreement of no-challenge clauses. Moreover, it is clear from recital 1174 that the presence of such a clause in the Ranbaxy agreement was not referred to by the Commission as one of the relevant factors in concluding that there was infringement by object.

702 In any event, it must be noted that the expression 'undertake not to initiate legal proceedings ... based on any of the patents set out above' contained in Article 1.4 of the Ranbaxy agreement is sufficiently flexible to include actions seeking to challenge the validity of the patents in question. Furthermore, it must be noted that Ranbaxy did not contest the validity of those patents during the term of the Ranbaxy agreement.

703 In the fourth place, the applicants claim that the complaint relating to Article 1.4 of the Ranbaxy agreement was raised only in the letter of facts, and not in the statement of objections, which constituted a breach of the applicants' rights of defence.

704 It is sufficient to note, in that regard, that the applicants acknowledge that that clause and the Commission's interpretation thereof in the contested decision appeared in the letter of facts, to which they replied, including in respect of that point. It follows that they had the opportunity to express their views in that regard, with the result that their rights of defence were not infringed (see, to that effect, judgment of 20 March 2002 in *LR AF 1998* v *Commission*, T-23/99, ECR, EU:T:2002:75, paragraph 190 and the case-law cited).

705 The present part must therefore be rejected, as must the sixth plea in law in its entirety.

III – *The seventh plea in law, alleging a manifest error of assessment in that the efficiency gains of the agreements at issue were not properly evaluated*

706 The applicants observe that they claimed, in their reply to the statement of objections, that the agreements at issue favoured competition, since settlement agreements preserve the incentive to innovate and can facilitate earlier market entry. The Commission failed to examine those arguments to the requisite standard. In addition, the Commission's *ex post* explanations in its defence are inadmissible.

707 The Commission disputes those arguments.

708 It must be noted that the Commission examined the possible application of Article 101(3) TFEU to the agreements at issue in recital 1212 et seq. of the contested decision.

709 The Commission therefore rightly observed that Article 101(3) TFEU allowed undertakings to defend themselves against a finding of an infringement of Article 101(1) TFEU by demonstrating that four conditions were met:

— first, the agreement in question must contribute to improving production or distribution or to promoting technical or economic progress;

— secondly, the agreement in question must not impose restrictions which are not indispensable to the attainment of those objectives;

— thirdly, it must give consumers a fair share of the benefits obtained;

— fourthly, it must not allow undertakings to eliminate all competition or a substantial part of that competition in respect of the products in question.

710 Article 2 of Regulation No 1/2003 provides, as does the case-law (see, to that effect, judgment of 6 October 2009 in *GlaxoSmithKline Services and Others* v *Commission*, C-501/06 P, C-513/06 P, C-515/06 P and C-519/06 P, ECR, EU:C:2009:610, paragraph 82), that it is for the party relying on the application of Article 101(3) TFEU to demonstrate, by means of convincing arguments and evidence, that the conditions for obtaining an exemption are satisfied.

711 The burden of proof thus falls on the undertaking requesting an exemption under Article 101(3) TFEU. However, the facts relied on by that undertaking may be such as to oblige the other party to provide an explanation or justification, failing which it is permissible to conclude that the burden of proof has been discharged (see, to that effect, judgment in *GlaxoSmithKline Services* v *Commission*, cited in paragraph 710 above, paragraph 83 and the case-law cited).

712 Contrary to the applicant's claim, the Commission examined to the requisite standard, in the contested decision, the various arguments relied upon by the generic undertakings and by the applicants during the administrative procedure.

713 First, as regards the argument that the agreements at issue encouraged the applicants' incentive to innovate, while it is true that such an argument was not examined specifically by the Commission in the part of the decision relating to the assessment of the applicability of Article 101(3) TFEU, it must be noted, as the Commission states, that, in their reply to the statement of objections, the applicants merely declared in a general manner that settlement agreements in respect of patents preserved the incentive to innovate, relying on an economic study, but without explaining how the agreements at issue contributed to the generation of such an incentive in the present case, beyond the regulatory protection attached to the patents, or how the four conditions for application of Article 101(3) TFEU were satisfied in the present case. The study put forward by the applicants rather called into question the applicability of Article 101(1) TFEU itself, in so far as it disputed that settlement agreements in respect of patents, such as the agreements at issue, could have negative effects on consumers. Accordingly, since that argument had already been rejected by the Commission in the assessment of a restriction by object (recitals 710 to 713 of the contested decision), it was not required to examine it again under Article 101(3) TFEU, in the absence of more substantiated arguments in that regard.

714 In any event, it is clear in the present case that the agreements at issue, which sought to delay the entry of generics on the market by means of reverse payments, were not essential in order to preserve the applicants' incentive to innovate. Furthermore, it is difficult to discern the benefits that consumers would derive from such agreements. Finally, the condition that all competition should not be eliminated is also not satisfied in the present case, given that the generic undertakings were indeed potential competitors when the agreements at issue were concluded and they agreed, against payment, not to enter the market during the term of those agreements.

715 It must therefore be held that the Commission did not err in not carrying out a further examination in the contested decision of the applicants' arguments relating to the incentive to innovate resulting from the agreements at issue, in the light of Article 101(3) TFEU.

716 Secondly, in recitals 1228 to 1230 of the contested decision the Commission was fully entitled to reject the claim that the agreements at issue were capable of ensuring earlier entry of generics on the market, because it was not corroborated by the facts, since the agreements at issue did not provide for any commitment whatsoever on the part of Lundbeck to authorise the entry of generics on the market once those agreements had expired and in fact they prevented their potentially immediate market entry.

717 It is clear from the evidence in the file and, in particular, the content of the agreements at issue, that they contained no precise date on which the generic undertakings could have entered the market before the expiry of Lundbeck's patents. As the Commission noted in recital 662 of the contested decision, the agreements at issue did not contain any commitment on Lundbeck's part to refrain from infringement proceedings in the event that generics entered the market after the expiry of those agreements. The agreements at issue did not therefore genuinely resolve a patent dispute or allow earlier entry of generics on the market, as the applicants claim, but merely allowed Lundbeck to gain time by delaying the entry of generics on the market against payment of significant sums to the generic undertakings.

718 Thirdly, the claim that the agreements at issue made it possible to avoid large litigation costs or differing court rulings is also not corroborated by the facts, since those agreements did not enable the underlying patent dispute between the parties to those agreements to be resolved, given that there was nothing to prevent Lundbeck from bringing legal proceedings against the generic undertakings on their expiry, including before different courts established in different EEA Member States. Accordingly, the figures put forward by the applicant, which report several million euros of legal costs avoided for the whole of the EEA, are irrelevant, in so far as it does not appear that those costs would certainly have been incurred in the absence of the agreements at issue. While it is true that, ultimately, no proceedings were initiated by Lundbeck after the expiry of those agreements, that is principally because such proceedings were of no further interest to Lundbeck, since other generic undertakings, such as Lagap in the United Kingdom, had already entered the market at that time.

719 In any event, even if the agreements at issue made it possible to avoid certain costs associated with potential proceedings before different courts, the applicants have failed to establish how the restrictions on competition arising from those agreements were indispensable for the achievement of that objective, given that the conclusion of other types of settlement agreements, with no anticompetitive aspect, was possible (see paragraphs 350 and 529 above). Furthermore, they have not explained how those agreements allowed consumers a fair share of the benefits allegedly obtained.

720 It must be held therefore that the Commission did not err or fail to observe the rules on the burden of proof in finding that the conditions laid down in Article 101(3) TFEU were not met in the present case.

