Reports of Cases

JUDGMENT OF THE GENERAL COURT (Ninth Chamber, Extended Composition)

12 December 2018 *

(Competition — Agreements, decisions and concerted practices — Abuse of a dominant position — Market for perindopril, a medicinal product intended for the treatment of cardiovascular diseases, in its originator and generic versions — Decision finding an infringement of Articles 101 and 102 TFEU — Principle of impartiality — Consultation of the Advisory Committee on Restrictive Practices and Dominant Positions — Right to an effective remedy — Brevity of the period of time for lodging applications in the light of the length of the contested decision — Patent dispute settlement agreements — Licensing agreements — Technology acquisition agreements — Exclusive purchasing agreement — Potential competition — Restriction of competition by object — Restriction of competition by effect — Balance between competition law and patent law — Classification as separate infringements or as a single infringement — Definition of the relevant market at the level of the compound of the medicinal product concerned — Fines — Imposition of cumulative fines under Articles 101 and 102 TFEU — Principle that offences and penalties must have a proper legal basis — Value of sales — Method of calculation in the event of cumulative infringements on the same markets)

In Case T-691/14,

Servier SAS, established in Suresnes (France),

Servier Laboratories Ltd, established in Wexham (United Kingdom),

Les Laboratoires Servier SAS, established in Suresnes,

represented initially by I.S. Forrester QC, J. Killick, Barrister, O. de Juvigny, lawyer, and M. Utges Manley, Solicitor, and subsequently by J. Killick, O. de Juvigny, M. Utges Manley, J. Jourdan and T. Reymond, lawyers,

applicants,

supported by

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

intervener,

v

* Language of the case: French.

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

defendant,

APPLICATION under Article 263 TFEU for annulment of Commission Decision C(2014) 4955 final of 9 July 2014 relating to a proceeding under Article 101 and Article 102 TFEU [Case AT.39612 — Perindopril (Servier)] in so far as it concerns the applicants and, in the alternative, for reduction of the fine imposed on the applicants by that decision,

THE GENERAL COURT (Ninth Chamber, Extended Composition),

composed of S. Gervasoni (Rapporteur), President, E. Bieliūnas, L. Madise, R. da Silva Passos and K. Kowalik-Bańczyk, Judges,

Registrar: G. Predonzani, Administrator,

having regard to the written part of the procedure and further to the hearing on 6 to 9 June 2017,

gives the following

Judgment [1]

I. Background to the dispute

A. The applicants

1 The Servier group, composed, inter alia, of Servier SAS, its parent company established in France, Les Laboratoires Servier SAS and Servier Laboratories Ltd (individually or jointly, 'Servier' or 'the applicants'), brings together pharmaceutical companies at the global level. Stichting FIRS, a non-profit foundation under Netherlands law, has exclusive control over the operation of the group's parent company.

B. Perindopril and its patents

1. Perindopril

2 Servier developed perindopril, a medicinal product used in cardiovascular medicine, primarily intended for the treatment of hypertension and heart failure, by inhibiting the angiotensin converting enzyme ('ACE').

3 The active pharmaceutical ingredient of perindopril ('API'), that is to say, the biologically active chemical substance which produces the desired therapeutic effects, takes the form of a salt. The salt used initially was erbumine (or tert-butylamine), which is in its crystalline form on account of the synthesis process applied by Servier.

1 Only the paragraphs of this judgment which the Court considers it appropriate to publish are reproduced here.

2. Compound patent

4 The perindopril compound patent (patent EP0049658, 'the 658 patent') was filed with the European Patent Office (EPO) on 29 September 1981. The 658 patent was due to expire on 29 September 2001, but protection was prolonged in a number of EU Member States, including the United Kingdom, until 22 June 2003, in accordance with 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). In France, protection under the 658 patent was prolonged until 22 March 2005 and, in Italy, until 13 February 2009.

3. Secondary patents

5 In 1988, Servier also filed a number of patents before the EPO relating to processes for the manufacture of the perindopril compound with an expiry date of 16 September 2008: patents EP0308339, EP0308340, EP0308341 and EP0309324 (respectively, 'the 339 patent', 'the 340 patent', 'the 341 patent' and 'the 324 patent').

6 Servier filed new patents relating to erbumine and its manufacturing processes with the EPO in 2001, including patent EP1294689 (known as 'the beta patent' — 'the 689 patent'), patent EP1296948 (known as 'the gamma patent' — 'the 948 patent'), and patent EP1296947 (known as 'the alpha patent' — 'the 947 patent').

7 The 947 patent application relating to the alpha crystalline form of erbumine and the process for its preparation was filed on 6 July 2001 and granted by the EPO on 4 February 2004.

8 Servier also filed national patent applications in several EU Member States before they were parties to the Convention on the Grant of European Patents, which was signed in Munich on 5 October 1973 and entered into force on 7 October 1977 ('the EPC'). Servier filed, for example, patent applications relating to the 947 patent in Bulgaria (BG 107 532), the Czech Republic (PV 2003-357), Estonia (P200300001), Hungary (HU225340), Poland (P348492) and Slovakia (PP0149-2003). All the patent applications in question were filed on the same date: 6 July 2001. The patents were granted on 16 May 2006 in Bulgaria, on 17 August 2006 in Hungary, on 23 January 2007 in the Czech Republic, on 23 April 2007 in Slovakia and on 24 March 2010 in Poland.

4. Second generation perindopril

9 From 2002, Servier began developing a second generation perindopril product, manufactured using another salt, arginine, instead of erbumine. Perindopril arginine showed improvements in terms of shelf life, which increased from two to three years; stability, enabling the use of a single type of packaging for all climatic zones; and storage, since it required no particular storage conditions.

10 Servier applied for a European patent for perindopril arginine (patent EP1354873B, 'the 873 patent') on 17 February 2003. The 873 patent was granted to Servier on 17 July 2004 with an expiry date of 17 February 2023. The introduction of perindopril arginine in the European Union markets started in 2006.

C. Disputes relating to perindopril

1. Disputes before the EPO

11 Ten generic companies, including Niche Generics Ltd ('Niche'), Krka Tovarna Zdravil d.d. ('Krka'), Lupin Ltd and Norton Healthcare Ltd, a subsidiary of Ivax Europe ('Ivax') which subsequently merged with Teva Pharmaceuticals Ltd (individually or together with other members of the Teva group, 'Teva'), filed opposition proceedings against the 947 patent before the EPO in 2004, seeking the revocation in full of that patent on grounds of lack of novelty, lack of inventive step and insufficient disclosure of the invention.

12 On 27 July 2006, the Opposition Division of the EPO confirmed the validity of the 947 patent after Servier made some minor amendments to its original claims ('the EPO decision of 27 July 2006'). Seven companies brought an appeal against that decision. Niche withdrew from the opposition procedure on 9 February 2005, Krka on 11 January 2007 and Lupin on 5 February 2007. By decision of 6 May 2009, the EPO's Technical Board of Appeal annulled the EPO decision of 27 July 2006 and revoked the 947 patent. Servier's request for a revision of that decision was rejected on 19 March 2010.

13 On 11 August 2004, Niche also filed an opposition against the 948 patent before the EPO, but withdrew from the procedure on 14 February 2005.

14 On 13 April 2005, Teva filed opposition proceedings against the 873 patent. The Opposition Division rejected that opposition on the ground that Teva had not demonstrated that that patent had insufficient inventive step. On 22 December 2008, Teva filed an appeal against that decision, before withdrawing the appeal on 8 May 2012.

2. Disputes before the national Courts

15 The validity of the 947 patent has, moreover, been challenged by generic companies before the courts of certain Member States, notably in the Netherlands and the United Kingdom.

(a) Dispute between Servier and Niche and Servier and Matrix

16 In the United Kingdom, on 25 June 2004, Servier brought an action for infringement before the High Court of Justice (England & Wales), Chancery Division (Patents Court), against Niche, in relation to the 339, 340 and 341 patents, after Niche applied for marketing authorisations in the United Kingdom for a generic version of perindopril, developed in partnership with Matrix Laboratories Ltd ('Matrix') under an agreement concluded on 26 March 2001 ('the Niche-Matrix agreement'). On 9 July 2004 Niche served on Servier a counterclaim for a declaration of invalidity of the 947 patent.

17 The hearing before the High Court of Justice (England & Wales), Chancery Division (Patents Court), concerning the merits of the alleged infringement, was finally scheduled for 7 and 8 February 2005, but lasted for only half a day because a settlement agreement was concluded between Servier and Niche on 8 February 2005, which put an end to the litigation between those parties.

18 Matrix was kept informed by Niche on the progress of that litigation procedure and was also associated with that procedure as it gave evidence before the High Court of Justice (England & Wales), Chancery Division (Patents Court), on behalf of Niche. Moreover, on 7 February 2005, Servier sent a formal warning letter to Matrix, accusing it of infringing the 339, 340 and 341 patents and threatening to bring an action for infringement.

19 In the autumn of 2004, Servier began to consider acquiring Niche. To that end, Servier carried out a due diligence, of which the first phase was completed on 10 January 2005, the date on which Servier submitted a preliminary non-binding offer to acquire Niche's capital for an amount between 15 and 45 million pounds sterling (GBP). Following the second phase of the due diligence, which took place on 21 January 2005, Servier informed Niche verbally on 31 January 2005 that it did not wish to proceed with the acquisition.

(b) Disputes between Servier and Ivax and Servier and Teva

20 In the United Kingdom, on 9 August 2005, Ivax requested the revocation of the 947 patent before the High Court of Justice (England & Wales), Chancery Division (Patents Court). In October 2005, Servier and Ivax decided, however, to stay the proceedings until the adoption of the final decision in the opposition proceedings before the EPO. In return, Servier gave Ivax, its licensees and its customers an undertaking that, for the period of the stay and in the United Kingdom, it would not commence proceedings, seek an account of profits or any financial relief other than a reasonable royalty in respect of any acts of infringement of the 947 patent, or seek injunctive relief or delivery up. Servier also undertook to continue proceedings before the EPO diligently and not to seek an interim injunction in any infringement action brought once the proceedings before the EPO had been concluded.

21 In the Netherlands, on 15 August 2007, Pharmachemie BV, a Teva subsidiary, brought an action before the Rechtbank Den Haag (District Court, The Hague, Netherlands) for revocation of the 947 patent, as validated in the Netherlands, on grounds of lack of novelty and inventive step and for non-reproducibility. The Rechtbank Den Haag (District Court, The Hague) upheld that action on 11 June 2008. Servier appealed against that judgment on 7 October 2008 but did not subsequently submit a statement of objections.

(c) Disputes between Servier and Krka

22 In Hungary, on 30 May 2006, Servier applied for an interim injunction preventing the marketing of a generic version of perindopril placed on the market by Krka, as a result of the infringement of the 947 patent. That application was rejected in September 2006.

23 In the United Kingdom, on 28 July 2006, Servier brought an action for infringement of the 340 patent against Krka before the High Court of Justice (England & Wales), Chancery Division (Patents Court). On 2 August 2006, it also brought an action for infringement of the 947 patent against Krka and applied for an interim injunction. On 1 September 2006, Krka brought a counterclaim for annulment of the 947 patent and, on 8 September 2006, a separate counterclaim for annulment of the 340 patent. On 3 October 2006, the High Court of Justice (England & Wales), Chancery Division (Patents Court), granted Servier's application for an interim injunction and denied the motion for summary judgment brought by Krka on 1 September 2006 seeking the invalidation of the 947 patent. On 1 December 2006, the infringement proceedings were discontinued as a result of the settlement reached between the parties and the interim injunction was lifted.

(d) Dispute between Servier and Lupin

24 On 18 October 2006, Lupin submitted an application to the High Court of Justice (England & Wales), Chancery Division (Patents Court), for a declaration of invalidity of the 947 patent, as validated in the United Kingdom, and a declaration that the generic version of perindopril which it intended to market in the United Kingdom did not infringe that patent.

(e) Disputes between Servier and Apotex

25 In the United Kingdom, Servier brought an action for infringement before the High Court of Justice (England & Wales), Chancery Division (Patents Court), against the company Apotex Inc. on 1 August 2006, claiming infringement of the 947 patent, since Apotex had launched a generic version of perindopril in the United Kingdom on 28 July 2006. Apotex brought a counterclaim for annulment of that patent. An interim injunction prohibiting Apotex from importing, offering to sell or selling perindopril was obtained on 8 August 2006. On 6 July 2007, the High Court of Justice (England & Wales), Chancery Division (Patents Court), ruled that the 947 patent was invalid because it lacked novelty and inventive step over the 341 patent. Consequently, the injunction was lifted immediately and Apotex was able to resume selling its generic version of perindopril on the United Kingdom market. On 9 May 2008, the Court of Appeal (England & Wales) (Civil Division) dismissed Servier's appeal against the judgment of the High Court of Justice (England & Wales), Chancery Division (Patents Court).

26 On 9 October 2008, the High Court of Justice (England & Wales), Chancery Division (Patents Court), awarded damages to Apotex in the amount of GBP 17.5 million on account of the loss of revenue suffered during the period when the injunction was in force. On 29 March 2011, however, the High Court of Justice (England & Wales), Chancery Division (Patents Court), ordered Apotex to repay that sum to Servier on the basis of the *ex turpi causa* principle, since a valid Canadian patent protected the perindopril compound until 2018 and Apotex produced and sold its product in Canada. However, the Court of Appeal (England and Wales) (Civil Division) set aside that decision by judgment of 3 May 2012. On 29 October 2014, the Supreme Court of the United Kingdom dismissed Servier's appeal against the judgment of the Court of Appeal (England and Wales) (Civil Division).

27 In the Netherlands, on 13 November 2007, Katwijk Farma BV, an Apotex subsidiary, brought an action before the Rechtbank Den Haag (District Court, The Hague) for annulment of the 947 patent, as validated in the Netherlands. Servier applied for an interim injunction against Katwijk Farma on 7 December 2007, which was rejected by the Rechtbank Den Haag (District Court, The Hague) on 30 January 2008. Following the annulment of the 947 patent for the Netherlands on 11 June 2008 by the Rechtbank Den Haag (District Court, The Hague) in the context of the action brought by Pharmachemie BV, Servier and Katwijk Farma withdrew from the ongoing proceedings.

D. Patent dispute settlements

28 Servier entered into a series of patent settlement agreements with a number of generic companies with which it was involved in patent disputes. However, it did not enter into a settlement agreement with Apotex.

1. Agreements concluded by Servier with Niche and Unichem and with Matrix

29 On 8 February 2005, Servier concluded two settlement agreements, one with Niche and its parent company, Unichem Laboratories Ltd ('Unichem'), and the other with Matrix. On the same day, Niche concluded a licensing and supply agreement with Biogaran, a wholly-owned subsidiary of Les Laboratoires Servier.

30 The agreement concluded by Servier with Niche and Unichem ('the Niche agreement') covered all the countries in which the 339, 340, 341 and 947 patents existed (Clause 3).

31 Under the Niche agreement, Niche and Unichem were to refrain from making, having made, keeping, importing, supplying, offering to supply or disposing of generic perindopril made using the process developed by Niche, which Servier regarded as infringing the 339, 340 and 341 patents, as validated in

the United Kingdom, using a substantially similar process or using any other process that would infringe the 339, 340 and 341 patents ('the process at issue') until the local expiry date of those patents (Clause 3). However, they would be free, under the Niche agreement, to market perindopril made using the process at issue without infringing the patents after the expiry of those patents (Clauses 4 and 6). Moreover, Niche was required to cancel, terminate or suspend until the expiry date of the patents all of its existing contracts relating, on the one hand, to perindopril made using the process at issue and, on the other, to marketing authorisation applications for that perindopril (Clause 11). Furthermore, Niche and Unichem undertook not to make any applications for marketing authorisations for perindopril made using the process at issue and not to assist any third parties to obtain such a marketing authorisation (Clause 10). Lastly, they were to abstain from any invalidity and non-infringement actions against the 339, 340, 341, 947, 689 and 948 patents until their expiry, except as a defence to a patent infringement action (Clause 8). Niche also agreed to withdraw its oppositions to the 947 and 948 patents before the EPO (Clause 7).

32 In return, Servier undertook, first, not to bring any infringement actions against Niche, Niche customers or Unichem based on the 339, 340, 341 and 947 patents in respect of any act of alleged infringement occurring before the conclusion of the Niche agreement (Clause 5) and, secondly, to pay Niche and Unichem the sum of GBP 11.8 million in two instalments (Clause 13). That sum was to be paid in consideration for the commitments made by Niche and Unichem and for the 'substantial costs and potential liabilities that may be incurred by Niche and Unichem as a consequence of ceasing their programme to develop perindopril made using the process [at issue]'.

33 Moreover, on 8 February 2005, Niche concluded a licensing and supply agreement with Biogaran ('the Biogaran agreement'), relating to the transfer, first, of all the information and data which Niche held concerning three medicinal products and which were necessary to obtain marketing authorisations and, secondly, of its French marketing authorisation for one of those medicinal products. In return, Biogaran was to pay Niche the sum of GBP 2.5 million, which was non-refundable even if Biogaran failed to obtain the marketing authorisations. Biogaran was also required, after obtaining its marketing authorisations, to order the products concerned from Niche. In the event that the marketing authorisations were not obtained within 18 months of the date of entry into force of the agreement, that agreement would be automatically terminated (Clause 14.4), without either party being entitled to any compensation (Clause 14.5).

34 The agreement concluded by Servier with Matrix ('the Matrix agreement') covered all the countries in which the 339, 340, 341 and 947 patents existed, with the exception of one non-Member State of the European Economic Area (EEA) (Section 1(1)(xiii) of the Matrix agreement).

35 Under the Matrix agreement, Matrix committed to refrain from making, having made, keeping, importing, supplying, offering to supply or disposing of perindopril made using the process at issue until the local expiry date of those patents (Clauses 1 and 2). However, the agreement stipulated that Matrix would be free to deal in perindopril made using the process at issue without infringing the patents after the expiry of those patents (Clause 4). Moreover, Matrix was required to cancel, terminate or suspend until the expiry date of the patents all of its existing contracts relating to perindopril made using the process at issue and to marketing authorisation applications for that perindopril by 30 June 2005 at the latest (Clauses 7 and 8). Furthermore, it committed not to apply for marketing authorisations for perindopril made using the process at issue and not to assist any third parties to obtain such a marketing authorisation (Clause 6). Finally, Matrix was to abstain from any invalidity and non-infringement actions against the 339, 340, 341, 947, 689 and 948 patents until their expiry, except as a defence to a patent infringement action (Clause 5).

36 In return, Servier committed, first, not to bring any infringement actions against Matrix, based on the 339, 340, 341 and 947 patents, in respect of any act of alleged infringement occurring before the conclusion of the Matrix agreement (Clause 3) and, secondly, to pay Matrix the sum of GBP 11.8 million in two instalments (Clause 9). That sum was consideration for the commitments made by

Matrix and for the 'substantial costs and potential liabilities that may be incurred by Matrix as a consequence of ceasing its programme to develop and manufacture perindopril made using the process [at issue]'.

2. Agreement concluded by Servier with Teva

37 On 13 June 2006, Servier concluded a settlement and exclusive purchasing agreement with Teva ('the Teva agreement'). The perindopril referred to in the Teva agreement was perindopril erbumine (Clause 1.12).

38 Under the clauses concerning the settlement agreement, Teva undertook to destroy all perindopril owned or controlled by it and intended for sale in the United Kingdom (Clause 2.2). Moreover, Teva was to refrain, in the United Kingdom, from making, having made, keeping, importing, supplying, offering to supply or disposing of generic perindopril either manufactured in accordance with the process it had developed, which was considered by Servier to infringe the 947 and 339 to 341 patents, as validated in the United Kingdom, or infringing those patents until the termination or expiration of the Teva agreement or the expiration of those patents (Clause 2.3). Furthermore, Teva undertook not to challenge the abovementioned patents in the United Kingdom for the duration of the Teva agreement, it being stipulated that Teva was not prevented from continuing opposition proceedings against the disputed patents before the EPO (Clause 2.4).

39 In return for Teva's undertakings, Servier undertook to waive any claims against Teva in respect of any infringement of the disputed patents in the United Kingdom prior to the entry into force of the Teva agreement (Clause 2.1).

40 Under the clauses concerning the exclusive purchasing obligation, Teva undertook to purchase exclusively from Servier all of its requirements for generic perindopril intended for distribution in the United Kingdom for the duration of the Teva agreement (Clauses 3.1 and 1.14). In the case of failure to supply by Servier, Teva had no other right of remedy or termination, but the right to payment of liquidated damages of GBP 500 000 per month (Clauses 1.8 and 3.8.3).

41 Under the general provisions of the Teva agreement, that agreement had a duration of three years and was renewable for an additional two year period (Clauses 8.1 and 8.2). Moreover, on signature of the Teva agreement, upon presentation of an 'appropriate invoice', Servier had to pay Teva GBP 5 million as a 'contribution towards the costs incurred by Teva in preparing to enter into this Agreement, including, without limitation, the costs of terminating its existing supply arrangements for the United Kingdom' (Clause 10).

42 On 23 February 2007, Servier and Teva concluded an amendment to the Teva agreement ('the amendment to the Teva agreement'), confirming the actual implementation of the exclusive purchasing obligation by setting a date on which Teva could start to distribute the generic perindopril supplied by Servier. That date either had to be set unilaterally by Servier, or it had to correspond to the date of revocation or expiry of the 947 patent, or be the date on which Apotex commenced distribution of generic perindopril in the United Kingdom following the settlement of its dispute with Servier.

3. Agreements concluded by Servier with Krka

43 On 27 October 2006, Servier entered into a settlement agreement and a licence agreement with Krka, supplemented by an amendment made on 2 November 2006.

44 The settlement agreement with Krka provides that the 947 patent also covers equivalent national patents (Annex B).

45 In accordance with the settlement agreement with Krka, in force until the expiry or the revocation of the 947 or 340 patents, Krka undertook to withdraw any existing claim against the 947 patent worldwide and against the 340 patent in the United Kingdom, and not to challenge either of those patents worldwide in the future (Clause I(ii)). Moreover, Krka and its subsidiaries were not authorised to launch or to market any generic form of perindopril which would infringe the 947 patent for the duration of the validity of that patent and in the country in which it was still valid, unless otherwise expressly authorised by Servier (Clause V). Similarly, Krka could not supply to any third party a generic version of perindopril that would infringe the 947 patent, unless otherwise expressly authorised by Servier (Clause V(2)). In return, Servier was required to withdraw the proceedings pending worldwide against Krka based on the infringement of the 947 and the 340 patents, including its applications for interim injunction (Clause I(i)).

46 Pursuant to the licence agreement concluded with Krka for a period corresponding to the validity of the 947 patent (Article 5), Servier granted Krka an exclusive, irrevocable licence on the 947 patent to use, manufacture, sell, offer for sale, promote and import its own products which contain the alpha crystalline form of erbumine (Article 2) in the Czech Republic, Latvia, Lithuania, Hungary, Poland, Slovenia and Slovakia (Article 1). In return, Krka was required to pay Servier 3% royalties on its net sales prices throughout those territories (Article 3). Servier was entitled, in those States, to use the 947 patent directly or indirectly (that is to say for one of its subsidiaries or for one third party per country) (Article 2).

47 On 5 January 2007, Servier also entered into an assignment and licence agreement with Krka.

48 Pursuant to the assignment and licence agreement, Krka assigned two patent applications to Servier, one concerning a process for the preparation of perindopril (WO 2005 113500) and the other the preparation of formulations of perindopril (WO 2005 094793) (Article 1). The technology protected in those patent applications was used for the production of Krka's perindopril.

49 Krka undertook not to challenge the validity of any patents granted on the basis of the applications at issue (Article 3).

50 In return for that assignment, Servier paid Krka EUR 15 million for each of the applications at issue (Article 2).

51 Servier also granted Krka a non-exclusive, irrevocable, non-assignable, royalty-free licence, with no right to sub-license (other than to its subsidiaries) on the applications or resulting patents, that licence being unrestricted in time, territory or scope of use (Article 4).

4. Agreement concluded by Servier with Lupin

52 On 30 January 2007, Servier entered into a settlement agreement with Lupin ('the Lupin agreement').

53 Both parties thus decided to bring an end to the disputes between them concerning perindopril (Clauses 1.1, 1.2 and 1.4).

54 Moreover, Lupin undertook not to directly or indirectly seek or assist or procure any third party to revoke, invalidate or challenge the 947 patent or any patent held by Servier or its subsidiaries protecting perindopril, in any country other than a specific non-Member State of the EEA (Clause 1.3). Furthermore, Lupin and its subsidiaries were to refrain from selling or offering for sale any pharmaceutical product containing, as an API, 'perindopril[-]erbumine … and any salt thereof' in any country other than a specific non-EEA Member State (Clause 1.6). Lupin was, however, authorised to market products supplied by Servier or its own perindopril in countries where a generic version of perindopril authorised by Servier was on the market or in the event that all Servier's relevant patents

had expired or in countries in which a third party had placed a generic version of perindopril on the market and in which Servier had not brought any application for injunction seeking the prohibition of its sale (Clauses 1.6 and 4.1).

55 Moreover, in the context of the Lupin agreement, Servier and Lupin also concluded an agreement for the assignment of intellectual property rights and a licence agreement.

56 Servier acquired three perindopril process patent applications filed by Lupin:

– application W0 2004/075889 (EP 1603558 B1) relating to a new process for the preparation of perindopril and salts thereof for EUR 20 million;

– application W0 2006/097941 (EP 1861367 A) relating to a new and improved process for the purification of perindopril for EUR 10 million;

– application W0 2005/037788 (EP 1675827 A1) relating to a new process for the preparation of 'crystalline perindopril erbumine' for EUR 10 million.

57 Servier also granted Lupin a non-exclusive, non-transferable, non-sublicensable, royalty-free, perpetual and irrevocable licence on those three patent applications for the purposes of manufacturing perindopril in the countries covered by the applications at issue (Clause 3.1).

58 The Lupin agreement provided, lastly, for the conclusion, within four weeks, of a supply contract between the parties, which was not, however, concluded.

E. The acquisition of enabling technologies

59 On 3 September 2001, the applicants concluded an agreement with Rolabo SL concerning the sale of a patent application filed by Rolabo on 24 July 2001, relating to a perindopril API and to a chemical dossier for the perindopril API, for 10 million US dollars (USD).

60 On 9 November 2004, the applicants concluded with Azad Pharmaceutical Ingredients AG ('Azad') an agreement to assign a patent application filed by Azad for two new polymorphic forms of perindopril, the delta and epsilon forms, and the related know-how worldwide, for an amount of EUR 13 374 243.

61 On 15 October 2007, the applicants concluded a memorandum of understanding with Sandoz AG, which provided that they would proceed with the acquisition of the perindopril API technology developed by Sandoz — if that technology proved to be a patent-free and industrially viable source of competition — for an amount possibly exceeding USD 50 million. Negotiations continued until July 2008, but no agreement was ultimately concluded.

F. The Sector Inquiry

62 On 15 January 2008, the Commission of the European Communities decided to open an inquiry into the pharmaceutical sector pursuant to Article 17 of Council Regulation (EC) No 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles [101] and [102 TFEU] (OJ 2003 L 1, p. 1) in order to identify the factors contributing to the decline in innovation in that sector, measured by the number of new medicines reaching the market, and the reasons for the delayed entry into the market of certain generic medicines.

63 The Commission published a preliminary report on the results of its inquiry on 28 November 2008, followed by a public consultation. On 8 July 2009, it adopted a communication giving a summary of its pharmaceutical sector inquiry report. The Commission stated, inter alia, in that communication, that the monitoring of patent settlements concluded between originator companies and generic companies should continue in order better to understand the use of that type of agreement and to identify those agreements that delay generic market entry to the detriment of EU consumers and may constitute an infringement of competition rules. The Commission subsequently published six annual reports on the monitoring of patent settlement agreements.

G. The administrative procedure and the contested decision

64 On 24 November 2008, the Commission made unannounced inspections, inter alia, of Servier's premises. The Commission sent requests for information to several companies, including Servier, in January 2009. On 2 July 2009 the Commission decided to open proceedings.

65 In August 2009 and then between December 2009 and May 2012, the Commission sent new requests for information to Servier. As the latter refused to respond to certain parts of the requests for information of 7 February and 11 April 2011 relating to the Biogaran agreement, the Commission adopted a decision based on the provisions of Article 18(3) of Regulation No 1/2003. Servier provided the requested information on 7 November 2011.

66 Between 2009 and 2012, Servier was invited to attend a number of state of play meetings.

67 On 27 July 2012, the Commission issued a Statement of Objections to several companies including Servier, which submitted its reply on 14 January 2013.

68 Following the hearing of the companies concerned on 15, 16, 17 and 18 April 2013, further state of play meetings were arranged and additional requests for information sent to Servier.

69 On 18 December 2013, the Commission granted Servier access to evidence gathered or more widely disclosed after the Statement of Objections and sent a Letter of Facts to which Servier replied on 31 January 2014. The hearing officer issued his final report on 7 July 2014.

70 On 9 July 2014, the Commission adopted Decision C(2014) 4955 final relating to a proceeding under Article 101 and Article 102 TFEU [Case AT.39612 — Perindopril (Servier)] ('the contested decision'), which was notified to the applicants on 11 July 2014.

71 The Commission considered that the applicants had infringed, first, Article 101 TFEU by participating in five patent settlement agreements with reverse payments (Articles 1 to 5 of the contested decision) and, secondly, Article 102 TFEU by drawing up and implementing — by means of technology acquisition and those five settlement agreements — an exclusionary strategy covering the market for formulations of perindopril in France, the Netherlands, Poland and the United Kingdom and the market for perindopril API technology (Article 6 of the contested decision).

72 For the infringements of Article 101 TFEU, the Commission imposed the following fines on the applicants, totalling EUR 289 727 200 (Article 7(1) to (5) of the contested decision):

– in respect of the Niche agreement: EUR 131 532 600, jointly and severally with Biogaran;

– in respect of the Matrix agreement: EUR 79 121 700;

– in respect of the Teva agreement: EUR 4 309 000;

– in respect of the agreements concluded with Krka: EUR 37 661 800;

– in respect of the Lupin agreement: EUR 37 102 100.

73 For the infringement of Article 102 TFEU, the Commission imposed on the applicants a fine of EUR 41 270 000 (Article 7(6) of the contested decision).

II. Procedure and forms of order sought by the parties

74 By application lodged at the Registry of the General Court on 21 September 2014, the applicants brought the present action.

75 The applicants claim that the Court should:

– annul, in whole or in part, Articles 1 to 8 of the contested decision in so far as they concern them;

– in the alternative, annul or reduce by a very substantial amount the fines imposed on them;

– grant them the benefit of any annulment, in whole or in part, of the contested decision in the actions brought by Biogaran and the other addressees of that decision;

– order the Commission to pay the costs.

76 The Commission contends that the Court should:

– dismiss the action;

– order the applicants to pay the costs.

77 By document lodged on 2 February 2015, the European Federation of Pharmaceutical Industries and Associations (EFPIA) ('the EFPIA' or 'the intervener') sought leave to intervene in the proceedings in support of the form of order sought by the applicants.

78 The Commission requested confidential treatment, vis-à-vis the EFPIA, of certain elements of the application, the defence, the reply, the rejoinder, the response to certain measures of organisation of procedure, the observations relating to those responses and the applicants' observations on the statement in intervention.

79 By order of the President of the Second Chamber of the Court of 14 October 2015, the EFPIA was granted leave to intervene in the present proceedings in support of the form of order sought by the applicants. Since the EFPIA did not challenge the requests for confidential treatment, the Court did not rule on whether they were well founded.

80 The intervener claims that the Court should:

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

– order the Commission to bear the costs of the intervener.

81 In the context of the measures of organisation of procedure provided for in Article 89(3)(a) and (d) of the Rules of Procedure of the General Court, the Commission was invited to respond in writing to questions and to produce documents relating, inter alia, to the consultation of the Advisory

Committee on Restrictive Practices and Dominant Positions, to the calculation of the amount of the fine and to data concerning the agreements with Krka which were made confidential in the contested decision. It sent its replies within the prescribed period.

82 Following a change in the composition of the Chambers of the Court, the Judge-Rapporteur was assigned to the Ninth Chamber, to which the present case was accordingly allocated.

83 Acting on a proposal from the Ninth Chamber, the Court decided, pursuant to Article 28 of the Rules of Procedure, to assign the case to a Chamber sitting in extended composition.

84 Acting on a proposal from the Judge-Rapporteur, the Court decided to open the oral part of the procedure and, by way of measures of organisation of procedure pursuant to Article 89(3)(a) of the Rules of Procedure, put written questions to the parties, requesting them to answer those questions at the hearing.

85 On 24 February 2017, the parties were invited by the Court to attend an informal meeting, under Article 89(3)(e) of the Rules of Procedure, before the President of the Ninth Chamber (Extended Composition) of the General Court and Judge-Rapporteur, with a view to discussing the arrangements for the hearing and the confidential treatment of certain information. The applicants and the Commission attended that meeting, which was held at the Court on 3 May 2017.

86 At the hearing held from 6 to 9 June 2017, the parties presented oral argument and their answers to the written and oral questions put by the Court.

III. Law

A. Admissibility

1. Admissibility of the third head of claim

(a) Arguments of the parties

…

(b) Findings of the Court

89 According to settled case-law, the conditions for the admissibility of an action concern an absolute bar to proceeding with the action which the Courts of the European Union may and must consider of their own motion should such an issue arise (judgments of 21 March 2002, *Joynson* v *Commission*, T-231/99, EU:T:2002:84, paragraph 154, and of 14 December 2005, *Honeywell* v *Commission*, T-209/01, EU:T:2005:455, paragraph 53). Therefore, even if the Commission, in its pleadings, did not dispute the admissibility of the applicants' third head of claim, but did so only at the hearing in response to a question from the Court, it is for the Court to consider of its own motion the admissibility of that head of claim.

90 Under the first paragraph of Article 21 of the Statute of the Court of Justice of the European Union, applicable to the procedure before the General Court by virtue of the first paragraph of Article 53 thereof, and Article 44(1)(c) and (d) of the Rules of Procedure of the General Court of 2 May 1991, applicable at the time the action was brought, each application is required to state the subject matter of the proceedings, the form of order sought and a summary of the pleas in law on which the application is based. The purpose of that requirement is to obtain sufficiently clear and precise

information to enable the defendant to defend itself properly and the EU judicature to exercise its power of review, if necessary without any further supporting information (judgments of 29 June 1995, *ICI* v *Commission*, T-37/91, EU:T:1995:119, paragraph 42; of 24 February 2000, *ADT Projekt* v *Commission*, T-145/98, EU:T:2000:54, paragraph 66; and of 16 March 2004, *Danske Busvognmænd* v *Commission*, T-157/01, EU:T:2004:76, paragraph 45). Thus, as the Commission argued at the hearing, a general reference in the application to the pleas and arguments relied on in support of an action brought in a related case does not meet that requirement (judgment of 24 March 2011, *Legris Industries* v *Commission*, T-376/06, not published, EU:T:2011:107, paragraph 32).

91 However, it should be noted that the Courts of the European Union were able to accept that pleas not expressly set out in the application could be regarded as validly raised by virtue of a reference to the pleas raised in another case in the event that the applicant had referred to its own written pleadings in another case (see judgment of 14 December 2005, *Honeywell* v *Commission*, T-209/01, EU:T:2005:455, paragraphs 61 and 62 and the case-law cited). Those cases covered situations in which the parties were identical, as were the agents and lawyers representing them. On the other hand, the General Court held that to accept the admissibility of pleas in law not set out expressly in the application on the ground that they were raised by a third party in another case, to which reference is made in that application, would be to allow the mandatory requirements of Article 21 of the Statute of the Court of Justice of the European Union and of Article 44(1) of the Rules of Procedure of the General Court of 2 May 1991, to be circumvented (see, to that effect, judgments of 14 December 2005, *Honeywell* v *Commission*, T-209/01, EU:T:2005:455, paragraphs 63 and 64; of 27 September 2012, *Dura Vermeer Infra* v *Commission*, T-352/06, not published, EU:T:2012:483, paragraphs 25 and 26; of 27 September 2012, *Koninklijke BAM Groep* v *Commission*, T-355/06, not published, EU:T:2012:486, paragraphs 26 and 27; and of 27 September 2012, *Heijmans* v *Commission*, T-360/06, not published, EU:T:2012:490, paragraphs 25 and 26). Lastly, it must be recalled that each party is solely responsible for the content of the pleadings which it lodges, a rule laid down notably in Article 43(1) of the Rules of Procedure of 2 May 1991 (see, to that effect, judgments of 29 June 1995, *ICI* v *Commission*, T-37/91, EU:T:1995:119, paragraph 46, and of 14 December 2005, *Honeywell* v *Commission*, T-209/01, EU:T:2005:455, paragraph 66). In the present case, however, it is common ground that the applicants wish to rely on any possible annulment obtained by third parties and that, accordingly, neither the parties nor their representatives are identical.

92 Moreover, it should be recalled that a decision adopted in the sphere of competition law with respect to several undertakings, although drafted and published in the form of a single decision, must be seen as a set of individual decisions finding that each of the addressees is guilty of the infringement or infringements of which they are accused and imposing on them, where appropriate, a fine (see, to that effect, judgments of 14 September 1999, *Commission and AssiDomän Kraft Products and Others*, C-310/97 P, EU:C:1999:407, paragraph 49, and of 15 October 2002, *Limburgse Vinyl Maatschappij and Others* v *Commission*, C-238/99 P, C-244/99 P, C-245/99 P, C-247/99 P, C-250/99 P to C-252/99 P and C-254/99 P, EU:C:2002:582, paragraph 100). The Court of Justice has held that, if an addressee of a decision decided to bring an action for annulment, the matter to be tried by the EU judicature related only to those aspects of the decision which concern that addressee, whereas aspects concerning other addressees did not form part of the matter to be tried by the EU judicature (judgments of 14 September 1999, *Commission and AssiDomän Kraft Products and Others*, C-310/97 P, EU:C:1999:407, paragraph 53; of 29 March 2011, *ArcelorMittal Luxembourg* v *Commission and Commission* v *ArcelorMittal Luxembourg and Others*, C-201/09 P and C-216/09 P, EU:C:2011:190, paragraph 142; and of 11 July 2013, *Team Relocations and Others* v *Commission*, C-444/11 P, not published, EU:C:2013:464, paragraph 66). Consequently, the Court of Justice considers that, in principle, the authority of a ground of a judgment annulling a measure cannot apply to the situation of persons who were not parties to the proceedings and with regard to whom the judgment cannot therefore have decided anything whatever (judgment of 14 September 1999, *Commission and AssiDomän Kraft Products and Others*, C-310/97 P, EU:C:1999:407, paragraph 55). Accordingly, the annulment of an individual decision has an *erga omnes* effect and is binding on everyone, but such

annulment does not benefit everyone, unlike the annulment of an act of general application (see judgment of 15 July 2015, *Emesa-Trefilería and Industrias Galycas* v *Commission*, T-406/10, EU:T:2015:499, paragraph 126 and the case-law cited).

93 Nevertheless, the Court of Justice introduced a qualification of that principle in the judgment of 22 January 2013, *Commission* v *Tomkins* (C-286/11 P, EU:C:2013:29, paragraphs 43 to 49), in which it held that, to the extent that the liability of the parent company was derived exclusively from that of its subsidiary and where the parent company and its subsidiary had brought parallel actions having the same object, the General Court had not ruled *ultra petita* by taking into account the outcome of the action brought by the subsidiary in order to annul the contested decision in respect of the period in question as regards the parent company, even though the parent company had not challenged the existence of the infringement for the whole of the period challenged by its subsidiary. Nevertheless, the Court of Justice, in order to be able to apply such a solution to the fine imposed on a parent company whose liability is derived solely from that of its subsidiary, considered that there had to be special circumstances, inter alia the two companies had to have raised pleas 'having the same object' and the applicant parent company had to claim that such circumstances existed (see, to that effect, judgment of 11 July 2013, *Team Relocation* v *Commission*, C-444/11 P, not published, EU:C:2013:464, paragraph 66).