721 The seventh plea in law must therefore be rejected.

IV – *The eighth plea in law, alleging breach of the rights of the defence*

722 The applicants claim that the contested decision breaches their rights of defence, since the Commission altered the constituent elements of the infringement alleged in the statement of objections without first hearing them. They were not given the opportunity to rebut the Commission's assertions about the generic undertakings being their potential competitors in spite of the possibility or likelihood that their patents were infringed, and about the Commission's view that the reverse payments alone sufficed to establish that the agreements at issue constituted infringements by object. The Commission should also have given the applicants access to its correspondence with the KFST, since it might have contained exculpatory evidence.

A – *The first part*

723 The applicants maintain that the complete reworking of the Commission's theory constitutes a breach of their right to be heard. They submit that, according to the case-law, even though all the factual elements on which the Commission relied in the contested decision were already in the statement of objections, the rights of the defence were not respected since those factual elements had been set out at various points in that statement of objections, without any link being established between them and without being characterised in any particular way by the Commission.

724 In the first place, the applicants claim that the contested decision substantially departed from the position expressed in the statement of objections as regards the question of potential competition, which is a key constituent element of the alleged infringement. Thus, in the contested decision, the Commission (i) substantially changed its position by stating that even the generic undertakings that did not have access to non-infringing citalopram had to be regarded as potential competitors of Lundbeck, (ii) distinguished two stages in which potential competition existed, and (iii) added that

potential competition was also expressed through challenges to the validity of patents, attempts to innovate on the basis of process patents, or proceedings seeking declarations of non-infringement, and even entry 'at risk', which is alleged to be the essence of competition in the pharmaceutical sector.

725 The Commission disputes those arguments.

726 It must be recalled that observance of the rights of the defence is a fundamental right of EU law, enshrined in Article 41(2)(a) of the Charter of Fundamental Rights of the European Union, which requires observance of those rights in all proceedings.

727 Respect for the rights of the defence thus requires that the undertaking concerned must have been afforded the opportunity, during the administrative procedure, to make known its views on the truth and relevance of the facts and circumstances alleged and on the documents used by the Commission to support its claim that there has been an infringement of the Treaty (see, to that effect, judgment in *Aalborg Portland and Others* v *Commission*, cited in paragraph 111 above, EU:C:2004:6, paragraph 66; see also, to that effect, judgment of 13 February 1979 in *Hoffmann-La Roche* v *Commission*, 85/76, ECR, EU:C:1979:36, paragraph 9)

728 In that connection, Article 27(1) of Regulation No 1/2003 provides (i) that the Commission is to give the undertakings or associations of undertakings which are the subject of the proceedings conducted by the Commission the opportunity to be heard on the matters to which the Commission has taken objection and (ii) that the Commission is to base its decisions only on objections on which the parties concerned have been able to comment.

729 That requirement must be interpreted in the light of the case-law to the effect that the statement of objections must set out clearly all the essential facts on which the Commission is relying at that stage of the procedure. However, that may be done summarily and the decision is not necessarily required to be a replica of the Commission's statement of objections, since the statement of objections is a preparatory document containing assessments of fact and of law which are purely provisional in nature (see judgment in *Aalborg Portland and Others* v *Commission*, cited in paragraph 111 above, EU:C:2004:6, paragraph 67 and the case-law cited).

730 In the first place, as regards the argument that the Commission substantially changed its position concerning the question of potential competition in the contested decision compared with the statement of objections, first, it must be held, contrary to what the applicants claim, that it did not consider that only generic undertakings which had access to non-infringing citalopram could be regarded as potential competitors of Lundbeck. It is clear from recitals 468 to 469 of the statement of objections, inter alia, that the Commission considered that the generic undertakings and the originator undertaking could be regarded as potential competitors, independently of whether or not the generic products that those undertakings intended to bring to the market could have infringed a process patent. In addition, it is clear from recitals 519, 550, 586, 612, 645, and 683 of the statement of objections that the Commission relied on a set of factors, including the fact that the generic undertakings had already made significant efforts in order to prepare for their market entry, and in some cases, had already obtained the necessary MAs or assembled a large stock of generic citalopram for that purpose, in order to conclude that there was at least potential competition between them and Lundbeck.

731 Secondly, while the Commission distinguished two stages in relation to potential competition in the pharmaceutical sector in the contested decision (paragraph 91 above), it must be noted that, in the present case, the parties agree that Lundbeck's original patents had expired in almost all EEA countries at the time when the agreements at issue were concluded, with the result that the generic undertakings were all at an advanced stage in their preparations for entering the market. The fact that the Commission considered, in recital 616 of the contested decision that potential competition could have begun years before the expiry of the patent on the API was not decisive or even relevant in

respect of the assessment of the situation relating to potential competition between the applicants and the generic undertakings in the present case. *A fortiori*, therefore, such an assessment could have no effect on the applicants' rights of defence in that regard.

732 Thirdly, it is also clear from the statement of objections that the entry 'at risk' of the generic undertakings was regarded as part of the competitive process between those undertakings and Lundbeck (see in particular recitals 29, 488, 528, 562, 594, 621 and 656 of the statement of objections). While it is true that the contested decision contains further developments in that regard, it must be recalled that that decision is not necessarily required to be a replica of the statement of objections (paragraph 729 above) and that the Commission must be able to take into account replies by the undertakings to the statement of objections, including by supplementing, developing or reformulating the arguments in support of the objections which it maintains (see, to that effect, judgments of 10 May 2007 in *SGL Carbon* v *Commission*, C-328/05 P, ECR, EU:C:2007:277, paragraph 62, and 15 March 2006 in *BASF* v *Commission*, T-15/02, ECR, EU:T:2006:74, paragraph 93 and the case-law cited).

733 Fourthly, the applicants are wrong to claim that the Commission noted, in the contested decision, that the possibility of patent litigation is sufficient to establish the existence of potential competition between them and the generic undertakings. The contested decision, like the statement of objections, is based on a set of factors in that regard, including the fact that the generic undertakings had taken significant steps to prepare for their market entry (paragraphs 96 and 730 above). Furthermore, the statement of objections also refers to the fact that patent disputes were an inherent part of the competitive process in the pharmaceutical sector (see in particular recital 27 of the statement of objections).

734 The applicants are therefore wrong to claim that between the statement of objections and the contested decision the Commission substantially changed its position concerning potential competition.

735 In the second place, the applicants submit that the statement of objections did not set out a clear and coherent legal standard for the review of reverse payments in patent settlement agreements under EU competition law.

736 Likewise, the applicants argue that the statement of objections provided no indication of the threshold above which an amount of money should be classified as 'considerable', the only reference point being that the generic undertakings were 'offered more money than they were likely to be able to make in the market by selling generic citalopram', which, it is claimed, led to 'an incentive to abandon their competitive challenge to Lundbeck' (recital 710 of the statement of objections).

737 The applicants claim that the absence of a clear review standard prevented them from putting their views forward, which is a particularly serious legal flaw, since the present case raises complex and novel legal issues and since no guidance, other than the 'scope of the patent' test, which is rejected by the decision, could be inferred from previous case-law.

738 It must be held in that regard, contrary to the applicants' claims, that recital 480 of the statement of objections expressly states that the existence of reverse payments is decisive for the purposes of the legal assessment of the agreements at issue, in the same words as contained in recital 660 of the contested decision. Furthermore, like the statement of objections, the contested decision is also based on the argument that the existence of reverse payments in the agreements at issue is one of the relevant factors for a finding of restriction by object (see recitals 661 and 662 of the contested decision). Moreover, the statement of objections states, like the contested decision, that the reverse payment amounts were problematic in so far as they took into account the profits or turnover that

the generic undertakings would have made in the event of market entry, which reduced the incentive for the generic undertakings to pursue their efforts for market entry (see, in particular, recitals 469, 496, 543, 588, 638, 687 of the statement of objections and paragraph 366 above).

739 The applicant's second complaint must therefore also be rejected.

740 In the third place, the applicants maintain that the contested decision and the letter of facts contain a number of elements that did not appear in the statement of objections, such as Lundbeck's market shares in the market for antidepressants in the EEA (recital 215 of the contested decision and paragraph 17 of the letter of facts). The method used by the Commission to calculate those market shares and the precise market definition remain obscure and unexplained, nor do they appear in the letter of facts.

741 As regards the applicants' market shares presented by the Commission in the letter of facts of 12 April 2013 in order to support its conclusion that the agreements at issue distorted competition, it must be noted, first, that an agreement that may affect trade between Member States and that has an anticompetitive object constitutes, by its nature and independently of any concrete effect that it may have, an appreciable restriction on competition (judgment of 13 December 2012 in *Expedia*, C-226/11, ECR, EU:C:2012:795, paragraph 37). The Commission was not therefore required to establish in detail, in the statement of objections or in the contested decision, the existence of an appreciable restriction on competition, since it established that the agreements at issue had an anticompetitive object and could affect trade between Member States (see inter alia recitals 196, 197, 209 to 213, 724 and 726 of the contested decision). In any event, the applicants were able to comment following the communication of the letter of facts, with the result that they may not rely on an infringement of their rights of defence in that regard (see paragraph 704 above).

742 The first part must therefore be rejected in its entirety.

B – *The second part*

743 The applicants maintain that the Commission was wrong to refuse them access to its communications with the KFST. While they accept that the Commission Notice on the rules for access to the Commission file in cases pursuant to Articles [101 TFEU] and [102 TFEU], Articles 53, 54 and 57 of the EEA Agreement and Council Regulation (EC) No 139/2004 (OJ 2005 C 325, p. 7) excludes correspondence between the Commission and the national competition authorities from the right of access to the file, it is settled case-law that, if the exceptional circumstances of the case so require, the Commission's internal documents may be communicated to the parties. It is sufficient that the applicants demonstrate that there was even a small chance that the documents not disclosed during the administrative procedure could have been useful for their defence. That is the case here, since the correspondence with the KFST contains potentially exculpatory evidence, which could prove, from a factual aspect and contrary to the Commission's contention, that there was uncertainty in competition law concerning settlement agreements specifying a reverse payment at the time when the applicants concluded the agreements at issue. In any event, the Commission's subsequent disclosure of those documents shows that they contained no confidential information and the Commission ought therefore to have made them accessible immediately. That is a sufficient ground on which to annul the contested decision.

744 The Commission disputes those arguments.

745 According to case-law, if, during the administrative procedure, the Commission has rejected an applicant's request for access to documents which are not in the investigation file, an infringement of the rights of the defence may be found only if it is proved that the outcome of the administrative

procedure might have been different if the applicant had had access to the documents in question during that procedure (see judgment of 16 June 2011 in *Solvay* v *Commission*, T-186/06, ECR, EU:T:2011:276, paragraph 227 and the case-law cited).

746 It must also be recalled that, in any event, an infringement of the rights of the defence is not capable, in itself, of affecting the validity of the contested decision as a whole where the decision is not based solely on the information in question. Instead, in such a case, it is for the Court to disregard the contents of those documents when it examines the validity of the decision (see, to that effect, judgments of 7 June 1983 in *Musique Diffusion française and Others* v *Commission*, 100/80 to 103/80, ECR, EU:C:1983:158, paragraph 30, and 14 May 1998 in *Mo och Domsjö* v *Commission*, T-352/94, ECR, EU:T:1998:103, paragraph 74).

747 In the present case, as regards those two documents reporting the correspondence between the Commission and the KFST, it must be recalled that the Commission produced them voluntarily, in the annexes to its defence, in reply to the applicants' request. The first of these is a report of the KFST of 7 October 2003 on the investigation carried out by that authority on Lundbeck's activities and the agreements concluded by that company on the antidepressant pharmaceuticals market and the second is a memo of the KFST of 10 June 2005 stating, in summary, the conclusions of that authority on the assessment of those agreements in the light of the provisions of the EC Treaty on free competition.

748 It must be held, first, that these are not documents issued directly by the Commission or its departments, but communications from a national competition authority. According to case-law, 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 in *Schenker & Co. and Others*, C-681/11, ECR, EU:C:2013:404, paragraph 42 and the case-law cited). Accordingly, even if they had found that there was no infringement or called into question the theory adopted by the Commission in the contested decision, those documents could not properly be relied on as exculpatory evidence, since, even if they had been sent to the applicants during the administrative procedure, such a communication would have had no effect on the outcome of that procedure.

749 In any event, those documents, far from calling into question the Commission's assessment of the agreements at issue in the contested decision, rather reinforce it, given that, in the KFST's view, in its report of 7 October 2003, the agreements at issue could influence competition, since Lundbeck had paid competitors to stay out of the market, leading indisputably to higher prices. The Commission therefore considered that those agreements constituted very serious infringements of Article 101 TFEU.

750 While it is true that it is also apparent from the memo of the KFST of 10 June 2005 that, in the Commission's view, there was doubt as to whether such agreements were anticompetitive or not, in the light in particular of the size of the payment made by Lundbeck to the generic undertakings, it must be held that that was merely a preliminary assessment by the Commission and that, as a result of that information, the Commission decided to initiate a wider investigation on that type of agreement in the pharmaceutical sector in order to form a more accurate opinion on the operation of that sector and the compatibility of such agreements with Articles 101 TFEU and 102 TFEU. Following that investigation, the Commission opened a procedure on the basis of Article 101(1) TFEU against Lundbeck and the generic undertakings.

751 Furthermore, it is also clear from that memo of the KFST that the Commission attached considerable importance to the fact that a large reverse payment could be an indication that the originator undertaking had paid the generic undertakings to stay out of the market. It is clear from that memo that 'whether the agreement can be justified ... depends, among other things, on the size of the

payment', that, '[i]f the payment only covers the costs that can be expected if the case is taken to court, then the agreement might fall out of the scope of Articles [101 TFEU] and [102 TFEU]' and that '[h]owever, if the payment is more substantial it can be seen as a way of paying your competitors to stay out of the market and thereby an infringement of Article [101 TFEU] or [102 TFEU]'. It is also clear from the contested decision that the fact that the reverse payments contained in the agreements at issue in the present case were substantial and corresponded roughly to the profits expected by the generic undertakings in the event of market entry, and not the cost of potential litigation which had been avoided, was a key factor in concluding that there was an infringement of Article 101(1) TFEU (paragraphs 354, 414 and 415 above).

752 The applicants are therefore wrong to state that those documents could have been useful for their defence if they had been received immediately during the administrative procedure, since they only permit the claim that there was doubt, at the time, as to whether the agreements at issue could be classified immediately, without detailed examination, as restrictions of competition by object within the meaning of Article 101(1) TFEU. The case-law does not, however, require that an agreement be considered to be prima facie or undoubtedly sufficiently harmful to competition, without a detailed examination of its content, purpose, legal and economic context in which it occurs, in order to be regarded as a restriction on competition by object within the meaning of that provision (paragraphs 338 to 344 and 438 above).