94 However, the Court of Justice did not define that concept of 'same object' and has developed its position on the question whether special circumstances such as those at issue in the judgment of 22 January 2013, *Commission* v *Tomkins* (C-286/11 P, EU:C:2013:29), involved a matter of public policy and had to be raised by a court of its own motion. Accordingly, it first applied that solution when two companies had contested the duration of the infringement and at least part of the contested period was identical (judgment of 22 January 2013, *Commission* v *Tomkins*, C-286/11 P, EU:C:2013:29, paragraphs 43 and 44). The Court of Justice nevertheless also upheld a judgment of the General Court which adopted the same approach where the subsidiary had obtained a reduction in the amount of the fine imposed on it, on the basis of a failure properly to take into account its cooperation under the leniency programme, holding, in that case, that the parent company had sought, in the alternative, the reduction of the fine imposed on its subsidiary and, jointly and severally, on itself, and that 'the purpose of [certain of its] pleas in law was, inter alia, to justify the grant of such a reduction' (judgment of 26 September 2013, *Alliance One International* v *Commission*, C-679/11 P, not published, EU:C:2013:606, paragraphs 103 to 107). Finally, in a judgment of 17 September 2015, *Total* v *Commission* (C-597/13 P, EU:C:2015:613, paragraphs 31 to 42), the Court of Justice criticised a judgment of the General Court which failed to take into account, in the judgment relating to the parent company, a reduction in the amount of the fine granted to its subsidiary in another judgment delivered on the same day, on account of the method which the Commission, when calculating the amount of the fine, had used to define the multiplier corresponding to the duration of the infringement. However, the parent company had neither raised such a plea (it had, by contrast, contested the duration of the infringement) nor asked the General Court to be allowed to benefit from a reduction in the amount of the fine which had been imposed on it, if its subsidiary obtained such a reduction.

95 In the present case, Biogaran, a subsidiary of Servier, has also brought an action (case giving rise to the judgment delivered today, *Biogaran* v *Commission* (T-677/14)) against Articles 1, 7 and 8 of the contested decision. Nevertheless, as the Commission pointed out at the hearing, the circumstances of the present case differ from those obtaining in the case which gave rise to the judgment of 22 January 2013, *Commission* v *Tomkins* (C-286/11 P, EU:C:2013:29), and in the subsequent case-law, in particular in that the applicants' liability is not solely derived from that of their subsidiary Biogaran (recitals 3006 to 3013 of the contested decision). Moreover, in any event, since the action brought by Biogaran in the case which gave rise to the judgment delivered today, *Biogaran* v *Commission* (T-677/14), was dismissed by that judgment, the applicants' claim to be allowed to benefit from any annulment in favour of Biogaran cannot succeed.

96 The applicants also claim that they should be allowed to benefit from any annulment obtained by another addressee of the contested decision 'in order to avoid any difference in the treatment of situations which are legally and factually identical'. They argue that both the principle of equal treatment and a 'general duty of consistency' require application of that approach.

97 It must be recalled, in that regard, that the principle of equal treatment is a general principle of EU law, enshrined in Articles 20 and 21 of the Charter of Fundamental Rights of the European Union, which requires that comparable situations must not be treated differently and that different situations must not be treated in the same way unless such treatment is objectively justified (see judgment of 14 September 2010, *Akzo Nobel Chemicals and Akcros Chemicals* v *Commission and Others*, C-550/07 P, EU:C:2010:512, paragraphs 54 and 55 and the case-law cited). A decision adopted in the sphere of competition law with respect to several undertakings, although drafted and published in the form of a single decision, must be seen as a set of individual decisions finding that each of the addressees is guilty of the infringement or infringements of which they are accused and imposing on them, where appropriate, a fine (see paragraph 92 above). Those undertakings are therefore, a priori, and without exception, in different situations. Consequently, the principle of equality of treatment does not allow the European Union judicature to derogate from the procedural rules governing the admissibility of the form of order sought by allowing an addressee of a competition law decision to benefit from annulment by another addressee of that decision on the basis of pleas raised only by the latter.

98 Moreover, the obligation on the General Court to state the reasons for its judgments cannot extend to imposing on it an obligation to justify the solution arrived at in one case in the light of that found in another, even if it concerned the same decision (see, to that effect, judgment of 11 July 2013, *Team Relocation* v *Commission*, C-444/11 P, not published, EU:C:2013:464, paragraph 66).

99 It follows from the foregoing that the applicants' third head of claim, seeking to benefit from any annulment obtained by other addressees of the contested decision on the basis of the pleas put forward by those other addressees, is inadmissible. Even if that head of claim were admissible, it must be rejected as unfounded, since the applicants cannot validly rely, for their benefit, as is apparent from paragraphs 92 to 98 above, on a solution adopted to the benefit of the other addressees of the contested decision.

2. Admissibility of certain annexes to the application

(a) Arguments of the parties

…

(b) Findings of the Court

102 The Commission argues that Annexes A 2 and A 3 to the application are inadmissible under the maxim *iura novit curia*. The annexes, which have a purely evidential and instrumental function, cannot, in fact, be used for the discussion or further development of a point of EU law, which falls within the sole competence of the Court. The Commission relies on the judgments of 5 July 2011, *Edwin* v *OHIM* (C-263/09 P, EU:C:2011:452, paragraph 53), and of 20 March 2013, *El Corte Inglés* v *OHIM — Chez Gerard (CLUB GOURMET)* (T-571/11, EU:T:2013:145, paragraph 35), according to which the maxim *iura novit curia* applies only to EU law and not to national law. It should be recalled that that maxim means that it is solely for the court, and not the parties, to determine the meaning of the law. The case-law has applied that maxim in order to emphasise that, although the Court must rule only on the heads of claim put forward by the parties, whose role it is to define the framework of the dispute, the Court cannot confine itself to the arguments put forward by the parties

in support of their claims, or it might be forced to base its decision on erroneous legal considerations (orders of 27 September 2004, *UER* v *M6 and Others*, C-470/02 P, not published, EU:C:2004:565, paragraph 69, and of 13 June 2006, *Mancini* v *Commission*, C-172/05 P, EU:C:2006:393, paragraph 41; judgments of 21 September 2010, *Sweden and Others* v *API and Commission*, C-514/07 P, C-528/07 P and C-532/07 P, EU:C:2010:541, paragraph 65, and of 8 July 2010, *Commission* v *Putterie-De-Beukelaer*, T-160/08 P, EU:T:2010:294, paragraph 65). Similarly, according to that maxim, determining the meaning of the law does not fall within the scope of application of a principle which allows the parties a free hand to determine the scope of the case and the EU Court is therefore not obliged to inform the parties of the interpretation it intends to give in order to enable them to adopt a position on that subject (see judgment of 5 October 2009, *Commission* v *Roodhuijzen*, T-58/08 P, EU:T:2009:385, paragraph 36 and the case-law cited), without prejudice to compliance by the EU Court with the obligation to allow the parties to be apprised of, and to be able to debate and be heard on, the matters of fact and of law which will determine the outcome of the proceedings (judgment of 2 December 2009, *Commission* v *Ireland and Others*, C-89/08 P, EU:C:2009:742, paragraph 56). That maxim cannot, however, mean that annexes to the application relating to the interpretation of EU law are inadmissible.

103 Moreover, the objection of inadmissibility raised by the Commission seems to be motivated by the fact that the two annexes at issue contain opinions given for the benefit of the applicants by Sir Jacobs and Ms Macken, in their capacity as lawyers, but whose status as former Members of the Court of Justice of the European Union is well known, and that the applicants are relying on that latter status. When the Commission was asked at the hearing whether, through its challenge to the admissibility of the legal opinions thus given, it intended to rely on the failure of those former members of the Court of Justice to fulfil their obligations under the Code of Conduct of the Members of the Court of Justice of the European Union (OJ 2007 C 223, p. 1), in particular under Article 6 of that Code of Conduct, concerning the undertakings of Members after ceasing to hold office, the Commission replied that it did not intend to do so. The Court took formal notice of this in the minutes of the hearing.

104 In the alternative, the Commission argues that, according to the case-law, a legal opinion annexed to an application is admissible only to support and supplement the essential elements which must be included in the application, provided that the relevant parts of the documents annexed are identified and referenced in the application. In the present case, with respect to certain pleas, the texts and arguments in Annexes A 2 and A 3 to the application contain most, if not all, of the applicants' arguments.

105 It must be borne in mind, in that regard, that, according to the case-law set out in paragraph 90 above, under Article 21 of the Statute of the Court of Justice of the European Union and Article 44(1)(c) of the Rules of Procedure of the General Court of 2 May 1991, applicable at the time the action was brought, each application is required to state the subject matter of the proceedings and a summary of the pleas in law on which the application is based, and it is necessary, in order for an action to be admissible, that the basic legal and factual particulars relied on be indicated, at least in summary form, coherently and intelligibly in the text of the application itself.

106 Whilst the body of the application may be supported and supplemented on specific points by references to extracts from documents annexed thereto, a general reference to other documents, even those annexed to the application, cannot make up for the absence of the essential arguments in law which, in accordance with the abovementioned provisions, must appear in the application. Furthermore, it is not for the Court to seek and identify in the annexes the pleas and arguments on which it may consider the action to be based, since the annexes have a purely evidential and instrumental function (see judgment of 17 September 2007, *Microsoft* v *Commission*, T-201/04, EU:T:2007:289, paragraph 94 and the case-law cited). Consequently, in the present case, the Court can take into consideration Annexes A 2 and A 3 to the application only in so far as they support or supplement pleas or arguments expressly set out by the applicants in the body of the application and

in so far as it is possible for the Court to determine precisely what are the matters they contain that support or supplement those pleas or arguments (judgment of 17 September 2007, *Microsoft* v *Commission*, T-201/04, EU:T:2007:289, paragraph 99).

107 As regards, more particularly, Annex A 2 to the application, it must be held, contrary to what the Commission submits, that the essence of the applicants' arguments is indeed contained in the body of the application and that the elements set out in that annex merely support and supplement, on specific points, the pleas and arguments contained in the body of the application, which it is easy for the Court to identify.

108 For example, the applicants stated, in paragraph 103 of the application, that the contested decision acknowledged that patent dispute settlements between competitors had in general a legitimate objective and that certain Member States encouraged the seeking of settlements. In paragraph 24 of Annex A 2 to the application, to which paragraph 103 of the application refers, it is likewise stated that there is a strong public interest in the settlement of disputes, that many national legal systems encourage, or even require, the seeking of a settlement as a pre-condition for bringing court proceedings, and that the contested decision, in that it constitutes a restriction on the right to reach a settlement, runs counter to that policy and results in the imposition of unnecessary costs on the parties and the courts. Since the applicants therefore put forward, in paragraph 24 of Annex A 2 to the application, arguments which merely support and supplement the elements expressly relied on in the body of the application, those arguments are admissible.

109 With regard to paragraphs 29 and 818 of the application, in connection with which the Commission claims that the applicants merely referred to Sir Jacobs' opinion, it should be noted that the applicants set out in detail in paragraphs 816 to 822 of the application the reasons why the Commission could not, in their view, impose a fine on them on account of the unprecedented and unforeseeable nature of the position adopted by the Commission and that paragraphs 70 and 76 of Annex A 2 to the application do not contain new arguments or discussions in that regard.

110 As regards paragraph 147 of the application, in which the applicants state that the approach which they propose to adopt in order to identify settlement agreements contrary to the provisions of Article 101 TFEU is consistent with the position adopted by the judgment of the Supreme Court of the United States of 17 June 2013, *Federal Trade Commission* v. *Actavis* (570 U. S. (2013), 'the *Actavis* judgment'), it must be observed that that paragraph refers, by means of footnote 153, to paragraphs 32 and 33 of Annex A 2. However, in paragraph 32 of that annex, the applicants merely support that argument and, in paragraph 33 of that annex, they confine themselves to arguing that the scope of the *Actavis* judgment cannot be limited to a national context unconnected with EU law and that the view of the Supreme Court of the United States deserves particular respect, given its reputation and experience in competition law. Consequently, those arguments are admissible.

111 As regards Annex A 3 to the application, it must be held, as the Commission argues, that, although, in paragraph 11 of the application, the applicants maintain that the Commission's attitude is not neutral with regard to intellectual property rights, they nevertheless merely refer to paragraphs 8, 15, 31, 34 and 41 of Annex A 3 to the application, in which Ms Macken puts forward arguments relating to (i) the need to draw a distinction between the various areas of intellectual property, (ii) the fact that the granting of a monopoly over patents is the quid pro quo for the disclosure of the invention to the public, (iii) the erroneous use of the concept of 'market exclusivity' by the Commission in the contested decision and (iv) a misinterpretation by the Commission of the EPC. Consequently, those arguments are not admissible, with the exception of that relating to the fact that the granting of a monopoly over patents is the quid pro quo for the disclosure of the invention to the public. In paragraph 67 of the application, the applicants referred to the fact that the Commission 'completely disregarded that essential aspect of patents, namely their publication for the purpose of disseminating inventions'.

112 Similarly, in paragraph 68 of the application, the applicants claim that the Commission cited in a biased way the statements of the Court of Appeal (England & Wales) (Civil division) in the judgment of 9 May 2008 dismissing Servier's appeal against the judgment of the High Court of Justice (England & Wales), Chancery Division (Patents Court), and criticise the Commission for not taking into account the report of Professor S. annexed to their response to the statement of objections in that regard. They also refer to paragraphs 113 to 117 of Annex A 3 to the application. In those paragraphs, Ms Macken does not merely supplement or expand on those arguments, but puts forward arguments relating to the Commission's alleged misuse of evidence which allowed it to conclude that the 947 patent was invalid. She thus sets out arguments seeking to call into question the Commission's interpretation of the statement by the applicant's Patent Director referred to in recitals 127 and 185 of the contested decision, of the statement by Krka's legal adviser referred to in recital 883 of that decision and of the statement by Krka's sales manager for western Europe referred to in paragraph 895 of that decision. Consequently, those arguments are not admissible.

113 With regard to paragraph 76 of the application, it is also necessary to hold, as the Commission points out, that, although the applicants stated in footnote 79 of the application that the sending of letters of formal notice was lawful, they merely referred to paragraphs 58 to 67 of Annex A 3 to the application to explain the grounds supporting a finding that the sending of such letters is lawful. The arguments put forward in Annex A 3 to the application on that point are therefore not admissible.

114 In paragraph 103 of the application, the applicants merely pointed out that the contested decision acknowledged that patent dispute settlements between competitors had in general a legitimate objective and that certain Member States encouraged the seeking of settlements. However, paragraphs 50 to 54 of Annex A 3 to the application, to which paragraph 103 of the application refers (footnote 113), criticise the Commission for not having adequately assessed the settlement practices used worldwide, which are set out in detail.

115 With regard to paragraph 46 of the reply, the applicants argue that the idea that it would be preferable for any litigation to result in a judgment is 'contrary to current thinking in relation to judicial proceedings', referring to paragraph 112 of Annex A 3 to the application, which states that the Commission's approach is contrary to Directive 2008/52/EC of the European Parliament and of the Council of 21 May 2008 on certain aspects of mediation in civil and commercial matters (OJ 2008 L 136, p. 3). Since those arguments do not merely support or supplement the elements expressly relied upon in the body of the application, they are inadmissible.

116 Finally, in paragraph 262 of the application, the applicants stated that it was of primary importance for Teva to be among the first generic undertakings to enter the market in the United Kingdom, referring to paragraph 90 of Annex A 3 to the application. Contrary to what the Commission maintains, in that paragraph of Annex A 3 to the application, the applicants have merely supported and supplemented that assertion by setting out the reasons why a generic undertaking has an interest in entering a market only if it is among the first entrants. Accordingly, the arguments put forward in Annex A 3 to the application on that point are admissible.

B. Substance

1. Infringement of the principle of impartiality and of the right to sound administration

(a) Arguments of the parties

…

(b) Findings of the Court

119 As a preliminary point it should be noted that the guarantees afforded by the EU legal order in administrative proceedings include, in particular, the principle of sound administration, affirmed in Article 41 of the Charter of Fundamental Rights, which entails the duty of the competent institution to examine carefully and impartially all the relevant aspects of the individual case (judgments of 30 September 2003, *Atlantic Container Line and Others* v *Commission*, T-191/98 and T-212/98 to T-214/98, EU:T:2003:245, paragraph 404, and of 27 September 2012, *Shell Petroleum and Others* v *Commission*, T-343/06, EU:T:2012:478, paragraph 170). That requirement of impartiality encompasses, on the one hand, subjective impartiality, in so far as no member of the institution concerned who is responsible for the matter may show bias or personal prejudice, and, on the other hand, objective impartiality, in so far as there must be sufficient guarantees to exclude any legitimate doubt as to bias on the part of the institution concerned (see judgment of 11 July 2013, *Ziegler* v *Commission*, C-439/11 P, EU:C:2013:513, paragraph 155 and the case-law cited). It is also important to note that the Commission may not be classified as a 'tribunal' within the meaning of Article 6 of the Convention for the Protection of Human Rights and Fundamental Freedoms, signed in Rome on 4 November 1950 ('the ECHR'), and it is thus Article 41 of the Charter of Fundamental Rights, not Article 47 thereof, which governs the administrative procedure relating to restrictive practices before the Commission (see judgment of 11 July 2013, *Ziegler* v *Commission*, C-439/11 P, EU:C:2013:513, paragraph 154 and the case-law cited).

120 The applicants rely on two judgments of the European Court of Human Rights ('the ECtHR'). In the first place, the applicants rely on the judgment of the ECtHR of 25 March 2008, *Vitan v. Romania* (CE:ECHR:2008:0325JUD004208402), relating to the presumption of innocence, enshrined in Article 6(2) of the ECHR, in which the ECtHR found a breach of that provision, because the prosecutor in charge of the criminal investigation relating to the applicant had stated at a press conference that the applicant was guilty of trading in influence, although the applicant's guilt had not yet been lawfully established, and the prosecutor had not 'qualified his remarks or taken care to place them in the context of the proceedings pending against the applicant' (paragraphs 70 and 71). In that respect, it is important to recall that, according to the case-law of the ECtHR, the principle of the presumption of innocence may be infringed not only by a court or tribunal but also by other public authorities, that it is appropriate to emphasise the importance of the choice of words used by State officials in the statements they make before a person has been tried and convicted of an offence and that what matters for the purposes of the application of Article 6(2) of the ECHR is the actual meaning of the statements in question and not their literal form (see ECtHR, 15 March 2011, *Begu v. Romania*, CE:ECHR:2011:0315JUD002044802, paragraph 126 and the case-law cited). The ECtHR nevertheless acknowledges that Article 6(2) of the ECHR cannot prevent, in the light of Article 10 thereof, which protects freedom of expression, the authorities from informing the public about criminal investigations in progress, but it requires that they do so with all the discretion and circumspection necessary if the presumption of innocence is to be respected (ECtHR, 10 February 1995, *Allenet de Ribemont v. France*, CE:ECHR:1995:0210JUD001517589, paragraph 38).

121 In the second place, the applicants rely on the judgment of the ECtHR of 16 September 1999, *Buscemi v. Italy* (CE:ECHR:1999:0916JUD002956995), in which the ECtHR found that there had been a breach of Article 6(1) of the ECHR and of the right of every person to a fair hearing by an independent and impartial tribunal, where the President of the court publicly used expressions which implied that he had already formed an unfavourable view of the applicant's case before presiding over the court that had to decide it (paragraphs 68 and 69). In that judgment, the ECtHR also recalled that the judicial authorities were required to exercise maximum discretion with regard to the cases with which they deal in order to preserve their image as impartial judges and that that discretion should dissuade them from making use of the press, even when provoked (paragraph 67). It should be recalled, however, that in the case-law of the EU Courts the Commission cannot be described as a 'court' within the meaning of Article 6 of the ECHR (see paragraph 119 above).

122 The applicants rely, moreover, on the judgment of 8 July 2008, *Franchet and Byk* v *Commission* (T-48/05, EU:T:2008:257, paragraphs 210 to 219), in which the General Court found, within the context of an action for compensation, an infringement by the European Anti-Fraud Office (OLAF) of the principles of the presumption of innocence and sound administration and of its obligation of confidentiality, in that it provoked the disclosure in the press of sensitive elements of ongoing investigations and stated that the applicants were likely to have committed a '"vast enterprise of looting" of European Union funds' (paragraph 216).

123 Moreover, the Court has already provided clarification concerning the duty of impartiality and the principle of sound administration which the Commission is required to observe in competition law cases. Accordingly, in the judgment of 20 March 2002, *ABB Asea Brown Boveri* v *Commission* (T-31/99, EU:T:2002:77, paragraphs 99 to 107), the Court rejected a plea alleging infringement of the principle of sound administration in a case in which the applicant had, at its hearing before the Commission, been subject to a derogatory remark concerning its reputation and to a series of tendentious questions about facts which it no longer disputed, on the part of a Commission official dealing with the case which led to the contested decision, and in which the same official had, at a conference on issues of competition law held before the adoption of the Commission's decision, expressed his views using a quotation casting discredit on the applicant's activities. Indeed, while acknowledging that those remarks showed regrettable behaviour and language on the part of a member of the team responsible for dealing with the case and recalling that the Commission's Director-General of the Directorate-General for Competition had apologised to the applicant following the remark made at the conference, the Court held that those remarks were not of such a kind as to cast doubt on the degree of care and impartiality with which the Commission conducted its investigation into the infringement at issue and that the regrettable conduct on the part of a member of the team dealing with a case did not in itself vitiate the legality of the decision adopted by the College of Commissioners.

124 As regards the combining by the Commission of the functions of investigation and punishment of infringements of the competition rules, the Court of Justice has ruled that it was not in itself contrary to Article 6 of the ECHR as interpreted by the ECtHR (see, to that effect, judgment of 18 July 2013, *Schindler Holding and Others* v *Commission*, C-501/11 P, EU:C:2013:522, paragraphs 33 and 34) and the General Court has held that it did not constitute an infringement of the requirement of impartiality (see, to that effect, judgment of 27 June 2012, *Bolloré* v *Commission*, T-372/10, EU:T:2012:325, paragraphs 65 to 67). The absence of separation between the functions of investigation and punishment within the Commission does, however, entail a particular responsibility on the part of the members of that institution, in particular on the part of the Commissioner responsible for competition, to avoid any bias in the investigation and conduct of infringement proceedings, since they have the power to punish the undertakings concerned at the end of those proceedings.

125 The Court has, moreover, held that the Commission's assertion that it is determined that the members of anticompetitive cartels should not escape, on procedural grounds, the penalties applicable under EU law is not an infringement of the principle of impartiality but merely the assertion of a clear intention, wholly consistent with the task entrusted to the Commission, of making good, on a case-by-case basis, the procedural irregularities found, in order not to undermine the effectiveness of EU competition law (judgment of 27 June 2012, *Bolloré* v *Commission*, T-372/10, EU:T:2012:325, paragraphs 73 and 74).

126 It should also be borne in mind that the EU judicature — in order to reject a plea alleging infringement of the right to a fair trial or of the principle of sound administration, based on the public positions adopted by the Commission or one of its representatives during the administrative procedure — has already relied on the ground that there was nothing in the Court's file to support the presumption that the contested decision would not have been taken, or would have been drawn up in a different way, if the public statements which are the subject matter of this submission had not been made (see, to that effect, judgments of 16 December 1975, *Suiker Unie and Others* v *Commission*, 40/73 to 48/73, 50/73, 54/73 to 56/73, 111/73, 113/73 and 114/73, EU:C:1975:174, paragraph 91, and of

7 July 1994, *Dunlop Slazenger* v *Commission*, T-43/92, EU:T:1994:79, paragraph 29). According to the case-law, it is thus for the applicant to produce at least some indicia to support such a conclusion (judgment of 15 March 2006, *BASF* v *Commission*, T-15/02, EU:T:2006:74, paragraph 606).

127 It is also important to recall that the functioning of the Commission is governed by the principle of collegiate responsibility laid down in Article 250 TFEU, which is based on the equal participation of the Commissioners in the adoption of decisions, from which it followed in particular that decisions should be the subject of collective deliberation and that all the members of the College of Commissioners should bear collective responsibility at political level for all decisions adopted. This is particularly so in the case of acts which are expressly described as decisions which the Commission finds necessary to adopt with regard to undertakings for the purpose of ensuring observance of the competition rules and by which it finds an infringement of those rules, issues directions to those undertakings and imposes pecuniary sanctions upon them. The operative part of, and the statement of reasons for, a decision constitute an indivisible whole and it is therefore for the College of Commissioners alone to adopt both the operative part and the statement of reasons, in accordance with the principle of collegiate responsibility (judgment of 27 September 2012, *Heijmans Infrastructuur* v *Commission*, T-359/06, not published, EU:T:2012:489, paragraphs 126 and 127). The Court has also held, in matters relating to State aid, that the expression of an opinion by the Commissioner responsible for competition matters on a procedure in progress is, in so far as it is strictly personal and without prejudice, attributable to that Commissioner alone and does not predetermine the position that the College of Members of the Commission will adopt at the end of the procedure (judgment of 8 July 1999, *Vlaamse Televisie Maatschappij* v *Commission*, T-266/97, EU:T:1999:144, paragraphs 49 and 54). Moreover, it cannot be assumed that the Commissioners were constrained in their freedom of assessment by a misplaced feeling of solidarity towards their colleague with responsibility for competition matters (judgment of 15 March 2006, *BASF* v *Commission*, T-15/02, EU:T:2006:74, paragraph 610).

128 As regards objective impartiality, which refers to the fact that the institution must provide sufficient guarantees to exclude any legitimate doubt, it should be pointed out that the Commission, as it stated at the hearing in reply to a question from the Court, has adopted several internal documents requiring it to comply with certain rules when communicating publicly. In particular, the Code of Conduct for Commissioners (C(2011) 2904), adopted in 2011, provides in Article 1.7 thereof that, in accordance with the principle of collegiality, Members of the Commission are to refrain from making any comment that would call into question a decision taken by the Commission and are also to refrain from disclosing what is said at meetings of the Commission. Moreover, the Annex to Decision 2000/633/EC, ECSC, Euratom of 17 October 2000 amending its Rules of Procedure (OJ 2000 L 267, p. 63), entitled 'Code of good administrative behaviour for Staff of the European Commission in their relations with the public', states in its provisions that 'quality service calls for the Commission and its staff to be courteous, objective and impartial', and in paragraph 2 thereof, concerning objectivity and impartiality, that 'staff shall always act objectively and impartially, in the [European Union] interest and for the public good' and that 'they shall act independently within the framework of the policy fixed by the Commission and their conduct shall never be guided by personal or national interest or political pressure'. Similarly, the Code of Ethics and Integrity of DG Competition, adopted on 28 June 2010, recommends that its staff, with regard to freedom of expression, avoid any discussion of a case concerning which the Commission has not adopted an official position and, with regard to contacts with the media, avoid talking about a case which is still the subject of investigation and in respect of which the Commission has not adopted an official position.

129 The applicants claim that the Ombudsman has already established an instance of maladministration concerning the Commissioner responsible for competition who was in office when the contested decision was adopted, in so far as he had, as in the present case, made public statements suggesting that he had already reached a conclusion before the end of the investigation.

130 In that regard, it should be recalled that a finding by the Ombudsman of an 'act of maladministration' is not binding on the Courts of the European Union and can constitute nothing more than an indication of infringement, by the institution concerned, of the principle of sound administration. Proceedings before the Ombudsman, who does not have the power to make binding decisions, are for EU citizens an extrajudicial alternative remedy to an action before those Courts, which meets specific criteria and does not necessarily have the same objective as legal proceedings (judgment of 25 October 2007, *Komninou and Others* v *Commission*, C-167/06 P, not published, EU:C:2007:633, paragraph 44). A fortiori, interpretations of EU law by the Ombudsman are incapable of binding the Courts of the European Union.

131 In the present case, as regards subjective impartiality, which relates to the fact that a member of the institution concerned who is responsible for the case must not show bias or personal prejudice, the applicants criticise each of the consecutive Commissioners for Competition, Ms N. Kroes and Mr J. Almunia, for having made, on three occasions, public comments on the outcome of the investigation relating to the applicants during the administrative procedure. As the applicants pointed out at the hearing, those two Commissioners were still in office within the Commission when the contested decision was adopted, were involved in adopting it and were directly responsible for the investigation of the case at various times. Moreover, the contested decision is signed by Mr Almunia.

132 In the first place, it is apparent from the file that, at the press conference on the presentation of the conclusions of the pharmaceutical sector inquiry report, Ms Kroes stated that 'unfortunately, the report confirm[ed] that there [we]re competition problems in the pharma sector', that 'company practices [we]re a significant factor behind them' and that, 'in particular, the report conclude[d] that makers of original medicines [we]re actively trying to delay the entry of generic medicines onto their markets' (speech published on the DG Competition website). According to the applicants, Ms Kroes further stated that 'overall it is indeed a conclusion that there [wa]s something rotten in the state' (extract from the website of the *EU Observer* online newspaper). The Commission submits in the rejoinder that those remarks were merely reported by a journalist and that the article confirms that the term 'rotten' related to the sector inquiry and not to the applicants. At the same press conference, the same Commissioner for Competition referred, in a separate part entitled 'Competition cases and scrutiny', to the opening of proceedings against the applicants and certain generic undertakings, stating that 'it concern[ed] suspected breaches of the [FEU] Treaty's rules on both restrictive business practices (Article [101 TFEU]) and abuse of a dominant market position (Article [102 TFEU])', that 'the case w[ould] look at the agreements between Servier and a number of generic companies' and that 'these agreements [had] affected the entry of generic competitors against perindopril, a leading drug that combat[ed] heart-disease and high blood pressure'. The Commissioner for Competition therefore clearly distinguished the results of the sector inquiry from the decision to initiate proceedings against the applicants. As regards the latter, the Commissioner for Competition was careful to point out that potential infringements of the competition rules were at issue. The mere circumstance that she referred, in the following sentence, to the fact that the agreements in question had affected the entry of generic medicines into the market cannot, in itself, imply that she considered that an infringement of the competition rules had taken place, in the light of the context referred to in the preceding sentence. At that press conference, the Commissioner for Competition therefore merely informed the public about investigations in progress, with the discretion and circumspection necessary if the presumption of innocence is to be respected.

133 In the second place, on 8 October 2012, during a speech to the European Parliament presenting the Commission's competition policy work programme for 2013-2014, Mr Almunia referred, in particular, to the procedure relating to the agreements at issue, stating that, 'in the pharmaceutical industry, … and Servier [had] received [the Commission's] objections before the summer', that he was 'concerned that these companies misused their patents to keep markets closed to cheap generic medicines' and that he 'hope[d] that the decisions [which would be] adopt[ed] — hopefully in 2013 — [would] change current practices by some players in the industry that le[ft] a lot to be desired' (speech published on the DG Competition website). By stating that the Commission had sent a statement of

objections to the applicants and to other undertakings in the present case and in another case and that decisions would be adopted in 2013, the Commissioner did not fail to fulfil his obligation of impartiality, however, and merely informed Parliament about investigations in progress, with the discretion and circumspection necessary if the presumption of innocence is to be respected. Indeed, it is necessary to recall the preliminary nature of the statement of objections, the function of that document, as defined by the European Union regulations, being to give undertakings all the information necessary to enable them properly to defend themselves, before the Commission adopts a final decision (see judgment of 27 September 2012, *Koninklijke Wegenbouw Stevin* v *Commission*, T-357/06, EU:T:2012:488, paragraph 43 and the case-law cited). Although the Commission, under Article 27(1) of Regulation No 1/2003, must thus base its final decision only on objections on which the parties have been able to comment, it is not required to reproduce all the evidence set out in the statement of objections, particularly if that evidence appears insufficient. It is therefore inherent in the nature of the statement of objections that it is provisional and subject to amendments to be made by the Commission in its further assessment on the basis of the observations submitted to it by the parties and subsequent findings of fact (judgment of 10 July 2008, *Bertelsmann and Sony Corporation of America* v *Impala*, C-413/06 P, EU:C:2008:392, paragraph 63). Moreover, following communication of the statement of objections, by which the Commission considers on first analysis that an infringement has been committed, the duty of circumspection of the Commissioner for Competition need not necessarily be so broad, since that Commissioner may, in public statements, set out with all due caution, as regards a provisional assessment, the allegations made against an undertaking at that stage of the procedure.

134 In the third place and finally, it is apparent from the file that, on 12 April 2013, Mr Almunia stated, in a speech to the American Bar Association in Washington which was transcribed in the press, that 'the Commission … [would] decide in the coming months on the legality of agreements between pharmaceutical undertakings seeking to delay the entry into the market of cheaper generic medicines' and that 'the results of the sector inquiry will be reflected in decisions in the … and Servier cases' (extract from the MLex website). It should be emphasised that that article only indirectly reports the remarks of the Commissioner. Moreover, even if the Commissioner for Competition actually made those remarks, they can be interpreted only as meaning that there was a possibility that a decision might be adopted in the case at issue (see, to that effect and by analogy, judgment of 8 July 1999, *Vlaamse Televisie Maatschappij* v *Commission*, T-266/97, EU:T:1999:144, paragraph 53). Therefore, the Commissioner for Competition merely informed the public about investigations in progress, with the discretion and circumspection necessary if the presumption of innocence is to be respected. In any event, it must be borne in mind that those remarks were merely the expression of the Commissioner for Competition's opinion on an ongoing procedure, and were attributable to that Commissioner alone and did not predetermine the position that the College of Members of the Commission adopted at the end of the procedure (see paragraph 127 above).

135 Consequently, there is no need to examine the applicants' argument that the contested decision would have been different in the absence of those statements by the Commissioners.

136 In support of this plea, the applicants also criticise the Commissioner for Competition and his cabinet for not having been present during most of the hearing. However, the fact, emphasised at the hearing by the applicants, that Mr Almunia did not attend their hearing before the Commission and was represented by a member of his cabinet is not such as to establish that the decision to impose a penalty had already been adopted, in principle, even before that hearing. Moreover, there is no provision requiring the participation of the Commissioner or a member of his cabinet at the hearing. The EU Courts take the view that the principle of proper administration cannot transform into an obligation that which the legislature did not view as being one (see, to that effect, judgment of 27 September 2012, *Koninklijke Wegenbouw Stevin* v *Commission*, T-357/06, EU:T:2012:488, paragraph 242).

137 The applicants also complain that the Commission failed to comply with the applicable rules and standards of evidence, referring to several recitals of the contested decision which they contest in other pleas in their application (distortion of the facts, error in the legal criterion applicable to the classification of an infringement by object, an unreasonable interpretation of the concept of potential competition, etc.). In the reply, they argue that those examples are intended to establish bias vitiating the investigation. As claimed by the Commission, that line of argument of the applicants is, however, indissociable from the question whether the findings of fact made in the contested decision are duly supported by the evidence which the institution has produced and whether the Commission committed errors of law in its analysis (see, to that effect, judgment of 24 October 1991, *Atochem* v *Commission*, T-3/89, EU:T:1991:58, paragraph 39). Consequently, those arguments will be examined subsequently, in the context of the substantive pleas. In any event, it must be pointed out that those arguments are based on mere assertions and are not such as to show that the Commission did in fact pre-judge the outcome of the administrative procedure or lacked objectivity in its investigation (see, to that effect, judgment of 6 July 2000, *Volkswagen* v *Commission*, T-62/98, EU:T:2000:180, paragraph 272).

138 Lastly, the applicants argue that the absence of a re-examination of the case by an internal panel within DG Competition demonstrates the partiality of the contested decision and justifies its annulment on the grounds of infringement of the principle of the presumption of innocence and of Article 41 of the Charter of Fundamental Rights. However, it is important to note that no provision of a regulation or internal rule of the Commission requires that the Commission organise a re-examination of every case by an internal panel and to recall that the principle of proper administration cannot transform into an obligation that which the legislature did not view as being one (see paragraph 136 above). A peer review system was indeed set up within DG Competition in 2004. Nevertheless, it is apparent from a document published in September 2011 by the Commission, entitled 'Procedure for the application of Articles 101 and 102 TFEU: key players and the balance of power', that the Director-General of DG Competition determines, in agreement with the Commissioner for Competition, the cases in which that internal panel is organised, that the decision to form such a panel and its composition are not made public and that the peer review of a case under no circumstances involves the parties to the proceedings or any other third party. The organisation of such a re-examination by DG Competition is therefore not required in all cases, with the result that the Commission cannot be criticised for not having organised such a re-examination in the present case.

139 The plea must therefore be rejected.

2. The lack of effective consultation of the Advisory Committee on Restrictive Practices and Dominant Positions

(a) Arguments of the parties

…

(b) Findings of the Court

142 Article 14(1) of Regulation No 1/2003, which is contained in Chapter IV on cooperation between the Commission and the competition authorities and courts of the Member States, provides that 'the Commission shall consult an Advisory Committee on Restrictive Practices and Dominant Positions prior to the taking of any decision under Articles 7, 8, 9, 10, 23, Article 24(2) and Article 29(1)' of that regulation. Article 14(2) of Regulation No 1/2003 provides that 'for the discussion of individual cases, the Advisory Committee shall be composed of representatives of the competition authorities of the Member States'. Article 14(3) of Regulation No 1/2003 stipulates that the Advisory Committee is to

deliver a written opinion on the Commission's preliminary draft decision and Article 14(5) of that regulation provides that 'the Commission shall take the utmost account of the opinion delivered by the Advisory Committee' and 'shall inform the Committee of the manner in which its opinion has been taken into account'. Furthermore, 'at the request of one or several members, the positions stated in the opinion shall be reasoned' (Article 14(3) of Regulation No 1/2003). Paragraph 58 of the Commission Notice on cooperation within the Network of Competition Authorities (OJ 2004 C 101, p. 43, 'the Notice on cooperation within the Network of Competition Authorities') provides that 'the Advisory Committee is the forum where experts from the various competition authorities discuss individual cases and general issues of [EU] competition law'.

143 As regards procedure, Article 14(3) of Regulation No 1/2003 provides that the consultation of the Advisory Committee 'may take place at a meeting convened and chaired by the Commission, held not earlier than 14 days after dispatch of the notice convening it, together with a summary of the case, an indication of the most important documents and a preliminary draft decision'. Nevertheless, 'where the Commission dispatches a notice convening the meeting which gives a shorter period of notice than those specified above, the meeting may take place on the proposed date in the absence of an objection by any Member State'. Paragraph 66 of the Notice on cooperation within the Network of Competition Authorities states that 'the Council Regulation allows for the possibility of the Member States agreeing upon a shorter period of time between the sending of the invitation and the meeting'. Article 14(3) of Regulation No 1/2003 provides, moreover, that the Advisory Committee 'may deliver an opinion even if some members are absent and are not represented'. Article 14(4) of Regulation No 1/2003 provides, lastly, that 'consultation may also take place by written procedure', but that 'if any Member State so requests, the Commission shall convene a meeting'. According to that provision, 'in case of written procedure, the Commission shall determine a time limit of not less than 14 days within which the Member States are to put forward their observations for circulation to all other Member States'.