753 It must be held, accordingly, that the applicants' rights of defence were not infringed in the present case, in so far as it does not appear that the administrative procedure could have led to a different result in the event that they had had access to the documents in question during that procedure (paragraph 745 above).

754 Accordingly, the second part of the plea and the eighth plea in law must be rejected in their entirety.

V – *The ninth plea in law, alleging, in the alternative that the imposition of fines on Lundbeck is vitiated by a manifest error of law*

755 The applicants claim, first, that there are no earlier cases assessing patent settlement agreements and, secondly, that the judgment of 1 July 2010 in *AstraZeneca* v *Commission* (T-321/05, ECR, EU:T:2010:266) cannot be applied to patent settlement agreements, so that the imposition of fines in relation to them was devoid of any foundation in law and was contrary to the principle of legal certainty.

756 The Commission disputes those arguments.

A – *The first part*

757 The applicants claim, first of all, that on the assumption that the Commission was correct to conclude that the agreements at issue had infringed Article 101 TFEU, there was no valid ground for imposing fines on them in the present case, because of the novelty and complexity of the factual and legal issues raised, which, moreover, the Commission acknowledges. The imposition of fines in such a situation fails to observe the principle of legal certainty and the principle that offences and penalties must have a proper legal basis (*nullum crimen, nulla poena sine lege*). Furthermore, the defence recognises that this is the first Commission decision finding an infringement in relation to 'pay for delay' agreements (agreements intended to delay the market entry of generics in exchange for payment).

758 The existing case-law, in particular the *BIDS* judgment, cited in paragraph 341 above (EU:C:2008:643), provided no guidance to the effect that the reverse payments specified in the agreements at issue would serve as the decisive element for the Commission's finding that the agreements infringed Article 101(1) TFEU. Indeed, the Commission maintained that, if those agreements had not made provision for

reverse payments, they would in principle have been legitimate tools that would allow Lundbeck's patents to be enforced. Moreover, the applicants claim that the *BIDS* judgment, cited in paragraph 341 above (EU:C:2008:643), had not been delivered at the time when the agreements at issue were concluded.

759 In addition, in early 2004, the KFST gave key indications as to the legal uncertainty surrounding reverse payment settlements. In particular, the KFST press release of 28 January 2004 shows that the Commission considered at the time that the amounts of the payments made by Lundbeck were such that it was not possible to show plausibly that they served as compensation in order to keep a competitor out of the market. Furthermore, the fact that the Commission took more than a decade to form a view on the legal characterisation of agreements specifying a reverse payment demonstrates the extreme complexity and the very great novelty of the underlying issues.

760 The Commission disputes those arguments.

761 The principle of legal certainty requires that EU rules enable those concerned to know precisely the extent of the obligations which are imposed on them, and that those persons must be able to ascertain unequivocally what their rights and obligations are and take steps accordingly (see judgment of 29 March 2011 in *ArcelorMittal Luxembourg* v *Commission* and *Commission* v *ArcelorMittal Luxembourg and Others*, C-201/09 P and C-216/09 P, ECR, EU:C:2011:190, paragraph 68 and the case-law cited).

762 However, with regard to whether an offence was committed intentionally or negligently and is therefore liable to be penalised by the imposition of a fine in accordance with the first subparagraph of Article 23(2) of Regulation No 1/2003, it is settled case-law that that condition is satisfied where the undertaking concerned cannot be unaware of the anticompetitive nature of its conduct, whether or not it is aware that it is infringing the competition rules of the Treaty (see judgment in *Schenker & Co. and Others*, cited in paragraph 748 above, EU:C:2013:404, paragraph 37 and the case-law cited).

763 Next, it must be noted that the principle of legal certainty and the principle that penalties must have a proper legal basis, laid down by Article 7 of the European Convention for the Protection of Human Rights and Fundamental Freedoms, signed in Rome on 4 November 1950, and Article 49 of the Charter of Fundamental Rights of the European Union, cannot be interpreted as prohibiting the gradual clarification of the rules of liability but may preclude the retroactive application of a new interpretation of a rule establishing an offence (see, to that effect, judgment of 10 July 2014 in *Telefónica and Telefónica de España* v *Commission*, cited in paragraph 113 above, EU:C:2014:2062, paragraph 148 and the case-law cited).

764 In the present case, contrary to what the applicants claim, it was not unforeseeable that agreements by which the originator company was able to remove potential competitors from the market for a specified period, by means of significant reverse payments, might be contrary to Article 101(1) TFEU, whether or not they went beyond the scope of that company's patents (see paragraphs 487 to 491).

765 As the Commission stated correctly in recitals 1312 and 1313 of the contested decision, a literal reading of Article 101(1) TFEU made it clear that agreements between competitors for the exclusion of some of them from the market were illegal. Market-sharing or exclusion agreements are among the most serious restrictions of competition expressly referred to in Article 101(1) TFEU (paragraph 338 above).

766 The fact that, in the present case, the agreements at issue were concluded in the form of settlement agreements concerning intellectual property rights cannot allow the applicants to infer that their unlawfulness under competition law was completely novel or unforeseeable.

767 The scope of the notion of foreseeability depends to a considerable degree on the content of the text in issue, the field it covers and the number and status of those to whom it is addressed. A law may still satisfy the requirement of foreseeability even if the person concerned has to take appropriate legal advice to assess, to a degree that is reasonable in the circumstances, the consequences which a given action may entail. This is particularly true in relation to persons carrying on a professional activity, who are used to having to proceed with a high degree of caution when pursuing their occupation. Such persons can therefore be expected to take special care in evaluating the risk that such an activity entails (judgment of 28 June 2005 in *Dansk Rørindustri and Others* v *Commission*, C-189/02 P, C-202/02 P, C-205/02 P to C-208/02 P and C-213/02 P, ECR, EU:C:2005:408, paragraph 219 and the case-law cited).

768 None of the arguments put forward by the applicants can call that conclusion into question.

769 First, while it is true that the *BIDS* judgment, cited in paragraph 341 above (EU:C:2008:643), relied on by the Commission in the contested decision, was delivered after the agreements at issue had been concluded, the earlier case-law nevertheless explained that an agreement was not exempt from competition law merely because it concerned a patent or was intended to settle a patent dispute (see, to that effect, judgment in *Bayer and Maschinenfabrik Hennecke*, cited in paragraph 427 above, EU:C:1988:448, paragraph 15) and that substituting the discretion of one of the parties for decisions of the national courts in order to find that a patent had been infringed clearly did not relate to the specific subject matter of the patent and constituted a restriction on free competition (see, to that effect, the *Windsurfing* judgment, cited in paragraph 119 above, EU:C:1986:75, paragraphs 52 and 92).

770 The judgment in *Centrafarm and de Peijper*, cited in paragraph 117 above (EU:C:1974:114, paragraphs 39 and 40) also specified that the conditions under which an intellectual property right may be exercised could fall under the prohibitions laid down in Article 101 TFEU and that that may be the case whenever the exercise of such a right appears to be the object, the means or the consequence of a restrictive agreement.

771 Secondly, as regards the KFST documents, in particular, the press release of 28 January 2004, it must be noted, first of all, that this is not a document originating from the Commission and therefore could not, as such, give rise to legitimate expectations on the part of the applicants. Moreover, it must be noted that national competition authorities 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(1) TFEU (paragraph 748 above).

772 Furthermore, it is clear from the KFST press release that agreements whose object is to acquire market exclusion of a competitor are anticompetitive. Following its detailed investigation of the pharmaceutical sector, the Commission was able to refine its approach and fully comprehend the anticompetitive nature of certain agreements, in particular where those agreements involved a significant reverse payment, as in the present case (paragraphs 349 to 403 above).

773 Thirdly, in so far as the applicants rely on the earlier practice of the Commission in order to claim that the infringement found in the present case was new and required only a symbolic fine, it must be observed that, according to case-law, the Commission has a margin of discretion when setting the amount of fines in order that it may direct the conduct of undertakings towards compliance with the competition rules. The fact that in the past the Commission has applied fines of a particular level for certain types of infringements does not mean that it is precluded from increasing that level within the limits indicated in Regulation No 1/2003, if that is necessary to ensure implementation of European Union competition policy. The proper application of the European Union competition rules in fact requires that the Commission may at any time adjust the level of fines to the needs of that policy (see judgment of 25 October 2011 in *Aragonesas Industrias y Energía* v *Commission*, T-348/08, ECR, EU:T:2011:621, paragraph 293 and the case-law cited).

774 Furthermore, the fact that in the past the Commission did not take the view that a certain kind of agreement was, by its very object, restrictive of competition cannot, in itself, prevent it from doing so in the future following an individual, detailed examination of the measures at issue in the light of their content, purpose and context. There is therefore no requirement for the same type of agreement to have been found unlawful by the Commission in order for them to be considered restrictive of competition by object (paragraph 438 above).

775 Nor does the case-law require that an agreement be considered to be prima facie or undoubtedly sufficiently harmful to competition, without a detailed examination of its content, purpose, legal and economic context, in order to be regarded as a restriction on competition by object within the meaning of that provision (paragraph 752 above).

776 Finally, it is apparent from the contested decision that certain generic undertakings were aware of the infringing nature of agreements similar to the agreements at issue and refused to enter into such agreements precisely for that reason (see recital 190 of the contested decision). Similarly, an employee of Lundbeck reacted to certain email exchanges establishing the price and volume of citalopram purchased by Merck (GUK) from Lundbeck under the agreements at issue, stating that he 'strongly disagree[d] with the content of this email' and that '[they could not] and [would] not agree selling prices', since 'this [was] illegal' (recital 265 of the contested decision). As regards the Ranbaxy agreement, Lundbeck also stated, during the negotiations concerning that agreement, that it would be costly and difficult, in particular from a competition law perspective (see recital 188 of the contested decision).

777 Those factors show that, far from being unforeseeable at the time, the restrictions on competition set out by the agreements at issue could reasonably have been perceived by the parties to those agreements as being contrary to Article 101(1) TFEU.

778 Consequently, the applicants are wrong to claim that the Commission infringed the principles of legal certainty and the principle that penalties must have a proper legal basis in the present case.

779 The first part must therefore be rejected.

B – *The second part*

780 According to the applicants, it follows from the judgment in *AstraZeneca* v *Commission*, cited in paragraph 755 above (EU:T:2010:266) that imposing fines is not justified, on account of the novelty of a case, where (i) no previous case-law covered the conduct under consideration and (ii) that conduct is not highly anticompetitive, so that the undertaking concerned could not expect it to be illegal. In the applicants' submission, recital 1300 of the contested decision acknowledges that the first condition is met in the present case, while, as regards the second condition, the agreements at issue are not abusive practices, such as those at issue in the case that gave rise to the judgment in *AstraZeneca* v *Commission*, cited in paragraph 755 above (EU:T:2010:266). In addition, no special responsibility is borne by undertakings which, like Lundbeck, are not in a dominant position. The Commission cannot therefore recycle in an investigation pursuant to Article 101(1) TFEU standards set in a case relating to an abuse of a dominant position.

781 The Commission disputes those arguments.

782 It must be noted, in that regard, as the Commission pointed out in recital 1300 of the contested decision that, in its judgment of 6 December 2012 in *AstraZeneca* v *Commission*, cited in paragraph 162 above (EU:C:2012:770), the Court of Justice held, in reply to the applicant's similar argument in that case, that 'even though the Commission and the Courts of the European Union had not yet had the opportunity to rule specifically on conduct such as that which characterised those

abuses, [AstraZeneca] was aware of the highly anticompetitive nature of its conduct and should have expected it to be incompatible with competition rules under EU law'. The applicants are therefore wrong to infer from that judgment that the Commission cannot impose a fine in the absence of similar precedents issued by the Courts of the European Union (paragraphs 438 and 774 above).

783 Furthermore, just as in the case that gave rise to the judgment in *AstraZeneca*, cited in paragraph 755 above (EU:T:2010:266), the applicants' conduct in the present case was clearly not part of normal competition, since they aimed to exclude potential competitors from the market by means of significant reverse payments. The fact that some patent settlement agreements, moreover, may be legitimate and not infringe the provisions of the Treaty on free competition does not alter the fact that, in the present case, the agreements at issue concluded by the applicants were anticompetitive, for the reasons set out by the Commission in the contested decision (see paragraph 354 above and recitals 661 and 662 of the contested decision).

784 Finally, while it is true that undertakings in a dominant position have a special responsibility under Article 102 TFEU not to adopt certain types of unilateral conduct that restrict competition, such as those at issue in the judgment in *AstraZeneca*, cited in paragraph 755 above (EU:T:2010:266), it is nevertheless the case that all undertakings, whether in a dominant position or not, are equally subject to Article 101 TFEU where the conditions for application of that article are met and may have fines imposed on them in that regard. It is that provision, and not Article 102 TFEU, that the Commission applied in the present case.

785 The second part must therefore be rejected, as must the ninth plea in law in its entirety.

VI – *The tenth plea in law, alleging, further in the alternative, manifest errors of law and of fact in calculating the fines*

786 The applicants maintain that when setting the fine in the contested decision, the Commission ought in any event, first, to have used a lower rate of gravity; secondly, to have taken account of the fact that the alleged infringements lasted a short time; thirdly, not to have imposed an additional amount; and, fourthly, to have applied mitigating circumstances.

787 The Commission disputes those arguments.

788 It should be recalled, as a preliminary point, that, as regards the applicants, the Commission followed the general methodology described in the 2006 Guidelines, based on the value of sales of the relevant product to which the infringement directly or indirectly relates, in the relevant geographic area within the EEA (points 13 and 19 of those Guidelines). The figure adopted was 10% or 11%, depending on the geographic scope of the agreements at issue (see paragraphs 68 to 75 above and recitals 1316 to 1358 of the contested decision).

789 It must also be recalled that, according to settled case-law, in order to determine the amount of the fines that are to be imposed for infringement of the competition rules, it is necessary to take account of the duration of the infringements and all the factors capable of affecting the assessment of their gravity, such as the conduct of each of the undertakings, the role played by each of them in the establishment of the concerted practices, the profit which they were able to derive from those practices, their size, the value of the goods concerned and the threat that infringements of that type pose (see judgment of 8 December 2011 in *KME Germany and Others* v *Commission*, C-272/09 P, ECR, EU:C:2011:810, paragraph 96 and the case-law cited).

790 The Court of Justice has also stated that objective factors such as the content and duration of the anticompetitive conduct, the number of incidents and their intensity, the extent of the market affected and the damage to the economic public order must be taken into account (see judgment in *KME Germany and Others* v *Commission*, cited in paragraph 789 above, EU:C:2011:810, paragraph 97 and the case-law cited).

791 In that regard, it should be noted that the obligation to state reasons is of particular importance. The Commission must state the reasons for its decision and, in particular, explain the weighting and assessment of the factors taken into account. The Court must establish of its own motion that there is a statement of reasons (see, to that effect, judgment in *KME Germany and Others* v *Commission*, cited in paragraph 789 above, EU:C:2011:810, paragraph 101 and the case-law cited).