144 The document entitled 'Working Arrangements for the Antitrust Advisory Committee' of 19 December 2008, adduced by the Commission on 6 November 2015 in response to a measure of organisation of procedure, sets out the various steps leading up to the consultation of the Advisory Committee and, in particular, those allowing the national competition authorities to assess the case as the investigation progresses.

145 In the first place, it should be noted, in that respect, that, under Article 11(2) of Regulation No 1/2003, 'the Commission shall transmit to the competition authorities of the Member States copies of the most important documents it has collected with a view to applying Articles 7, 8, 9, 10 and Article 29(1)' of that regulation and, 'at the request of the competition authority of a Member State, the Commission shall provide it with a copy of other existing documents necessary for the assessment of the case'. Article 11(6) of Regulation No 1/2003 provides, in addition, that 'the initiation by the Commission of proceedings for the adoption of a decision under Chapter III shall relieve the competition authorities of the Member States of their competence to apply Articles [101 and 102 TFEU]' and that, 'if a competition authority of a Member State is already acting on a case, the Commission shall only initiate proceedings after consulting with that national competition authority'. Under those provisions, the Commission is to immediately deliver to the national competition authorities, after their notification to the undertaking concerned or their reception, the initial decision initiating the proceedings, the statement of objections addressed to that undertaking, the latter's response to that statement of objections and the other most important documents relating to the case (see paragraphs 6 and 7 of the Working Arrangements for the Antitrust Advisory Committee).

146 In the second place, the Working Arrangements for the Antitrust Advisory Committee provide, in paragraphs 33 to 36, that, for each case in which the Commission addresses a statement of objections to an undertaking, the Commission must, not later than 45 days following the notification of the statement of objections to the parties concerned, appoint one of the national competition authorities as the rapporteur in the case ('the NCA rapporteur'), on a rotating basis that corresponds to the rotating presidencies of the Council of the European Union, unless it is necessary to choose another

national competition authority in the interests of objectivity, in which case the Commission may, subject to the agreement of the first national competition authority, choose the next authority on that list of rotating presidencies (paragraphs 28, 33 and 34). The NCA rapporteur, who is responsible for helping the other national competition authorities to understand the case and for informing them of the significant procedural steps in the administrative proceedings, works to that end in close cooperation with the Commission (paragraphs 40 and 42). The Working Arrangements for the Antitrust Advisory Committee also recommend that the NCA rapporteur should circulate a list of key questions in the case not later than five days prior to the Advisory Committee meeting (paragraph 44(i)) and should present the case and its issues at the beginning of the Advisory Committee meeting (paragraph 44(ii)).

147 In the third place, according to Article 11(1) of Commission Regulation (EC) No 773/2004 of 7 April 2004 relating to the conduct of proceedings by the Commission pursuant to Articles [101 and 102 TFEU] (OJ 2004 L 123, p. 18), 'the Commission shall give the parties to whom it has addressed a statement of objections the opportunity to be heard before consulting the Advisory Committee referred to in Article 14(1) of Regulation … No 1/2003'. Article 14(3) of Regulation No 773/2004 provides, moreover, that 'the Commission shall invite the competition authorities of the Member States to take part in the oral hearing' and that 'it may likewise invite officials and civil servants of other authorities of the Member States'. Paragraph 12 of the Working Arrangements for the Antitrust Advisory Committee states that the participation of the national competition authorities in the oral hearing of a case is useful for the efficient functioning of the Advisory Committee. However, no provision stipulates that the NCA rapporteur is to play a particular role at the hearing.

148 According to the case-law on the corresponding provisions of Regulation No 17 of the Council of 6 February 1962, First Regulation implementing Articles [101 and 102 TFEU] (OJ, English Special Edition 1959-1962, p. 87), which was succeeded by Regulation No 1/2003, consultation of the Advisory Committee is an essential procedural requirement, breach of which affects the legality of the Commission's final decision if it is proved that the failure to comply with the rules on consultation prevented the Advisory Committee from delivering its Opinion in full knowledge of the facts. The substance of the obligations under the provisions governing the consultation of the Advisory Committee, and the question whether or not they constitute essential requirements, must therefore be determined in each case in the light of that purpose of enabling the committee to carry out its advisory task in full knowledge of the facts (see, to that effect, judgments of 10 July 1991, *RTE* v *Commission*, T-69/89, EU:T:1991:39, paragraphs 21 and 23, and of 15 March 2000, *Cimenteries CBR and Others* v *Commission*, T-25/95, T-26/95, T-30/95 to T-32/95, T-34/95 to T-39/95, T-42/95 to T-46/95, T-48/95, T-50/95 to T-65/95, T-68/95 to T-71/95, T-87/95, T-88/95, T-103/95 and T-104/95, EU:T:2000:77, paragraph 742).

149 In that regard, it was considered, with regard to the documents to be sent to the Advisory Committee, that, although that consultation falls within the framework of cooperation between the Commission and the Member States and is not intended to set up adversarial proceedings against the undertakings concerned, the committee must have, in particular, entirely objective information on the views and essential arguments expressed by the undertakings concerned in their comments on all the objections raised against them by the Commission once the investigation is completed. The minutes of the hearing are thus, in principle, among the 'most important documents' within the meaning of Article 10(5) of Regulation No 17, and must therefore be sent to the Advisory Committee when it is convened. However, it is not an essential procedural requirement that the minutes of the hearing be sent to the Advisory Committee unless, in a specific case, it proves necessary in order to enable the committee to deliver its Opinion in full knowledge of the facts, that is to say without being misled in a material respect by inaccuracies or omissions. That is not the case when the minutes of the hearing do not contain any important new information not contained in the written comments, accompanying the notice convening the Advisory Committee, made by the undertaking concerned in reply to the statement of objections. In such an event, the fact that the Commission did not send the minutes of the hearing to the Advisory Committee when it was convened does not affect the applicant's right to

a fair hearing and has no repercussions on the outcome of the consultation procedure. The omission cannot, therefore, render the whole administrative procedure invalid and thereby call into question the legality of the final decision (judgment of 10 July 1991, *RTE* v *Commission*, T-69/89, EU:T:1991:39, paragraphs 21 to 23).

150 Moreover, it was held that the fact that the Commission did not provide the exact amount of a proposed fine to the Advisory Committee did not constitute a breach of the essential procedural requirement to consult the Advisory Committee, since that committee was given all the essential information required to draw up an opinion concerning fines. The Advisory Committee must be kept informed only of the proposed criteria for imposing the fine (see, to that effect, judgment of 15 March 2000, *Cimenteries CBR and Others* v *Commission*, T-25/95, T-26/95, T-30/95 to T-32/95, T-34/95 to T-39/95, T-42/95 to T-46/95, T-48/95, T-50/95 to T-65/95, T-68/95 to T-71/95, T-87/95, T-88/95, T-103/95 and T-104/95, EU:T:2000:77, paragraphs 747 and 748). Paragraph 23 of the Working Arrangements for the Antitrust Advisory Committee thus points out the need to ensure the confidentiality of exchanges of views within the committee, in particular about the level of fines. Paragraph 24 of the Working Arrangements for the Antitrust Advisory Committee provides that, with respect to fixing the level of the fine, the Commission should distribute at the meeting of the Advisory Committee a document explaining the method of calculation chosen, with specific reference to 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 Guidelines on the method of setting fines'), that members of the Advisory Committee may request additional time to examine that document and that, at the end of the meeting, that document is to be returned to the Commission.

151 In the present case, in the first place, the applicants submit that the Commission did not effectively consult the Advisory Committee, based on the failure to send the part of the preliminary draft decision relating to the fines and the responses of the undertakings to the statement of objections, on the short notice period for the transmission of the contested preliminary draft decision to its members, on the omissions contained in the summary of the preliminary draft decision sent to the national competition authorities and on the insufficient reasoning for the Advisory Committee's opinion. Those arguments must be examined in the light of the documents in the file and, in particular, the factual details provided by the Commission on 6 November 2015, in response to the abovementioned measure of organisation of procedure, and at the hearing.

152 As regards the applicants' argument relating to the failure to send the part of the preliminary draft decision concerning the fines, the applicants withdrew it at the hearing, and formal notice of this was taken in the minutes of the hearing. Although, at the hearing, the applicants nevertheless argued that the national competition authorities had not received notification of the method of calculating the amount of the fine at the meetings of the Advisory Committee, that criticism has no basis in fact, since it is apparent from the file that, on 3 July 2014, Chapter 10, concerning the fines, a chapter containing an explanation of the main elements of that method, was sent by the Commission to the national competition authorities with a reminder of the invitation to the second meeting of the Advisory Committee of 7 July 2014. In that regard, it should be pointed out that the national competition authorities had previously received the responses of the undertakings to the statement of objections, on 23 July 2013, as well as a Letter of Facts, on 19 December 2013, and the replies of the undertakings to that letter, on 13 February 2014. Finally, on 20 May 2014, the Commission sent them a Letter of Facts concerning the imputation of the liability for the infringements and the replies of Mylan, Niche and Unichem to that letter.

153 As regards the notice period for the transmission of the draft decision, it is apparent from the file that the Commission sent that draft decision to the national competition authorities of the Member States in three steps: Chapters 1 to 4 were sent on 12 June 2014 with the invitation to the first meeting of the Advisory Committee on 30 June 2014, Chapters 5 to 9 were sent on 20 June 2014 with a summary of the draft decision and Chapter 10, concerning the fines (excluding the exact amount of those fines), was sent on 3 July 2014, with a reminder of the invitation sent on 30 June 2014 to the second

meeting of the Advisory Committee of 7 July 2014, which was to cover the entirety of the draft decision. In that regard, it is important to point out that, although, as the applicants claim, on page 109 of the DG Competition manual of procedure for competition policy matters, paragraph 10 provides that two meetings of that Committee are usually organised, one dealing with the substance of the case and the other with the amount of the fines, those provisions nonetheless do not require systematic compliance with that organisational arrangement. Moreover, it is clear from the file that, in the present case, the Commission expressly indicated, in the invitation to the second meeting, sent on 30 June 2014, and in the email of 3 July 2014, that the agenda for the meeting of 7 July 2014 concerned the discussion of the case in its entirety.

154 It is true that that staggered transmission of the documents, which in some cases did not comply with the prescribed period of 14 days, showed some haste on the Commission's part — probably linked to the fact that it had, as from its transmission of the invitation to the meeting of 30 June 2014, announced to the national competition authorities that it intended to adopt its decision on 9 July 2014 — and that it did not place the members of the Advisory Committee in the best conditions to express their views. However, it must be noted that no national competition authority raised any objection to the dates of these meetings, even though, under Article 14(3) of Regulation No 1/2003, such objections would have prevented the meetings in question from being held. In addition, it is clear from the file that the Commission sent the national competition authorities, on 6 July 2009, the initial decision opening the proceedings, on 31 July 2012, the statement of objections addressed to the undertakings concerned, on 23 July 2013, the responses of the undertakings to the statement of objections, on 19 December 2013, a Letter of Facts, on 13 February 2014, the replies of the undertakings to that letter and, on 20 May 2015, a Letter of Facts concerning the imputation of the liability for the infringements and the replies of Mylan, Niche and Unichem to that letter. In addition, on 25 June 2014, the Commission sent the national competition authorities the draft final report drawn up by the Hearing Officer.

155 Consequently, although it may be regrettable, in particular, that Chapters 5 to 9 of the draft decision, given their length (approximately 600 pages) and complexity, were sent by the Commission to the national competition authorities of the Member States only 10 days before the first meeting of the Advisory Committee, it must be considered, in the light of all the considerations set out in paragraphs 153 and 154 above, that the members of the Advisory Committee were sufficiently informed of the substance of the case and of the content of the draft decision and that, consequently, the Advisory Committee was able to give its opinion in full knowledge of the facts.

156 It must also be noted that, contrary to the submissions of the applicants, neither Article 14(3) of Regulation No 1/2003 nor paragraph 66 of the Commission Notice on cooperation within the Network of Competition Authorities provides that the Commission must obtain the express prior agreement of the competition authorities of the Member States in order to derogate from the prescribed period of 14 days between the transmission of the invitation to the members of the Advisory Committee and the meeting of that committee. Indeed, it follows from Article 14(3) of Regulation No 1/2003 that, where the Commission dispatches a notice convening a meeting which gives a period of notice shorter than that stated above, it is for Member States to raise any objection in that respect, failing which the meeting is to take place on the date set by the Commission. Moreover, as regards the alleged infringement of the principle of sound administration, it is important to recall that that principle cannot transform into an obligation that which the legislature did not view as being one (see paragraph 136 above).

157 As regards the opinion delivered by the Advisory Committee, it must be borne in mind, first, that, under Article 14(6) of Regulation No 1/2003, that opinion is not published as a matter of course, the Court of Justice even holding that the failure to disclose the opinion to the undertakings concerned is not contrary to the principle of the right to a fair hearing (see, to that effect, judgment of 7 June 1983, *Musique Diffusion française and Others* v *Commission*, 100/80 to 103/80, EU:C:1983:158, paragraphs 35 and 36), and, secondly, that the provisions of Article 14(3) of Regulation No 1/2003

provide that the positions stated in that opinion are to be reasoned only at the request of one or several members of that committee, which was not the case here. Moreover, Article 27(2) of Regulation No 1/2003 provides that the parties which are the subject of the procedure conducted by the Commission under Article 101 TFEU do not have access to the correspondence exchanged between the Commission and the competition authorities of the Member States or between those competition authorities, including the documents drawn up pursuant to Articles 11 and 14 of that regulation. Furthermore, under Article 28(2) of Regulation No 1/2003, officials and servants of the Commission and of the competition authorities of the Member States are not to disclose information acquired or exchanged by them pursuant to that regulation and of the kind covered by the obligation of professional secrecy, and that obligation also applies to all representatives and experts of Member States attending meetings of the Advisory Committee pursuant to Article 14 of Regulation No 1/2003. Consequently, the applicants cannot effectively argue that the opinion given by the Advisory Committee was insufficiently reasoned. In addition, having regard to the applicable provisions, the fact that the opinion was brief and lacking in detail does not mean that the Advisory Committee did not have at its disposal all the elements necessary to reach a decision in full knowledge of the facts, nor that that committee did not deliver its opinion in full knowledge of the facts, even if its opinion was brief.

158 Lastly, the applicants claim that, since the summary of the preliminary draft decision sent by the Commission to the members of the Advisory Committee was partial and incomplete, the committee was not able to take a decision in full knowledge of the facts. However, it should be recalled, as the Commission argues, that the purpose of that summary is not to identify the arguments put forward by the undertaking concerned in its defence, but to facilitate discussion within the Advisory Committee on the wording of the preliminary draft decision. In any event, in the present case, it is clear from the Commission's reply to the measure of organisation of procedure that the Commission, in its summary accompanying the preliminary draft decision, presented the main points of that preliminary draft decision, highlighting the most difficult aspects of its analysis (criteria for identifying the existence of a restriction of competition by object, definition of the market, application of Article 102 TFEU). The mere fact that the Commission failed to mention, in that summary, the status of all the disputes relating to the 947 patent, the interpretation of the scope of certain stipulations in the settlement agreements, the facts subsequent to the invalidation of patent 947 by the EPO or the differences between the acquisition of Rolabo's technology and the technology of another company cannot lead to the conclusion that the Advisory Committee — which had, moreover, a considerable number of documents relating to the case and, in particular, the arguments put forward by the applicants in their observations on the statement of objections and on the Letter of Facts (see paragraphs 152 and 154 above) — was unable to give its opinion in full knowledge of the facts.

159 In the second place, the applicants maintain that the Advisory Committee was not properly consulted, in that only a small number of its members attended its meetings and the NCA rapporteur in the case, who had not been appointed within the prescribed period, was not present at the hearing of the parties and at the second meeting of the Advisory Committee.

160 The applicants complain that the Commission failed to appoint the NCA rapporteur not later than 45 days following the notification of the statement of objections and deliberately chose a national competition authority which had not been present at the hearing.

161 It is common ground that the Working Arrangements for the Antitrust Advisory Committee provide that the appointment of the NCA rapporteur is to be made, in principle, not later than 45 days following the notification of the statement of objections and on the basis of an objective criterion, that is to say, in principle, on a rotating basis that corresponds to the rotating presidencies of the Council (see paragraph 146 above). In the present case, it is apparent from the file that the procedure for appointing the NCA rapporteur commenced on 7 May 2014, that the appointment of the Bundeswettbewerbsbehörde (Federal Competition Authority, Austria, 'the BWB') as the NCA rapporteur was made on 3 June 2014 — or after the hearing but well before the meetings of the

Advisory Committee — and that it was made on the basis of an objective criterion, that is to say the order of the rotating presidencies of the Council. However, the mere infringement of the 45-day time limit for the appointment of the NCA rapporteur, an infringement acknowledged by the Commission at the hearing, cannot be regarded in the present case as having prevented the Advisory Committee from exercising its functions in full knowledge of the facts. Indeed, the NCA rapporteur's role in the understanding of the case by the national competition authorities and in providing them with information is particularly important only at the stage of preparing the meetings of the Advisory Committee (see paragraph 164 below) and, in the present case, at that stage of the procedure, the NCA rapporteur had been appointed. With regard to the appointment of the BWB as the NCA rapporteur, it is important to point out, first, that the applicants have not adduced any evidence to show that the appointment was linked to the absence of that national competition authority from the hearing of 15, 16, 17 and 18 April 2013 and, secondly, that the appointment was, in any event, made on the basis of a purely objective criterion, that is to say the order of the rotating presidents of the Council.

162 The applicants also claim that the Advisory Committee could not have reached a decision in full knowledge of the facts, since the NCA rapporteur attended neither the hearing of the parties of 15, 16, 17 and 18 April 2013 nor the Advisory Committee meeting of 7 July 2014. The Commission maintains that no provision is made for the mandatory participation of the NCA rapporteur at the hearing and submits that eight Member States were present at the hearing.

163 It is important to point out that, although paragraph 12 of the Working Arrangements for the Antitrust Advisory Committee states that the participation of the national competition authorities in the oral hearing of a case is useful for the efficient functioning of the Advisory Committee, there is, by contrast, no provision requiring the NCA rapporteur to participate in the hearing, as Article 14(3) of Regulation No 773/2004 provides solely that the competition authorities of the Member States are invited to take part in the oral hearing, especially since all the national competition authorities receive a copy of the minutes of the hearing. It may also be pointed out that, as the Commission argues, the national competition authorities were duly invited to participate in the hearing and eight of them were indeed represented (see, for a case in which the national competition authorities were not invited to the hearing, judgment of 21 September 2017, *Feralpi* v *Commission*, C-85/15 P, EU:C:2017:709, paragraphs 38 to 44). It is also appropriate to recall that the NCA rapporteur's role in the understanding of the case by the NCAs and in providing them with information is of particular importance before the Advisory Committee but not at the stage of the hearing. The Working Arrangements for the Antitrust Advisory Committee thus recommend that the NCA rapporteur circulates a list of key questions in the case — not later than five days prior to the first Advisory Committee meeting, seeking in particular to determine whether the NCAs can indicate their overall agreement with the preliminary draft decision, whether they have observations on certain aspects and whether they recommend publication of the opinion (paragraph 44(i)) — and presents the case and its issues at the beginning of the first Advisory Committee meeting (paragraph 44(ii)). However, it is clear from the file that the BWB actually had discussions with the Commission in order to draw up the list of questions sent by the Commission to the members of the Advisory Committee for examination and that it participated in the first meeting of the Advisory Committee, during which it presented its report, and it is not disputed by the applicants that, on that occasion, it fully played its role as the NCA rapporteur. Moreover, the mere fact that the Commission sent the other national competition authorities the list of the main issues in the case on the morning of 26 June 2014, that is four days before the first meeting of the Advisory Committee, while the Working Arrangements for the Antitrust Advisory Committee recommend that that period should be five days, is not sufficient to conclude that the Advisory Committee was not in a position to reach a decision in full knowledge of the facts. Contrary to what the applicants claim, the Commission was also not required to appoint another NCA rapporteur, since paragraph 38 of the Working Arrangements for the Antitrust Advisory Committee provides only for the possibility of replacing the natural person representing the national competition authority with another natural person from the same authority where necessary.

Therefore, the fact that, in the present case, the BWB attended neither the hearing of the parties on 15, 16, 17 and 18 April 2013 nor, regrettably, the second meeting of the Advisory Committee of 7 July 2015 did not prevent the Advisory Committee from reaching a decision in full knowledge of the facts.

164 As regards the complaint concerning the presence of a limited number of Member States at the meetings of the Advisory Committee, it is apparent from the file that, at the meeting of 30 June 2014, only five national competition authorities were represented (those of the Kingdom of Spain, the Italian Republic, the Republic of Austria, the Republic of Finland and the Kingdom of Sweden) and that, at the meeting of 7 July 2014, only two national competition authorities were represented (those of the Federal Republic of Germany and the Republic of Finland). It indeed follows that a limited number of representatives of Member States participated in the opinion delivered by the Advisory Committee in the present case, since, under paragraphs 20 and 21 of the Working Arrangements for the Antitrust Advisory Committee, only the observations and comments made by members present at the meeting are to be taken into account in the opinion of the Advisory Committee. When asked at the hearing about the reasons for such low participation and the possibility of postponement of the Advisory Committee meetings, the Commission stated that it had known about strikes on the railways and had contacted the members of the committee to ascertain whether they had specific comments but had not considered postponing the meetings.

165 Although it is true that, in such circumstances, it would have been appropriate for the Commission to postpone the meetings of the Advisory Committee, it cannot, however, be inferred from the low number of representatives of Member States at the meetings that the Commission disregarded the procedural requirement to consult the Advisory Committee in the present case.

166 It should be noted, first of all, that, although it may seem unusual and scarcely compatible with a certain conception of sound administration, no provision is made for any quorum rule for the adoption of opinions of the Advisory Committee. Moreover, Article 14(3) of Regulation No 1/2003 expressly provides that the Advisory Committee may deliver an opinion 'even if some members are absent and are not represented'. Next, it must be borne in mind that the Commission is required to enable the competition authorities of the Member States to participate in the Advisory Committee and that, in the present case, it took all the necessary steps to that end, since it sent them the invitations to the meetings of the Advisory Committee of 30 June and 7 July 2014 as well as all the necessary documents since the opening of the proceedings (see paragraphs 153 and 154 above) and that no objection was raised as regards the date of those meetings (see paragraph 154 above). Lastly, it should be noted that the Advisory Committee can act as a forum helping to safeguard the consistent application of the EU competition rules, as stated in recital 19 of Regulation No 1/2003, only if the competition authorities of the Member States are willing to cooperate effectively, since the Commission has no enforcement powers in that respect.

167 The plea must therefore be rejected.

3. Infringement of the right to an effective remedy, the rights of the defence and the principle of equality of arms

(a) Arguments of the parties

…

(b) Findings of the Court

170 It should be pointed out that the principle of effective judicial protection is a general principle of EU law to which expression is now given by Article 47 of the Charter of Fundamental Rights (judgment of 8 December 2011, *Chalkor* v *Commission*, C-386/10 P, EU:C:2011:815, paragraph 52). That principle comprises various elements; in particular, the rights of the defence, the principle of equality of arms, the right of access to a tribunal and the right to be advised, defended and represented (judgment of 6 November 2012, *Otis and Others*, C-199/11, EU:C:2012:684, paragraph 48). The principle of equality of arms, which is a corollary of the very concept of a fair hearing, implies that each party must be afforded a reasonable opportunity to present his case, including his evidence, under conditions that do not place him at a substantial disadvantage vis-à-vis his opponent (judgments of 6 November 2012, *Otis and Others*, C-199/11, EU:C:2012:684, paragraph 71, and of 12 November 2014, *Guardian Industries and Guardian Europe* v *Commission*, C-580/12 P, EU:C:2014:2363, paragraph 31).

171 The applicants claim that the constraints to which they were subject in lodging the application placed them at a substantial disadvantage vis-à-vis the Commission, which was not subject to any constraints of time or length in drafting the contested decision. It should, however, be recalled that, according to the case-law of the ECtHR on the interpretation of Article 6(1) of the ECHR, to which reference must be made in accordance with Article 52(3) of the Charter of Fundamental Rights, the 'right to a court' is not absolute. The exercise of that right is subject to limitations, inter alia as to the conditions for the admissibility of an action (judgment of 28 February 2013, *Review Arango Jaramillo and Others* v *EIB*, C-334/12 RX-II, EU:C:2013:134, paragraph 43). While the persons concerned should expect those rules to be applied, the application of such rules should nevertheless not prevent litigants from availing themselves of an available legal remedy (judgment of 28 February 2013, *Review Arango Jaramillo and Others* v *EIB*, C-334/12 RX-II, EU:C:2013:134, paragraph 43). The ECtHR thus considers that those limitations must not restrict a litigant's access in such a way or to such an extent that the very essence of the right is impaired, and such limitations will not be compatible with Article 6(1) of the ECHR if they do not pursue a legitimate aim or if there is not a reasonable relationship of proportionality between the means employed and the aim sought to be achieved (see ECtHR, 6 December 2011, *Anastasakis v. Greece*, CE:ECHR:2011:1206JUD004195908, paragraph 24 and the case-law cited).

172 According to settled case-law of the Court of Justice, the strict interpretation of European Union legislation concerning procedural time limits satisfies the requirement of legal certainty and the need to avoid any discrimination or any arbitrary treatment in the administration of justice (see judgment of 15 January 1987, *Misset* v *Council*, 152/85, EU:C:1987:10, paragraph 11 and the case-law cited, and order of 8 November 2007, *Belgium* v *Commission*, C-242/07 P, EU:C:2007:672, paragraph 16 and the case-law cited) and in no way affects the right to effective judicial protection (see, to that effect, order of 17 May 2002, *Germany* v *Parliament and Council*, C-406/01, EU:C:2002:304, paragraph 20). As the Commission argues, the principle of equality of arms does not require that the period allowed for bringing the action for annulment should be the same length as the administrative procedure. The purpose of the administrative procedure is to enable the Commission to carry out an investigation to determine whether a decision finding an infringement of Articles 101 and 102 TFEU must be adopted and to enable the undertakings to prepare their defence. It must be borne in mind, in that regard, that respect for the rights of the defence 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 (judgments of 7 June 1983, *Musique Diffusion française and Others* v *Commission*, 100/80 to 103/80, EU:C:1983:158, paragraph 10, and of 7 January 2004, *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, EU:C:2004:6, paragraph 66). To that effect, Regulation No 1/2003 provides that the parties are to be sent a statement of objections which must set forth clearly all the essential facts upon 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. For that reason, the Commission may, and even must, take into account the factors emerging from the administrative procedure in order, inter alia, to abandon such objections as have been shown to be unfounded (judgment of 7 January 2004, *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, EU:C:2004:6, paragraph 67).

173 In the present case, it must be held that, although, in accordance with the provisions of the sixth paragraph of Article 263 TFEU and Article 102(2) of the Rules of Procedure of 2 May 1991, the applicants had a period of 2 months and 10 days from the date of notification of the contested decision in which to bring an action against it, and although that period made the task of drafting the application particularly difficult, in view of the exceptional length of the contested decision, which was moreover notified during the summer period, they nevertheless had the opportunity to have many exchanges with the Commission in relation to the case during the administrative procedure. The Commission, for example, sent requests for information to the applicants in January 2009, August 2009 and then from December 2009 to May 2012. Furthermore, the applicants were invited to attend a number of state of play meetings from 2009 to 2012. On 27 July 2012, the Commission issued a Statement of Objections, to which the applicants submitted a reply on 14 January 2013. The applicants were subsequently heard on 15, 16, 17 and 18 April 2013, further state of play meetings were arranged and additional requests for information sent to the applicants. On 18 December 2013, the Commission granted the applicants access to evidence gathered or more widely disclosed after the Statement of Objections and sent a Letter of Facts to which the applicants replied on 31 January 2014. In addition, it is important to recall that, during the written phase of the proceedings before the Court, the applicants were able to benefit from all the extensions of the time limits which they had requested and therefore were not, broadly speaking, placed at a substantial disadvantage vis-à-vis the Commission in the present proceedings, in spite of the particular constraints to which they were subject in submitting the application.

174 As regards the length of the application, it should be recalled that, according to the case-law of the ECtHR, the rules relating to the formalities to be complied with in bringing an action are intended to ensure the sound administration of justice and that the persons concerned should expect those rules to be applied (ECtHR, 6 December 2011, *Anastasakis v. Greece*, CE:ECHR:2011:1206JUD004195908, paragraph 24). As regards the procedure before the Court, it is important to note that, pursuant to paragraph 15 of the Practice Directions to Parties before the General Court of 24 January 2012 (OJ 2012 L 68, p. 23), in force on the date the application was lodged, the length of the application is in principle limited to 50 pages, but is always determined on the basis of the complexity in law or in fact of the case in question (see, to that effect, order of 10 April 2014, *Langguth Erben* v *OHIM*, C-412/13 P, not published, EU:C:2014:269, paragraph 63). In the present case, the applicants have relied on the complexity in law of the case in question and have been authorised by the Court to lodge a 186-page application, drafted with reduced line spacing and accompanied by 10 158 pages of annexes. Although it is true that the contested decision is particularly lengthy and in certain respects repetitive, this is nonetheless explained, as the Commission argues, by the number of infringements which are alleged against the applicants and which have certain common features, as well as by the standards of proof required by the case-law of the EU Courts concerning infringements of Articles 101 and 102 TFEU. Moreover, as the Commission points out, the applicants had the opportunity to respond to the statement of objections, which is 755 pages in length, and produced a document of more than 600 pages. The length of the application and the number of pleas raised show, furthermore, that the applicants had the time — with no doubt considerable effort, it is true — to prepare their arguments. They cannot, therefore, claim to have been subject to insurmountable difficulties in accessing the Court and to have been placed at a substantial disadvantage vis-à-vis the Commission.

175 As regards the argument relating to the repetitions and references on which the Commission relied in the contested decision, it must be recalled that it is for the Commission, in accordance with Article 296 TFEU, to set out its reasoning in a clear and unequivocal fashion, so as to make the persons concerned aware of the reasons for the measure and to enable the court having jurisdiction to exercise its power of review. Those requirements to be satisfied by the statement of reasons depend on the circumstances of each case, in particular the content of the measure in question, the nature of the reasons given and the interest which the addressees of the measure, or other parties to whom it is of direct and individual concern, may have in obtaining explanations. It is not necessary for the reasoning to go into all the relevant facts and points of law, since the question whether the statement of reasons for a measure meets the requirements of Article 296 TFEU must be assessed with regard not only to its wording but also to its context and to all the legal rules governing the matter in question (see judgment of 27 September 2012, *Heijmans Infrastructuur* v *Commission*, T-359/06, not published, EU:T:2012:489, paragraph 133 and the case-law cited). Contrary to what the applicants maintain, the mere fact that the Commission referred to the same internal documents on numerous occasions in the contested decision and that it made a significant number of references to other parts of the contested decision cannot suffice to establish that the contested decision did not allow them to ascertain the reasons for the measure taken or prevented the Court from exercising its power of review.

176 As regards the argument based on the absence of a clear legal criterion, the applicants have stated that it corresponds with other pleas in their application. It will therefore be examined in the context of the corresponding pleas.

177 Finally, nor is it possible to accept the applicants' arguments based on the judgments of the ECtHR of 27 October 1993, *Dombo Beheer B. V. v. The Netherlands* (CE:ECHR:1993:1027JUD001444888), of 15 July 2003, *Ernst and Others v. Belgium* (CE:ECHR:2003:0715JUD003340096), and of 18 April 2006, *Vezon v. France* (CE:ECHR:2006:0418JUD006601801). Indeed, the facts and points of law in those cases were very different from those in the present case. Accordingly, the case which gave rise to the judgment of the ECtHR of 27 October 1993, *Dombo Beheer B. V. v. The Netherlands* (CE:ECHR:1993:1027JUD001444888), in which the ECtHR found a breach of Article 6 of the ECHR, involved a dispute between two private individuals in which one of the two parties had been placed at a substantial disadvantage vis-à-vis the other party, who was the only one able to use witness statements. In the case which gave rise to the judgment of the ECtHR of 15 July 2003, *Ernst and Others v. Belgium* (CE:ECHR:2003:0715JUD003340096), in which the ECtHR held that there was no breach of Article 6 of the ECHR, the question at issue was whether a State could offer an applicant court access limited to a preliminary issue of admissibility, on the ground that his action was directed against a judge having the right to choose the court having jurisdiction. Finally, the case which gave rise to the judgment of the ECtHR of 18 April 2006, *Vezon v. France* (CE:ECHR:2006:0418JUD006601801), concerned an infringement of the right to a fair trial, on account of a legislative measure definitively and retroactively determining the merits of ongoing disputes before national courts, which was not, however, justified by an adequate reason relating to the public interest.

178 It follows from the foregoing that the plea, even assuming that it is effective in supporting a criticism of the lawfulness of the contested decision, is, in any event, unfounded.

4. The distortion of the facts

(a) Arguments of the parties

…

(b) Findings of the Court

184 The Commission challenges the admissibility of this plea on the basis of the provisions of Article 44(1)(c) of the Rules of Procedure of 2 May 1991, applicable in the present case, according to which the application must contain the subject matter of the proceedings and a summary of the pleas in law on which the application is based. That information must be sufficiently clear and precise to enable the defendant to prepare its defence and the Court to rule on the application, if necessary without any further information. In order to guarantee legal certainty and sound administration of justice it is necessary, in order for an action to be admissible under the aforementioned provisions, that the basic legal and factual particulars relied on be indicated, at least in summary form, coherently and intelligibly in the application itself (order of 28 April 1993, *De Hoe* v *Commission*, T-85/92, EU:T:1993:39, paragraph 20). More particularly, the Court of Justice has held that, although it must be accepted that the statement of the grounds for instituting the proceedings need not conform with the phraseology or the list provided for by the second paragraph of Article 263 TFEU, it may be sufficient for the grounds for instituting the proceedings to be expressed in terms of their substance rather than of their legal classification, provided, however, that it is sufficiently clear from the application which of the grounds referred to in the Treaty is being invoked (judgment of 15 December 1961, *Fives Lille Cail and Others* v *High Authority*, 19/60, 21/60, 2/61 and 3/61, EU:C:1961:30, p. 294).

185 In the present case, the applicants essentially criticise the Commission for having failed to present certain facts objectively and for having relied on irrelevant facts in order to establish the existence of an infringement. However, although they describe this plea as 'distortion of the factual context underlying the practices which are the subject of the decision', the applicants have not specified which rule of law infringed by the Commission is capable of forming the basis for the action, and the information which they provide in their application is not sufficiently clear and precise to enable the Commission to respond to the arguments raised and the EU judicature to exercise its power of review. Indeed, the arguments they put forward could form part of a plea alleging an error of fact, an error regarding the legal characterisation of the facts, an infringement of the principle of impartiality or the duty of diligence, misuse of powers or even damage to reputation capable of justifying an action for compensation.

186 Accordingly, this plea must, for that reason, be declared inadmissible.

187 In the alternative, the Commission argues that this plea is also inadmissible since only the applicants' conduct which was held to constitute an infringement of Articles 101 and 102 TFEU in the operative part of the contested decision adversely affects them and is capable of being challenged in legal proceedings.

188 According to the case-law, only the operative part of a decision is capable of producing legal effects and of adversely affecting a person's interests and the assessments made in the recitals are not in themselves capable of forming the subject of an application for annulment. Those assessments can be subject to judicial review by the EU judicature only to the extent that, as grounds of an act adversely affecting a person's interests, they constitute the essential basis for the operative part of that act (order of 28 January 2004, *Netherlands* v *Commission*, C-164/02, EU:C:2004:54, paragraph 21, and judgment of 17 September 1992, *NBV and NVB* v *Commission*, T-138/89, EU:T:1992:95, paragraph 31) and if, in particular, those grounds are likely to alter the substance of what was decided in the operative part of the measure in question (see judgment of 12 October 2007, *Pergan Hilfsstoffe für industrielle Prozesse* v *Commission*, T-474/04, EU:T:2007:306, paragraph 73 and the case-law cited). It must be borne in mind in that regard that the statement of the reasons for an act is indispensable for determining the exact meaning of what is stated in the operative part (judgments of 15 May 1997, *TWD* v *Commission*, C-355/95 P, EU:C:1997:241, paragraph 21, and of 20 November 2002, *Lagardère and Canal+* v *Commission*, T-251/00, EU:T:2002:278, paragraph 67).

189 In the present case, it must therefore be determined whether the elements criticised by the applicants contained in Section 4 of the contested decision constitute the essential basis for its operative part and whether those assessments are likely to alter the substance of what was decided in that operative part.

190 It is important to note that the Commission stated, in recitals 85 and 110 of the contested decision, as regards the presentation of the various constituent elements of the applicants' anti-generic strategy (in particular the creation of a 'patent cluster' with 'paper' patents and the gradual transition to the arginine salt), that the description of the practices which were not assessed in Section 5 (examination of the settlements under Article 101 TFEU) and Section 8 (examination of the technology acquisition and settlements under Article 102 TFEU) of the contested decision was without prejudice to their legality under competition law. Similarly, in recital 2764 of the contested decision, the Commission specified that none of the elements of the applicants' general strategy 'can *per se* be qualified as problematic under Union competition law'. Moreover, in recitals 2917 and 2960, the Commission recalled that, 'concerning the abuse of a dominant position, the subject matter of this decision is the overall infringement of Article 102 [TFEU], which consists in the combination of the chain of patent settlements agreements and the acquisition of the Azad technology'. Furthermore, the applicants themselves asked the Court to make confidential vis-à-vis the intervener a number of passages of the contested decision relating to their anti-generic strategy, on the ground that that factual information and its interpretation did not fall within the scope of the complaints made against them by the Commission and that, if that information were disclosed to the public, it would have a serious adverse effect on the applicants by undermining the presumption of innocence and their reputation. The constituent elements of the applicants' anti-generic strategy which were not classified as an infringement by the Commission therefore were not taken into account for the purposes of establishing and penalising the infringements referred to in the operative part of the contested decision.

191 The applicants claim, however, that, in recital 2766 of the contested decision, which appears in Section 8 of the contested decision, the Commission stated that the assessment of the practices penalised in the case of Article 102 TFEU 'will take into account the full factual setting, including other practices flowing from the strategy for which the contribution to foreclosure effects is not established in this Decision'. Moreover, in recital 2772 of the contested decision, the Commission stated that the applicants' anti-generic strategy, described in Section 4 of that decision, and in particular the creation of a patent cluster, constituted 'important factual elements which help to explain, for example in assessing the anticompetitive foreclosure effects of Servier's conduct, why the degree of (potential) competition for the supply of generic perindopril was particularly limited'.

192 In its defence, the Commission submits that it was required to set out in the contested decision practices forming part of the applicants' anti-generic strategy but not classified as infringements of Articles 101 and 102 TFEU, in order to be able to examine the infringements in their legal, economic and factual context. At the hearing, the Commission emphasised the importance of Section 4 of the contested decision in understanding Servier's overall strategy towards generic companies and the scope of its practices on the market, by distinguishing between the factual context of those practices, clarified in particular by Section 4 of that decision, and whether or not they constituted an infringement. That distinction was clearly made in recital 2766 of the contested decision.

193 It is true that, according to settled case-law, in order to determine whether an agreement between undertakings reveals a sufficient degree of harm that it may be considered a 'restriction of competition by object' within the meaning of Article 101(1) TFEU, regard must be had, inter alia, to the economic and legal context of which it forms part (see judgment of 16 July 2015, *ING Pensii*, C-172/14, EU:C:2015:484, paragraph 33 and the case-law cited). In order to assess the agreement at issue, it is important to place it in the economic and legal context in the light of which it was concluded by the parties. Such a procedure is not to be regarded as an unwarrantable interference in legal transactions or circumstances which were not the subject of the proceedings before the Commission (judgment of 13 July 1966, *Consten and Grundig* v *Commission*, 56/64 and 58/64,

EU:C:1966:41, p. 342). When determining that legal and economic context, it is 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 (see judgments of 11 September 2014, *CB* v *Commission*, C-67/13 P, EU:C:2014:2204, paragraph 53 and the case-law cited, and of 19 March 2015, *Dole Food and Dole Fresh Fruit Europe* v *Commission*, C-286/13 P, EU:C:2015:184, paragraph 117 and the case-law cited).