792 Furthermore, the Court must carry out the review of legality incumbent upon it on the basis of the evidence adduced by the applicant in support of the pleas in law put forward. In carrying out such a review, the Court cannot rely on the Commission's margin of discretion — either as regards the choice of factors taken into account in the application of the criteria mentioned in the Guidelines or as regards the assessment of those factors — as a basis for dispensing with an in-depth review of the law and of the facts (judgment in *KME Germany and Others* v *Commission*, cited in paragraph 789 above, EU:C:2011:810, paragraph 102).

793 The review of legality is supplemented by the unlimited jurisdiction which the Court enjoys under Article 31 of Regulation No 1/2003, in accordance with Article 261 TFEU. That jurisdiction empowers the Court, in addition to carrying out a mere review of the lawfulness of the penalty, to substitute its own appraisal for the Commission's and, consequently, to cancel, reduce or increase the fine or penalty payment imposed (see, to that effect, judgment in *KME Germany and Others* v *Commission*, cited in paragraph 789 above, EU:C:2011:810, paragraph 103 and the case-law cited).

794 It must, however, be pointed out that the exercise of unlimited jurisdiction is not a review that is conducted by the Court of its own motion, and that proceedings before the Court are *inter partes*. With the exception of pleas involving matters of public policy which the Court is required to raise of its own motion, such as the failure to state reasons for a contested decision, it is for the applicant to raise pleas in law against that decision and to adduce evidence in support of those pleas (judgment in *KME Germany and Others* v *Commission*, cited in paragraph 789 above, EU:C:2011:810, paragraph 104).

795 The applicants' arguments must be assessed in the light of those considerations.

A – *The first part*

796 The applicants claim that the rates of gravity, fixed at 11% of the value of sales for the agreements with Merck (GUK), Alpharma and Ranbaxy, and 10% for the agreements with Arrow, are too high. They maintain, in the first place, that the contested decision fails to take account of the limited scope of the restrictions in the agreements at issue, which are, at least in part, within the scope of Lundbeck's patents. Lundbeck's market share was below 19% in most EEA countries and the geographic scope of the agreements ought to have been limited to the EEA countries in which the generic undertakings had realistic prospects of entering the market.

797 In the second place, the decision fails to take account of the fact that the agreements at issue were not secret and that they contained standard clauses for that type of agreement, which justifies a lower rate of gravity, in accordance with the Commission's practice when adopting decisions. In the third place, the agreements at issue are not collusive in nature, as, moreover, the contested decision recognises. In the past, the Commission has either not imposed a fine, or imposed a very low fine, or set the rate of gravity at the lowest end of the scale for this type of non-collusive agreement. The decision therefore

errs where it finds that the agreements at issue constitute serious infringements of Article 101 TFEU. The principle of proportionality requires, on the contrary, that the rate of gravity in the present case be set at the lowest level of the scale.

798 The Commission disputes those arguments.

799 In that regard, it must be noted that, by virtue of point 21 of the 2006 Guidelines, the proportion of the value of sales will be set at a level of up to 30%. Point 22 of those guidelines specifies that in order to determine 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.

800 First, it must be noted that the Commission correctly classified the infringements in the present case as 'serious', in so far as they concerned restrictions of competition by object, whose harmful effect on competition was sufficiently established, consisting of paying competitors to stay out of the market for a specified period (recital 1331 of the contested decision).

801 The fact that certain restrictions contained in the agreements at issue may have fallen within the scope of Lundbeck's patents (as defined in paragraphs 335 and 569 above) is not such as to call into question that finding since it was only one factor among a number taken into account by the Commission in order to establish the existence of a restriction by object in the present case (paragraph 354 above). It is therefore irrelevant that they also contained restrictions falling within the scope of those patents, since, as the Commission correctly noted in the contested decision, the decisive factor is that, at the time when the agreements at issue were concluded, there was uncertainty as to whether or not the products that the generic undertakings intended to sell infringed any of Lundbeck's patents, that their validity could have been called into question before a court, and that it was by means of a significant reverse payment that the applicants had acquired the certainty that the generic undertakings would not enter the market during the term of the agreements at issue (paragraphs 363 and 429 above). In any case, the Commission was right to consider that the agreements at issue contained, in the great majority of cases, restrictions going beyond the scope of Lundbeck's patents (see sixth plea in law above).

802 Secondly, the Commission did not err in taking the view that Lundbeck held a very large share of the market of the product concerned by the infringements in question in the geographical markets affected by the agreements at issue. Indeed, it is apparent, at least implicitly, from the contested decision that Lundbeck had a monopoly in respect of citalopram at the time of concluding the agreements at issue, since its original patents concerning the citalopram API had just expired and no undertaking selling generics had yet entered the market. Furthermore, even if the relevant market had been larger and had included all antidepressant medicinal products, the Commission noted, in recital 215 of the contested decision, that Lundbeck held a significant share of that market in most EEA countries.

803 Thirdly, the Commission was right to consider that the infringements in question had a wide geographic scope, since, with the exception of the infringement with Arrow, they all covered the whole of the EEA.

804 Contrary to the applicants' claim in that regard, the Commission was not required to reduce the basic amount of the fine in order to take into account only the value of sales in the countries where the generic undertakings were at a more advanced stage in their preparations for entering the market. 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 generic undertakings in each EEA State.

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).

805 Nor, fourthly, did the Commission err in taking into account the fact that all the agreements at issue had been implemented, which the applicants do not dispute, because the generic undertakings did not enter the market during the term of the agreements at issue, with the exception of Merck (GUK) before the second extension of the GUK United Kingdom agreement (paragraphs 28, 131 and 399 above).

806 Accordingly, in the light of all those circumstances, it must be held that, in setting the proportion of the value of sales to be taken into account in order to determine the basic amount of the fine imposed on Lundbeck at 11% or 10% depending on whether or not the geographic scope of the agreements to which the infringement relates was the whole of the EEA, the Commission did not err in law. Moreover, in the light of the foregoing, such rates of gravity, which are at the lower end of the scale provided for in point 21 of the 2006 Guidelines, cannot be considered to be disproportionate.

807 The applicant also claims in vain that the lack of secrecy in respect of the agreements justified the Commission's establishing a lower level of gravity when setting the amount of the fine imposed on them.

808 Point 23 of the 2006 Guidelines provides that 'horizontal price-fixing, market-sharing and output-limitation agreements, which are usually secret, are, by their very nature, among the most harmful restrictions of competition', that '[a]s a matter of policy, they will be heavily fined' and that, '[t]herefore, the proportion of the value of sales taken into account for such infringements will generally be set at the higher end of the scale'.

809 It suffices to note that, even if the agreements at issue were not secret, by setting the proportion of sales taken into account at 10% and 11% respectively in the present case, the Commission was not at the top of the scale set out in point 21 of the Guidelines, which is set at 30% of the value of sales.

810 In addition, while the Commission has been able, in some cases, to consider that it was not necessary to impose a fine or to take into consideration a proportion of the value of sales at the lower end of the scale of gravity, for various reasons, it must be recalled that, according to settled case-law, the Commission's earlier decision-making practice does not in itself serve as a legal framework for the imposition of fines in competition matters, since that framework is defined solely in Regulation No 1/2003 and in the Guidelines. Consequently, decisions in other cases can give only an indication for the purpose of determining whether there might be discrimination, since the facts of those cases, such as markets, products, the undertakings and periods concerned, are not likely to be the same (see, to that effect, judgment in *E.ON Ruhrgas and E.ON* v *Commission*, cited in paragraph 98 above, EU:T:2012:332, paragraphs 260 to 262 and the case-law cited). In the present case, the facts of the case in the previous decisions relied on by the applicants, such as the markets, goods, countries, undertakings and periods in question, are not comparable to those of the present case, with the result that those decisions are not relevant from the point of view of observance of the principle of equal treatment, in accordance with the case-law cited above.

811 Finally the applicants are wrong to allege infringement of the principle of proportionality in the present case. In this context, that principle requires only that the Commission set the fine proportionately to the factors taken into account for the purposes of assessing the gravity of the infringement and that it must apply those factors in a way which is consistent and objectively justified (see judgment of 27 September 2006 in *Jungbunzlauer* v *Commission*, T-43/02, ECR, EU:T:2006:270, paragraph 228 and the case-law cited). It is clear from recitals 1330 to 1333 of the contested decision that the Commission applied the principles set out in point 22 of the 2006 Guidelines in a manner which is consistent and objectively justified in the present case.

812 The first part must therefore be rejected.

B – *The second part*

813 The applicants claim that the contested decision was wrong, in recital 1335, to refuse to accept that the alleged infringements were of shorter duration. The duration should be limited to the period during which the generic undertakings were actually ready to enter the market, which means that they must have had at least one MA in the relevant countries. In Austria, for example, the API patent did not expire until April 2003 and the infringements committed with GUK, Alpharma and Ranbaxy cannot therefore have restricted competition in Austria before that date. That approach is similar to the position taken by the Commission in Decision C(2009) 5355 final of 8 July 2009 relating to a proceeding under Article [101 TFEU] (Case COMP/39.401 — E.ON/GDF) (summary published in OJ 2009 C 248, p. 5; the 'E.ON/GDF decision'), where only the period after 1998 was taken into consideration for the purposes of calculating the amount of the fine.

814 The Commission disputes those arguments.

815 In that respect, it must be noted, as the Commission states, that such an argument amounts to denying the distinction between actual competition and potential competition, and the fact that Article 101 TFEU also protects the latter (paragraph 99 above). The Commission has sufficiently established, for all the generic undertakings concerned, that they had real concrete possibilities of entering the market and that they were therefore potential competitors of Lundbeck at the time of conclusion of the agreements at issue (see the first plea in law above).

816 The case that gave rise to the judgment in *E.ON Ruhrgas and E.ON* v *Commission*, cited in paragraph 98 above (EU:T:2012:332), is of no assistance to the applicants, since in that case, as the applicants recognise, no competition was possible, even in the absence of the anticompetitive agreement for part of the infringement period, since the market was legally shielded against any competition by virtue of the national legislation applicable during that period, which created a *de facto* monopoly. It is moreover for that reason that the Commission decision was partially annulled by the Court, in so far as the existence of a restriction of competition on the German gas market was not sufficiently established during that period (judgment in *E.ON Ruhrgas and E.ON* v *Commission*, paragraph 98 above, EU:T:2012:332, paragraphs 105 and 155). In the present case, by contrast, the Commission established to the requisite legal standard in the contested decision that competition had been restricted by virtue of the agreements at issue, during their entire term. The applicants have failed to demonstrate that, in the absence of the agreements at issue, competition — even potential — between them and the generic undertakings would have been impossible or non-existent or that those agreements placed no restriction on competition.

817 The second part must therefore be rejected.

C – *The third part*

818 The applicants maintain that no additional amount ought to have been imposed on them, not even for the agreements concluded with Arrow (see paragraph 73 above), since the alleged infringements do not correspond to any of the examples for which the 2006 Guidelines recommend the application of an additional amount (those cases being 'horizontal price-fixing, market-sharing and output limitation agreements') and since no increased deterrent effect is necessary in the case of infringements which began more than 10 years ago and have not been repeated.

819 The Commission disputes those arguments.

820 First, it must be noted that point 25 of the 2006 Guidelines, which provides for the inclusion of an entry fee in the basic amount of the fine, states as follows:

'Irrespective of the duration of the undertaking's participation in the infringement, the Commission will include in the basic amount a sum of between 15% and 25% of the value of sales …, in order to deter undertakings from even entering into horizontal price-fixing, market-sharing and output-limitation agreements. The Commission may also apply such an additional amount in the case of other infringements. For the purpose of deciding the proportion of the value of sales to be considered in a given case, the Commission will have regard to a number of factors, in particular those referred in point 22 [namely, 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].'

821 The applicants claim, in essence, that the Commission could not include such an entry fee in the fine imposed on them, as a deterrent, since the alleged infringements did not correspond to any example for which the 2006 Guidelines recommend the application of an additional amount, and in so far as the infringements, which began more than 10 years ago, have not been repeated.

822 However, it must be noted that the task of supervision conferred upon the Commission by EU law in the field of competition law includes the duty to investigate and punish individual infringements, as well as the duty to pursue a general policy designed to apply, in competition matters, the principles laid down by the Treaty and to guide the conduct of undertakings in the light of those principles. It follows that the Commission must ensure that fines have a deterrent effect (see, to that effect, judgment of 17 December 2014 in *Pilkington Group and Others* v *Commission*, T-72/09, EU:T:2014:1094, paragraph 302 and the case-law cited).

823 Accordingly, the deterrent effect of the fine is not designed solely to deter the undertaking in question from repeating the infringement. The Commission has the power to determine the level of fines with a view to reinforcing their deterrent effect in general, especially where infringements of a given type are still relatively frequent or are regarded as serious (see judgment in *Pilkington Group and Others* v *Commission*, cited in paragraph 822 above, EU:T:2014:1094, paragraph 303 and the case-law cited).

824 Furthermore, as the Commission states, in the present case the agreements at issue were strongly akin to market-sharing or output-limitation agreements, which are explicitly referred to in point 25 of the 2006 Guidelines (point 820 above). In any event, that point of those Guidelines authorises the Commission, in accordance with the case-law, to apply such an additional amount in order to ensure that the fine has deterrent effect in respect of other types of infringements.

825 It must therefore be concluded that the Commission did not exceed its discretion in respect of fines or infringe its 2006 Guidelines by applying an additional amount of 10% of the value of annual sales for the first infringement committed with Arrow in order to ensure that the fine imposed on the applicants had a sufficient deterrent effect (recital 1340 of the contested decision).

826 Accordingly, the third part must also be rejected.

D – *The fourth part*

827 The applicants maintain, first, that the Commission was wrong to refuse to grant Lundbeck the benefit of a mitigating circumstance on the basis of the existence of reasonable doubt on the part of the undertaking as to whether the restrictive conduct did indeed constitute an infringement. The argument in the contested decision that the mitigating circumstance based on reasonable doubt as to the existence of an infringement no longer appeared in the 2006 Guidelines (recital 1343 of the contested decision) is not a valid reason for not applying it, since both those Guidelines and the

Court acknowledge that the list of mitigating circumstances is not exhaustive. In addition, the applicants argue that it is clear from the communications between KFST and the Commission that, in the Commission's view, the legal standard was not clear at the time and cannot therefore have been clear to Lundbeck either.

828 In the second place, the applicants claim that they were unjustly deprived of the benefit of the mitigating circumstance that the alleged infringements were committed as a result of negligence, whereas they had concluded the agreements at issue in good faith in order to prevent the infringement of their patents by the generic undertakings, restricting the scope of the agreements solely to products infringing those patents and making no attempt to keep the agreements secret, as they would have done had they intended to infringe European Union competition law.