194 Similarly, as part of its examination of the conduct of a dominant undertaking and for the purposes of identifying any abuse of a dominant position, the Commission, is obliged to consider all the relevant facts surrounding that conduct (see, to that effect, judgments of 15 March 2007, *British Airways* v *Commission*, C-95/04 P, EU:C:2007:166, paragraph 67, and of 27 March 2012, *Post Danmark*, C-209/10, EU:C:2012:172, paragraph 26). Moreover, it must be observed in that regard that where the Commission undertakes an assessment of the conduct of an undertaking in a dominant position, that assessment being an essential prerequisite of a finding that there is an abuse of such a position, the Commission is necessarily required to assess the business strategy pursued by that undertaking. For that purpose, it is clearly legitimate for the Commission to refer to subjective factors, such as the motives underlying the business strategy in question (judgment of 19 April 2012, *Tomra Systems and Others* v *Commission*, C-549/10 P, EU:C:2012:221, paragraph 19).

195 It is apparent from paragraphs 193 and 194 above that, although the Commission is required to take into consideration the context in which the conduct of an undertaking takes place in order to examine whether it is compatible with Articles 101 and 102 TFEU, that consideration of the context cannot lead to the conclusion or support a finding that there has been an infringement based on different behaviour found to be contrary to or not consistent with competition law, without that behaviour itself being classified as an infringement.

196 In the present case, it is apparent from the contested decision (see paragraph 190 above) that the constituent elements of the applicants' anti-generic strategy, referred to in Section 4 of the contested decision and presenting Servier's actions in a negative light, were not classified as an infringement by the Commission and were not taken into account in classifying as an infringement the practices which it penalised with a fine. If the Commission had indeed taken them into consideration in order to classify the practices penalised as an infringement, it would have been open to the criticism that it found infringements based in part on suspicions or assertions resulting not solely from the practices which it decided to penalise but from other conduct. Such an approach could result in an undertaking's presumed poor reputation, inferred from mere allegations or from facts not clearly established, being analysed as a factor in the examination of the anticompetitive practices alleged against it. However, the impartiality and objectivity which must prevail in the Commission's classification of infringements and their penalisation, as well as the right to respect for the presumption of innocence, exclude in principle that type of assumption. The Commission's ambiguity as to the significance of those elements – very critical of Servier's attitude – set out in Section 4 of the contested decision, which the Commission claims to be both important in its analysis and not open to challenge before the courts, is indicative of possible uncertainties surrounding those grounds of the contested decision.

197 Finally, it should be noted that, even if the various aspects of the applicants' overall anti-generic strategy form part of the context of the infringements established by the contested decision, those assessments do not, however, appear to have been capable of altering the substance of the operative part of the contested decision. Indeed, it must be borne in mind that consideration of the context in identifying the anticompetitive object cannot remedy a failure actually to identify an anticompetitive object (Opinion of Advocate General Wahl in *CB* v *Commission*, C-67/13 P, EU:C:2014:1958, point 44). Similarly, as regards Article 102 TFEU, although the Commission is obliged to consider all of the relevant facts surrounding the conduct at issue for the purposes of identifying any abuse of a dominant position, the existence of any anticompetitive intent nevertheless constitutes only one of a

number of facts which may be taken into account in order to determine that a dominant position has been abused (see, to that effect, judgment of 19 April 2012, *Tomra Systems and Others* v *Commission*, C-549/10 P, EU:C:2012:221, paragraphs 18 to 20).

198 This plea must therefore, and in any event, be rejected as ineffective, since it is directed against the grounds of the contested decision which do not relate to the applicants' conduct and practices constituting infringements of competition law and penalised by that decision. It should be noted, however, that many of the factual elements criticised by the applicants under this plea (in particular the acquisition of alternative technologies and the patent dispute settlements) relate directly to the practices which the Commission classified as an infringement and are also reproduced under other pleas, as the Commission argues in its defence. Those elements, which may thus be relevant, will be examined in the course of the analysis of those pleas.

5. Errors of law in defining the concept of a restriction of competition by object

…

211 By this plea, the applicants and the intervener submit that the Commission erred in law by classifying the patent dispute settlement agreements as restrictions of competition by object and that it disregarded the scope of the intellectual property rights represented by the patents. Consequently, it is for the Court to determine whether such settlement agreements may constitute a restriction of competition by object and, if so, under what conditions, and also to examine whether, in its analysis, the Commission disregarded the scope of the patents.

212 It should be borne in mind, in that regard, that, in the contested decision, the Commission analysed how, in its view, patent dispute settlement agreements should be assessed in the light of the provisions of Article 101(1) TFEU and, in particular, the possibility of classifying such agreements as restrictions by object (recitals 1102 to 1155 of the contested decision).

213 In essence, while acknowledging that companies are generally entitled to settle litigation, including patent litigation (recital 1118 of the contested decision), the Commission considered that patent dispute settlement agreements must comply with EU competition law and, more specifically, with the provisions of Article 101(1) TFEU (see inter alia recitals 1119, 1122 and 1123 of the contested decision).

214 The Commission also took into account the specific context in which competition operates between originator undertakings and generic companies in the pharmaceutical sector. In particular, it referred to the importance of patent challenges in that sector (recitals 1125 to 1132 of the contested decision).

215 In the light of those factors, the Commission considered that, in principle, it might be reasonable for parties to conclude a settlement agreement to resolve a dispute and even to include non-marketing and non-challenge clauses (recitals 1133 and 1136 of the contested decision).

216 However, the Commission took the view that, depending on the specific circumstances of the case, a patent dispute settlement agreement by which a generic company accepts restrictions on its ability and incentives to compete in return for a value transfer, either in the form of significant sums of money or another significant inducement, could be a restriction of competition by object contrary to Article 101 TFEU (recital 1134 of the contested decision). In such a situation, the generic company's decision not to pursue its independent efforts to enter the market results, not from the parties' assessment of the merits of the patent, but from a transfer of value from the originator company to the generic company (recital 1137 of the contested decision) and, accordingly, from an exclusionary payment which amounts to the 'buying off' of competition (recital 1140 of the contested decision).

217 Consequently, the Commission stated that, in order to determine whether or not the settlement agreements at issue constituted restrictions of competition by object, it would carry out a case-by-case analysis of the facts relating to each of those agreements. To that end, it stated that it would seek in particular to determine (i) whether 'the generic undertaking and the originator undertaking were at least potential competitors', (ii) whether 'the generic undertaking committed itself in the agreement to limit, for the duration of the agreement, its independent efforts to enter one or more EU markets with a generic product' and (iii) whether 'the agreement was related to a transfer of value from the originator undertaking as a significant inducement which substantially reduced the incentives of the generic undertaking to independently pursue its efforts to enter one or more EU markets with the generic product' (recital 1154 of the contested decision).

218 The Commission then applied the three criteria referred to in paragraph 217 above to each of the patent dispute settlement agreements at issue and concluded, in respect of each of those agreements, that those three criteria were met and that, consequently, those agreements should be classified, inter alia, as restrictions of competition by object.

(a) Whether the patent settlement agreements are restrictions by object

(1) Restrictions of competition by object

219 Article 101(1) TFEU provides that 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 are to be prohibited as incompatible with the internal market. According to settled case-law since the judgment of 30 June 1966, *LTM* (56/65, EU:C:1966:38, p. 249), the alternative nature of those requirements, indicated by the use of the conjunction 'or', leads to the need to consider, in the first place, the precise purpose of the agreement, in the economic context in which it is to be applied. Where, however, an analysis of the terms of the agreement at issue does not reveal a sufficient degree of harm to competition, the effects of the agreement should then 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 (see judgments of 19 March 2015, *Dole Food and Dole Fresh Fruit Europe* v *Commission*, C-286/13 P, EU:C:2015:184, paragraph 116 and the case-law cited, and of 16 July 2015, *ING Pensii*, C-172/14, EU:C:2015:484, paragraph 30 and the case-law cited). However, where the anticompetitive object of an agreement is established, it is not necessary to examine its effects on competition (see judgment of 20 January 2016, *Toshiba Corporation* v *Commission*, C-373/14 P, EU:C:2016:26, paragraph 25 and the case-law cited). Thus, in the contested decision, the Commission rightly pointed out, first, that the anticompetitive object and effect of an agreement are not cumulative but alternative conditions for assessing whether an agreement comes within the scope of the prohibition laid down in Article 101(1) TFEU (recital 1109) and, secondly, that it is not necessary to show actual anticompetitive effects of conduct where the anticompetitive object of that conduct is proved (recital 1112).

220 The concept of restriction of competition by object can be applied only to certain types of coordination between undertakings that reveal, by their very nature, a sufficient degree of harm to the proper functioning of normal competition that it may be found that there is no need to examine their effects (see, to that effect, judgments of 30 June 1966, *LTM*, 56/65, EU:C:1966:38, p. 249; of 11 September 2014, *CB* v *Commission*, C-67/13 P, EU:C:2014:2204, paragraphs 49, 50 and 58 and the case-law cited; of 16 July 2015, *ING Pensii*, C-172/14, EU:C:2015:484, paragraph 31; and of 26 November 2015, *Maxima Latvija*, C-345/14, EU:C:2015:784, paragraph 20).

221 According to the case-law of the Court of Justice, in order to determine whether an agreement between undertakings reveals a sufficient degree of harm that it may be considered a 'restriction of competition by object' within the meaning 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 part (see judgment of 16 July 2015, *ING Pensii*, C-172/14, EU:C:2015:484, paragraph 33 and the case-law cited). When determining the economic and legal 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 (see judgment of 19 March 2015, *Dole Food and Dole Fresh Fruit Europe* v *Commission*, C-286/13 P, EU:C:2015:184, paragraph 117 and the case-law cited). Nevertheless, it must be borne in mind that the examination of the real conditions of the functioning and structure of the market in question cannot lead the General Court to assess the effects of the coordination concerned (see, to that effect, judgment of 11 September 2014, *CB* v *Commission*, C-67/13 P, EU:C:2014:2204, paragraphs 72 to 82), since otherwise the distinction established in Article 101(1) TFEU would lose its effectiveness.

222 In addition, although the parties' intention is not a necessary factor in determining whether a type of coordination 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 (see judgment of 19 March 2015, *Dole Food and Dole Fresh Fruit Europe* v *Commission*, C-286/13 P, EU:C:2015:184, paragraph 118 and the case-law cited). However, the mere fact that an agreement also pursues legitimate objectives is not sufficient to preclude a finding of restriction of competition by object (judgment of 20 November 2008, *Beef Industry Development Society and Barry Brothers*, C-209/07, EU:C:2008:643, paragraph 21; see also, to that effect, judgments of 8 November 1983, *IAZ International Belgium and Others* v *Commission*, 96/82 to 102/82, 104/82, 105/82, 108/82 and 110/82, EU:C:1983:310, paragraph 25, and of 6 April 2006, *General Motors* v *Commission*, C-551/03 P, EU:C:2006:229, paragraph 64).

223 The applicants maintain that the Commission erred in law by considering that a mere possibility that an agreement might have a negative effect on competition was sufficient in order to classify it as a restriction of competition by object. It is true that, in recital 1111 of the contested decision, the Commission stated, citing the case-law of the Court of Justice (judgments of 4 June 2009, *T-Mobile Netherlands and Others*, C-8/08, EU:C:2009:343, paragraph 31, and of 14 March 2013, *Allianz Hungária Biztosító and Others*, C-32/11, EU:C:2013:160, paragraphs 35 to 38), that, 'in order for an agreement to be regarded as having an anticompetitive object, it is sufficient that it has the potential to have a negative impact on competition' and that 'in other words, the agreement must simply be capable in an individual case, having regard to the specific legal and economic context, of resulting in the prevention, restriction or distortion of competition within the internal market'.

224 In that regard, it is necessary, first of all, to point out that the Commission, in the contested decision, correctly set out the case-law on the definition of restriction of competition by object, as referred to in paragraphs 219 to 222 above. It can be seen from recitals 1109, 1110, 1112 to 1117 and 1211 of the contested decision that the Commission set out that case-law without erring in law and that it applied that case-law in its analysis of each agreement (see, inter alia, recitals 1369 to 1375, 1475 to 1481, 1622 to 1627, 1763, 1804 to 1810 and 1994 to 2000 of the contested decision). It is irrelevant that the Commission did not use the words 'sufficient degree of harm' in the contested decision, since it is apparent from that decision that it correctly grasped the concept of restriction of competition by object. In particular, it indicated in recitals 1110 and 1113 of that decision that those restrictions were 'those which, "by their very nature", can be regarded as being injurious to the proper functioning of normal competition', that, 'in order to assess if an agreement involves a restriction by object, regard must be had inter alia to the content of its provisions, the objectives it seeks to attain and the economic and legal context of which it forms a part', and that 'when determining that context, it is also appropriate 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'. It also rightly noted that, 'although the parties' intention is not a necessary factor in determining whether an agreement involves a restriction of competition by object, there is nothing prohibiting the Commission or the Courts of the Union from taking that aspect into account' (recital 1113 of the contested decision).

225 Next, it must be pointed out that, in paragraph 31 of the judgment of 4 June 2009, *T-Mobile Netherlands and Others* (C-8/08, EU:C:2009:343), repeated in paragraph 38 of the judgment of 14 March 2013, *Allianz Hungária Biztosító and Others* (C-32/11, EU:C:2013:160), the Court of Justice did not intend to assert that an agreement with a low degree of harm which, as a consequence, only might have a negative effect on competition could constitute a restriction of competition by object, but only, first, that the identification of the actual effects of an agreement on competition was not relevant in the analysis of a restriction of competition by object and, secondly, that the mere fact that an agreement was not implemented cannot preclude a finding that it constitutes a restriction of competition by object. A reading of paragraph 31 of the judgment of 4 June 2009, *T-Mobile Netherlands and Others* (C-8/08, EU:C:2009:343), in particular in the light of paragraphs 29 and 30 thereof and of point 46 of the Opinion of Advocate General Kokott in that case, to which the judgment refers expressly, and point 47 of that Opinion, allows that paragraph to be placed in the context of the distinction between restrictions of competition by effect and by object.

226 Consequently, the applicants' arguments that the Commission committed an error of law in recital 1111 of the contested decision must be rejected.

227 The applicants and the intervener further claim, relying on the judgment of 11 September 2014, *CB* v *Commission* (C-67/13 P, EU:C:2014:2204), that the concept of infringement by object should be interpreted restrictively, contrary to the approach taken by the Commission in the contested decision.

228 In that regard, it must be noted that, in the judgment of 11 September 2014, *CB* v *Commission* (C-67/13 P, EU:C:2014:2204, paragraph 58), the Court of Justice stated that the concept of restriction of competition by object could be applied only to certain types of coordination between undertakings which reveal a sufficient degree of harm to competition that it may be found that there is no need to examine their effects and not to agreements which are in no way established to be, by their very nature, harmful to the proper functioning of normal competition. It therefore held that the General Court had erred in law in finding that the concept of restriction of competition by object must not be interpreted restrictively. The Court of Justice did not, however, call into question the case-law according to which the types of agreement referred to in Article 101(1)(a) to (e) TFEU do not constitute an exhaustive list of prohibited collusion (judgment of 20 November 2008, *Beef Industry Development Society and Barry Brothers*, C-209/07, EU:C:2008:643, paragraph 23; see also, to that effect, judgment of 11 September 2014, *CB* v *Commission*, C-67/13 P, EU:C:2014:2204, paragraph 58), which is clear from the use of the term 'in particular' in Article 101(1) TFEU (Opinion of Advocate General Trstenjak in *Beef Industry Development Society and Barry Brothers*, C-209/07, EU:C:2008:467, point 46).

229 It must next be pointed out that, in the present case, the Commission took an approach consistent with the judgment of 11 September 2014, *CB* v *Commission* (C-67/13 P, EU:C:2014:2204), by assessing the agreements at issue in the light of the criteria set out in paragraphs 219 to 222 above (see paragraph 224 above), criteria which are in themselves restrictive, since they require the identification of a sufficient degree of harm. Contrary to the applicants' and the intervener's assertions, the Commission's analysis did not, a priori, have to apply a more restrictive approach than that entailed by the criteria for assessing the concept of restriction of competition by object, but it required the identification of a restriction of competition revealing a sufficient degree of harm or, failing that, an analysis of the actual anticompetitive effects of the agreements at issue.

230 The applicants also submit that the absence of precedent precludes any classification as a restriction by object and argue that the former head of unit responsible for the case publicly recognised that it was unprecedented, as the Commission acknowledged in the contested decision itself. However, it should be noted that the practices referred to in Article 101(1)(a) to (e) TFEU do not constitute an exhaustive list of prohibited collusion (judgment of 20 November 2008, *Beef Industry Development Society and Barry Brothers*, C-209/07, EU:C:2008:643, paragraph 23) and that, even though experience may undoubtedly show that certain types of cooperation are inherently harmful to competition

(judgment of 11 September 2014, *CB* v *Commission*, C-67/13 P, EU:C:2014:2204, paragraph 51), 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 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 (see judgment of 8 September 2016, *Lundbeck* v *Commission*, T-472/13, under appeal, EU:T:2016:449, paragraph 438 and the case-law cited).

231 Similarly, contrary to what is maintained by the applicants, the mere fact that a case-by-case approach is necessary in order to identify a restriction of competition by object does not preclude such a classification. The case-law does not require that an agreement be considered to be prima facie or undoubtedly sufficiently harmful to competition, without a concrete and individual examination of its content, its purpose, and its legal and economic context by the Commission or the EU judicature, in order to be regarded as a restriction of competition by object within the meaning of Article 101(1) TFEU (see, to that effect, judgments of 14 March 2013, *Allianz Hungária Biztosító and Others*, C-32/11, EU:C:2013:160, paragraph 51, and of 8 September 2016, *Lundbeck* v *Commission*, T-472/13, under appeal, EU:T:2016:449, paragraph 775).

232 The applicants and the intervener also complain that the contested decision is vitiated by a contradiction in the reasoning, since it is stated in recital 2764 that the patent settlements are not in themselves anticompetitive under Article 102 TFEU. However, it is clear from the sentence in question in recital 2764 of the contested decision that the Commission was referring solely to the practices which were described in the contested decision as forming part of the applicants' general anti-generic strategy but which were not classified in the contested decision as infringements of competition law. Consequently, that sentence did not refer to the settlements concluded by the applicants. Moreover, it is apparent from the contested decision, and in particular Section 8.3 thereof, that the Commission considered that the settlements concluded by the applicants constituted abusive conduct contributing to the overall single and continuous exclusionary strategy which infringed the provisions of Article 102 TFEU. The contested decision is therefore not vitiated by the alleged contradiction in the reasoning.

233 Having set out the conditions for applying the concept of restriction of competition by object and having examined the applicants' complaints criticising the interpretation of that concept, it must be noted that, in the present case, the agreements at issue were intended, according to the applicants, to settle disputes between the contracting parties and were concluded in the specific context of patent law, since the disputes in question concerned the applicants' patents. Since determining whether there is a restriction by object entails an examination of the content of the terms of the agreement in question, its objectives, and its economic and legal context (see paragraph 221 above), it is necessary in the present case to analyse the clauses prohibiting patent challenges and the clauses prohibiting the marketing of products which infringe those patents, contained in settlement agreements in general and in the agreements at issue in particular, in the light of their objective of settling patent disputes and the specific context, namely that of patents, in order to verify whether the Commission, correctly and in accordance with legally appropriate criteria, classified those agreements as restrictive of competition by object.

(2) Intellectual property rights and, in particular, patents

234 The specific purpose of awarding a patent is to ensure that its proprietor, 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, *Centrafarm and de Peijper*, 15/74, EU:C:1974:114, paragraph 9). When granted by a public authority, a patent is normally presumed to be valid and an undertaking's ownership of that right is presumed to be lawful. The mere possession by an undertaking of such an exclusive right

normally results in keeping competitors away, since public regulations require them to respect that exclusive right (judgment of 1 July 2010, *AstraZeneca* v *Commission*, T-321/05, EU:T:2010:266, paragraph 362).

235 The exercise of the rights arising under a patent granted in accordance with the legislation of a Member State does not, of itself, constitute an infringement of the rules on competition laid down by the Treaty (judgment of 29 February 1968, *Parke, Davis and Co.*, 24/67, EU:C:1968:11, p. 71). Intellectual property rules are even essential in order to maintain competition undistorted on the internal market (judgment of 16 April 2013, *Spain and Italy* v *Council*, C-274/11 and C-295/11, EU:C:2013:240, paragraph 22). First, by rewarding the creative effort of the inventor, patent law contributes to promoting an environment conducive to innovation and investment and, secondly, it is intended to make public the modes of operation of inventions and thus allow further breakthroughs to emerge. Paragraph 7 of the 2004 Guidelines on technology transfer agreements, the provisions of which were included in their entirety in point 7 of the 2014 Guidelines on technology transfer agreements, thus acknowledges that:

'[There is no] inherent conflict between intellectual property rights and the Community competition rules. Indeed, both bodies of law share the same basic objective of promoting consumer welfare and an efficient allocation of resources. Innovation constitutes an essential and dynamic component of an open and competitive market economy. Intellectual property rights promote dynamic competition by encouraging undertakings to invest in developing new or improved products and processes. So does competition by putting pressure on undertakings to innovate. Therefore, both intellectual property rights and competition are necessary to promote innovation and ensure a competitive exploitation thereof.'

236 According to settled case-law, the right to property, which includes intellectual property rights, constitutes a general principle of EU law (judgment of 29 January 2008, *Promusicae*, C-275/06, EU:C:2008:54, paragraph 62; see also, to that effect, judgment of 12 July 2005, *Alliance for Natural Health and Others*, C-154/04 and C-155/04, EU:C:2005:449, paragraph 126 and the case-law cited).

237 However, intellectual property rights, and in particular patent rights, are not absolute; rather they must be viewed in relation to their social function and must be reconciled with other fundamental rights, and they may be restricted in order to meet the objectives of general interest pursued by the European Union, provided that those restrictions do not constitute, in relation to the aim pursued, a disproportionate and intolerable interference, impairing the very substance of the right guaranteed (see judgment of 12 July 2005, *Alliance for Natural Health and Others*, C-154/04 and C-155/04, EU:C:2005:449, paragraph 126 and the case-law cited). For example, the Court of Justice has held, in disputes relating to the interpretation of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (OJ 2009 L 152, p. 1), that it is necessary to balance the interests of the patent-holding pharmaceutical industry and those of public health (see, to that effect, judgment of 12 March 2015, *Actavis Group PTC and Actavis UK*, C-577/13, EU:C:2015:165, paragraph 36 and the case-law cited).

238 It should also be borne in mind that Article 3(3) TEU states that the European Union is to establish an internal market, which — in accordance with Protocol No 27 on the internal market and competition, annexed to the Treaty of Lisbon (OJ 2010 C 83, p. 309), which, under Article 51 TEU, has the same legal value as the Treaties — includes a system ensuring that competition is not distorted. Articles 101 and 102 TFEU are among the competition rules referred to in Article 3(1)(b) TFEU which are necessary for the functioning of that internal market. The function of those rules is precisely to prevent competition from being distorted to the detriment of the public interest, individual undertakings and consumers, thereby ensuring the well-being of the European Union (judgment of 17 February 2011, *TeliaSonera Sverige*, C-52/09, EU:C:2011:83, paragraphs 20 to 22).

239 Although the Treaties have never expressly provided for reconciliation between intellectual property rights and competition law, Article 36 EC, the provisions of which were reproduced in Article 36 TFEU, nevertheless provided for a reconciliation of intellectual property rights with the principle of free movement of goods, by indicating that the provisions of the Treaty relating to the prohibition of quantitative restrictions between Member States were not to preclude restrictions on imports, exports or goods in transit justified, inter alia, on grounds of the protection of industrial and commercial property, while specifying that those restrictions should not constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States. The Court of Justice considers that Article 36 EC thus intended to draw a distinction between the existence of a right conferred by the legislation of a Member State in regard to the protection of artistic and intellectual property, which cannot be affected by the provisions of the Treaty, and the exercise of such right, which might constitute a disguised restriction on trade between Member States (see, to that effect, judgment of 6 October 1982, *Coditel and Others*, 262/81, EU:C:1982:334, paragraph 13).

240 The EU legislature has moreover had occasion to point out the need for such reconciliation. Thus, Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights (OJ 2004 L 157, p. 45), the objective of which is to approximate national laws so as to ensure a high, equivalent and homogeneous level of protection of intellectual property in the internal market (recital 10) and 'to ensure full respect for intellectual property, in accordance with Article 17(2) of [the Charter of Fundamental Rights]' (recital 32), states that it 'should not affect the application of the rules of competition, and in particular Articles [101] and [102 TFEU]' and that 'the measures provided for in this Directive should not be used to restrict unduly competition in a manner contrary to the Treaty' (recital 12).

241 The Court of Justice has developed case-law in relation to various types of intellectual property rights intended to reconcile the competition rules with the exercise of these rights, without affecting their substance, by using the same reasoning as that which allows it to reconcile those rights and the free movement of goods. Thus, for the Court of Justice, the misuse of intellectual property rights must be penalised, but not the lawful exercise of those rights, which it defines on the basis of their specific subject matter, a concept which is used synonymously in the Court's case-law with the concepts of the actual substance of those rights and the essential prerogatives of their proprietor. According to the Court of Justice, the exercise of the prerogatives which form part of the specific subject matter of an intellectual property right thus concerns the existence of that right (see, to that effect, Opinion of Advocate General Gulmann in *RTE and ITP* v *Commission*, C-241/91 P, EU:C:1994:210, points 31 and 32 and the case-law cited). Nevertheless, the Court of Justice considers that the exercise of the exclusive right by the proprietor may, in exceptional circumstances, also give rise to conduct contrary to the competition rules (judgment of 6 April 1995, *RTE and ITP* v *Commission*, C-241/91 P and C-242/91 P, EU:C:1995:98, paragraph 50; see also, to that effect, judgment of 17 September 2007, *Microsoft* v *Commission*, T-201/04, EU:T:2007:289, paragraph 691).

242 As regards patents, the Court of Justice has ruled that it is possible that the provisions of Article 101 TFEU may apply if the use of one or more patents, in concert between undertakings, were to lead to the creation of a situation which may come within the concepts of agreements between undertakings, decisions of associations of undertakings or concerted practices within the meaning of Article 101(1) TFEU (judgment of 29 February 1968, *Parke, Davis and Co.*, 24/67, EU:C:1968:11, p. 71). It further considered, in 1974, that although the existence of rights recognised under the industrial property legislation of a Member State is not affected by Article 101 TFEU, the conditions under which those rights may be exercised may nevertheless fall within the prohibitions contained in that article and that this may be the case whenever the exercise of such a right appears to be the object, the means or the consequences of a restrictive agreement (judgment of 31 October 1974, *Centrafarm and de Peijper*, 15/74, EU:C:1974:114, paragraphs 39 and 40).

243 It must borne in mind that, in the absence of harmonisation at the European Union level of the patent law applicable in the present case, the extent of the patent protection conferred by a patent granted by a national patent office or by the EPO can only be determined in the light of non-European Union rules, that is to say, national law or the EPC (see, to that effect, judgments of 16 September 1999, *Farmitalia*, C-392/97, EU:C:1999:416, paragraph 26, and of 24 November 2011, *Medeva*, C-322/10, EU:C:2011:773, paragraphs 22 and 23). Consequently, where, in the context of an action for annulment brought against a Commission decision, the EU judicature is called upon to examine a settlement agreement in relation to a patent governed by rules other than those of EU law, it is not for it to define the scope of that patent or to rule on its validity. It should also be noted that, in the present case, in the contested decision, although the Commission referred, in recitals 113 to 123, to the applicants' strategy of creating a 'patent cluster' and 'paper patents', it did not, however, rule on the validity of the disputed patents at the time the agreements were concluded.

244 While it is not for the Commission or the General Court to rule on the validity of a patent, the existence of the patent must nevertheless be taken into account in the analysis carried out in the framework of the EU competition rules. The Court of Justice has already stated that although the Commission is not competent to determine the scope of a patent, it is still the case that 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 Article 101 or 102 TFEU, since even in cases where the protection afforded by a patent is the subject of proceedings before the national courts, the Commission must be able to exercise its powers in accordance with the provisions of Regulation No 1/2003, the Commission's findings do not in any way pre-empt the determinations made later by national courts in disputes brought before them on the subject of patent rights and the Commission's decision is subject to review by the EU judicature (judgment of 25 February 1986, *Windsurfing International* v *Commission*, 193/83, EU:C:1986:75, paragraphs 26 and 27).

245 Lastly, it must be noted that intellectual property rights are protected by the Charter of Fundamental Rights. Under Article 17(1) of the Charter of Fundamental Rights, to which the Treaty of Lisbon has conferred the same legal value as the Treaties (Article 6(1) TEU), 'everyone has the right to own, use, dispose of and bequeath his or her lawfully acquired possessions', 'no one may be deprived of his or her possessions, except in the public interest and in the cases and under the conditions provided for by law, subject to fair compensation being paid in good time for their loss', and 'the use of property may be regulated by law in so far as is necessary for the general interest'. Article 17(2) of the Charter of Fundamental Rights states, moreover, that 'intellectual property shall be protected'. Consequently, the guarantees provided for in Article 17(1) of the Charter of Fundamental Rights apply also to intellectual property. The Court of Justice has held that the recognition of intellectual property rights in the Charter of Fundamental Rights entails a need for a high level of protection of those rights and that it is necessary to strike a balance between maintaining free competition — in respect of which primary law and, in particular, Articles 101 and 102 TFEU prohibit anticompetitive agreements, decisions and concerted practices and abuses of a dominant position — and the requirement to safeguard the patent holder's intellectual property rights, guaranteed by Article 17(2) of the Charter of Fundamental Rights (see, to that effect, judgment of 16 July 2015, *Huawei Technologies*, C-170/13, EU:C:2015:477, paragraphs 42 and 58).

(3) Patent dispute settlements

246 As a preliminary point, it must be noted that the discussion below does not concern patents obtained fraudulently, 'fictitious' disputes or disagreements which have not reached the judicial stage. The Commission acknowledged in recital 1170 of the contested decision that, at the time the settlement agreements were concluded, the applicants and the generic companies were all parties to, or associated with a dispute before a national court or the EPO concerning the validity of some of the applicants' patents or the infringing nature of the product developed by the generic company.

247 First of all, it should be noted that it is a priori legitimate for the parties to a dispute relating to a patent to conclude a settlement agreement rather than pursuing litigation before a court. As the Commission rightly stated in recital 1102 of the contested decision, companies are generally entitled to settle litigation, including patent litigation, and those settlements often benefit both parties to the dispute and allow for a more efficient allocation of resources than if litigation were to be pursued to judgment. An applicant is not required to pursue litigation which it voluntarily initiated. It should be added that the settlement of disputes before the courts, in addition to the fact that it generates a cost for society, cannot be regarded as the preferred and ideal route for conflict resolution. An increase in litigation before the courts may reflect failures or shortcomings which could be remedied in other ways or be dealt with by appropriate prevention actions. If the national systems for granting patents or that of the EPO were experiencing such difficulties, for example by being too liberal in granting protection to processes which are devoid of inventive character, those problems could not justify an obligation or even an incentive for undertakings to pursue patent disputes until a judicial outcome is reached.

248 Likewise, paragraphs 204 and 209 of the 2004 Guidelines on technology transfer agreements, which are applicable at the very least to agreements concerning the licensing of technology, acknowledge the possibility of concluding settlement and non-assertion agreements which include the granting of licences and indicate that, in the context of such a settlement and non-assertion agreement, non-challenge clauses are generally considered to fall outside the scope of Article 101(1) TFEU. Point 235 of the 2014 Guidelines on technology transfer agreements, which replaced the 2004 Guidelines, also states that 'settlement agreements in the context of technology disputes are, as in many other areas of commercial disputes, in principle a legitimate way to find a mutually acceptable compromise to a bona fide legal disagreement'. That paragraph also states that 'the parties may prefer to discontinue the dispute or litigation because it proves to be too costly, time-consuming and/or uncertain as regards its outcome', and that 'settlements can also save courts and/or competent administrative bodies effort in deciding on the matter and can therefore give rise to welfare enhancing benefits'.

249 Moreover, the Commission itself uses an administrative procedure in relation to agreements and concerted practices which is similar in some respects to a settlement agreement. The settlement procedure, which was established by Commission Regulation (EC) No 622/2008 of 30 June 2008 amending Regulation No 773/2004, as regards the conduct of settlement procedures in cartel cases (OJ 2008 L 171, p. 3), is intended to simplify and speed up administrative procedures and to reduce the number of cases brought before the EU judicature, and thus to enable the Commission to handle more cases with the same resources (judgment of 20 May 2015, *Timab Industries and CFPR* v *Commission*, T-456/10, EU:T:2015:296, paragraphs 59 and 60).

250 In addition, according to the case-law, the ability to assert one's rights through the courts and the judicial control which that entails constitute the expression of a general principle of law which underlies the constitutional traditions common to the Member States and which is laid down in Articles 6 and 13 of the ECHR. As access to the courts is a fundamental right and a general principle ensuring the rule of law, it is only in wholly exceptional circumstances that the fact that legal proceedings are brought is capable of constituting an infringement of competition law (judgment of 17 July 1998, *ITT Promedia* v *Commission*, T-111/96, EU:T:1998:183, paragraph 60). As the Court of Justice noted, the need for a high level of protection for intellectual-property rights means that, in principle, the proprietor may not be deprived of the right to have recourse to legal proceedings to ensure effective enforcement of his exclusive rights (judgment of 16 July 2015, *Huawei Technologies*, C-170/13, EU:C:2015:477, paragraph 58). Symmetrically, the fact that a company decides to use extrajudicial means of resolving a dispute rather than pursuing the litigation route is merely an expression of the same freedom to choose the means of defending its rights and cannot, in principle, constitute an infringement of competition law.

251 Although access to the courts is a fundamental right, it cannot however be considered that it is an obligation, even if it would help to increase competition between economic operators. First, it should be noted that, despite the wide range of procedures and systems for the grant of patents in the various EU Member States and before the EPO at the time of the facts of the present case, an intellectual property right granted by a public authority is normally assumed to be valid and an undertaking's ownership of that right is assumed to be lawful (judgment of 1 July 2010, *AstraZeneca* v *Commission*, T-321/05, EU:T:2010:266, paragraph 362). Secondly, while it is indeed in the public interest to eliminate any obstacle to economic activity which might arise where a patent was granted in error (see, to that effect, judgment of 25 February 1986, *Windsurfing International* v *Commission*, 193/83, EU:C:1986:75, paragraphs 92 and 93) and while it is generally acknowledged that public budgets, including those dedicated to covering health expenditure, are under significant constraints and that competition, in particular competition provided by generic medicinal products developed by generic companies, can effectively contribute to keeping those budgets under control, it should also be borne in mind, as the Commission rightly stated in recital 1201 of the contested decision, that any undertaking remains free to decide whether or not to bring an action against the patents covering the originator medicinal products held by the originator companies. In addition, such a decision to bring or not to bring an action or to settle a dispute does not, in principle, prevent other undertakings from challenging those patents.

252 It follows from all the foregoing that, for the purposes of reconciling patent law and competition law in the particular context of settlements between parties to a patent dispute, a balance must be struck between, on the one hand, the need to allow undertakings to make settlements, the increased use of which is beneficial for society and, on the other hand, the need to prevent the risk of misuse of settlement agreements, contrary to competition law, leading to entirely invalid patents being maintained and, especially in the medicinal products sector, an unjustified financial burden for public budgets.

(4) The reconciliation of patent settlement agreements and competition law

253 It should be noted that the use of a settlement to resolve a patent dispute does not exempt the parties from the application of competition law (see, to that effect, judgments of 27 September 1988, *Bayer and Maschinenfabrik Hennecke*, 65/86, EU:C:1988:448, paragraph 15, and of 8 September 2016, *Lundbeck* v *Commission*, T-472/13, under appeal, EU:T:2016:449, paragraph 118; see, by analogy, judgment of 30 January 1985, *BATCigaretten-Fabriken* v *Commission*, 35/83, EU:C:1985:32, paragraph 33; see, also, paragraph 204 of the 2004 Guidelines on technology transfer agreements and point 237 of the 2014 Guidelines on technology transfer agreements).

254 The Court of Justice has thus held, in particular, that a non-challenge clause in respect of a patent, including when it was inserted into an agreement intended to settle a dispute pending before a court, might, in the light of the legal and economic context, restrict competition within the meaning of Article 101(1) TFEU (judgment of 27 September 1988, *Bayer and Maschinenfabrik Hennecke*, 65/86, EU:C:1988:448, paragraphs 14 to 16).

255 It is therefore necessary to identify the relevant factors which justify a conclusion that a non-challenge clause in respect of a patent and, more broadly, a patent settlement agreement restricts competition by object, bearing in mind that determining whether there is a restriction by object entails an examination of the content of the terms of the agreement in question, its objectives, and its economic and legal context (see paragraph 221 above).

256 As a preliminary point, it should be noted that a patent dispute settlement agreement may have no negative impact on competition. That is the case, for example, if the parties agree that the patent at issue is not valid and therefore provide for the immediate market entry of the generic company.

257 The agreements at issue in the present case do not fall into that category because they contain non-challenge clauses in respect of patents and non-marketing clauses in respect of products, which are, by themselves, restrictive of competition. The non-challenge clause undermines the public interest in eliminating any obstacle to economic activity which may arise where a patent was granted in error (see, to that effect, judgment of 25 February 1986, *Windsurfing International* v *Commission*, 193/83, EU:C:1986:75, paragraph 92) and the non-marketing clause entails the exclusion from the market of one of the patent holder's competitors.

258 Nevertheless, the insertion of such clauses may be legitimate, but only in so far as it is based on the parties' recognition of the validity of the patent in question (and, consequently, of the infringing nature of the generic products concerned).

259 First, non-marketing and non-challenge clauses are necessary for the settlement of some disputes related to patents. If the parties to a dispute were unable to make use of such clauses, the settlement of the dispute would be of no interest in cases in which both parties agree on the validity of the patent. It must, moreover, be noted in this connection that the Commission stated, in paragraph 209 of the 2004 Guidelines on technology transfer agreements, that 'it is inherent in [settlement agreements] that the parties agree not to challenge *ex post* the intellectual property rights covered by the agreement [since] the very purpose of the agreement is to settle existing disputes and/or to avoid future disputes'. It is equally necessary, in order to achieve that purpose, that the parties agree that no infringing product may be marketed.

260 Secondly, the insertion of non-marketing clauses merely, in part, reinforces the pre-existing legal effects of a patent which the parties explicitly or implicitly recognise as valid. A patent normally enables its holder to prevent its competitors from marketing the product covered by the patent or a product obtained through the process covered by the patent (see paragraph 234 above). However, by agreeing to a non-marketing clause, the generic company undertakes not to sell products likely to infringe the patent in question. If that clause is limited to the scope of the patent at issue, it may be regarded as essentially duplicating the effects of that patent, in so far as it is based on the recognition of the validity of that patent. As regards non-challenge clauses, the patent cannot be interpreted as affording protection against actions brought in order to challenge the validity of a patent (judgment of 25 February 1986, *Windsurfing International* v *Commission*, 193/83, EU:C:1986:75, paragraph 92). The effects of those clauses therefore do not overlap with the effects of the patent. However, when a non-challenge clause is adopted as part of the settlement of a genuine dispute in which the competitor has already had the opportunity to challenge the validity of the patent concerned and ultimately acknowledges that validity, such a clause cannot be regarded, in that context, as undermining the public interest in eliminating any obstacle to economic activity which may arise where a patent was granted in error (see paragraph 257 above).

261 The Commission itself stated, in the contested decision, that non-marketing clauses and non-challenge clauses were generally inherent in any settlement. It thus considered that 'when in a patent dispute or patent litigation, a settlement is reached on the basis of each party's assessment of the patent case before them, such a patent settlement is unlikely to infringe competition law even though it may contain an obligation on the generic undertaking not to use the invention covered by the patent during the period of patent protection (e.g. a non-compete clause) and/or an obligation not to challenge the patent concerned in court (e.g. a non-challenge clause)' (recital 1136 of the contested decision).

262 Thus, the mere presence, in settlement agreements, of non-marketing clauses and non-challenge clauses whose scope is limited to that of the patent in question does not — despite the fact that those clauses are, by themselves, restrictive (see paragraph 257 above) — justify a finding of a restriction of competition sufficiently harmful to be described as a restriction by object, where those agreements are based on the recognition, by the parties, of the validity of the patent (and, consequently, the infringing nature of the generic products concerned).

263 The presence of non-marketing and non-challenge clauses whose scope is limited to that of the patent in question is, however, problematic when it is apparent that the generic company's agreement to those clauses is not based on its recognition of the validity of the patent. As the Commission rightly points out, 'even if the limitations in the agreement on the generic undertaking's commercial autonomy do not go beyond the material scope of the patent, they constitute a breach of 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 1137 of the contested decision).

264 In that respect, it should be noted that the existence of a 'reverse payment', that is to say a payment from the originator company to the generic company, is doubly suspect in the context of a settlement agreement. In the first place, it must be borne in mind that a patent is intended to reward the creative effort of the inventor by allowing him to make a fair profit from his investment (see paragraph 234 above) and that a valid patent must, in principle, allow a transfer of value to its holder — for example, through a licence agreement — and not vice versa. In the second place, the existence of a reverse payment gives rises to doubts as to whether the settlement is actually based on the recognition, by the parties to the agreement, of the validity of the patent in question.

265 However, the mere presence of a reverse payment does not mean that there is a restriction by object. It is possible that some reverse payments, where they are inherent in the settlement of the dispute in question, may be justified (see paragraphs 277 to 280 below). However, where an unjustified reverse payment occurs in the conclusion of the settlement, the generic company must then be regarded as having been induced by that payment to agree to the non-marketing and non-challenge clauses and it must be concluded that there is a restriction by object. In that case, the restrictions of competition introduced by the non-marketing and non-challenge clauses no longer relate to the patent and to the settlement, but rather can be explained by the conferral of a benefit inducing the generic company to abandon its competitive efforts.

266 It must be pointed out that, although neither the Commission nor the Courts of the European Union are competent to rule on the validity of the patent (see paragraphs 243 and 244 above), it is nevertheless the case that those institutions may, in the context of their respective powers and without ruling on the intrinsic validity of the patent, find that it has been used abnormally, in a manner which has no relation to its specific subject matter (see, to that effect, judgments of 29 February 1968, *Parke, Davis and Co.*, 24/67, EU:C:1968:11, pp. 71 and 72, and of 31 October 1974, *Centrafarm and de Peijper*, 15/74, EU:C:1974:114, paragraphs 7 and 8; see also, by analogy, judgments of 6 April 1995, *RTE and ITP* v *Commission*, C-241/91 P and C-242/91 P, EU:C:1995:98, paragraph 50, and of 4 October 2011, *Football Association Premier League and Others*, C-403/08 and C-429/08, EU:C:2011:631, paragraphs 104 to 106).

267 Inducing a competitor to accept non-marketing and non-challenge clauses, in the sense described in paragraph 265 above, or its corollary, accepting such clauses because of an inducement, constitutes an abnormal use of the patent.

268 As the Commission rightly stated in recital 1137 of the contested decision, 'patent law does not provide for a right to pay actual or potential competitors to stay out of the market or to refrain from challenging a patent prior to entering the market'. Likewise, according to the Commission, 'patent holders are not entitled to pay generic companies to keep them off the market and reduce the risks of competition, whether in the context of a patent settlement agreement or otherwise' (recital 1141 of the contested decision). Lastly, the Commission correctly added that 'paying or otherwise inducing potential competitors to stay out of the market [was] not part of any patent right, nor [was] it one of the means provided for under patent law to enforce the patent' (recital 1194 of the contested decision).

269 Where an inducement has been found, the parties may no longer rely on their recognition, in the context of the settlement, of the validity of the patent. The fact that the validity of the patent is confirmed by a judicial or administrative body is, in that regard, irrelevant.

270 It is then the inducement, and not the recognition of the validity of the patent by the parties to the settlement, which must be regarded as the real cause of the restrictions of competition introduced by the non-marketing and non-challenge clauses (see paragraph 257 above), which — since they are in that case entirely illegitimate — therefore reveal a sufficient degree of harm to the proper functioning of normal competition that a restriction by object may be found.

271 Where they involve an inducement, the agreements in question must therefore be regarded as market exclusion agreements, in which the 'stayers' are to compensate the 'goers'. Such agreements actually constitute a buying-off of competition and must therefore be classified as restrictions of competition by object, as follows from the judgment of 20 November 2008, *Beef Industry Development Society and Barry Brothers* (C-209/07, EU:C:2008:643, paragraphs 8 and 31 to 34), and the Opinion of Advocate General Trstenjak in *Beef Industry Development Society and Barry Brothers*, (C-209/07, EU:C:2008:467, point 75), referred to in inter alia recitals 1139 and 1140 of the contested decision. Moreover, the exclusion of competitors from the market constitutes an extreme form of market sharing and of limitation of production (judgment of 8 September 2016, *Lundbeck* v *Commission*, T-472/13, under appeal, EU:T:2016:449, paragraph 435) which, in a context such as that of the agreements in question, reveals a degree of harm which is all the greater since the companies excluded are generic companies, the market entry of which is, as a rule, favourable to competition and which also contributes to the public interest in lowering the cost of healthcare. Lastly, that market exclusion is augmented, in the agreements at issue, by the fact that it is not possible for the generic company to challenge the patent at issue.

272 It follows from all the foregoing that, in the context of patent dispute settlement agreements, a finding of a restriction of competition by object presupposes that the settlement agreement contains both an inducement in the form of a benefit for the generic company and a corresponding limitation of the generic company's efforts to compete with the originator company. Where those two conditions are met, a finding of restriction of competition by object must be made in view of the harmfulness of that agreement to the proper functioning of normal competition.

273 Thus, where a patent settlement agreement contains non-marketing and non-challenge clauses, the inherently restrictive nature of which (see paragraph 257 above) has not been validly called into question, the existence of an inducement for the generic company to agree to those clauses supports the conclusion that there is a restriction by object, even if there is a genuine dispute, the settlement agreement includes non-marketing and non-challenge clauses the scope of which does not exceed that of the patent at issue and that patent could — having regard, in particular, to the decisions adopted by the competent administrative authorities or courts — legitimately be regarded as valid by the parties to the agreement at the time it was adopted.

274 In the contested decision, the Commission rightly examined whether the agreements at issue in the present case involved a value transfer from the originator company to the generic company representing a 'significant' inducement, that is to say liable to lead the latter to accept non-marketing and non-challenge clauses, and concluded, having found such an inducement, that there was a restriction of competition by object.

275 It follows from all the foregoing that the Commission did not vitiate the contested decision by an error of law by applying the inducement criterion for the purpose of distinguishing settlement agreements which constitute restrictions by object from those which do not constitute such restrictions, referred to below as the 'inducement' or 'inducive benefit' criterion.

276 Nor can such an error of law be inferred from any alleged failure to take into account the context of the agreements at issue (see, as regards the concept of context, judgment of 11 September 2014, *CB* v *Commission*, C-67/13 P, EU:C:2014:2204, paragraph 53), since it also follows from the foregoing considerations that the inducement criterion is based on an analysis of the substance of the agreements at issue not only with regard to their stated aim, namely to settle patent disputes, but also their specific context, which is characterised by the presence, in the pharmaceutical sector, of patents constituting exclusive rights which enjoy a presumption of validity and the possession of which normally results in keeping competitors away (see paragraph 234 above). The context in which the agreements at issue were concluded was given particular attention in the present case since the Commission sought to demonstrate, for each of those agreements, that the generic company in question was a potential competitor to Servier, that is to say that it had real concrete possibilities of entering the market (see paragraph 317 et seq. below). For the purposes of supplementing the response provided to the plea alleging an error of law committed by the Commission in finding the existence of a restriction by object and making it possible subsequently to examine whether, for each agreement, the Commission committed an error of assessment, it remains necessary to set out in detail the circumstances in which an inducement may be found to exist.

(5) The inducement

277 In order to establish whether or not a reverse payment, that is to say a transfer of value from the originator company to the generic company, constitutes an inducement to accept non-marketing and non-challenge clauses, it is necessary to examine, taking into account its nature and its justification, whether the transfer of value covers costs inherent in the settlement of the dispute. In the contested decision, the Commission therefore rightly examined whether the value transfer corresponded to the specific costs of the settlement for the generic company (recitals 1333 et seq., 1461 et seq., 1592 et seq. and 1969 et seq. of the contested decision).

278 If a reverse payment provided for in a settlement agreement containing clauses restrictive of competition is aimed at compensating costs borne by the generic company that are inherent in that settlement, that payment cannot in principle be regarded as an inducement. Because they are inherent in the settlement agreement, there is an implication that those costs are, as such, based on the recognition of the validity of the disputed patents which that settlement is intended to affirm by bringing to an end the challenges to that validity and the potential infringement of those patents. It therefore cannot be considered that such a reverse payment creates doubts as to whether that settlement is based on the parties' recognition of the validity of the patent in question (see paragraphs 264 and 265 above). Nevertheless, a finding of an inducement and of a restriction of competition by object is not ruled out in such a case. It means however that the Commission must prove that the amounts corresponding to those costs inherent in the settlement, even if they are established and precisely quantified by the parties to that settlement, are excessive (see, to that effect, recitals 1338, 1465, 1600 and 1973 of the contested decision). Such a disproportion would demonstrate that the costs concerned are not inherently linked with the settlement and, accordingly, it could not be inferred from the reimbursement of those costs that the settlement agreement is based on the recognition of the validity of the patents at issue.

279 It may be considered, as the applicants and the Commission acknowledged at the hearing, that the costs inherent in the settlement of the dispute include, in particular, litigation expenses incurred by the generic company in the context of the dispute between it and the originator company. These expenses were incurred solely for the purposes of the litigation concerning the validity or the infringement of the patents in question, which the settlement is intended to bring to an end on the basis of an agreement acknowledging the validity of the patents. The compensation of those costs is therefore directly linked to that settlement. Consequently, where the litigation expenses of the generic company are established by the parties to the settlement, the Commission can find them to be inducive only by showing that they are disproportionate. In that respect, amounts corresponding to litigation

expenses which have not been proved, on the basis of specific and detailed documents, to be objectively indispensable for the conduct of the litigation — having regard inter alia to the legal and factual complexity of the issues dealt with and the generic company's financial interest in the dispute — must be regarded as disproportionate.

280 By contrast, some costs incumbent upon the generic company are, a priori, too extraneous to the dispute and to its settlement to be regarded as inherent in the settlement of a patent dispute. Those include, for example, the costs of manufacturing the infringing products, corresponding to the value of the stock of those products, and research and development expenses incurred in developing those products. Such costs and expenses are a priori incurred independently of the occurrence of litigation and its settlement and do not represent losses because of that settlement, as is clear from, in particular, the fact that, despite the marketing of the products in question being prohibited under the settlement agreement, they are often sold on markets not covered by that agreement and the fact that the research in question may be used to develop other products. The same is true of sums which must be paid by the generic company to third parties as a result of contractual commitments which were not undertaken in the context of the dispute (for example supply contracts). Such costs incurred in terminating contracts concluded with third parties or in compensating third parties are usually imposed by the contracts in question or are directly connected with those contracts, which, moreover, were concluded by the generic company concerned independently of any dispute with the originator company or its settlement. It is therefore for the parties to the agreement in question, if they do not wish the payment of those costs to be regarded as an inducement, and indicative of a restriction of competition by object, to demonstrate that those costs are inherent in the dispute or in its settlement, and then to justify the amount. They could also, to the same end, invoke the insignificant amount of the repayment of those costs which are a priori not inherent in the settlement of the dispute, showing that that amount is insufficient to constitute a significant inducement to accept the clauses restricting competition stipulated in the settlement agreement (see, to that effect, judgment of 8 September 2016, *Lundbeck* v *Commission*, T-472/13, under appeal, EU:T:2016:449, paragraph 360).

281 It is necessary, in order to conclude the analysis of the Commission's alleged error of law in finding that there was a restriction of competition by object, to examine three subordinate arguments put forward by the applicants and the intervener, based on the applicability to the agreements at issue of the ancillary restraints doctrine, on the implications of US law for the solution to the dispute and on the ambivalent effects caused by the patent settlement agreements.

(6) Whether the ancillary restraints doctrine is applicable to settlement agreements

282 The applicants and the intervener submit that, because of the legitimate objective of patent settlement agreements, the Commission should have applied the objective necessity test, according to which an agreement may be exempted from the application of Article 101(1) TFEU if it has a legitimate purpose and the restrictions on competition which it imposes are objectively necessary and proportionate.

283 As a preliminary point, it should be noted that the applicants did not invoke the application of the ancillary restraints doctrine during the administrative procedure and that the contested decision does not mention it.

284 According to the case-law, if a given operation or activity is not covered by the prohibition 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 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, *MasterCard and Others* v *Commission*, C-382/12 P, EU:C:2014:2201, paragraph 89 and the case-law cited). Where it is not possible to dissociate such a restriction, classified as an

ancillary restraint, 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 in Article 101(1) TFEU (judgment of 11 September 2014, *MasterCard and Others* v *Commission*, C-382/12 P, EU:C:2014:2201, paragraph 90).

285 The Commission argues that the precondition for the application of the objective necessity test is not fulfilled, since a patent dispute settlement cannot, in principle, be regarded as an operation which is in no way anticompetitive because of its neutrality or its positive effect on competition. It is true that it follows from settled case-law that the settlement of a dispute does not exempt the parties from the application of the competition rules, since Article 101(1) TFEU made no distinction between agreements whose object is to put an end to litigation and those concluded with other aims in mind (see paragraph 253 above). However, as the applicants and the intervener correctly argue, the case-law does not rule out the possibility that a settlement may not fall within the scope of the prohibition laid down in Article 101(1) TFEU because of its neutrality or its positive effects as regards competition. The application of the objective necessity test in a particular case presupposes that the main operation or activity is in no way anticompetitive because of its neutrality or its positive effect on competition, but it does not require that the main operation or activity be, by its very nature and irrespective of the circumstances of each case, in no way anticompetitive. It is also apparent from the case-law that the main operation or activity cannot be assessed *in abstracto* but rather depends on the ancillary clauses and restrictions specific to each case (see, to that effect, judgments of 28 January 1986, *Pronuptia de Paris*, 161/84, EU:C:1986:41, paragraph 14; of 15 December 1994, DLG, C-250/92, EU:C:1994:413, paragraph 31; and of 12 December 1995, *Oude Luttikhuis and Others*, C-399/93, EU:C:1995:434, paragraphs 12 to 14). In addition, it must be borne in mind that numerous provisions of EU law encourage the settlement of disputes (see paragraphs 247 to 250 above).

286 Moreover, the Commission cannot rely on the judgment of 27 September 1988, *Bayer and Maschinenfabrik Hennecke* (65/86, EU:C:1988:448), to reject, in principle, any possibility of applying the ancillary restraints doctrine to the settlement of disputes. While it is apparent from that judgment that the Court of Justice refused to follow the reasoning proposed by the Commission consisting in regarding a clause prohibiting challenges to a patent contained in a licensing agreement as compatible with Article 101(1) TFEU where certain conditions are fulfilled and stated that Article 101(1) TFEU made no distinction between agreements whose object is to put an end to litigation and those concluded with other aims in mind, it did not however rule out the possibility that a settlement agreement which contains non-challenge and non-marketing clauses might, depending on the legal and economic context, not be anticompetitive (judgment of 27 September 1988, *Bayer and Maschinenfabrik Hennecke* (65/86, EU:C:1988:448, paragraph 21). Furthermore, that judgment was delivered not in the context of the settlement of a dispute but in the context of a licence agreement.

287 Although a patent dispute settlement agreement which has a neutral or positive effect as regards competition cannot in principle be excluded from the scope of the ancillary restraints doctrine, it is nonetheless necessary to carry out an assessment of the scope of the ancillary restraint of competition, which entails a double assessment. It is necessary to establish, first, whether the restriction is objectively necessary for the implementation of the main operation or activity and, secondly, whether it is proportionate to it (judgments of 18 September 2001, *M6 and Others* v *Commission*, T-112/99, EU:T:2001:215, paragraph 106, and of 29 June 2012, *E.ON Ruhrgas and E.ON* v *Commission*, T-360/09, EU:T:2012:332, paragraph 64).

288 As regards the first condition, according to the case-law, it is necessary to establish whether that operation or activity would be impossible to carry out in the absence of the restriction in question. Thus, the fact that that operation or activity 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 or activity. Such an outcome would undermine the effectiveness of the prohibition laid down in Article 101(1) TFEU (see, to that effect, judgment of 11 September 2014, *MasterCard and Others* v *Commission*, C-382/12 P, EU:C:2014:2201, paragraph 91).

289 As regards, non-challenge and non-marketing clauses, they are inherent in some settlement agreements, namely those which are based on the recognition of the validity of the patent or patents in question (see paragraph 259 above). Such clauses — provided that they reflect the recognition of the validity of the patents by each of the parties and that their scope is limited to that of the patent in question must therefore be regarded as capable of satisfying the first condition of the exception provided by the ancillary restraints doctrine.

290 As regards the second condition, it must be borne in mind that, where a restriction is objectively necessary to implement a main operation or activity, it is still necessary to verify whether its duration and its material, temporal and geographic scope do not exceed what is necessary to implement that operation or that activity. If the scope of the restriction exceeds what is necessary in order to implement the main operation or activity, it must be assessed separately under Article 101(3) TFEU (judgment of 18 September 2001, *M6 and Others* v *Commission*, T-112/99, EU:T:2001:215, paragraph 113). Consequently, a settlement agreement containing non-challenge and non-marketing clauses which do not exceed the duration and scope of the patent the validity of which is recognised therein could benefit from the application of the ancillary restraints doctrine.

291 However, in the present case, the Commission was entitled to refrain from examining whether it was necessary to apply the ancillary restraints doctrine, since it considered that the non-challenge and non-marketing clauses were not based on the recognition of the validity of the patent, but on a transfer of value from the originator company to the generics company constituting an inducement, for the latter, not to exert competitive pressure on the company holding the patent. In such a case, the settlement agreement constitutes a restriction of competition by object which cannot be regarded as an operation which is in no way anticompetitive because of its neutrality or its positive effect on competition. Moreover, non-challenge and non-marketing clauses may be a necessary ancillary only to a settlement agreement based on recognition of the validity of the patent in question by the parties to that agreement (see paragraph 289 above). However, where it involves an inducement, a settlement is not based on such recognition. The non-challenge and non-marketing clauses cannot therefore be regarded as necessary for such a settlement.

(7) The reconciliation of patent settlement agreements and US competition law

292 The applicants rely on the *Actavis* judgment, maintaining that the Supreme Court of the United States has rejected the approach adopted by the Commission in the present case. The Commission, which referred to that judgment in the contested decision (recital 1199), nevertheless argues that it adopted the same approach as the Supreme Court of the United States, by taking the view that there was no presumption that settlement agreements entailing a transfer of value from the originator company to the generic company were unlawful.

293 The *Actavis* judgment concerns settlement agreements concluded in the pharmaceutical sector, in which generic companies undertook not to enter the market until a date prior to the expiry date of the patent of the originator company (65 months before the expiry date of the patent for Actavis) and to promote the medicinal product in question to doctors, in return for significant payments (for Actavis, annual payments of USD 19 to 30 million for nine years).

294 It should be noted that, according to settled case-law, national practices, even on the supposition that they are common to all the Member States, cannot prevail in the application of the competition rules set out in the Treaty (see, to that effect, judgment of 17 January 1984, *VBVB and VBBB* v *Commission*,

43/82 and 63/82, EU:C:1984:9, paragraph 40) and that is the case, a fortiori, as regards the national practices of third countries (see, to that effect, judgment of 28 February 2002, *Compagnie générale maritime and Others* v *Commission*, T-86/95, EU:T:2002:50, paragraph 341 and the case-law cited). The approach adopted by EU competition law as regards the distinction between restrictions on competition by object and by effect differs from United States antitrust law, which draws a distinction between restrictions of competition per se, namely cases in which the anticompetitive effects are so obvious that they require only a 'quick look' approach, without taking the context into account, and which are necessarily and irremediably prohibited, and infringements which must be proved according to the rule of reason, that is to say following an examination balancing the pro- and anticompetitive effects of the agreement. First, EU law does not regard any restriction of competition as necessarily and irremediably unlawful, since a restriction of competition by object may, in principle, fall within the exceptions laid down in Article 101(3) TFEU. Secondly, as noted in the case-law, the existence of a rule of reason in EU competition law cannot be upheld (judgment of 29 June 2012, *E.ON Ruhrgas and E.ON* v *Commission*, T-360/09, EU:T:2012:332, paragraph 65; see also, to that effect, judgment of 23 October 2003, *Van den Bergh Foods* v *Commission*, T-65/98, EU:T:2003:281, paragraph 106). Moreover, the differences between the prevailing regulatory context in the United States and in the European Union, as regards pharmaceutical patents in particular, make it even more difficult to apply the approach adopted in the *Actavis* judgment, by analogy, to the present case (see, to that effect, judgment of 8 September 2016, *Lundbeck* v *Commission*, T-472/13, under appeal, EU:T:2016:449, paragraph 513).

295 Accordingly, the applicants' argument alleging the failure to have regard to the position of the Supreme Court of the United States must be rejected as ineffective.

(8) The ambivalent effects of the settlement agreements

296 The applicants take the view that the effects of the settlement agreements are ambivalent in nature and cannot, therefore, be classified as a restriction of competition by object.

297 They argue, in the first place, that such agreements have ambivalent potential effects on patent challenges, where there are parallel disputes and where, in proceedings before the EPO, the withdrawal by a party of its opposition does not preclude continuation of the proceedings, since its arguments may be raised by the EPO's Opposition Division, or Board of Appeal, of its own motion. Moreover, the contested decision failed to take into account the fact that settlement agreements have only ambivalent effects on future disputes, since generic undertakings remain free as to whether or not to bring costly legal proceedings, which may in any event prove to be pointless in certain Member States where proceedings before the EPO are pending.

298 In the second place, the applicants take the view that the potential effects of those agreements on the entry of generics onto the market are also ambivalent, depending on the terms of the agreements and the context in which they apply. Accordingly, it is necessary to take into account the existence of the dispute and the parties' likelihood of success, the existence of other disputes and the possibility of developing other alternative forms of the product. Moreover, those agreements could allow a faster entry of generics onto the market. Finally, the Commission should take into account the ability and intention of generic undertakings to enter the market at risk.

299 In the third place, the applicants take the view that the Commission cannot penalise patent dispute settlement agreements without assessing their actual effects on the market, in common with the position adopted by the Supreme Court of the United States in the *Actavis* judgment.

300 The Commission contends that that argument is ineffective, since, in order to determine whether an agreement constitutes a restriction of competition by object, its effects need not be taken into account and a restriction of competition by object may even, in some cases, owing to subsequent circumstances, have no effect. When analysing a restriction by object, it is therefore not necessary to establish which counterfactual situations might arise in the absence of the agreements.

301 In the alternative, the Commission submits, with regard to the effects of the settlement agreements on the patent challenges, that, in the present case, the applicants endeavoured to conclude agreements with all their potential competitors and that only two of the five agreements concluded by them included a clause allowing the entry of the generic undertakings into the market if the patent at issue was annulled.

302 The Commission further submits that it examined, in the contested decision, the ability and intention of each generic undertaking to enter the market at risk.

303 Finally, the Commission argues that the contested decision is not inconsistent with the approach adopted by the Supreme Court of the United States in the *Actavis* judgment, in the light of the differences between the European concept of restriction by object and the American concept of restriction per se. It also recalls that the case-law of the EU Courts rejects the existence of a rule of reason, since the pro-competitive benefits of an agreement must be examined in the context of Article 101(3) TFEU.

304 As the applicants submit, it must be held that the Commission and the Courts of the European Union cannot, when examining whether an agreement restricts competition by object and, in particular, in assessing the economic and legal context of that agreement, completely ignore its potential effects (Opinion of Advocate General Wahl in *ING Pensii*, C-172/14, EU:C:2015:272, point 84). It should be borne in mind that agreements which are restrictive of competition by object are those which reveal a sufficient degree of harm, in that they are so likely to have anticompetitive effects, that it may be found that there is no need to examine their specific effects on the market (see, to that effect, judgment of 11 September 2014, *CB* v *Commission*, C-67/13 P, EU:C:2014:2204, paragraphs 49 and 51 and the case-law cited). It follows that agreements which, having regard to their context, have ambivalent potential effects on the market cannot be regarded as being a restriction of competition by object (Opinion of Advocate General Wahl in *CB* v *Commission*, C-67/13 P, EU:C:2014:1958, point 56).

305 However, in the present case, in so far as the applicants are primarily putting forward, in support of their claims concerning the ambivalent potential effects of the agreements at issue, arguments based on each of those agreements and their context, it is appropriate to respond to the claims in question in the context of the response to the criticisms levelled against the classification of each agreement as a restriction by object, especially since, as the Commission rightly points out, the assessment of the existence of a restriction by object must be made for each agreement as a whole, without separately analysing the restrictive nature of the non-challenge clauses and the non-marketing clauses.

306 In the response to the pleas criticising the assessment of each of the agreements at issue, the question whether the Commission validly found that there was a restriction by object in spite of the claimed potentially pro-competitive effects resulting, in particular, from the context in which those agreements were concluded will therefore be examined and it should be noted in this connection that only those forming the subject matter of the analysis of the restrictions of competition by object will be taken into account (see paragraphs 525, 644 and 989 below).

307 Moreover, as is clear from paragraphs 293 to 295 above, the applicants cannot rely effectively on the *Actavis* judgment.

(b) The Commission's criteria for classifying the settlement agreements as restrictions by object

308 It is in the light of the foregoing considerations that it is necessary to examine the applicants' arguments relating specifically to each of the three main criteria used by the Commission to classify the settlement agreements at issue as restrictions of competition by object, that is to say, first, the status of the generic undertakings as potential competitors, secondly, the commitment of those undertakings to limit their efforts to enter the market with a generic product and, thirdly, a transfer of value from the originator company to the generic company representing a significant inducement for the latter to limit its efforts at entry (recital 1154 of the contested decision).

(1) The criterion of potential competition

(i) Arguments of the parties

…

(ii) Findings of the Court

316 The applicants complain, in essence, that the Commission erred in law in using incorrect criteria in order to classify as potential competitors the generic undertakings which concluded the agreements at issue with the applicants. The applicants also criticise the Commission's assessment of the obstacles to the existence of that potential competition resulting from their patents.

– *The criteria for assessing potential competition*

The definition of the concept of potential competitor

317 The applicants criticise the Commission for having confined itself, for the purposes of ascertaining whether there was potential competition between the parties to the agreements at issue, to verifying the absence of insurmountable barriers to the entry of generic companies to the market and for not having examined whether those companies had real concrete possibilities of entering that market (see paragraph 309 above).

318 It is indeed apparent from the case-law cited by the applicants that an undertaking is a potential competitor if there are real concrete possibilities for it to enter the market in question and compete with established undertakings. Such a demonstration must not be based on a mere hypothesis, but must be supported by 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 (judgment of 29 June 2012, *E.ON Ruhrgas and E.ON* v *Commission*, T-360/09, EU:T:2012:332, paragraph 86; see also, to that effect, judgment of 14 April 2011, *Visa Europe and Visa International Service* v *Commission*, T-461/07, EU:T:2011:181, paragraphs 166 and 167 and the case-law cited). 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 (judgments of 14 April 2011, *Visa Europe and Visa International Service* v *Commission*, T-461/07, EU:T:2011:181, paragraph 168, and of 29 June 2012, *E.ON Ruhrgas and E.ON* v *Commission*, T-360/09, EU:T:2012:332, paragraph 87).

319 In other contexts, it has also been held that an undertaking constitutes a potential competitor if there exist no insurmountable barriers to its entry to the market (see, to that effect, judgments of 21 May 2014, *Toshiba* v *Commission*, T-519/09, not published, EU:T:2014:263, paragraph 230, confirmed by

the judgment of 20 January 2016, *Toshiba Corporation* v *Commission*, C-373/14 P, EU:C:2016:26, paragraphs 28, 29, 32 and 34, and of 28 June 2016, *Portugal Telecom* v *Commission*, T-208/13, EU:T:2016:368, paragraph 181).

320 It thus follows from the case-law that, depending on the context and the unlawful conduct in question, the threshold for a finding of potential competition may vary. The examination solely of insurmountable barriers to market entry implies that any possibility — even hypothetical — of market entry is sufficient to establish the existence of potential competition, whereas the analysis of real concrete possibilities for market entry means that potential competition could be found to exist only if there are realistic possibilities of entry, which could have taken place in the absence of any restrictive measure

321 Nevertheless, the fact remains that verifying whether certain barriers to entry to the market, in the present case mainly consisting of patents and the obligation to obtain a marketing authorisation, are insurmountable neither calls into question nor is inconsistent with the examination of the real concrete possibilities for entry of generic undertakings based on the examination of their ability and their intention to enter. As the Commission rightly emphasised in the contested decision (footnote 1666) and at the hearing, that verification of the absence of insurmountable barriers 'served to verify if, in spite of generic company's general ability and proven intention to enter, there were objective reasons rendering generic entry impossible' and, thus, to supplement the analysis based on the real concrete possibilities criterion. Indeed, in the presence of insurmountable barriers to entry on a market, it cannot be considered that an operator has real concrete possibilities of entering that market. Therefore, if a market is characterised by barriers to entry, an objective examination of whether those barriers are insurmountable is a useful adjunct to the examination of whether there are real concrete possibilities, based on the individual criteria of the ability and intention of the undertaking in question to enter the market.

322 Reference to the criterion of insurmountable barriers on several occasions in the contested decision (see, in particular, recitals 1125 and 1181) cannot, therefore, lead to the conclusion, as drawn by the applicants, that the Commission adopted a definition of potential competition based solely on that criterion.

323 This is particularly true, since the Commission cited, together with the judgment of 21 May 2014, *Toshiba* v *Commission* (T-519/09, not published, EU:T:2014:263), which applied the criterion of insurmountable barriers (see paragraph 319 above), the judgments of 15 September 1998, *European Night Services and Others* v *Commission* (T-374/94, T-375/94, T-384/94 and T-388/94, EU:T:1998:198), and of 14 April 2011, *Visa Europe and Visa International Service* v *Commission* (T-461/07, EU:T:2011:181), which used the real concrete possibilities criterion, referring to them, moreover, in the introduction to its presentation of the rules on the determination of potential competitors (recitals 1156 and 1157 of the contested decision), as well as several other judgments recalling and applying that definition of potential competition, including the judgment of 29 June 2012, *E.ON Ruhrgas and E.ON* v *Commission* (T-360/09, EU:T:2012:332) (see paragraph 318 above). The Commission also clearly indicated that the ability to enter a market, which is a characteristic of the real concrete possibilities criterion (see paragraph 318 above), remained 'the crucial aspect in demonstrating potential competition' (recital 1163 of the contested decision). Lastly, and above all, in its assessment of each of the generic companies in question as a potential competitor, the Commission concluded — on the basis of several pieces of information specific to each of them, concerning inter alia their production capacities and their stocks of products, their commercial contracts, the steps they had taken to obtain marketing authorisations and their litigation against Servier — that all of them had real concrete possibilities of entering the market (see paragraphs 432 to 438, 579 to 585 and 718 to 722 below). Such a detailed analysis on the basis of information specific to each alleged potential competitor is characteristic of the examination of its real concrete possibilities of entering

the market and is not the same as merely checking whether there are insurmountable barriers to entry on a given market, which could result in a finding of potential competition simply because any operator entered the market in question.

324 Those findings are not called into question by the applicants' claims that the Commission relied essentially on the intention of the generic undertakings to enter the market and on a set of unrealistic assumptions (see paragraph 309 above), since it is clear from the wording of the reply that the applicants are contesting, by those claims, not the criterion used, but the application in the present case of the real concrete possibilities criterion, which is examined below in the context of the response to the complaints directed against the assessment of each of the agreements at issue.

325 It follows that, contrary to what the applicants claim, the Commission assessed potential competition on the relevant market on the basis of the real concrete possibilities criterion.

326 Moreover, it may be noted that, contrary to what the Commission claimed in the rejoinder, referring to the judgment of 20 January 2016, *Toshiba Corporation* v *Commission* (C-373/14 P, EU:C:2016:26) (see paragraph 312 above), it could not limit itself in the present case to verifying the absence of insurmountable barriers to market entry in order to infer the existence of potential competition on that market (see, to that effect, judgment of 8 September 2016, *Lundbeck* v *Commission*, T-472/13, under appeal, EU:T:2016:449, paragraphs 99 to 101).

327 It is indeed apparent from paragraphs 28, 29, 32 and 34 of the judgment of 20 January 2016, *Toshiba Corporation* v *Commission* (C-373/14 P, EU:C:2016:26), that, in respect of market-sharing agreements, the analysis of the economic and legal context of which the practice forms part may be limited to what is strictly necessary in order to establish the existence of a restriction of competition by object and, in particular, to verifying that the barriers to entry on the market at issue cannot be described as insurmountable (see also, to that effect, judgment of 28 June 2016, *Portugal Telecom* v *Commission*, T-208/13, EU:T:2016:368, paragraphs 177 and 181).

328 However, it must be borne in mind, first of all, that it is clear from the judgment of 20 January 2016, *Toshiba Corporation* v *Commission* (C-373/14 P, EU:C:2016:26), read in the light of the Opinion of Advocate General Wathelet in *Toshiba Corporation* v *Commission* (C-373/14 P, EU:C:2015:427, points 69, 70, 89 and 90), that the limitation established by that judgment of the analysis of the economic and legal context results from the particularly obvious nature of some restrictions by object which, in particular because the agreements in question are neither atypical nor complex, do not require an in-depth analysis of the economic and legal context to establish that they are by nature sufficiently harmful.

329 In the present case, because the agreements at issue were concluded in the form of patent settlements, the unlawful nature of those agreements and the fact that they constituted restrictions on competition by object might not have been evident to an outside observer. It is, in that regard, revealing that the Commission analysed both their anticompetitive objective and their anticompetitive effect. It is also confirmed by the Commission's classification of the agreements at issue as restrictions by object within the meaning of the judgment of 20 November 2008, *Beef Industry Development Society and Barry Brothers* (C-209/07, EU:C:2008:643), without it being necessary to rule at this stage on that classification. Indeed, although it is clear from paragraph 34 of that judgment that market exclusion agreements conflict 'patently' with the conception inherent in the Treaty provisions relating to competition, the Court of Justice did not hold that the agreements at issue in that case were, for an outside observer, patently or evidently, exclusion agreements and thus restrictions by object which do not require a detailed analysis of their economic and legal context. On the contrary, it carried out such an analysis of that context and of the clauses and objectives of the agreements at issue in order to conclude therefrom that they were exclusion agreements and, consequently, 'patently' agreements restrictive of competition by object (judgment of 20 November 2008, *Beef Industry Development Society and Barry Brothers*, C-209/07, EU:C:2008:643, paragraphs 31 to 40).

330 It should be noted, next, that in the case which gave rise to the judgment of 20 January 2016, *Toshiba Corporation* v *Commission* (C-373/14 P, EU:C:2016:26), the production and marketing ability of the producers which participated in the practices at issue were not disputed and the relevant market was not subject to any monopoly. In the present case, however, the ability of the generic companies to produce and market the product at issue is precisely what is disputed, particularly in the light of the exclusive rights represented by the applicants' patents (see paragraph 234 above and paragraph 357 below). It cannot therefore be inferred from that judgment that the finding that an agreement is a restriction of competition by object does not require, in general, and in particular in circumstances such as those in the present case, verification that the parties to the agreement have real concrete possibilities of entering the relevant market.

331 It follows from all the foregoing that the complaint based on the application of an incorrect definition of potential competition must be rejected.

The criterion of sufficiently fast entry

332 In the contested decision, the Commission, based on the judgments of 3 April 2003, *BaByliss* v *Commission* (T-114/02, EU:T:2003:100), and of 14 April 2011, *Visa Europe and Visa International Service* v *Commission* (T-461/07, EU:T:2011:181), considered that the essential factor for an undertaking to be classified as a potential competitor was that it could enter the market sufficiently quickly to form a constraint on market participants. The Commission pointed out that, although delays might reflect the difficulty of entry in terms of costs and time and that market entry might be less commercially attractive because of those delays, they did not in themselves call into question the ability to enter the market or the constraint on Servier or the other generic undertakings. In the present case, the Commission concluded, referring to the temporal indications given in the exemption regulations and in its guidelines — in particular the Guidelines on the applicability of Article 101 [TFEU] to horizontal cooperation agreements (OJ 2011 C 11, p. 1, 'the 2011 Guidelines on horizontal cooperation agreements'), which provide for a period not exceeding three years — as well as the indicative and actual lengths of legal proceedings, of the granting of marketing authorisations and of the development of APIs, that the delays alleged by the applicants and the generic companies did not appear to be sufficiently long for the generic challenger not to exert competitive pressure (recitals 1158, 1159, 1182 and footnote 1669 of the contested decision, see also recitals 1125, 1126 and 1296 of that decision).

333 Contrary to the applicants' assertions, that analysis, from a temporal perspective, of potential competition carried out by the Commission is consistent with the applicable principles.

334 According to settled case-law, an operator cannot be described as a potential competitor unless its potential entry could take place sufficiently quickly to form a constraint on market participants and thus exert competitive pressure on them (judgment of 14 April 2011, *Visa Europe and Visa International Service* v *Commission*, T-461/07, EU:T:2011:181, paragraph 189; see also, to that effect, judgment of 29 June 2012, *E.ON Ruhrgas and E.ON* v *Commission*, T-360/09, EU:T:2012:332, paragraph 114).

335 That case-law took into account the Guidelines on the applicability of Article [101 TFEU] to horizontal cooperation agreements (OJ 2001 C 3, p. 2; 'the 2001 Guidelines on horizontal cooperation agreements') (see also the 2011 Guidelines on horizontal cooperation agreements), which not only affirm the need for a sufficiently fast entry, but also set out indicative periods — of no more than one or three years, depending on the circumstances — that may constitute a sufficiently fast entry, on the basis on other guidelines as well as the Block Exemption Regulations.