829 The Commission disputes those arguments.

830 In the first place, it must be noted, as the applicants observe, that the fact that the existence of reasonable doubt as to the existence of an infringement does not appear explicitly among the mitigating circumstances explicitly referred to in the 2006 Guidelines does not suffice for the Commission automatically to reject its application as a mitigating circumstance. Case-law specifies in that regard that in the absence of a mandatory indication in the Guidelines of the mitigating circumstances which may be taken into account, it must be held that the Commission retained a certain discretion in its global assessment of the size of any reduction in the fines to reflect mitigating circumstances (see, to that effect, judgment of 8 July 2004 in *Dalmine* v *Commission*, cited in paragraph 380 above, EU:T:2004:220, paragraph 326 and the case-law cited).

831 However, the fact that a Commission decision is the first application of the competition rules to a particular sector of the economy cannot be regarded as a mitigating factor if the perpetrator of the infringement knew or could not have been unaware that its conduct could lead to a restriction of competition on the market and pose problems with regard to competition law (see, to that effect, judgment of 8 March 2011 in *World Wide Tobacco España* v *Commission*, T-37/05, EU:T:2011:76, paragraph 160).

832 In the present case, the applicants could not have been unaware that the agreements at issue were capable of infringing Article 101 TFEU. The agreements at issue intended to exclude potential competitors from the market during their terms, against payment, which falls within the scope of the serious infringements referred to explicitly in Article 101(1) TFEU.

833 Furthermore, it is clear from the contested decision that Lundbeck was aware of the potentially infringing nature of those agreements (see paragraph 776 above).

834 Moreover, as regards the KFST press releases relied on by the applicants, it must be noted that an undertaking which has infringed Article 101 TFEU may not escape imposition of a fine where the infringement has resulted from that undertaking erring as to the lawfulness of its conduct on account of the legal advice given by a lawyer or of the terms of a decision of a national competition authority (see judgment in *Schenker & Co. and Others*, cited in paragraph 748 above, EU:C:2013:404, paragraph 43). Furthermore, in the present case, far from raising doubts as to the applicability of Article 101 TFEU to the agreements at issue, those press releases specified that the agreements at issue could influence competition if it appeared that Lundbeck had paid competitors to stay out of the market.

835 In any event, even if reasonable doubt could have existed, at the time of concluding the agreements at issue, with regard to the factors to be taken into account for the purposes of establishing the existence of a restriction of competition by object in the present case, in a context where the applicants held process patents capable of preventing the entry of generic undertakings to the market, it is nevertheless the case that there could be no doubt, at that time, that agreements under which, as in

the present case, potential competitors were to be paid to stay out of the market for a specified period could not comply with Article 101(1) TFEU, since they did not permit the entry of generics to the market to be facilitated in any way, including after their expiry, and they did not in fact allow the underlying patent dispute to be resolved between the parties (paragraphs 475 and 497 above).

836 Furthermore, as established in the context of the sixth plea in law above, the agreements at issue, with the exception of the GUK United Kingdom agreement, contained restrictions going beyond the scope of Lundbeck's patents, with the result that, even if the criterion of the scope of the patents, put forward by the applicants, had been the relevant legal criterion for assessing the legality of those agreements with regard to Article 101(1) TFEU, the agreements at issue would not have fulfilled that criterion and would therefore have constituted restrictions of competition by object within the meaning of that provision. As regards the GUK United Kingdom agreement, it must be noted that it forms part, with the EEA GUK agreements, of the same single and continuous infringement committed by Lundbeck and Merck (GUK). As stated above, the Commission has sufficiently established that the EEA GUK agreement contained restrictions going beyond the scope of Lundbeck's patents.

837 In the second place, the applicants claim that the infringements at issue in the present case were committed as a result of negligence, which also constitutes a mitigating circumstance justifying a reduction of the fine.

838 Point 29 of the 2006 Guidelines provides that the basic amount of the fine may be reduced where the Commission finds that mitigating circumstances exist, inter alia, for example, where the undertaking provides evidence that the infringement has been committed as a result of negligence.

839 In the present case, however, it must be noted that the agreements at issue were concluded by the applicants intentionally and that they were part of a deliberate strategy to prevent the potentially immediate entry of generics to the market (paragraphs 126 and 528 above).

840 The applicants' argument again relies on the premiss that the agreements at issue only prevented access to the market of generic products which potentially infringed their patents. As demonstrated in the context of the sixth plea in law above, this is not the case. In any event, there was uncertainty as to whether Lundbeck's patents were valid and whether they were infringed by the products that the generic undertakings had intended to sell at the time of conclusion of the agreements at issue (see the second plea in law above), uncertainty which was removed by those agreements. The applicants therefore wrongly claimed that the infringements were committed as a result of negligence in the present case and that the Commission should have granted them the benefit of that mitigating circumstance.

841 Furthermore, even if the infringements had been committed as a result of negligence in the present case, the Commission was not required to grant a reduction in the fine to the applicants. As the wording of point 29 of the 2006 Guidelines confirms, the Commission has a discretion in that regard, taking account of all the circumstances of the case. Accordingly, although the circumstances set out in the Guidelines are certainly among those which may be taken into account by the Commission in a specific case, it is not required, where an undertaking puts forward evidence capable of indicating the presence of one of those circumstances, to grant a further reduction as a matter of course without performing an overall analysis. The appropriateness of any reduction in the fine in respect of mitigating circumstances must be examined comprehensively on the basis of all the relevant circumstances (see, to that effect, judgment of 5 December 2013 in *Caffaro* v *Commission*, C-447/11 P, EU:C:2013:797, paragraph 103).

842 In the light of all of the circumstances of the case and the fact, in particular, that the Commission took into account the length of the procedure in granting a 10% reduction in the basic amount of the fine imposed on the applicants, the Court considers, exercising its unlimited jurisdiction conferred by

Article 31 of Regulation No 1/2003 in accordance with Article 261 TFEU (paragraph 793 above), that it is not necessary to grant the benefit of mitigating circumstances in the present case, and that the fine imposed on the applicants in the contested decision must be upheld.

843 As regards, in particular, the GUK United Kingdom agreement, it must be stressed that, although it was observed in the context of the sixth plea in law, that the Commission had not sufficiently established, in the contested decision, that that agreement contained restrictions going beyond the scope of Lundbeck's patents, such a complaint was deemed ineffective, for the reasons set out in paragraphs 539 and 570 to 577 above. There is therefore no need for the Court to grant a reduction in the amount of the fine imposed on the applicants in that regard.

844 Accordingly, the fourth part and the tenth plea in law in its entirety must be rejected.

845 Since none of the pleas in law relied on by the applicants in support of their application for annulment of the contested decision is well founded or effective and since the examination of the arguments put forward in support of their application for reduction of the amount of the fine has not revealed inappropriate elements in the Commission's calculation of the amount of that fine, the action must be dismissed in its entirety.

Costs

846 Under Article 134 of the Rules of Procedure, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings. Since the applicants have been unsuccessful, they must be ordered to pay the costs, in accordance with the form of order sought by the Commission.

847 In accordance with Article 138(3) of the Rules of Procedure and the form of order sought by the Commission, the intervener must be ordered to bear its own costs.

On those grounds,

THE GENERAL COURT (Ninth Chamber)

hereby:

1. **Dismisses the action;**

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

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

Berardis Czúcz Popescu

Delivered in open court in Luxembourg on 8 September 2016.

[Signatures]

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