336 However, as stated in both those guidelines (footnote 9 of the 2001 Guidelines on horizontal cooperation agreements and footnote 3 of the 2011 Guidelines on horizontal cooperation agreements) and the case-law (see, to that effect, judgment of 14 April 2011, *Visa Europe and Visa International*

Service v *Commission*, T-461/07, EU:T:2011:181, paragraphs 171 and 189), these periods are indicative only and the concept of 'sufficiently fast' entry depends on the facts of the case at hand and its legal and economic context, which must be taken into account in order to determine whether the undertaking outside the market exerts competitive pressure on the undertakings currently operating in that market (see, to that effect, judgment of 14 April 2011, *Visa Europe and Visa International Service* v *Commission*, T-461/07, EU:T:2011:181, paragraph 169).

337 In the present case, the Commission took into account the specific features of the economic and legal context of the present case by assessing the duration of each of the steps required in order to enter the market. It should be pointed out that, precisely because of the particular features of the pharmaceutical sector and in particular the various steps that must be taken and the existence of patents, generic companies often begin their efforts to enter the market well before the expiry of the patents, in order to have completed the necessary steps by the time those patents expire at the latest. These efforts are therefore likely to exert competitive pressure on the originator undertaking, before, or even well before, the expiry of the patents and the actual market entry of the generic companies (see paragraph 356 below; see also, to that effect, judgments of 6 December 2012, *AstraZeneca* v *Commission*, C-457/10 P, EU:C:2012:770, paragraph 108; of 8 September 2016, *Lundbeck* v *Commission*, T-472/13, under appeal, EU:T:2016:449, paragraph 163; and of 8 September 2016, *Sun Pharmaceutical Industries and Ranbaxy (UK)* v *Commission*, T-460/13, not published, under appeal, EU:T:2016:453, paragraphs 77 to 79).

338 As the applicants rightly maintain (see paragraph 311 above), it cannot be inferred from this that a generic undertaking may be regarded as one of their potential competitors as soon as and solely because it starts to develop a generic form of perindopril. It is true that the Commission stated, in recital 1125 of the contested decision, that potential competition from generic companies starts when the companies that want to launch a generic medicine begin developing commercially viable technologies for production of the API and the finished product. However, it is apparent from the following statements in that recital, which refer to the subsequent analysis of each of the generic undertakings in question as a potential competitor, and above all from that analysis and the general considerations of the contested decision relating to the criterion of sufficiently fast entry (see paragraph 332 above), that the Commission did not intend to find that the exertion of competitive pressure began on the date that development of the generic product commenced, but wished to highlight the possibility of the exertion of competitive pressure from that commencement date, in the event that the conditions for the exertion of such pressure were met. In any event, even if recital 1125 is interpreted as fixing the start of potential competition on the date that development of the generic product commenced, the criticism of that assessment should be rejected as ineffective, since the Commission has not relied on that recital to conclude that the generic undertakings in question were potential competitors. As the Commission rightly points out, on the date of assessing whether the generic companies were potential competitors, that is at the time of concluding the agreements at issue, it had considered that all those companies had reached an advanced stage of development of their perindopril and had not given a view on their prior status as potential competitors, when they commenced that development (see paragraph 315 above).

339 Similarly, the Commission indeed noted, in footnote 1840 in recital 1296 of the contested decision, the three-year period mentioned in the 2011 Guidelines on horizontal cooperation agreements, but it did not draw any decisive inference from that in the present case, with the result that the complaints criticising it for taking that period into account, in view inter alia of the time required to develop perindopril (recital 3137 of the contested decision), must be rejected as ineffective.

340 Secondly, the Commission relied on the idea of competitive pressure inherent in potential competition in considering that any delays in the process of entering the market experienced by the generic companies were not sufficient by themselves to prevent those companies being regarded as potential competitors when they continued to exert such pressure due to their ability to enter the market and cited, to that effect, the judgment of 3 April 2003, *BaByliss* v *Commission* (T-114/02, EU:T:2003:100).

Contrary to the applicants' assertions, the Commission relied, correctly, on that judgment, since, even though, in that judgment, the Court was ruling on a very different context from that of the present case, it nevertheless took a position on the impact of several deferrals of BaByliss' market entry on its status as a potential competitor, an impact which is precisely examined in the contested decision. The Court held, in that respect — which, moreover, is not disputed by the applicants — that the deferrals of market entry did not call into question BaByliss' status as a potential competitor, relying on several factors showing that competitive pressure was exerted as a result of its ability to enter the market in question (judgment of 3 April 2003, *BaByliss* v *Commission*, T-114/02, EU:T:2003:100, paragraphs 102 to 106). It therefore also follows that, in so far as the interest on the part of generic companies to be the first to enter the market may, at the most, have an impact on their intention to enter that market, in view of the size of the expected profits, but not, as such, on their ability to enter it, the Commission was correct, in recital 1182 of the contested decision and contrary to the applicants' submissions, to dismiss the relevance of that interest on the part of generic companies for the purposes of assessing the alleged delays. In fact, the ability to enter the market must be examined in the light of the economically viable strategy criterion (see paragraph 318 above), that is to say it corresponds to a merely profitable entry, and not to the most profitable of possible market entries, in which the generic company in question would be the first to enter the market and thus the only company to compete with the originator company during a certain period (see, to that effect, judgment of 8 September 2016, *Xellia Pharmaceuticals and Alpharma* v *Commission*, T-471/13, not published, under appeal, EU:T:2016:460, paragraph 124).

341 It follows that all the complaints directed against the Commission's temporal assessment of the potential competition must be rejected.

The criterion of the incumbent operators' perception

342 In the contested decision, la Commission found, relying on the judgments of 12 July 2011, *Hitachi and Others* v *Commission* (T-112/07, EU:T:2011:342), and of 21 May 2014, *Toshiba* v *Commission* (T-519/09, not published, EU:T:2014:263), that the perception of the market incumbent should play a role in the assessment of potential competition. According to the Commission, if a market incumbent, who is an experienced operator, perceives a competitive threat from generic companies, such a threat is likely to form a competitive constraint on its behaviour on the market, which is relevant for assessing potential competition. The Commission stated, referring to the judgment of 14 April 2011, *Visa Europe and Visa International Service* v *Commission* (T-461/07, EU:T:2011:181), that potential competition could be no more than the existence of an undertaking outside the market, and its mere existence could give rise to competitive pressure, which is represented by the likelihood of entry (recitals 1160 to 1162). The Commission concluded that, in order to answer the question whether generic companies exert competitive pressure on Servier, the perception of the incumbent operator, Servier, and the perception of other generic competitors would also be taken into account (recital 1163). In the present case, the Commission considered that the generic companies were perceived as potential competitors by both Servier and their own generic rivals (recital 1183).

343 It may be noted from the outset that the Commission, in the contested decision, used the criterion of the incumbent operator's perception as one of a number of criteria for determining the status of the generic undertakings as potential competitors, as is demonstrated both by the adverb 'also' recalled in paragraph 342 above and by the examination of the other criteria for assessing potential competition for each of those companies (see paragraphs 432 to 438, 579 to 585 and 718 to 722 below).

344 Contrary to what the applicants claim, the use of the criterion of the incumbent's perception as one of a number of criteria for assessing potential competition is consistent with the case-law applicable in the present case, as relied on by the applicants.

345 Indeed, contrary to the applicants' assertions, the General Court clearly took account of the criterion of the incumbent's perception in the judgment of 12 July 2011, *Hitachi and Others* v *Commission* (T-112/07, EU:T:2011:342), in order to establish the existence of potential competition. It follows in particular from paragraphs 90, 226 and 319 of that judgment, referred to in recital 1160 of the contested decision, that not only did the agreements at issue in that case between the European and Japanese producers constitute serious indicators that the Japanese producers were perceived by the European producers as potential credible competitors, they also showed that there were possibilities for the Japanese producers to penetrate the European market (see also, to that effect, judgment of 21 May 2014, *Toshiba* v *Commission*, T-519/09, not published, EU:T:2014:263, paragraph 231). It is true that the General Court also carried out an objective analysis of potential competition, by examining inter alia the ability of the Japanese producers to enter the European market (judgment of 12 July 2011, *Hitachi and Others* v *Commission*, T-112/07, EU:T:2011:342, paragraphs 157 and 160), as, moreover, the Commission pointed out in recital 1160 of the contested decision. However, that objective analysis only serves to demonstrate that the subjective criterion of the incumbent's perception is only one criterion among others for assessing the existence of potential competition.

346 In the judgment of 29 June 2012, *E.ON Ruhrgas and E.ON* v *Commission* (T-360/09, EU:T:2012:332, paragraph 115), invoked by the applicants, the Court held that the existence of an agreement, and thus the perception of the parties to that agreement, was not enough, by itself, to demonstrate or did not necessarily imply the existence of potential competition at the date of signature of the agreement. Contrary to the applicants' assertions, it was thus not concluded in that judgment that the criterion of the incumbent operator's perception was irrelevant, but merely that that operator's perception alone was not sufficient to establish the existence of potential competition in the absence of any other evidence capable of doing so.

347 It follows that, according to the case-law, the criterion of the incumbent operator's perception is a relevant, but not sufficient, criterion for assessing the existence of potential competition. As the applicants rightly submit, given its subjective, and thus variable nature — which depends on the operators in question, their knowledge of the market and their contacts with their possible competitors — the perception of these operators, even experienced ones, cannot by itself lead to the conclusion that another operator is one of their potential competitors. However, that perception may support the conclusion that an operator has the ability to enter a market and, accordingly, may contribute to its classification as a potential competitor (see, to that effect, judgments of 8 September 2016, *Lundbeck* v *Commission*, T-472/13, under appeal, EU:T:2016:449, paragraphs 103 and 104, and of 8 September 2016, *Sun Pharmaceutical Industries and Ranbaxy (UK)* v *Commission*, T-460/13, not published, under appeal, EU:T:2016:453, paragraph 88).

348 The applicants' arguments directed against the Commission's taking into account of the perception of incumbent operators in order to establish the existence of potential competition must therefore be rejected.

– *The barriers to potential competition constituted by the applicants' patents*

349 The applicants and the intervener criticise the Commission for classifying the generic companies as potential competitors of Servier in spite of the barriers to their entry to the market constituted by the patents held by Servier.

350 In the contested decision, the Commission considered that the parties were wrong to contend, relying in particular on the judgment of 1 July 2010, *AstraZeneca* v *Commission* (T-321/05, EU:T:2010:266, paragraph 362), that market entry was impossible because the existence of a patent excluded any possibility of competition, and to draw the conclusion that Servier's patents created a 'one-way blocking position' within the meaning of the 2004 Guidelines on technology transfer agreements, which, moreover, were not applicable in the present case (recitals 1167 and 1168 and footnote 1638).

351 The Commission added that, in any event, first, the generic companies could contest the validity of Servier's patents. It referred, in that respect, to the judgment of 25 February 1986, *Windsurfing International* v *Commission* (193/83, EU:C:1986:75, paragraph 92), according to which it is in the public interest to eliminate, inter alia by contesting the validity of the patents, any obstacle to economic activity which may arise where a patent was granted in error, and to the judgment of 6 December 2012, *AstraZeneca* v *Commission* (C-457/10 P, EU:C:2012:770, paragraph 108), which stated that potential competition may exist even before the expiry of the compound patent (recitals 1132, 1165 and 1169 and footnote 1640 of the contested decision). The Commission added that the fact that Servier had alleged or was expected to allege infringements of its patents was inconclusive for the determination whether those patents were able to block the entry of generics, emphasising that there was no presumption of infringement and that, throughout the relevant period, no court decision had established such an infringement (recitals 1169 to 1171 of the contested decision). It stated that, with respect to the perceived possibility of invalidity or of infringement of Servier's patents, it would rely on the assessments of the parties themselves, as well as third parties, as indicated in documents pre-dating or contemporaneous with the conclusion of the agreements at issue (recital 1172 of the decision).

352 The Commission took the view that, secondly, the generic companies could also use alternative routes to access the markets where litigation was taking place (recital 1175). The generic companies remained free to launch perindopril at risk, that is to say with the risk that the originator undertaking might bring an infringement action. The Commission noted, in that respect, that, given the practice of filing process patents following the expiry of the compound patent, virtually all sales after that expiry are at risk and that Apotex's market entry at risk in 2006 resulted in a judgment invalidating the 947 patent and the award of damages against Servier (recitals 1176 and 1177 of the contested decision). Furthermore, the generic companies could have changed their processes, either directly or by switching to another API supplier, in order to avoid infringement claims. According to the Commission, while those changes in the manufacturing process might have engendered some regulatory delays, they represented a viable alternative route to the market (recital 1178 of the contested decision).

353 The Commission concluded, in recital 1179 of the contested decision, as follows:

'... the settlements were concluded in a situation where the perindopril compound patent had expired, and all of the generic parties were involved, directly or indirectly, in legal actions or disputes concerning one or more of Servier's remaining patents, whether in the form of a defence against claims of infringement or actions or counterclaims to invalidate such patents. Generics could also elect other patent related measures as potential avenues to the market. The Commission will examine in detail if generic undertakings seeking to overcome patent barriers and launch generic perindopril were a source of competitive pressure on Servier in spite of its patents. It may be recalled, in this respect, that all of the agreements covered by this Decision were concluded at a point in time where there was uncertainty whether any patent had been infringed and whether in particular the 947 patent could be invalidated. The mere existence, and enforcement, of Servier's patents thus did not bar all scope for potential or actual competition.'

354 The applicants and the intervener argue, in essence, that that analysis by the Commission fails to take into account the effects, as provided for the legislation or established by case-law, of a patent declared or presumed to be valid. They also criticise the Commission for disregarding the 2004 and 2014 Guidelines on technology transfer agreements and certain considerations which the Commission expressed in its assessment of Servier's abuse of a dominant position in the contested decision and in other decisions.

The failure to take into account the effects of Servier's patents declared or presumed to be valid

355 According to the applicants and the intervener, a patent presumed to be valid constitutes, at the very least from the declaration of validity until its expiry, a legal prohibition on market entry preventing any potential competition.

356 However, it is clear from paragraph 108 of the judgment of 6 December 2012, *AstraZeneca* v *Commission* (C-457/10 P, EU:C:2012:770), cited by the Commission in the contested decision (see paragraph 351 above), that potential competition may exist in a market even before the expiry of a patent. More specifically, the Court of Justice held that supplementary protection certificates which are intended to extend the protection conferred by a patent lead to significant exclusionary effects after the expiry of the patents, but that they were also liable to alter the structure of the market by adversely affecting potential competition even before that expiry, and that finding concerning the exertion of potential competition before the expiry of the patents was independent of the fact that the supplementary protection certificates at issue in that judgment had been obtained fraudulently or irregularly (judgment of 8 September 2016, *Lundbeck* v *Commission*, T-472/13, under appeal, EU:T:2016:449, paragraph 164). Accordingly, the exclusive right represented by the patent does not, as such, prevent potential competition from taking place during the exclusivity period in question.

357 Although, as the applicants and the intervener state, such an exclusive right normally has the effect of keeping competitors away, since public regulations require them to respect that exclusive right (judgment of 1 July 2010, *AstraZeneca* v *Commission*, T-321/05, EU:T:2010:266, paragraph 362; see, also, paragraph 234 above), that competition-excluding effect concerns the actual competitors selling infringing products. A patent confers on its holder the exclusive right to use an invention with a view to manufacturing industrial products and putting them into circulation for the first time, as well as the right to oppose infringements (judgments of 31 October 1974, *Centrafarm and de Peijper*, 15/74, EU:C:1974:114, paragraph 9, and of 16 July 2015, *Huawei Technologies*, C-170/13, EU:C:2015:477, paragraph 46; see, also, paragraph 234 above), but does not, by itself, preclude operators from taking the necessary steps to be in a position to enter the relevant market following the expiry of the patent and, thus, exerting competitive pressure on the patent holder characteristic of the existence of potential competition before that expiry. Nor does it preclude operators from carrying out the actions necessary for the manufacture and marketing of a non-infringing product, as a result of which they may be regarded as actual competitors of the patent holder upon their market entry and, as the case may be, as potential competitors until that market entry (see, to that effect, judgment of 8 September 2016, *Lundbeck* v *Commission*, T-472/13, under appeal, EU:T:2016:449, paragraph 164).

358 That is particularly the case in the pharmaceutical sector, in which, under the legislation governing the grant of the marketing authorisations required in order to market a medicinal product, the competent authorities may grant a marketing authorisation for a generic product even if the reference product is protected by a patent. It follows from 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 2001 L 311, p. 67), as amended, that marketing authorisation applications for generic products may be dealt with in a shortened procedure based on the results of tests and trials submitted in the marketing authorisation application for the originator product and that the data relating to these results may be used and allow, consequently, the grant of a marketing authorisation before the expiry of the patent on the originator product (Article 10 of Directive 2001/83; see also recitals 74 and 75 of the contested decision). Thus, the legislation on the marketing of pharmaceutical products itself states that a generic company can enter the market with a lawfully granted marketing authorisation or, at the very least, begin the procedure for obtaining the marketing authorisation during the protection period of the originator undertaking's patent. Contrary to the applicants' submissions, the same is true in the national legislation transposing Directive 2001/83, since it is clear from the final report of 8 July 2009 of the Commission's sector inquiry into the pharmaceutical sector, on which they rely, that the Slovak authorities amended their legislation to that effect and that the Hungarian authorities require only a 'patent declaration' whereby a generic company undertakes not to market an infringing product before the expiry of the patent in question. The fact, emphasised by the applicants, that an internal

email from Servier states that 'it seems that the perindopril dossiers [of certain generic companies] are blocked by [the Slovak regulatory authority] for as long as the 947 patent is in force' cannot call that finding into question.

359 Furthermore, the system of protection of patents is designed in such a way that, although patents are presumed to be valid from the date of their registration (judgment of 1 July 2010, *AstraZeneca* v *Commission*, T-321/05, EU:T:2010:266, paragraph 362), that presumption of validity does not automatically imply that all products placed on the market are infringing (see, to that effect, judgment of 8 September 2016, *Lundbeck* v *Commission*, T-472/13, under appeal, EU:T:2016:449, paragraphs 121 and 122). As the Commission rightly points out in the contested decision (see paragraph 351 above), and the applicants do not specifically dispute this, there is no presumption of infringement, since infringement must be established by a court. As can be seen from the judgment of 25 February 1986, *Windsurfing International* v *Commission* (193/83, EU:C:1986:75, paragraph 52), if a private operator which holds a patent could substitute its own discretion for that of the competent authority as regards the existence of an infringement of its patent, it could use that discretion in order to extend the protection of its patent (see also recital 1171 and footnote 1642 of the contested decision). It is therefore possible for an operator to take the risk of entering the market with a product, including by potentially infringing the patent in force, and that at risk entry or launch (see inter alia recitals 75 and 1176 of the contested decision) could be successful, if the patent holder decides not to bring an infringement action or, in the event that such an action is brought, if that infringement action is dismissed (see, to that effect, judgment of 8 September 2016, *Lundbeck* v *Commission*, T-472/13, under appeal, EU:T:2016:449, paragraphs 128 and 165). It should be pointed out, in that regard, that this possibility of entering the market at risk helps to demonstrate that patents do not constitute insurmountable barriers to the market entry of generic companies, but does not in itself imply that those companies have real concrete possibilities of entering that market, which depend on their ability and their intention to make such an at risk market entry.

360 Contrary to the intervener's assertions, the Commission's approach in that respect does not overturn the presumption of validity enjoyed by patents, by finding that potential competition exists, unless a court has confirmed the validity of the patent and a court has ruled that the valid patent was infringed. The intervener relies on an erroneous reading of the contested decision, since the Commission indicated in that decision, in essence and correctly (see paragraphs 357 to 359 above), not that the patent was presumed invalid until the adoption of a court decision relating to its validity and to the existence of an infringement, but that, until the adoption of such a decision, the presumption of validity of the patent did not prevent an at risk market entry (see recitals 1171 and 1176 of the contested decision).

361 It should be noted that the same lack of a presumption of infringement applies where the patent in question has been declared valid by a competent authority. Since a patent does not, as such, prevent the market entry of actual or potential competitors, the declaration of validity of that patent, if it is not accompanied by a declaration of infringement, does not preclude such competition. Accordingly, contrary to the applicants' submissions, the fact that the EPO decision of 27 July 2006 declared the 947 patent valid is not in itself sufficient to prevent potential competition from taking place.

362 Those findings are not called into question by the case-law cited by the intervener.

363 First, the judgments of 15 September 1998, *European Night Services and Others* v *Commission* (T-374/94, T-375/94, T-384/94 and T-388/94, EU:T:1998:198), and of 29 June 2012, *E.ON Ruhrgas and E.ON* v *Commission* (T-360/09, EU:T:2012:332), do not concern intellectual property rights, but rather exclusive rights precluding, *de jure* or de facto, the provision of the services at issue and access to infrastructure. In addition, even if it were considered that the 'de facto territorial monopolies' mentioned in the judgment of 29 June 2012, *E.ON Ruhrgas and E.ON* v *Commission* (T-360/09, EU:T:2012:332, paragraph 102), are not unlike the exclusive rights which patents constitute (see paragraph 234 above), it is clear from that judgment that the Court found that there was no potential

competition, not because of the mere existence of those monopolies, but because the Commission had not demonstrated to the requisite legal standard that there were real concrete possibilities for another gas supplier to enter the German gas market despite those monopolies, thereby acknowledging that such monopolies did not suffice by themselves to preclude the existence of potential competition (see, to that effect, judgment of 29 June 2012, *E.ON Ruhrgas and E.ON* v *Commission*, T-360/09, EU:T:2012:332, paragraphs 103 to 107).

364 Secondly, although the judgments of 31 May 1979, *Hugin Kassaregister and Hugin Cash Registers* v *Commission* (22/78, EU:C:1979:138), and of 6 October 1994, *Tetra Pak* v *Commission* (T-83/91, EU:T:1994:246), concern intellectual property rights and, in particular, as regards the latter, patents, it cannot however be inferred from those judgments that the patents and other intellectual property rights in question constituted insurmountable barriers to market entry precluding the existence of potential competition. In the judgment of 31 May 1979, *Hugin Kassaregister and Hugin Cash Registers* v *Commission* (22/78, EU:C:1979:138, paragraph 9), the Court of Justice found that a monopoly existed, as moreover the applicant in that case admitted, and thus the lack of effective competition on the market for spare parts for cash registers manufactured by that party, for a number of 'commercial reasons', including, but not limited to — as is, incidentally, more apparent from the report for the hearing in that case (p. 1885) — the United Kingdom legislation on designs and trade marks. Likewise, in the judgment of 6 October 1994, *Tetra Pak* v *Commission* (T-83/91, EU:T:1994:246, paragraph 110), the General Court indeed held that the numerous patents at issue prevented new competitors from entering the market in aseptic machines. However, it cannot be inferred from this that the patents were regarded in themselves as insurmountable barriers to market entry on the market concerned, given the large number of patents at issue, emphasised by the Court, the existence of technological obstacles which were also taken into account in concluding that there were barriers to entry, and above all the presence of a competitor holding 10% of the market in question.

365 Nor are those findings called into question by Article 9(1) of Directive 2004/48, also referred to by the intervener, which provides that Member States are to ensure that the judicial authorities may issue against the alleged infringer an interlocutory injunction intended to prevent any imminent infringement of an intellectual property right or to forbid on a provisional basis the continuation of the alleged infringements of that right.

366 Such interlocutory or provisional injunctions indeed preclude the entry of an alleged infringer onto the market and thus the operation of real competition on that market for the period established by those injunctions. However, in view of that provisional nature, and in the absence of a final decision finding such an infringement and adopting the necessary corrective measures, such interlocutory or provisional injunctions are only temporary obstacles and not insurmountable barriers preventing steps being taken to market the allegedly infringing product and thus precluding the operation of potential competition.

367 Indeed, in the light of the limited time for analysis available to the competent authority to reach its decision and of the requirements laid down by Article 9(3) of Directive 2004/48 for the imposition of a provisional measure — in particular that the competent authority must satisfy itself with a sufficient degree of certainty that an intellectual property right is being infringed — the adoption of such provisional decisions is based only on a, necessarily summary, prima facie assessment of the alleged infringement, which must be confirmed or, where appropriate, invalidated following a more in-depth assessment of the conditions required to establish the existence of an infringement. Moreover, the generic companies concerned have the possibility of preventing the adoption of a decision against them, not only by submitting contrary arguments in the course of the proceedings on the merits, but also by challenging at the same time the validity of the patent at issue by way of a counterclaim for a declaration of invalidity of that patent. Accordingly, the granting of a provisional order or interim injunction, and a fortiori the mere risk of such an order or injunction being adopted, in the light in particular of the adoption of such interim decisions against other generic companies, cannot as such prevent a generic company actually or potentially affected by that type of decision from being a potential competitor.

368 Moreover, a judgment on the merits finding the existence of an infringement is itself provisional as long as the possible remedies have not been exhausted. Contrary to the intervener's assertions, the Commission was entitled to take the view, in recitals 1132 and 1169 of the contested decision, that patent challenges and decisions in relation to these patents constituted an 'expression of competition' as regards patents. In view of the risk of infringement to which all generic companies are exposed and the fact that private operators are not competent to determine whether infringement has occurred (see paragraph 359 above), litigation is one of the means by which generic companies can reduce that risk and enter the market, either by obtaining a declaration of non-infringement or by having the potentially infringed patent declared invalid (see, to that effect, judgment of 8 September 2016, *Lundbeck* v *Commission*, T-472/13, under appeal, EU:T:2016:449, paragraph 122). It also follows that, as long as the generic company has the possibility to bring litigation to challenge the patents concerned and the infringement of them and thus clear a path to the market, it may be considered that those patents do not, in principle, constitute insurmountable barriers to access.

Failure to take into account the 2004 and 2014 Guidelines on technology transfer agreements

369 It cannot be considered that the 2004 and 2014 Guidelines on technology transfer agreements, assuming that they are applicable in the present case, were disregarded by the Commission in the contested decision.

370 First, contrary to the assertions of the applicants and the intervener, the decisions finding that the patents at issue were valid, and in particular the EPO decision of 27 July 2006, do not attest to a 'blocking position' resulting from the patents and regarded by the 2004 and 2014 Guidelines on technology transfer agreements as preventing potential competition from taking place. Indeed, in the 2004 Guidelines on technology transfer agreements (paragraph 32) and in the 2014 Guidelines on technology transfer agreements (paragraph 32), blocking positions are defined as situations in which an operator cannot enter the market without infringing the intellectual property rights of another operator. However, it should be recalled that decisions declaring the validity of a patent do not, on their own, prevent an at risk market entry and that this can be prevented only by a decision finding an infringement of the intellectual property right concerned, that is to say an infringement of the patent at issue (see paragraphs 359 and 361 above). Thus, the 'court decisions' referred to in the 2004 Guidelines on technology transfer agreements (paragraph 32) and the 'final court decision[s]' referred to in the 2014 Guidelines on technology transfer agreements (paragraph 33) as evidence of the existence of a blocking position refer not to decisions finding the validity of a patent but to decisions finding an infringement of that patent.

371 Secondly, contrary to the applicants' submissions, nor has the Commission disregarded the recommendations in the 2014 Guidelines on technology transfer agreements concerning the analysis of potential competition in the absence of a blocking position established by a court decision. It should be recalled in that regard that, under paragraph 31 of the 2014 Guidelines on technology transfer agreements, an operator 'can be considered a potential competitor on the product market if it is likely that, in the absence of the agreement, it would undertake the necessary additional investments to enter the relevant market in response to a small but permanent increase in product prices' and 'likely entry should be assessed on realistic grounds, that is to say based on the facts of the case at hand'. Moreover, according to paragraph 33 of those guidelines:

'In the absence of certainty, for example in the form of a final court decision, that a blocking position exists, the parties, when addressing the question whether they are potential competitors, will have to base themselves on all the available evidence at the time, including the possibility that intellectual property rights are infringed and whether there are effective possibilities to work around existing intellectual property rights. Substantial investments already made or advanced plans to enter a particular market, can support the view that the parties are at least potential competitors, even if a blocking position cannot be excluded ...'

372 As is apparent from paragraphs 323 and 325 above, the Commission applied in the present case the real concrete possibilities criterion to establish whether the generic companies in question were potential competitors and thus relied, in accordance with the abovementioned paragraphs of the 2014 Guidelines on technology transfer agreements, not on the absence of impossibility of entry, but on the likelihood of entry assessed on realistic grounds and available information concerning, inter alia, the existence of any dispute between the parties, the state of development of their products and the steps taken by them to obtain marketing authorisation (see also paragraphs 432 to 438, 579 to 585 and 718 to 722 below). Moreover, in the event that the applicants' arguments are to be interpreted as calling into question the Commission's finding of the generic companies' probability of entry onto the market, those arguments will be examined below in the context of the analysis of the complaints challenging the status of each of those companies as potential competitors.

373 It must also be added that, contrary to the intervener's assertions, it is precisely as a result of that analysis of the generic companies' probabilities of entry to the market, as required by the 2004 and 2014 Guidelines on technology transfer agreements and as carried out by the Commission, that the existence of potential competition is not inferred *ipso facto* from the absence of an established blocking position, but requires, in order to be demonstrated, a true analysis which could lead to a company being found not to be a potential competitor in spite of the absence of a blocking position resulting from the patents.

Inconsistency in the contested decision

374 According to the applicants, the Commission's position is contrary to its findings in the contested decision relating to Servier's abuse of a dominant position. In particular, they criticise the Commission for having, in a contradictory manner, recognised the exclusionary power of Servier's patents in the part of the contested decision dedicated to the abuse of Servier's dominant position (recitals 2572, 2857 and 2972) and ruled out the risk of the generic companies being excluded from the market as a result of those patents in the part of the contested decision relating to Article 101 TFEU.

375 That allegation of contradiction can be rejected at this stage, without it being necessary to rule on the Commission's definition of the relevant markets in its analysis of the restrictive effects on competition of the agreements at issue and the abuse of Servier's dominant position.

376 It should be pointed out, first, that, although the Commission did in fact conclude in the contested decision (recitals 2857 and 2972) that there was no actually viable source of competition on the market, the concept of viability used in those recitals to define the relevant market, namely the upstream technology market for the production of perindopril API, and to determine the existence of a dominant position on that market for the purposes of applying Article 102 TFEU differs from that used to determine the economically viable nature of a market entry in the context of the application of Article 101 TFEU. That concept of viability is more broadly understood as covering 'economic and regulatory viability' and that regulatory viability is strictly understood as being excluded where there is a patent on the market which prevents the technology in question being regarded as substitutable for that covered by the patent (footnote 3386 of the contested decision; see also recitals 2748 and 2754 of the contested decision). It may further be pointed out, for the purpose of ruling out the relevance in the present case of the assessments made by the Commission in recitals 2857 and 2972 of the contested decision, that they relate to the existence of actual and effective competition on the market in question, and not to the prospect of entry to the market of potential competitors.

377 It should also be pointed out, secondly, that in the other passages of the contested decision cited by the applicants and the intervener (recitals 2571 and 2572), devoted to defining the finished product market and determining whether Servier held a dominant position on that market, the Commission considered in essence that Servier's patents were significant but not absolute barriers to market entry, in accordance with its assessment of the potential competition on that market.

The contradiction between the contested decision and other Commission decisions

378 According to the applicants and the intervener, the Commission's position contradicts some of its previous decisions (Commission Decision 94/770/EC of 6 October 1994 relating to a proceeding pursuant to Article [101 TFEU] and Article 53 of the EEA Agreement (Case IV/34.776 — Pasteur Mérieux-Merck) and Commission Decision C(2013) 8535 final of 26 November 2013, relating to a proceeding under Article 6 of Council Regulation No 139/2004 (Case COMP/M.6944 — Thermo Fisher Scientific/Life Technologies)). Whereas, in those other decisions, the Commission concluded from the existence of patents or patent disputes that there was no significant competitive pressure from generic companies, in the contested decision it considered that, despite the existence of those same disputes that could lead to the generic companies' market exclusion, those generic companies were potential competitors to Servier capable of exerting a significant competitive pressure on Servier's perindopril.

379 It must be held, in that regard, that the contested decision does not, in any event, contradict the Commission decisions cited by the applicants and the intervener. It must be borne in mind, first of all, that since patents do not, in principle, constitute insurmountable barriers to the market entry of a competitor, but may give rise to such barriers depending on the outcome of patent litigation and have an impact on the real concrete possibilities of entering that market (see paragraph 359 to 368 above and paragraphs 442 to 453, 589 to 597 and 726 to735 below), it cannot be ruled out that the Commission could, in some of its decisions, including inter alia the two abovementioned decisions, have relied on the existence of patents in order to find a lack of potential competition. It should be noted, next, that in those two decisions, the Commission found the existence of barriers to market entry and the lack of potential competition by relying, not only on the existence of patents or patent disputes, but also on other factors, such as the difficulty of obtaining marketing authorisations, the size of the investments required or the existing commercial relationships, with the result that it cannot be inferred that the existence of patents or patent disputes precludes, as such, the operation of potential competition.

380 It follows from all the foregoing that the Commission did not err in finding that, in the present case, Servier's patents were not insurmountable barriers to the market entry of the generic companies. At the time the agreements at issue were concluded, no final decision on the merits of an infringement action had found that the products of those companies were infringing.

381 It therefore remains to be examined whether the Commission also correctly considered that the generic undertakings had, given the particular characteristics of each, real concrete possibilities of entering the relevant market and, to that end, to respond to the arguments calling into question the existence of such possibilities put forward in the specific line of argument relating to each of the agreements at issue. It should be made clear at this stage that that examination of the complaints directed against the Commission's assessment of the real concrete possibilities for generic undertakings to enter the market must be assessed in the light of the following four principles and considerations.

382 First, it is important to recall that it is apparent from the case-law relating to the determination of whether there are real concrete possibilities of entering a market (see paragraph 318 above) that the essential factor on which the description of an undertaking as a potential competitor must be based is whether it has the ability to enter that market and that its intention of entering that market, while relevant for the purposes of verifying whether it may be classified as a potential competitor, is used only on a supplementary basis. More specifically, while the intention to enter the market is neither necessary in order to find that there is potential competition on that market (judgment of 14 April 2011, *Visa Europe and Visa International Service* v *Commission*, T-461/07, EU:T:2011:181, paragraph 169), nor capable of calling that finding into question, nevertheless, when such an intention is established, it may support the conclusion that a given operator has the ability to enter the market and thus contribute to its classification as a potential competitor.

383 It is also apparent that the criterion based on market entry representing an economically viable strategy, as required by that case-law, does not constitute an independent criterion separate from the main criterion of the ability to enter the market and from the supplementary criterion of the intention to enter that market (see, to that effect, judgment of 8 September 2016, *Xellia Pharmaceuticals and Alpharma* v *Commission*, T-471/13, not published, under appeal, EU:T:2016:460, paragraph 81). On the one hand, that criterion is referred to in the judgments in question as an elaboration of the real and concrete nature of the possibilities of entry to the market and precedes the setting out of the main criterion of the ability of entering the market and the supplementary criterion of the intention to enter that market, presented as 'necessarily result[ing]' therefrom. On the other hand, those same judgments do not examine it distinctly and independently of verification of the ability and intention to enter the market, since it can reasonably be inferred from the fact that an undertaking has both the ability to enter the market — in the light of its means of production and marketing as well as its financial resources — and the intention to enter that market — having regard in particular to the prospects of profit and profitability — that that entry represents an economically viable strategy for the undertaking concerned.

384 Secondly, as the Commission rightly found in the contested decision (recital 1172; see also paragraph 351 above), the assessments of the parties themselves concerning the possibilities of the applicants' patents being declared invalid or being infringed may be taken into account in order to determine whether the generic companies had real concrete possibilities of entering the market (see, to that effect, judgment of 8 September 2016, *Lundbeck* v *Commission*, T-472/13, under appeal, EU:T:2016:449, paragraph 141). In the absence of any decision by a public authority relating to the infringement and validity of Servier's patents, the assessments of the parties themselves concerning the possibilities of those patents being declared invalid or being infringed are liable to shed light on those parties' intentions as regards, amongst other things, litigation. In particular, when those assessments are made by generic companies, they may contribute to establishing their intention — taking into account their subjective perception of the patents concerned — of entering the market, but not their ability to enter as such, since establishing the infringement and invalidity of patents falls within the exclusive competence of the national courts and the EPO (see paragraph 243 and 359 above). Since intention is regarded as a relevant criterion for determining whether there are real concrete possibilities of entering the market (see paragraph 382 above), it follows that the parties' subjective assessments may validly be taken into account for the purpose of establishing those possibilities. It must nevertheless be pointed out that, inasmuch as the intention of entering a market, while relevant for the purposes of verifying whether a company may be classified as a potential competitor, is used only on a supplementary basis, those assessments are also used only on a supplementary basis in determining whether that company constitutes a potential competitor. They must, moreover, be compared with other elements also capable of showing a company's intentions as regards market entry.

385 Thirdly, the existence of real concrete possibilities of entering the market is assessed on the date of conclusion of the agreements at issue (see, to that effect, judgments of 8 September 2016, *Lundbeck* v *Commission*, T-472/13, under appeal, EU:T:2016:449, paragraphs 138, 139 and 203, and of 8 September 2016, *Sun Pharmaceutical Industries and Ranbaxy (UK)* v *Commission*, T-460/13, not published, under appeal, EU:T:2016:453, paragraphs 94 and 95). In order to determine whether such agreements are restrictive of competition for the purposes of Article 101 TFEU, it is necessary to determine what actual or potential competition existed on the relevant market at the time the agreements were concluded. It follows that arguments and documents based on data subsequent to the conclusion of the agreements at issue cannot be taken into account, since such data reflect the implementation of those agreements and not the competitive situation on the market when they were concluded.

386 Fourthly, the burden of proving the existence of real concrete possibilities of a competitor entering the market, like the more general burden of proving the existence of an infringement (Article 2 of Regulation No 1/2003), rests with the Commission (see, to that effect, judgment of 8 September 2016, *Lundbeck* v *Commission*, T-472/13, under appeal, EU:T:2016:449, paragraph 105). Nevertheless, to the

extent that most of the data which may be used to establish the ability and intention of generic undertakings to enter the market, and thus their real concrete possibilities of entering that market, are data internal to those undertakings, which the latter are best placed to gather, it must be held that the Commission has, in the absence of evidence to the contrary concerning technical, regulatory, commercial or financial difficulties, sufficiently established the existence of such possibilities in the circumstances of the case in question, if it has gathered a body of consistent evidence attesting, at the very least, to steps being taken to produce and market the product at issue within a sufficiently short period to form a constraint on the incumbent operator. It may be inferred from such steps that the company in question had not only the ability but also the intention to take the risk of entering the market (see, to that effect, paragraph 33 of the 2014 Guidelines on technology transfer agreements; see also, to that effect, judgment of 8 September 2016, *Arrow Group and Arrow Generics* v *Commission*, T-467/13, not published, under appeal, EU:T:2016:450, paragraph 81).

(2) The criterion relating to the commitment of the generic companies to limit their independent efforts to enter the market

(i) Arguments of the parties

…

(ii) Findings of the Court

391 First, it must be noted that the Commission, in the contested decision, did not examine in isolation the general lawfulness of non-challenge and non-marketing clauses. It is apparent from recital 1154 of the contested decision that, in order to determine whether the agreements at issue constituted restrictions of competition by object, the Commission did not merely examine whether they contained non-challenge and non-marketing clauses, but also analysed whether the parties to the settlement were potential competitors and whether the non-challenge and non-marketing clauses were based on a transfer of value from the originator company to the generics company constituting an inducement, for the latter, not to exert competitive pressure on the company holding the patent. Consequently, the applicants and the intervener cannot criticise the Commission for having found that the mere presence of non-challenge and non-marketing clauses in a settlement suffices to establish its anticompetitive nature.

392 Next, as regards the arguments of the applicants and the intervener relating to the necessary presence of non-challenge and non-marketing clauses in any settlement, reference should be made to the considerations set out in paragraphs 258 to 275 above, setting out the conditions under which the Commission may establish the existence of a restriction by object where a settlement contains such clauses.

393 As regards the arguments of the applicants and the intervener relating to the application of the ancillary restraints doctrine in the present case, it is appropriate to reject those arguments by reference to paragraph 291 above.

394 As regards the applicants' argument that the Commission has already regarded as unproblematic an agreement requiring a generic company to withdraw from the market pending the settlement of a parallel dispute, in exchange for compensation in the event that the litigation was unsuccessful, it is important to recall that, according to the case-law, the principle of equal treatment, which constitutes a general principle of EU law, requires that comparable situations must not be treated differently and that different situations must not be treated in the same way unless such treatment is objectively justified (judgments of 13 December 1984, *Sermide*, 106/83, EU:C:1984:394, paragraph 28, and of 14 May 1998, *BPB de Eendracht* v *Commission*, T-311/94, EU:T:1998:93, paragraph 309).

395 It must be emphasised, however, that, when an undertaking has, by its conduct, infringed Article 101 TFEU, it cannot escape being penalised on the ground that another undertaking has not been fined. Even if the Commission had erred in considering that the Lundbeck-Neolab agreements were consistent with Article 101(1) TFEU, respect for the principle of equal treatment must be reconciled with respect for the principle of legality, according to which no person may rely, in support of his claim, on an unlawful act committed in favour of another (judgments of 31 March 1993, *Ahlström Osakeyhtiö and Others* v *Commission*, C-89/85, C-104/85, C-114/85, C-116/85, C-117/85 and C-125/85 to C-129/85, EU:C:1993:120, paragraph 197, and of 14 July 1994, *Parker Pen* v *Commission*, T-77/92, EU:T:1994:85, paragraph 86).

396 In any event, there are important differences between the agreements at issue and the Lundbeck-Neolab agreements, which the Commission described as unproblematic in the light of competition law in 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). Indeed, it is clear from recital 164 of that decision that Neolab entered the United Kingdom citalopram market in October 2002, that Lundbeck brought an action for infringement of one of its patents in November 2002 and that Neolab then lodged a counterclaim for invalidity of the patent at issue. In the context of a voluntary injunction granted in the course of the national court proceedings, Neolab undertook, by a first agreement, not to market its generic product until the judgment was delivered in a parallel case between Lundbeck and Lagap concerning the same patent or at the latest until 30 November 2003. In return, Lundbeck undertook to pay compensation to Neolab in the event of invalidation of the patent at issue. However, since Lundbeck reached a settlement with Lagap on 13 October 2003, Lundbeck and Neolab were released from their undertakings and Neolab resumed the sale of its generic product on 30 October 2003. On 22 December 2003, Neolab and Lundbeck, by a second agreement, concluded a settlement providing for the payment by Lundbeck to Neolab of damages as compensation for the inability to sell the generic product during the period covered by the voluntary injunction and containing an undertaking by both parties to the agreement not to pursue the litigation relating to the infringement and invalidity of the patent at issue until 31 March 2004.

397 As regards the first agreement, it differed from the agreements at issue in the present case, in so far as (i) it was concluded after the generic undertaking first entered the market, (ii) the restriction at issue appeared to result from an injunction granted in the context of court proceedings, (iii) the subject matter of the agreement was solely a non-marketing commitment of limited duration, namely pending settlement of the dispute having the same subject matter, and (iv) that agreement provided for the payment of damages by the originator company only in the event that its patent was declared invalid.

398 As regards the second agreement, although it indeed provided for a payment from the originator company to the generic company, it nevertheless also differed from the agreements at issue in that the generic company was already present on the market when that agreement was concluded and that agreement did not call into question that presence on the market. Moreover, the payment by the originator company to the generic company was intended only to compensate for the inability to sell the generic product during the period covered by the voluntary injunction and thus to prevent Neolab from bringing an action for damages on that basis.

399 Finally, as regards the applicants' argument that the Commission must, in order to find that the interruption of litigation constitutes a restriction of competition, establish that the continuance of litigation is necessary and sufficient to maintain competition, it is necessary to recall that the determination of a restriction of competition by object (see paragraph 220 et seq. above) requires the Commission neither to assess the degree to which competition might be affected by the agreement at issue nor to establish that the continuance of litigation is necessary to maintain competition.

(3) The criterion relating to the transfer of value to the generic companies

(i) Arguments of the parties

…

(ii) Findings of the Court

406 It must be noted at the outset that the Commission did not consider in the contested decision that the mere presence of a transfer of value from the originator company to the generic company was sufficient, in itself, to prove the existence of a sufficient degree of harm to competition. It is apparent from recital 1154 of the contested decision that, in order to determine whether the agreements at issue constituted restrictions of competition by object, the Commission examined whether the parties to the settlements were potential competitors, whether those settlements included non-challenge and non-marketing clauses and whether the originator company had obtained the non-marketing and non-challenge undertaking from the generic company in return for a transfer of value (see also paragraphs 265 to 272 above).

407 Moreover, it is clear from paragraphs 265 to 273 above that, where a patent settlement is concluded between two potential competitors and contains non-marketing and non-challenge clauses, the existence of an inducement for the generic company to accept those clauses is, in itself, a basis for the finding of a restriction by object.

408 The arguments put forward by the applicants and the intervener do not allow that finding to be called in question.

409 First, as regards the argument that originator producers are required to make greater concessions in settlements than are required of generic companies, on account of the more significant litigation risks to which originator producers are exposed, it is necessary to bear in mind, as the Commission points out, that the applicants have not adduced any evidence to support that claim, and merely refer to their response to the statement of objections. Moreover, even assuming the existence of a more significant risk for the originator company, such a risk would not be such as to justify a reverse transfer of value constituting an inducement for the generic company to give up its efforts to enter the market.

410 As regards the intervener's arguments that national pricing systems for medicinal products have an adverse effect on originator producers and that national judicial mechanisms do not provide an effective remedy to the entry of generic companies on the market at risk, it is important to recall that, assuming those facts to be established, they are not such as to justify an agreement having an anticompetitive object. According to settled case-law, it is unacceptable for undertakings to attempt to mitigate the effects of legal rules which they consider excessively unfavourable by entering into restrictive arrangements intended to offset those disadvantages on the pretext that those rules have created an imbalance detrimental to them (judgment of 27 July 2005, *Brasserie nationale and Others* v *Commission*, T-49/02 to T-51/02, EU:T:2005:298, paragraph 81; see also, to that effect, judgment of 15 October 2002, *Limburgse Vinyl Maatschappij and Others* v *Commission*, C-238/99 P, C-244/99 P, C-245/99 P, C-247/99 P, C-250/99 P to C-252/99 P and C-254/99 P, EU:C:2002:582, paragraphs 487 and 488).

411 As regards the applicants' arguments that the Commission should have taken account of the commercial considerations and profit expectations of the parties to the settlements in order to assess the inducive nature of the transfer of value, it is apparent from paragraph 277 above that, in order to establish whether or not the transfer of value from the originator company to the generic company constitutes an inducement to accept non-marketing and non-challenge clauses, the Commission

rightly examined whether the value transfer corresponded to the specific costs of the settlement for the generic company. The relevant criterion therefore involves identification of the costs borne by the generic company that are inherent in that settlement and not the taking into account of the commercial considerations of the parties to the settlement.

412 It should be added, as regards all the arguments referred to in the three preceding paragraphs, 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, *Corus UK* v *Commission*, T-48/00, EU:T:2004:219, paragraph 73, and of 8 July 2004, *Dalmine* v *Commission*, T-50/00, EU:T:2004:220, paragraph 211), in particular if that behaviour consists in paying actual or potential competitors not to enter the market (see, to that effect, judgment of 8 September 2016, *Lundbeck* v *Commission*, T-472/13, under appeal, EU:T:2016:449, paragraphs 379 and 380).

413 Secondly, the applicants cannot criticise the Commission for having derogated from the three criteria set out in recital 1154 of the contested decision by classifying agreements for the early entry of generic companies to the market as lawful, even though they include a significant inducement. It is clear from recitals 1138, 1200 and 1203 of the contested decision that the Commission merely noted that a settlement agreement authorising the entry of a generic company to the market before the expiry of the patent at issue could constitute an agreement which is favourable to competition and therefore lawful. However, in such an agreement, although the parties agree an early date for the entry of the generic product to the market, they do not provide for the originator company to grant an inducement to the generic company in order for that generic company to delay the entry of its product to the market.

414 Moreover, the applicants cannot criticise the Commission for having failed to investigate the 57 settlements listed in its annual monitoring exercises involving a transfer of value. On the one hand, it must be recalled that, when an undertaking has, by its conduct, infringed Article 101 TFEU, it cannot escape being penalised on the ground that another undertaking has not been fined, since respect for the principle of equal treatment must be reconciled with respect for the principle of legality, according to which no person may rely, in support of his claim, on an unlawful act committed in favour of another (see paragraph 395 above). On the other hand, a patent dispute settlement cannot be regarded as unlawful merely because it involves a transfer of value from the originator company to the generic company, an approach that was not adopted by the Commission in the contested decision, in which the Commission correctly examined whether the parties to the settlements were potential competitors, whether those settlements contained non-challenge and non-marketing clauses and whether the originator company had obtained the non-marketing and non-challenge undertakings from the generic company in exchange for a transfer of value (see paragraph 406 above).

415 Thirdly, the applicants criticise the Commission for having used a broad definition of significant value transfer, by taking into account side deals concluded at arm's length. However, as the Commission rightly pointed out in recital 1190 of the contested decision, the inducement from the originator company to accept non-marketing and non-challenge clauses may take the form of a side deal to the settlement. Although side deals are normal commercial agreements, which may exist independently, the Commission, rightly, examined in the present case whether certain side deals forming an integral part of the dispute settlements at issue involved transfers of value from the patent holder to the generic company.

416 Fourthly, the applicants criticise the Commission for having taken into account the incentives of the generic company to continue litigation solely in the context of the analysis of the potential competition and not in the assessment of the transfer of value. However, it is apparent from paragraph 277 above that, in order to establish whether or not the transfer of value from the originator company to the generic company constituted an inducement to accept non-marketing and non-challenge clauses, the Commission rightly examined whether the value transfer corresponded to

the specific costs of the settlement for the generic company. The relevant criterion therefore lies in the identification of the costs borne by the generic company that are inherent in that settlement and not in any asymmetry of information existing between the parties or in their respective commercial interests.

417 Finally, the applicants complain that the Commission disregarded certain contractual stipulations in the agreements concluded with Teva, Krka and Lupin which were likely to accelerate the entry of generic producers onto the market. That argument will be examined in the context of the pleas relating to the agreements at issue.

418 It follows from all the foregoing that the Commission correctly defined the three criteria used to classify the patent dispute settlements as restrictions by object and has not, therefore, committed any error of law relating to the concept of restriction of competition by object.

6. The agreements concluded with Niche and Matrix

(a) The status of Niche and Matrix as potential competitors

…

(b) Errors of law and of assessment in relation to the classification of the Niche and Matrix agreements as restrictions of competition by object

(1) Arguments of the parties

…

(2) Findings of the Court

525 As regards the errors of law allegedly committed by the Commission in classifying the Niche and Matrix agreements as restrictions by object, without examining whether they were 'so likely' to have negative effects and therefore whether their potential effects were ambivalent (see paragraph 503 above), reference should be made to paragraphs 223 to 226, 304 to 306 and 418 above. As regards the ambivalent potential effects relied on by the applicants, based on the patent-related difficulties and the technical, regulatory and financial difficulties faced by Niche and Matrix, it should be added that those difficulties were properly considered by the Commission as not impeding Niche and Matrix's real and concrete possibilities of competing with the applicants (see paragraph 501 above) and those difficulties therefore cannot support the conclusion that the Niche and Matrix agreements have ambivalent potential effects.

526 As regards the errors of assessment relied on, it is necessary to examine the applicants' arguments relating to the presence in the Niche and Matrix agreements, on the one hand, of an inducement in the form of a benefit for Niche and Matrix and, on the other hand, of a corresponding limitation of their efforts to compete with the originator company, conditions which, if fulfilled, require a finding of the existence of a restriction by object (see paragraph 272 above). It must be pointed out in that regard that the applicants do not call into question the existence of non-marketing and non-challenge clauses in the Niche and Matrix agreements, which are by themselves restrictive of competition (see paragraph 257 above), but argue that those clauses do not reveal a sufficient degree of harm in the present case and dispute that the transfers of value provided for by the Niche and Matrix agreements may be regarded as inducive value transfers.

(i) The absence of inducive value transfer

527 It should be noted, as a preliminary point, that the mere presence of a transfer of value from the originator company to the generic company cannot lead to the conclusion that there is a restriction by object. Only where an unjustified reverse payment occurs in the conclusion of the settlement, that is to say where the generic company is induced by that payment to agree to the non-marketing and non-challenge clauses, must it be concluded that there is such a restriction. In that case, the restrictions of competition introduced by the non-marketing and non-challenge clauses no longer relate to the patent and to the settlement, but rather can be explained by the inducement (see paragraph 265 above).

528 In order to establish whether or not a reverse payment, that is to say a transfer of value from the originator company to the generic company, constitutes an inducement to accept non-marketing and non-challenge clauses, it is necessary to examine, taking into account its nature and its justification, whether the transfer of value covers costs inherent in the settlement of the dispute (see paragraph 277 above). In the contested decision, the Commission therefore rightly examined whether the value transfer provided for in the Niche and Matrix agreements corresponded to the specific costs of the settlement for the generic company (recitals 1333 to 1337 and 1461 to 1464 of the contested decision).

529 If a reverse payment provided for in a settlement agreement containing clauses restrictive of competition is aimed at compensating costs borne by the generic company that are inherent in that settlement, that payment cannot in principle be regarded as an inducement. Nevertheless, a finding of an inducement and of a restriction of competition by object is not ruled out in such a case. It means however that the Commission must prove that the amounts corresponding to those costs inherent in the settlement, even if they are established and precisely quantified by the parties to that settlement, are excessive (see paragraph 278 above).

530 The costs inherent in the settlement of the dispute include, in particular, litigation expenses incurred by the generic undertaking in the context of the dispute between it and the originator company. The compensation of those costs is directly linked to that settlement. Consequently, where the litigation expenses of the generic company are established by the parties to the settlement, the Commission can find them to be inducive only by showing that they are disproportionate (see paragraph 279 above).

531 By contrast, some costs incumbent upon the generic company are, a priori, too extraneous to the dispute and to its settlement to be regarded as inherent in the settlement of a patent dispute. Those include, for example, the costs of manufacturing the infringing products, corresponding to the value of the stock of those products, and research and development expenses incurred in developing those products. The same is true of sums which must be paid by the generic undertaking to third parties as a result of contractual commitments which were not undertaken in the context of the dispute (for example supply contracts). It is therefore for the parties to the agreement, if they do not wish the payment of those costs to be regarded as an inducement, and indicative of a restriction of competition by object, to demonstrate that those costs are inherent in the dispute or in its settlement, and then to justify the amount. They could also, to the same end, invoke the insignificant amount of the repayment of those costs which are a priori not inherent in the settlement of the dispute, showing that that amount is insufficient to constitute a significant inducement to accept the clauses restricting competition stipulated in the settlement agreement (see paragraph 280 above).

532 In the present case, as regards the Niche agreement and as the Commission correctly observed in recital 1322 of the contested decision, the existence of such an inducement is clear from the actual wording of the agreement, which states in Clause 13 that, ‘in consideration for the undertakings set out [in the agreement], and the substantial costs and potential liabilities that may be incurred by Niche and Unichem as a consequence of ceasing their programme to develop and manufacture Perindopril made

using the Process [at issue], Servier shall pay Niche and Unichem … the sum of [GBP] 11 800 000.00'. The undertakings given are the non-marketing and non-challenge clauses, payment for which is thus expressly provided for in Clause 13.

533 That interpretation of the wording of the Niche agreement is, moreover, not called into question by the applicants' claim that the phrase 'in consideration for' is the standard formula in English law to indicate the reciprocity necessary for the validity of any contract. Even if it were concluded that that phrase is a kind of stylistic formula to which it would not be appropriate to attach significance, the fact remains that that formula, according to the applicants themselves, indicates reciprocity and thus the fact that the sum provided for in Article 13 of the Niche agreement is given in exchange for the obligations imposed on Niche by that agreement.

534 Nor is that interpretation of the Niche agreement invalidated by the alleged asymmetry between the risks for the originator company and those to which the generic company is exposed or by the alleged negotiating talents of Niche. It is true that such an asymmetry of risks and the negotiating talents of the generic company may partly explain why the originator company may be led to grant significant reverse payments to the generic company. However, the grant of a significant payment is intended precisely to avoid all risk, even minimal, that the generic companies may enter the market and, thus, supports the finding that the originator company has paid in order to side-line the generic companies. It must also be noted that the fact that the adoption of anticompetitive conduct may prove to be the most profitable or least risky solution for an undertaking, or that it is intended to correct an imbalance detrimental to that undertaking, in no way precludes the application of Article 101 TFEU (see, to that effect, judgments of 8 July 2004, *Corus UK* v *Commission*, T-48/00, EU:T:2004:219, paragraph 73; of 8 July 2004, *Dalmine* v *Commission*, T-50/00, EU:T:2004:220, paragraph 211; and of 27 July 2005, *Brasserie nationale and Others* v *Commission*, T-49/02 to T-51/02, EU:T:2005:298, paragraph 81), in particular if that behaviour consists in paying actual or potential competitors not to enter the market (judgment of 8 September 2016, *Lundbeck* v *Commission*, T-472/13, under appeal, EU:T:2016:449, paragraphs 379 and 380).

535 Furthermore, it is irrelevant in this case that Clause 13 of the Niche agreement stipulates that the payment of the sum of GBP 11.8 million is consideration not only for the non-marketing and non-challenge clauses, but also — in some undefined proportion — consideration for other expenses, since that other compensation does not call into question the finding that the restrictive clauses at issue were purchased by the applicants and, thus, the existence of an inducement for Niche to accept those clauses.

536 Those other expenses, described in the Niche agreement as 'substantial costs and potential liabilities that may be incurred by Niche and Unichem as a consequence of ceasing their programme to develop Perindopril made using the Process [at issue]', were described by Niche, during the administrative procedure (recital 1326 of the contested decision), and by the applicants themselves, in their pleadings, as covering the costs of developing Niche's perindopril and the compensation due to Niche's customers for breach of its contractual obligations to them. Such costs are not, a priori, inherent in the settlement of a patent dispute (see paragraph 531 above) and the applicants fail to establish that they are inherent in the settlement concluded in the present case.

537 In particular, even if, as the applicants argue in essence, the compensation payable to Niche's customers would not have been payable if Niche had pursued its litigation against the applicants, such compensation is in the present case too extraneous to the dispute and to its settlement to be regarded as costs inherent in that settlement, since that compensation was payable, according to the applicants, in the event of 'voluntary termination of the project', implying termination of the contracts with their customers, and the Niche agreement gave Niche the option of merely suspending, rather than terminating, contractual relations with its customers (Clause 11 of the Niche agreement). Moreover, the applicants themselves conceded at the hearing that the compensation in question might have had to be paid to Niche's customers irrespective of the Niche agreement. It may also be noted that the

information provided by the applicants to contest the amount of that compensation, as assessed by the Commission in the contested decision at GBP 1.3 million (recital 1335), is not conclusive, since it indicates either sums lower than that amount or mere claims of higher sums.

538 As regards 'the legal costs' referred to in the contested decision (recital 1334), Niche described them during the administrative procedure as relating to legal costs included in the costs of development (recital 601 of the contested decision), which, it should be recalled, are not inherent in the settlement (see paragraph 531 above), whereas the applicants describe them as 'lawyers' fees and patent fees', which may constitute litigation expenses inherent in the settlement (see paragraph 530 above). However, even assuming that the amount of GBP 1.1 million claimed for 'lawyers' fees and patent fees' is a litigation expense the reimbursement of which may, in principle, reasonably be provided for in a settlement, that amount cannot form part of the costs inherent in the settlement concluded in the present case. It is clear from the arguments and documents produced by the applicants that the costs in question related to a period until the end of 2003, that is to say prior to the start of the litigation between Niche and the applicants (see paragraphs 11, 13 and 16 above) which was brought to an end by the Niche agreement.

539 It may be added, for the sake of completeness, that even if that amount of GBP 1.1 million were to be added to the development costs and costs of compensation to Niche's customers assessed, respectively, at GBP 1.2 million and 1.3 million by the Commission in the contested decision (recital 1336), without those amounts being validly contested by the applicants (see in particular paragraph 537 above), the total amount resulting (GBP 3.6 million) is clearly less than GBP 11.8 million.

540 It follows that the Commission validly found, in the contested decision (recital 1348), that the Niche agreement contained an inducement for Niche to accept the non-marketing and non-challenge clauses set out in that agreement, and the Commission was not also required, as the applicants maintain (see paragraph 513 above), to ascertain whether those clauses would have been less restrictive in scope in the absence of that inducive payment. A finding that there was an inducement to accept non-marketing and non-challenge clauses requires only the existence of such clauses — irrespective of whether they are more or less restrictive in scope — and an analysis of the costs covered by the transfer of value in question (see paragraphs 528 to 531 above).

541 It also follows that it is necessary to reject as ineffective the complaint alleging that the Commission committed an error of assessment in declaring that the amount paid to Niche pursuant to the Niche agreement was equivalent to more than 10 years of planned sales and more than 20 years of planned gross profit (see paragraph 514 above). Even if the Commission committed such an error, it has no bearing on the classification of the transfer of value from the applicants to Niche as an inducement, since it is clear from paragraphs 536 to 538 above that that transfer of value did not cover the costs inherent in the settlement of the dispute and it is in no way claimed, nor a fortiori established, that the amount of that transfer was insignificant and thus insufficient to qualify as an inducement.

542 Moreover, as regards the additional inducement resulting from the amount paid to Niche pursuant to the Biogaran agreement (recitals 1349 to 1354 of the contested decision), it is necessary to consider, as will be set out in detail in paragraphs 798 to 810 below, that the fact that a commercial agreement, which does not normally have the settlement of a dispute as its subject matter, and which serves as a vehicle for a transfer of value from the originator company to the generic company, is linked with a settlement agreement containing competition-restricting clauses is a strong indication of the existence of a 'reverse payment', that is to say of a transfer of value for which there is no real consideration under that commercial side deal (see paragraph 804 below), a payment which therefore also constitutes an inducive benefit if it is not intended to compensate for costs inherent in the settlement of the dispute. Where there is information or evidence put forward by the Commission in order to support such a strong indication and thereby establish the existence of a reverse payment, the parties to the agreements may present their version of the facts, supporting their claims with the evidence

that they are able to provide and which permit the conclusion that the commercial agreement, although linked to the settlement agreement, is justified by reasons other than the exclusion of a competitor by means of a reverse payment.

543 In the present case, the Commission has put forward several items of evidence showing the existence of a link between the Niche agreement and the Biogaran agreement and of a mismatch between the transfer of value provided for by the Biogaran agreement and the obligations imposed on Niche by that agreement. First, the Commission took into account the fact that the agreements were negotiated during the same period and were concluded between the same undertakings on the same date as well as the fact that both agreements provided for a payment in two instalments, on the same dates. Secondly, while the applicants argued that there was no link between the two agreements, Niche stated that the Biogaran agreement had been proposed by the applicants in order to provide Niche with 'the total overall consideration agreed for entering into the Global Settlement Agreement'. The Commission also interpreted an email sent by Biogaran's counsel to Niche on 4 February 2005, stating that 'in consideration of the amount at stake we find it necessary to have further rights on additional products and certain freedom on the supply side of the Products', as meaning that the amount to be transferred to Niche had been fixed before the parties agreed on the scope of the products covered by the Biogaran agreement. The Commission also considered that the contractual provisions of the Biogaran agreement, and in particular Clauses 14.4 and 14.5 thereof, provided for automatic termination of that agreement in the event of a failure to obtain marketing authorisations within 18 months, without Biogaran having any entitlement to compensation from Niche, contrary to the provisions contained in other agreements concluded by Biogaran relating to the acquisition of product dossiers. Finally, the Commission noted that, with the exception of one product, Biogaran had not obtained marketing authorisations on the basis of the dossiers transferred by Niche and that Biogaran's turnover connected with the Biogaran agreement had amounted to between EUR 100 000 and 200 000.

544 The applicants do not put forward any argument calling into question that analysis, with the exception of a complaint alleging that Biogaran's interest in concluding the Biogaran agreement was not taken into account. Apart from the fact that such an interest cannot be regarded as sufficient to justify the amount of the transfer of value provided for by the Biogaran agreement, it may be noted that recital 1351 of the contested decision reveals a number of findings which cast doubt on the existence of such an interest on the part of Biogaran. According to those findings, which are not disputed by the applicants, the amount which was to be transferred to Niche by Biogaran had been decided before Niche and Biogaran agreed on the products covered by the Biogaran agreement, that agreement could be terminated by the parties within 18 months without either party being entitled to compensation and no provision was made for any reimbursement to Biogaran in the event that the transferred marketing authorisations were not obtained within a certain period. Accordingly, the Commission was right to consider that the Biogaran agreement constituted an additional inducement for Niche to accept the restrictive clauses of the Niche agreement.

545 Moreover, as regards the applicants' claims seeking to be allowed to benefit from any annulment of the contested decision or from any reduction in the amount of the fine which Biogaran might obtain in Case T-677/14, it is appropriate to refer to paragraphs 89 to 99 above.

546 As regards the Matrix agreement, it should be noted that Clause 9 thereof is similar to Clause 13 of the Niche agreement and that it is therefore necessary to reject, for the same reasons, the arguments criticising the Commission's assessments concerning the Matrix agreement in the same way as the assessments concerning the Niche agreement. As regards the argument, specifically directed against the Commission's analysis of the Matrix agreement, that the compensation of Niche's customers was also of concern to Matrix, on the basis of its joint liability with Niche, it is necessary to recall that such costs cannot be regarded as costs inherent in the settlement of a dispute (see paragraph 531

above) and, accordingly, justify the transfer of value provided for by the Matrix agreement, especially since neither the applicants nor Matrix were in a position to establish that the amount of GBP 11.8 million covered such costs or other costs inherent in the settlement of the dispute.

547 It follows that the Commission also validly found, in the contested decision (see, in particular, recitals 1452, 1453, 1463, 1464 and 1467), that the Matrix agreement included an inducement for Matrix to agree to the non-marketing and non-challenge clauses provided for by that agreement.

(ii) The non-challenge and non-marketing clauses were not sufficiently harmful

548 It should be noted that the applicants do not dispute the existence of non-challenge and non-marketing clauses in the Niche and Matrix agreements.

549 Under the non-challenge clauses contained in the Niche and Matrix agreements, those two companies had to abstain from any invalidity and non-infringement actions against the 339, 340, 341, 689, 947 and 948 patents, and Niche was also required to withdraw its oppositions to the 947 and 948 patents before the EPO (Clauses 7 and 8 of the Niche agreement and Clause 5 of the Matrix agreement). Under the non-marketing clauses contained in the Niche and Matrix agreements, those two undertakings were to refrain from making, keeping, importing, supplying, offering to supply or disposing of perindopril and from carrying out an act likely to infringe the 339 to 341 patents concerning perindopril (Clause 3 of the Niche agreement and Clause 1 of the Matrix agreement). They also had to refrain from applying for marketing authorisations for perindopril (Clause 10 of the Niche agreement and Clause 6 of the Matrix agreement) and were obliged to terminate or suspend their contracts relating to perindopril concluded with third parties (Clause 11 of the Niche agreement and Clause 7 of the Matrix agreement).

550 However, the applicants dispute that the non-challenge and non-marketing clauses contained in the Niche and Matrix agreements were sufficiently harmful or significant in nature.

551 In the first place, they argue that the non-challenge and non-marketing clauses are inherent in the settlement agreements.

552 Although non-challenge and non-marketing clauses are indeed necessary for the settlement of certain patent disputes (see paragraph 259 above), it should be recalled that such clauses lose their legitimacy and reveal a sufficient degree of harm to normal competition where it is the inducement, such as that found in the present case, and not the recognition of the validity of the patents at issue by the parties, which is the real cause of the restrictions of competition introduced by those clauses (see paragraph 270 above).

553 It should also be noted — in response to the applicants' argument that the loss of the opportunity to have a dispute settled in one's favour which is entailed by the non-challenge clause cannot be sufficient to classify an agreement intended to settle a genuine dispute as a restriction by object (see paragraph 505 above) — that, while not precluding entry to the market as such, the non-challenge clause prevents inter alia litigation intended to 'clear the way' in the context of an at-risk launch and thus the use of one of the means to allow such entry to the market (see also paragraph 257 above). It is also important to recall that the Commission, in the present case, classified as a restriction by object not merely the non-challenge clauses contained in the Niche and Matrix agreements, but those agreements in their entirety, including the non-challenge clauses and non-marketing clauses and an inducement to accept such clauses (recitals 1375 and 1481 of the contested decision).

554 The applicants submit, in the second place, that the non-challenge and non-marketing clauses contained in the Niche and Matrix agreements do not reveal a sufficient degree of harm, in that their effects derive from the existence of the patents at issue and not from the terms of those agreements.

555 In that regard, it should be recalled that the existence of an inducement for the generic undertaking to agree to non-marketing and non-challenge clauses supports a finding of a restriction by object, even though the settlement includes clauses having a scope not exceeding that of the patent at issue (see paragraph 273 above). Thus, even if, as the applicants claim, the non-marketing clauses do not prevent Niche and Matrix from entering the market with a non-infringing product and are limited to the effects produced by an injunction for infringement of the patents at issue, or even allow those companies, as a result also of the amount received in the context of the transfer of value, to undertake with their partners the development of a new non-infringing perindopril project (see paragraph 506 above), the Niche and Matrix agreements nonetheless constitute a restriction by object.

556 In the third place, the applicants dispute that the non-challenge clauses are sufficiently harmful in nature, claiming that they concerned only one of the many opponents who brought opposition proceedings against the 947 patent before the EPO and had no effect on the other generic undertakings on account of the limitation of the litigation to that concerning the infringement.

557 It must be held that even if the claims that the Niche and Matrix agreements had effects only on the generic undertakings party to those agreements were established, those claims would not call into question the exclusion of those companies from the market imposed by the non-marketing and non-challenge clauses in return for an inducive value transfer and, thus, the sufficient degree of harm of the agreements concerned, thereby rendering the examination of their specific effects superfluous.

558 It follows that the Commission did not wrongly consider that the Niche and Matrix agreements were restrictive of competition by object.

559 That conclusion is not called into question by the alleged errors of assessment made by the Commission in the presentation of the economic and legal context of the Niche and Matrix agreements and in its consideration of the parties' subjective intentions.

560 Indeed, the applicants' allegation concerning the lack of anticompetitive intent and the pursuit of legitimate objectives of the parties to the Niche and Matrix agreements, which in particular led Niche to take the initiative in contacting the applicants, is not capable of calling into question either the existence of an inducive benefit or the anticompetitive nature of the non-marketing and non-challenge clauses in the agreements. Consequently, even if the arguments in question had an established factual basis, they would not be capable, in any event, of invalidating the Commission's finding that the Niche and Matrix agreements constituted restrictions by object.

561 It should also be added that the parties' intention is not a necessary factor in determining whether a type of coordination between undertakings is restrictive (see paragraph 222 above).

562 In addition, since the Niche and Matrix agreements contained non-marketing and non-challenge clauses, the inherently restrictive nature of which has not been validly called into question, and since the Commission found that there was an inducement, it could correctly regard those agreements as market exclusion agreements, which thus pursued an anticompetitive objective. According to settled case-law, the mere fact that an agreement also pursues legitimate objectives is not enough to preclude the classification of that agreement as a restriction of competition by object (see paragraph 222 above).

563 As regards the alleged errors of assessment made by the Commission in taking into account the economic and legal context of the Niche and Matrix agreements, the applicants repeat, in that regard, their arguments criticising the ability and the intention of Niche and Matrix to enter the market, having regard, in particular, to the applicants' patents and the disputes relating to those patents as well as Niche's financial and regulatory difficulties (see paragraphs 507 and 519 above). Since those arguments were examined and rejected in the context of the plea challenging the status of Niche and Matrix as potential competitors (see paragraphs 432 to 501 above), they cannot call into question the nature of the Niche and Matrix agreements as restrictions by object.

564 It follows from the foregoing that the plea alleging errors of law and of assessment in relation to the classification of the Niche and Matrix agreements as restrictions of competition by object must be rejected in its entirety.

(c) Errors of law and of assessment in relation to the classification of the Niche and Matrix agreements as restrictions of competition by effect

565 The applicants maintain that the Commission made various errors of law and of assessment in relation to the classification of the Niche and Matrix agreements as restrictions of competition by effect.

566 It should be borne in mind that where some of the grounds in a decision on their own provide a sufficient legal basis for the decision, any errors in the other grounds of the decision have no effect on its operative part. Moreover, where the operative part of a Commission decision is based on several pillars of reasoning, each of which would in itself be sufficient to justify that operative part, that decision should, in principle, be annulled by the Court only if each of those pillars is vitiated by an illegality. In such a case, an error or other illegality which affects only one of the pillars of reasoning cannot be sufficient to justify annulment of the decision at issue because that error could not have had a decisive effect on the operative part adopted by the Commission (see judgment of 14 December 2005, *General Electric* v *Commission*, T-210/01, EU:T:2005:456, paragraphs 42 and 43 and the case-law cited).

567 As noted in paragraph 219 above, in deciding whether an agreement is prohibited by Article 101(1) TFEU, there is no need to take account of its actual effects once it is apparent that its object is to prevent, restrict or distort competition within the internal market.

568 Consequently, where the Commission bases a finding of infringement both on the existence of a restriction by object and on the existence of a restriction by effect, an error rendering unlawful the ground based on the existence of a restriction by effect does not, in any event, have a decisive effect on the operative part adopted by the Commission in its decision, since the ground based on the existence of a restriction by object, which can by itself justify the finding of an infringement, is not vitiated by an illegality.

569 In the present case, it is clear from the examination of the plea alleging errors of law and of assessment in relation to the classification of the Niche and Matrix agreements as restrictions of competition by object that the applicants have not shown that the Commission erred in concluding, in the contested decision, that the agreements in question had as their object the prevention, restriction or distortion of competition within the internal market, within the meaning of Article 101(1) TFEU.

570 The present plea in law must therefore be rejected as ineffective.

7. The agreement concluded with Teva

(a) The status of Teva as a potential competitor

…

(b) Errors of law and of assessment in relation to the classification of the Teva agreement as a restriction of competition by object

(1) Arguments of the parties

…

(2) Findings of the Court

643 It is necessary to examine the applicants' arguments relating to the presence in the Teva agreement, first, of an inducement in the form of a benefit for Teva and, secondly, of a corresponding limitation of Teva's efforts to compete with the originator company, conditions which, if fulfilled, require a finding of the existence of a restriction by object (see paragraph 272 above). In the present case, since the finding of an inducement depends in part on the restrictive nature of certain clauses in the Teva agreement, the complaints directed against the assessment of the clauses of the agreement will be examined in the first place, before those criticising the assessment of the value transfer provided for in that agreement. As regards the alternative complaint concerning the duration of the applicants' alleged infringement on the basis of the Teva agreement, it will be examined last.

(i) The absence of a limitation of the generic company's efforts to compete with the originator company

644 As a preliminary point, it is necessary to reject the applicants' allegations of errors of law and of assessment made by the Commission in classifying the Teva agreement as a restriction by object, although its potential effects were pro-competitive and its restrictive effects purely hypothetical (see paragraph 634 above). It must of course be recalled that the Commission and the Courts of the European Union cannot, when examining whether an agreement restricts competition by object and, in particular, in assessing the economic and legal context of that agreement, completely ignore its potential effects (see case-law cited in paragraph 304 above). However, it is also apparent from the case-law that establishing the existence of a restriction of competition by object cannot, under the guise, inter alia, of the examination of the economic and legal context of the agreement at issue, lead to the assessment of the effects of that agreement, since otherwise the distinction between a restriction of competition by object and by effect laid down in Article 101(1) TFEU would lose its effectiveness (see paragraph 221 above). For the purposes of verifying the specific capability of an agreement to produce competition-restricting effects characteristic of agreements with an anticompetitive object, the analysis of the potential effects of an agreement must therefore be limited to those resulting from information objectively foreseeable at the time of the conclusion of that agreement (see, to that effect, Opinion of Advocate General Wahl in *ING Pensii*, C-172/14, EU:C:2015:272, point 84; see also, to that effect, judgment of 11 September 2014, *CB* v *Commission*, C-67/13 P, EU:C:2014:2204, paragraphs 80 to 82). In the present case, the alleged potential effects, whether they are non-restrictive of competition or pro-competitive, are based on hypothetical circumstances which were therefore not foreseeable at the time of the conclusion of the Teva agreement, such as the decision of the EPO concerning the validity of the 947 patent or the entry of other generic companies into the United Kingdom market, which cannot be taken into account in assessing whether that agreement is restrictive of competition by object (see also paragraphs 667 and 668 below).

645 As regards, next, the claims that the clauses of the Teva agreement are not by nature intrinsically anticompetitive, it should be recalled, in the first place, that the fact that non-challenge and non-marketing clauses are inherent in settlements does not prevent settlement agreements which include such clauses from being classified as restrictions of competition by object (see paragraph 273 above). It may be added that, although the applicants claim that the ancillary restraints doctrine is applicable to the Teva agreement, on the ground that its non-challenge and non-marketing clauses

are necessary and proportionate to the settlement of the dispute in question, it has already been held that that link of necessity and proportionality could be broken in the event of a finding that there is an inducement to accept such clauses (see paragraph 291 above). Thus, that doctrine could be applied to the Teva agreement only if the transfer of value provided for by that agreement did not constitute an inducement (see paragraphs 679 to 699 below).

646 It must be considered, in the second place, that the arguments put forward by the applicants do not call into question the restrictive nature of the non-challenge clause in the Teva agreement.

647 Under that clause, Teva undertook not to challenge the 947 and 339 to 341 patents in the United Kingdom for the duration of the Teva agreement, it being stipulated that it was not prevented from continuing opposition proceedings against those patents before the EPO (Clause 2.4 of the Teva agreement).

648 The Commission considered, in the contested decision, that that non-challenge clause had two main consequences: first, it prevented Teva from establishing that the product it intended to market was non-infringing and, secondly, it prevented an objective legal review of the validity of the applicants' patents in the United Kingdom (recital 1546).

649 It must be noted, first of all, that the applicants do not dispute that first consequence of the non-challenge clause contained in the Teva agreement, but maintain that such a consequence is inherent in any non-challenge clause contained in a settlement (see paragraph 625 above). It must be borne in mind, in that regard, that the fact that such a clause is inherent in the settlement is not in itself sufficient to preclude the finding of an anticompetitive objective (see paragraphs 273 and 645 above).

650 It must be held, next, that it is irrelevant in the present case that the non-challenge clause covers only litigation in the United Kingdom and does not include proceedings before the EPO, since the territorial scope of the Teva agreement is limited to the United Kingdom, within which any challenge to the validity of the 947 patent and the process patents is prohibited. It should be borne in mind, in that respect, that an agreement may be classified as a restriction by object, even if its territorial scope is limited to one Member State (see, to that effect, judgment of 24 September 2009, *Erste Group Bank and Others* v *Commission*, C-125/07 P, C-133/07 P and C-137/07 P, EU:C:2009:576, paragraph 38 and the case-law cited).

651 Moreover, even if, as the applicants argue, the non-challenge clause were not capable of affecting the proceedings for the revocation of the 947 patent initiated in the United Kingdom by a subsidiary of Teva, proceedings which were suspended pending a final decision in the opposition proceedings before the EPO not covered by the Teva agreement, that clause nevertheless prevents, at the very least, the introduction of other invalidity actions against that patent for the term of the Teva agreement and, under Clause 2.4 of that agreement, that prohibition applies to both Teva UK Ltd and its subsidiaries and both to direct actions and to any assistance to a third party with a view to invalidating the applicants' patents. Teva's active participation in the opposition proceedings before the EPO, inter alia by the notification of the decisions of the United Kingdom courts concerning the validity of the 947 patent, as alleged by the applicants (see paragraph 635 above), is therefore irrelevant in the present case.

652 Nor can the Commission be criticised for not having established that there was a serious basis for calling into question the validity of the applicants' process patents (see paragraph 635 above). Such evidence is not required to establish the restrictive nature of a non-challenge clause, which depends on the elimination of real concrete possibilities of overcoming patent-related obstacles, which, in order to be established, do not necessarily presuppose evidence of the likely success of the action for invalidity of the patents concerned (see paragraph 368 above).

653 Lastly, the applicants' claim that the non-challenge clause did not prevent third parties from challenging their patents (see paragraph 635 above) is irrelevant. Indeed, such a claim that the Teva agreement had potential effects solely on that generic company does not call into question, as such, the restrictive nature of the non-challenge clause contained in the Teva agreement (see also paragraphs 556 and 557 above).

654 It must be held, in the third place, that the exclusive purchasing clause was rightly classified by the Commission as restrictive of competition.

655 That clause, as provided for in Clause 3 of the Teva agreement, reads as follows:

'3. Exclusive purchasing obligation

3.1. For the duration of this Agreement, Teva shall purchase all Teva and its Affiliates' requirements for Perindopril for supply or disposal in the United Kingdom exclusively from Servier or Servier's Affiliates.

…

3.3. Teva shall not, and shall procure that its Affiliates shall not, actively sell or promote Product to consumers outside the United Kingdom.

3.4. Subject to receipt by Servier or its Affiliates of confirmed orders from Teva for the quantities of Product set out below, submitted on or before the Order Dates, Servier or its Affiliates shall supply Teva with the following quantities of Product by the following dates:

3.4.1. 150 000 (one hundred and fifty thousand) packs of 30, 2 mg tablets by 1 August 2006 and in subsequent months 75 000 (seventy five thousand) such packs per month;

3.4.2. 240 000 (two hundred and forty thousand) packs of 30, 4 mg tablets by 1 August 2006 and in subsequent months 120 000 (one hundred and twenty thousand) such packs per month; and

3.4.3. 80 000 (eighty thousand) packs of 30, 8 mg tablets by 1 January 2007 (or such date as the parties may agree) and in subsequent months 40 000 (forty thousand) such packs per month.

…

3.8. If, in respect of any month during the term of this Agreement:

3.8.1. Servier has received from Teva confirmed orders for Product, for delivery for the United Kingdom during such month, such confirmed orders having been submitted on or before the relevant Order Dates; and

3.8.2. Servier and its Affiliates have, within ten Working Days of the delivery date thereof, failed to deliver to Teva the total Product ordered by Teva in accordance with the provisions of Clause 3.4 and 3.8.1 for delivery during such month,

3.8.3. Servier shall, subject to Clause 3.9 pay Teva the Liquidated Damages in respect of that month and Teva and its Affiliates shall have no other right or remedy (including any right of termination) in respect of any failure by Servier to supply Product to Teva.

…'

656 It must also be borne in mind that, under the non-marketing clause laid down in Clause 2.3 of the Teva agreement, Teva was to refrain, in the United Kingdom, from making, having made, keeping, importing, supplying, offering to supply or disposing of generic perindopril either manufactured in accordance with the process it had developed, and which Servier regarded as infringing the 947 and 339 to 341 patents, or infringing those patents until the termination or expiration of the Teva agreement or the expiration of those patents.

657 The Commission considered, in recitals 1552 to 1555 of the contested decision, that, since the non-marketing clause (Clause 2.3) and the exclusive purchasing clause (Clause 3.1) of the Teva agreement affected Teva's ability to compete or to choose independently its source of perindopril for supply on the United Kingdom market, those clauses should be analysed together as a single non-compete obligation. It stated that, whatever the patent situation of the possible alternative sources of perindopril (infringing or non-infringing), the only options left open to Teva by the exclusive purchasing clause were either to sell Servier's product exclusively, or to receive compensation for failure to supply (liquidated damages of GBP 500 000 per month of default).

658 It must be pointed out that the applicants' arguments challenging the Commission's assessment in that respect are based on an erroneous interpretation of the exclusive purchasing clause of the Teva agreement.

659 It is apparent from the Teva agreement that there was an alternative between supply and the payment of damages in the event of a failure to supply, since, alongside the obligation to supply, which is indeed mentioned as such in Clause 3.4 of the Teva agreement, that agreement envisaged the possibility of non-supply, which could not be challenged before a court, would not enable Teva to terminate the agreement, and was not even subject to any conditions, such as a temporal limitation, other than the payment of damages (Clauses 3.8.2, 3.8.3 and 8.3 of the Teva agreement).

660 It should be noted that the prohibition of challenges and of termination in the event of failure to supply provided for in Clause 3.8.3 of the Teva agreement ('the non-termination clause') played a decisive role in that interpretation of the exclusive purchase clause, since it replaced the penalisation of a breach of a contractual obligation by a court or by the termination of the contractual relationship with pre-established pecuniary compensation and thus created an alternative between supply and damages. In that regard, it is irrelevant whether those damages result from a breach of the supply obligation or from a possibility for Servier not to supply Teva.

661 The result is, in any event, as the Commission rightly considered in the contested decision (recital 1559), a non-supply option, left entirely to Servier's discretion, which prevented Teva from entering the market and which also distinguishes the clauses concerned from the clauses typically contained in a supply agreement.

662 By contrast, Teva was subject to an exclusive purchasing obligation, rightly described as an 'absolute' obligation by the Commission (recital 1588 of the contested decision), since Teva could not withdraw from it in order to source perindopril from other perindopril suppliers — whether that perindopril was infringing or not — and enter the market with that perindopril, even if Servier failed to supply, since, under the non-termination clause, the agreement could not be terminated on that basis. As the Commission rightly stated in recital 1557 of the contested decision, the non-termination clause, combined with the exclusive purchasing clause, obliged Teva to source generic perindopril exclusively from Servier, and thus prevented it from sourcing from other suppliers, including those that did not infringe any of Servier's patents.

663 It follows that the exclusive purchasing and non-termination clauses not only overlap with the non-marketing obligation laid down in Clause 2.3 of the Teva agreement, since they prohibit the acquisition and, accordingly, the sale of perindopril produced by third parties that infringes the

patents at issue, but also extend that obligation beyond the patents at issue, since they prohibit the acquisition and the sale of perindopril produced by third parties that does not infringe the patents at issue.

664 It follows that the Teva agreement's exclusive purchasing and non-termination clauses are, by themselves, particularly capable of preventing Teva from procuring and thus entering the market with a third party's product, just as that entry is moreover already prevented both as regards the applicants' products and those of third parties by the non-marketing clause set out in Clause 2.3 of the agreement, the competition-restricting nature of which is not disputed by the applicants.

665 It must also be held that the limitation of the exclusive purchasing clause and of the non-marketing clause to perindopril erbumine cannot call into question their restrictive nature (see paragraph 626 above).

666 The applicants point out that those clauses related only to perindopril erbumine and do not dispute that the product which Teva intended to market at the time of the conclusion of the Teva agreement was perindopril erbumine. Thus, the non-marketing and exclusive purchasing clauses prevented Teva from entering the market with perindopril erbumine, which it was planning to market for the duration of the Teva agreement. Therefore, even if Teva could have entered the market with perindopril composed of a salt other than erbumine during the period covered by the Teva agreement, the fact remains that that agreement prevented Teva from competing with the applicants using perindopril erbumine and restricted competition in that respect. In addition, it may be noted that the evidence submitted by the applicants to establish Teva's entry into the United Kingdom market with a salt other than erbumine concerns information subsequent to the expiry of the Teva agreement.

667 The claims of the applicants concerning the ambivalent potential effects of the exclusive purchasing clause are also irrelevant in the present case (see paragraph 636 above). It must be borne in mind that such potential effects, based, in the present case, on circumstances which were not foreseeable when the Teva agreement was concluded, cannot be taken into account in assessing whether that agreement is restrictive of competition by object (see paragraph 644 above). It may be added that, in any event, contrary to the applicants' submissions, it cannot be considered that the alleged potential effects of the Teva agreement were not restrictive of competition, or indeed pro-competitive.

668 If the 947 patent had been invalidated by the EPO, the Teva agreement would have prevented Teva from entering the market with its product or that of Krka by virtue of the non-marketing clause, which would have remained in force — as shown by the reference to the 'expiration' of the patents in Clause 2.3 of the Teva agreement, as opposed to the term 'revocation' used in Clause II of the amendment to the Teva agreement — even though that invalidation would have allowed the market entry of generic products that potentially infringed that patent. In addition, even if the applicants supplied Teva with generic perindopril in that situation, as they assert (see paragraph 616 above), that market entry of Teva with the applicants' generic product would not have created a situation of competition as regards the applicants and Teva would not, moreover, have been the sole, and thus the first, market entrant given the abovementioned entry of other generic companies. Likewise, in the event that the validity of the 947 patent had been confirmed by the EPO, Teva would still have been prevented from obtaining generic perindopril, including non-infringing generic perindopril, from any undertakings other than the applicants, and its supply by the applicants, even more hypothetical in that case, as they themselves recognise (see paragraph 636 above), would also not have allowed it to enter into competition with the applicants. It must be added, in that latter regard, that the fact that the Commission set the end of the infringement on the date that Teva had entered the United Kingdom market with the applicants' product cannot be interpreted as acknowledgement, by the Commission, that Teva entered the market in July 2007 in competition with the applicants. The Commission itself

indicated in the contested decision (recitals 2125 and 3133) that the end date of the infringement was set at 6 July 2007 in order to adopt a conservative approach and to use a date which would be favourable to the parties to the agreement.

669 For the same reasons, the applicants' allegations concerning their intention to supply Teva in the event that the 947 patent was invalidated by the EPO and Teva's objective of early entry, or even entry as the first generic company, to the United Kingdom market are also irrelevant in the present case.

670 Lastly, the Commission cannot be criticised (see paragraph 624 above) for relying, solely for the purposes of supporting its analysis, on the interpretation of the Teva agreement carried out by the High Court of Justice (England & Wales), Chancery Division (Patents Court), in its judgment of 9 October 2008 (recitals 1572 and 1573 of the contested decision).

671 It follows from all the foregoing that the Commission did not erroneously assess the exclusive purchasing and non-termination clauses in the Teva agreement in considering that those two clauses, combined in the non-marketing clause set out in Clause 2.3 of the Teva agreement, had to be analysed together as a 'non-compete obligation' (recital 1552 of the contested decision) and, thus, as an overall non-marketing obligation imposed on Teva.

672 It follows that, contrary to what the applicants essentially submit, those clauses do not correspond to those typically set out in a supply agreement, nor to those in a typical exclusive purchasing agreement (see also paragraphs 661 and 662 above), and cannot therefore be analysed in the same way as clauses contained in a side deal to a settlement, since such side deals correspond to typical commercial agreements (see paragraphs 798 to 808 below).

673 It also follows that the applicants' arguments based on typical supply agreements or exclusive purchasing agreements must be rejected.

674 In particular, the applicants' allegation that such agreements are a common practice in the pharmaceutical sector is irrelevant in the present case, since the exclusive purchasing clause of the agreement does not correspond to the typical clauses mentioned by the applicants. It should be added that, in any event, practices of private undertakings cannot prevail in the application of the competition rules set out in the Treaty, even where they are tolerated or approved by the authorities of a Member State (see, to that effect, judgment of 17 January 1984, *VBVB and VBBB* v *Commission*, 43/82 and 63/82, EU:C:1984:9, paragraph 40).

675 Nor is Regulation No 2790/1999 relevant, especially since, under Article 2(4) thereof, it does not apply to exclusivity agreements concluded by competing undertakings, such as those in question in the present case, both of which are seeking to market perindopril under their own name. Indeed, it has been found that Teva was a potential competitor of the applicants (see paragraph 614 above) and that status is not called into question by the conclusion of an agreement usually concluded between undertakings operating at different levels of the production or distribution chain.

676 As regards the Commission's assessment of the Servier/Generics agreement concluded less than a year after the Teva agreement, it should be noted that the Commission found, in recital 745 of the contested decision, without being contradicted by the applicants, that the exclusive purchasing clause contained in the Servier/Generics agreement did not provide for any payment or damages in the event of failure to supply by the applicants. Moreover, it is clear from the file that nor was that clause combined with a non-termination clause and a non-marketing clause, since Generics had not developed any competing perindopril, with the result that the assessments relating to that agreement could not be transposed to the Teva agreement.

677 Finally, in so far as the Commission clearly identified the specific and, in the present case, problematic aspects of the exclusive purchasing clause in the Teva agreement (see, in particular, recitals 1553 to 1574 of the contested decision), it cannot be inferred from the contested decision that the Commission prohibited, in principle, any concurrent conclusion of an exclusive distribution agreement and a settlement agreement.

678 It follows from all the foregoing that the Commission rightly considered that the Teva agreement restricted Teva's efforts to compete with the applicants.

(ii) The absence of an inducement in the form of a benefit

679 The Commission considered, in the contested decision, that the lump sum of GBP 5 million ('the lump sum') and the liquidated damages of GBP 500 000 per month totalling GBP 5.5 million for the 11 months of non-supply by Servier ('the final liquidated damages'), represented a substantial sum of money — GBP 10.5 million — which had served as a significant inducement for Teva to refrain from competing with the applicants (recital 1622).

680 In order to establish whether or not a reverse payment, that is to say a transfer of value from the originator company to the generic company, constitutes an inducement to accept non-marketing and non-challenge clauses, it is necessary to examine, taking into account its nature and its justification, whether the transfer of value covers only costs inherent in the settlement of the dispute. In the contested decision, the Commission therefore rightly examined whether the value transfer corresponded to the specific costs of the settlement for the generic company (see recitals 1592 to 1599 of the contested decision).

681 If a reverse payment provided for in a settlement agreement containing clauses restrictive of competition is aimed at compensating costs borne by the generic company that are inherent in that settlement, that payment cannot in principle be regarded as an inducement. Nevertheless, a finding of an inducement and of a restriction of competition by object is not ruled out in such a case. It means however that the Commission must prove that the amounts corresponding to those costs inherent in the settlement, even if they are established and precisely quantified by the parties to that settlement, are excessive (see paragraph 278 above).

682 The costs inherent in the settlement of the dispute include, in particular, litigation expenses incurred by the generic undertaking in the context of the dispute between it and the originator company. The compensation of those costs is directly linked to that settlement. Consequently, where the litigation expenses of the generic company are established by the parties to the settlement, the Commission can find them to be inducive only by showing that they are disproportionate (see paragraph 279 above).

683 By contrast, some costs incumbent upon the generic company are, a priori, too extraneous to the dispute and to its settlement to be regarded as inherent in the settlement of a patent dispute. Those include, for example, the costs of manufacturing the infringing products, corresponding to the value of the stock of those products, and research and development expenses incurred in developing those products. The same is true of sums which must be paid by the generic undertaking to third parties as a result of contractual commitments which were not undertaken in the context of the dispute (for example supply contracts). It is therefore for the parties to the agreement, if they do not wish the payment of those costs to be regarded as an inducement, and indicative of a restriction of competition by object, to demonstrate that those costs are inherent in the dispute or in its settlement, and then to justify the amount. They could also, to the same end, invoke the insignificant amount of the repayment of those costs which are a priori not inherent in the settlement of the dispute, showing that that amount is insufficient to constitute a significant inducement to accept the clauses restricting competition stipulated in the settlement agreement (see paragraph 280 above).

– *The final liquidated damages*

684 Contrary to the applicants' submissions, the Commission rightly considered that the final liquidated damages represented a payment made to Teva in exchange for its commitment not to compete with Servier (recital 1588 of the contested decision) and, accordingly, an inducement to accept a non-marketing obligation. The Commission rightly considered that the exclusive purchasing and non-termination clauses of the Teva agreement amounted to the imposition of a non-marketing obligation excluding Teva from the market (see paragraph 671 above) and, since Clauses 1.8 and 3.8.3 of the agreement provided for the payment of liquidated damages of GBP 500 000 per month in the event that Servier failed to supply the product and that market exclusion thus materialised, the liquidated damages clearly constitute the quid pro quo for Teva's not entering the market.

685 In that respect, the applicants' argument that the liquidated damages are a traditional contractual arrangement in English law and reflect what could have been granted by a court for non-compliance with a supply obligation must be rejected as irrelevant. The existence of an inducement may be inferred in the present case from the fact that the payment was made, not in order to compensate for costs inherent in the settlement agreement or in the performance of a normal supply agreement, but as a quid pro quo for Teva's not entering the market as provided for in the abovementioned clauses, irrespective of the legal mechanism used to achieve that quid pro quo and of whether that quid pro quo corresponds to the damages that a court would have granted (see paragraphs 680 and 681 above).

686 Nor is the applicants' comparison with the Commission's assessment relating to the Lundbeck-Neolab agreements (see paragraphs 394 to 398 above) capable of calling into question the nature of the final liquidated damages as an inducement.

– *The lump sum*

687 The arguments put forward by the applicants as regards the lump sum, provided for in Clause 10.1 of the Teva agreement, do not call into question the Commission's finding of an inducement.

688 It should be noted, in that respect, that Clause 10.1 of the Teva agreement stipulates as follows:

'Servier shall, subject to receipt of an appropriate invoice from Teva, pay or procure that one of its Affiliates shall pay, Teva [GBP] 5 000 000 … within 10 Working Days of receipt of Teva's invoice. Such invoice may be raised on signature of this Agreement and will be due immediately, always provided that Servier shall have 10 Working Days to make payment. Such payment shall be a contribution towards the costs incurred by Teva in preparing to enter into this Agreement, including without limitation the costs of terminating its supply arrangements for the United Kingdom.'

689 In the contested decision, the Commission found, as a preliminary point, that no specific amount had been reported by Teva *ex post* for the various costs alleged to have been compensated by the lump sum, with the exception of legal costs of less than EUR 100 000 for the litigation brought by Ivax against Servier in the United Kingdom (recitals 1594 and 1597). It nevertheless evaluated the other costs liable, in its view, to fall within the scope of Clause 10.1 of the Teva agreement, including those corresponding to the value of Teva's perindopril stock that had to be destroyed and to Teva's perindopril development costs, and found that they represented in total less than 40% of the lump sum (recitals 1596 to 1599 of the contested decision).

690 It follows that the Commission considered that, even though some of the costs covered by Clause 10.1 of the Teva agreement could be regarded as inherent in the settlement of the dispute between the applicants and Teva, the latter had not quantified the costs in question, nor a fortiori established the amount of those costs, with the exception of legal costs that had been quantified, but in an approximate way and without establishing the amount of those costs. In the contested decision, the

Commission referred to the fact that Teva only 'reported' (recital 797) or 'submitted' (recital 1597) legal costs of 'less than EUR 100 000' and confirmed, in response to a question asked at the hearing, that Teva had not submitted any evidence with its estimated figure.

691 The applicants do not put forward any argument, nor a fortiori adduce any evidence, such as the 'appropriate invoice' mentioned in Clause 10.1 of the agreement, capable of calling into question the Commission's analysis in that respect.

692 First, the applicants merely refer to 'the destruction of stock' and indicate its value. However, compensation for the value of stock to be destroyed cannot, a priori, be described as costs inherent in a settlement (see paragraphs 280 and 683 above).

693 In any event, the applicants fail to establish the value of that stock. On the one hand, the amount in euros claimed by them does not correspond to the amount in pounds sterling referred to in the contested decision (recital 1596), having regard to the exchange rate used by the Commission (see, in particular, footnote 4109 of the contested decision). On the other hand, and above all, the applicants adduce no evidence in support of their claim other than their own statements and those of Teva in reply to the statement of objections, as well as a document from Teva making no reference to any specific figure. Thus, even if it were to be considered that, in the present case, payment of the value of the stock of Teva products to be destroyed was inherent in the Teva agreement, in that that destruction was provided for by that agreement (Article 2.2), that payment could not, in the absence of evidence of its amount, avoid being classified as an inducive payment (see paragraph 683 above).

694 The applicants refer, secondly, to the sum of GBP 1 million which Teva contemplated having to pay to one of its commercial partners as a result of the termination of the commercial partnership in question. In addition to the fact that the sums to be paid by the generic undertaking to third parties by reason of the termination of ongoing contracts are not a priori costs inherent in a settlement (see paragraph 683 above), it may be noted that the alleged amount is nowhere set out in the contract in question annexed to the application.

695 Although the applicants claim, thirdly, that the initial amount corresponded to the damages which they would have had to pay Teva in the event that an injunction was wrongly granted and which they would have avoided paying by virtue of the Teva agreement, it must be noted that, by that allegation, the applicants seek, in essence, to prove that the lump sum was justified by comparing that sum to the amount of costs of a different nature which are not covered by Article 10.1 of the agreement. That provision — although drafted in a non-restrictive manner — is limited to the 'costs incurred by Teva' and does not include costs incurred or avoided by the applicants. By their allegation, the applicants also confuse the issue whether the lump sum is justified in the light of the settlement, which is the only settlement at issue in the present case, and the issue of the proportionality of that amount; the proposed comparison might in certain circumstances be relevant for assessing the latter. However, it should be noted that they are two separate assessments that the Commission must carry out in turn. Thus, it is for the Commission, when assessing the restrictive nature of a patent dispute settlement involving a value transfer, to examine, in the first place, whether the costs covered by the value transfer are justified in the light of the settlement and, in particular, whether the value transfer corresponds to the established amount of costs which may by their very nature be regarded as inherent in the settlement, then, in the second place, if it considers those costs are justified, to verify that the amount of those costs is not disproportionate in view of, inter alia, the type of costs concerned (see paragraphs 681 and 682 above).

696 It should also be noted that, even if the proposed comparison were relevant for the purpose of ascertaining whether the lump sum was justified in the light of the settlement, the applicants have not provided any assessment of the costs allegedly avoided. They merely refer to substantial damages in the event of a decision against them in the substantive proceedings which follow the grant of an injunction in their favour.

697 Finally, in so far as the applicants maintain, fourthly, that the initial amount was intended to 'secure' the exclusive purchasing clause (see paragraph 628 above), it must be concluded that they regard that amount as a quid pro quo for that clause and thus, essentially acknowledge that it is an inducement, since that clause has been interpreted as imposing a non-marketing obligation on Teva (see paragraphs 684 and 685 above).

698 It follows that the Commission validly found, in the contested decision (recitals 1608 and 1622), that the Teva agreement contained an inducement for Teva to accept the non-marketing and non-challenge clauses set out in that agreement, and the Commission was not also required to ascertain, as the applicants maintain (see paragraph 628 above), whether those clauses would have been less restrictive in scope in the absence of that inducive payment. A finding that there was an inducement to accept non-marketing and non-challenge clauses requires only the existence of such clauses — irrespective of whether they are more or less restrictive in scope — and an analysis of the costs covered by the transfer of value in question (see paragraphs 680 and 681 above).

699 The existence of that inducement is not capable of being called into question by the applicants' allegation that the Commission wrongly 'conflated' the initial amount and the final liquidated damages in order to infer 'a net value transfer for the amount of GBP 10.5 million'. Admittedly, as the applicants rightly point out, unlike the initial amount determined by Clause 10.1 of the Teva agreement, the amount of the final liquidated damages results from the implementation of the Teva agreement, in particular from the applicants' failure to supply Teva, and not, with respect to an amount of GBP 5.5 million thereof, from the relevant clause of the agreement providing solely for monthly compensation of GBP 500 000. However, although it may be inferred that the amount of GBP 10.5 million corresponds to the amount of the transfer of value actually paid to Teva and not to the amount of the transfer of value arising solely from the clauses of the Teva agreement, the fact remains that, for the same reasons as those that led to the conclusion that the initial amount and the monthly compensation of GBP 500 000 were an inducement, the full amount of that actual transfer also constitutes an inducement.

700 It follows that, in view of the foregoing (see, in particular, paragraphs 265 to 271 above), the Commission rightly inferred from the finding of that inducement, the two parts of which were provided for in the Teva agreement, that that agreement restricted competition by object.

701 That conclusion is not called into question by the alleged distortion of the objective of the Teva agreement and of the intentions of the parties to that agreement.

702 The applicants' allegation that the parties to the Teva agreement lack anticompetitive intent and that the agreement pursues legitimate objectives, including inter alia Teva's early entry — or even entry as the first generic company — to the United Kingdom market, is not capable of calling into question either the existence of an inducive benefit or the competition-restricting nature of the non-marketing and non-challenge clauses in the Teva agreement (see also paragraph 669 above). Consequently, even if the arguments in question had an established factual basis, they would not be capable, in any event, of invalidating the Commission's finding that the Teva agreement constituted a restriction by object.

703 It should also be added that the parties' intention is not a necessary factor in determining whether a type of coordination between undertakings is restrictive (see paragraph 222 above).

704 In addition, since the Teva agreement contained non-marketing and non-challenge clauses, the inherently restrictive nature of which has not been validly called into question, and since the Commission found that there was an inducement, it could correctly regard the Teva agreement as a market exclusion agreement, which thus pursued an anticompetitive objective. According to settled case-law, the mere fact that an agreement also pursues legitimate objectives is not enough to preclude the classification of that agreement as a restriction of competition by object (see paragraph 222 above).

(iii) The alternative complaint concerning the duration of the infringement

705 The applicants criticise the Commission for having fixed the start of the infringement alleged against them based on the Teva agreement on the date that that agreement was concluded (13 June 2006), instead of on the date on which Teva obtained the marketing authorisation in the United Kingdom (12 December 2006) (see paragraph 641 above).

706 It should be recalled, in that regard, that, on the one hand, the examination of conditions of competition and the restrictions imposed on that competition must be based not only on existing competition between undertakings already present on the market but also on potential competition between those established undertakings and other undertakings not yet present on the market (see judgment of 29 June 2012, *E.ON Ruhrgas and E.ON* v *Commission*, T-360/09, EU:T:2012:332, paragraph 85 and the case-law cited) and that, on the other hand, the Commission rightly found that Teva was a potential competitor of the applicants on the date that the Teva agreement was concluded (see paragraph 614 above), even though it did not have a marketing authorisation on that date (see paragraphs 478 and 599 above). It follows that the Commission did not err in considering that competition was restricted as soon as the Teva agreement was concluded on 13 June 2006 and that the infringement alleged against the applicants on the basis of that agreement started on that date.

707 The complaint criticising the Commission's assessment of the duration of the infringement found to have occurred on the basis of the Teva agreement must therefore be rejected, as must the plea alleging errors of law and of assessment in classifying the Teva agreement as a restriction by object.

(c) Errors of law and of assessment in relation to the classification of the Teva agreement as a restriction of competition by effect

708 The applicants maintain that the Commission made various errors of law and of assessment in relation to the classification of the Teva agreement as a restriction of competition by effect.

709 It is appropriate, in applying *mutatis mutandis* the considerations set out in paragraphs 566 to 570 above, to reject the present plea as ineffective.

8. The agreement concluded with Lupin

(a) The status of Lupin as a potential competitor

…

(b) Errors of law and of assessment in relation to the classification of the agreement concluded with Lupin as a restriction of competition by object

(1) Arguments of the parties

…

(2) Findings of the Court

787 As regards the plea relating to the actual finding of the infringement, it is necessary to examine, in the first place, the applicants' arguments seeking to call into question the two conditions for a finding of a restriction by object, that is to say an inducement in the form of a benefit for the generic company and the corresponding limitation of its efforts to compete with the originator company. It will next be

necessary to consider whether the Commission could properly conclude that there was an infringement. Finally, it will be necessary to ensure that the Commission did not err in the definition of the scope *ratione materiae* of that infringement.

788 As regards the plea relating to the duration of the infringement, on which the applicants relied in the alternative, it will be examined last.

(i) The absence of an inducive benefit

789 It follows from Article 2 of Regulation No 1/2003 and from settled case-law that, in the field of competition law, where there is a dispute as to the existence of an infringement, it is incumbent on the Commission to prove the infringements found by it and to adduce evidence capable of demonstrating to the requisite legal standard the existence of the circumstances constituting an infringement (judgments of 17 December 1998, *Baustahlgewebe* v *Commission*, C-185/95 P, EU:C:1998:608, paragraph 58, and of 8 July 1999, *Commission* v *Anic Partecipazioni*, C-49/92 P, EU:C:1999:356, paragraph 86; see, also, judgment of 12 April 2013, *CISAC* v *Commission*, T-442/08, EU:T:2013:188, paragraph 91 and the case-law cited).

790 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 of 12 April 2013, *CISAC* v *Commission*, T-442/08, EU:T:2013:188, paragraph 92 and the case-law cited).

791 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. 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 judgment of 12 April 2013, *CISAC* v *Commission*, T-442/08, EU:T:2013:188, paragraph 93 and the case-law cited).

792 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 of 12 April 2013, *CISAC* v *Commission*, T-442/08, EU:T:2013:188, paragraph 95 and the case-law cited).

793 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 of 12 April 2013, *CISAC* v *Commission*, T-442/08, EU:T:2013:188, paragraph 96 and the case-law cited).

794 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 Commission, viewed as a whole, meets that requirement (see judgment of 12 April 2013, *CISAC* v *Commission*, T-442/08, EU:T:2013:188, paragraph 97 and the case-law cited).

795 The existence of an anticompetitive practice or agreement must sometimes even be inferred from a number of coincidences and indicia which, taken together, may, in the absence of another plausible explanation, constitute evidence of an infringement of the competition rules (judgment of 7 January 2004, *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, EU:C:2004:6, paragraph 57).

796 For example, although parallel behaviour may not by itself be identified with a concerted practice, it may however amount to strong evidence of such a practice if it leads to conditions of competition which do not correspond to the normal conditions of the market (judgment of 14 July 1972, *Farbenfabriken Bayer* v *Commission*, 51/69, EU:C:1972:72, paragraph 25).

797 Likewise, the presence of a 'side deal' — the expression used by the Commission in recital 1190 of the contested decision — may constitute, as regards the settlement of a patent dispute, a strong indication of the existence of an inducement and, consequently, of a restriction of competition by object (see paragraphs 265 to 273 above).

798 It should be explained in that respect that a side deal is a normal commercial agreement linked to a settlement agreement which contains clauses which are by themselves restrictive (see paragraph 257 above). Such a link exists, in particular, where the two agreements are concluded on the same day, where they are legally linked, the binding nature of one of the agreements being conditional upon the conclusion of the other agreement, or where, in the light of the context in which they are concluded, the Commission is able to establish that they are indissociable. It may be added that, the shorter the time between the conclusion of each agreement, the easier it will be for the Commission to establish that indissociable nature.

799 It should also be noted that the fact that the settlement agreement and the side deal are concluded on the same day or that there is a contractual link between them is an indication that those agreements form part of a single contractual framework. If those agreements were not concluded on the same day (and if there were no contractual link between them), one of the parties to the negotiation would grant the other party everything it wants without any certainty of ultimately obtaining the expected quid pro quo. That temporal or legal link between the two agreements is also an indication that they were negotiated together.

800 The side deal is a normal commercial agreement that could exist independently without the settlement of a dispute being at issue. Likewise, the conclusion of a settlement agreement does not require the concurrent conclusion of a commercial agreement. Thus, the two agreements do not need to be linked. Moreover, that linkage cannot be justified by the settlement of a dispute, because the purpose of the side deal is not to reach such a settlement but rather to carry out a commercial transaction.

801 In addition, a side deal involves value transfers, of a financial or non-financial nature, between the parties. It may involve, in particular, the transfer of value from the patent holder to the generic company.

802 There is therefore a risk that the linking of a commercial agreement with a settlement agreement containing non-marketing and non-challenge clauses, which are, by themselves, restrictive of competition (see paragraph 257 above), is actually intended — under the guise of a commercial transaction, taking the form, as the case may be, of a complex contractual arrangement — to induce the generic company to accept those clauses, through a value transfer provided for in the side deal.

803 Consequently, the fact that a commercial agreement, which does not normally have the settlement of a dispute as its subject matter (see paragraph 800 above), and which serves as a vehicle for a transfer of value from the originator company to the generic company, is, in the circumstances set out in paragraph 798 above, linked with a settlement agreement containing competition-restricting clauses is a strong indication of the existence of a reverse payment (see paragraph 264 above).

804 However, the strong indication referred to in the preceding paragraph is not sufficient and the Commission must therefore support it with other consistent evidence justifying the conclusion that there is a reverse payment. Such a payment, in the specific context of side deals, corresponds to the

part of the payment made by the originator company which exceeds the 'normal' value of the asset traded (or, as the case may be, to the part of the 'normal' value of the asset traded which exceeds the payment made by the generic company).

805 It should be noted, in that respect, that the Commission, relying on various indicia, including the fact that Lupin gave no guarantee that a patent would be granted, that it would be valid or that the products or processes claimed would be non-infringing (Clause 2.2(a) of the Lupin agreement), stated twice in the contested decision that the acquisition of Lupin's technology had not been negotiated 'at arm's length' (recitals 1950 and 1952).

806 It should be noted that the concept of 'normal competitive conditions', which is similar to that of 'arm's length', even though it is not used in relation to agreements, decisions and concerted practices, is not alien to competition law, since it is used in the particular field of State aid in order to determine whether a State has acted like a private investor (judgment of 2 September 2010, *Commission* v *Scott*, C-290/07 P, EU:C:2010:480, paragraph 68), that is to say, whether the advantage granted to the undertakings in question constitutes the normal remuneration for a quid pro quo obtained by the State. That concept may therefore constitute, by analogy, a relevant reference parameter when determining whether two companies that concluded a commercial transaction did so on the basis of economic considerations limited to the economic value of the asset traded, for example to its prospects of profitability, and, thus, at arm's length.

807 Where there are indicia or evidence put forward by the Commission in order to support a finding that the side deal was not concluded at arm's length, the parties to the agreements may present their version of the facts, supporting their claims with the evidence that they are able to provide and which permits the conclusion that the commercial agreement, although linked to the settlement agreement, is justified by reasons other than the exclusion of a competitor by means of a reverse payment. The parties to the agreements may thus argue that the side deal was concluded at arm's length by adducing relevant evidence concerning, for example, the industrial and commercial practices in the sector or the particular circumstances of the case.

808 In the light of all the evidence available to it and, as the case may be, the lack of an explanation or the lack of a plausible explanation from the parties to the agreements, the Commission may be justified in finding, following an overall assessment, that the side deal was not concluded at arm's length, that is to say that the payment made by the originator company exceeds the value of the asset traded (or that the value of the asset transferred to the generic company exceeds the payment made by the latter). The Commission may thus conclude that there is a reverse payment (see paragraph 804 above).

809 A reverse payment, if it is not intended to compensate for costs inherent in the settlement, therefore constitutes an inducive benefit (see paragraphs 265 and 278 to 280 above). That is the case where the purpose of a side deal is not to settle a dispute but rather to carry out a commercial transaction (see paragraph 800 above).

810 However, the parties to the agreement may still argue that the benefit in question is insignificant, if the amount of that benefit is insufficient to be regarded as a significant inducement to accept the competition-restricting clauses set out in the settlement agreement (see paragraph 280 above).

811 The specific circumstances of the present case must be examined in the light of the foregoing considerations.

812 It should be noted that Servier and Lupin concluded, on the same day, a settlement agreement containing non-marketing and non-challenge clauses and a technology assignment agreement by which Servier purchased from Lupin three patent applications filed by the latter. Moreover, those two agreements were concluded in the form of a single agreement. The link between the two agreements is therefore clear.

813 In addition, the assignment agreement served as a vehicle for a transfer of value from Servier to Lupin.

814 It follows from paragraphs 812 and 813 above that the assignment agreement constituted a side deal which served as a vehicle for a transfer of value from the originator company to the generic company. It is a strong indication that the transfer of value in question is not merely the quid pro quo for the asset transferred under the side deal, but also involves a reverse payment (within the meaning of that expression in relation to side deals).

815 Moreover, it is common ground that Servier paid Lupin EUR 40 million under the assignment agreement, which is a significant amount in absolute terms, as the Commission correctly noted in recitals 1871 and 1947 of the contested decision.

816 That amount exceeded the profits that Lupin could expect from its independent market entry during the first two to three years of marketing, as the Commission rightly found in recital 1974 of the contested decision.

817 It is also common ground that the amount in question was greater than the investments made by another comparable generic company, for the purposes of developing its own perindopril, as highlighted by the Commission in recital 1962 of the contested decision. That piece of evidence, relied on by the Commission, is particularly relevant, contrary to the applicants' submissions.

818 It should be added that Lupin did not transfer patents, but mere patent applications. In addition, it was expressly stipulated in the Lupin agreement that Lupin gave no assurance that a patent would be granted, that it would be valid or that any product or process claimed would be non-infringing (Clause 2.2(a) of the Lupin agreement).

819 Lastly, it is common ground that although, in their replies to the statement of objections, Servier and Lupin both denied that the settlement depended on the terms of the assignment of the patent applications, Lupin had previously stated that the assignment of those applications was an integral part of the discussions concerning the settlement of the dispute. It had also described the payments received as 'settlement monies' or 'settlement sums' (recital 1937 of the contested decision).

820 However, the applicants have not adduced any specific evidence to show that the acquisition of Lupin's patent applications for EUR 40 million could reasonably be regarded as a profitable investment (see, to continue the analogy with the concept of a 'private investor in a market economy' begun in paragraph 806 above, paragraph 84 of the judgment of 12 December 2000, *Alitalia* v *Commission*, T-296/97, EU:T:2000:289, in which it is stated that the conduct of a private investor in a market economy is guided by prospects of profitability) or, at the very least, as being such as to generate, for the acquirer of those applications, income capable of compensating for the high cost of acquiring them.

821 Admittedly, the applicants refer, albeit in scant detail, to the existence of transactions which, in their view, are comparable to the assignment agreement concluded with Lupin. Those transactions were, however, agreements to which the applicants were parties and may therefore only on an ancillary basis serve as a reference for the purpose of establishing that a transaction was carried out at arm's length. Moreover, some of those transactions have been classified as an infringement of competition law by the Commission. Lastly, the applicants do not establish that the technology transferred in the context of those various transactions was equivalent to that at issue in the assignment agreement.

822 It is true that the applicants also refer, in that regard, to the opinion of a person who describes himself as an intellectual property consultant. However, that person himself states that he drew up his opinion on behalf of Servier. This necessarily limits the probative value of such an opinion. Most importantly, the conclusion of that opinion ('I therefore consider that the purchases are within the limits of a company's normal practice') and the evidence upon which that conclusion is based are too general to

establish that the transfer of value in question corresponded to a transaction carried out at arm's length. Moreover, the transactions serving as a reference are again transactions in which Servier was involved and which, in some cases at least, have been regarded by the Commission as infringements of competition law.

823 Furthermore, even if it were established, as the applicants maintain, that Servier's patent and production or other departments regarded Lupin's technology as 'interesting', that fact would nevertheless not support a finding that the transfer of value in question corresponded to a transaction carried out at arm's length.

824 Likewise, even assuming that 'the price was negotiated from the initial claims until a level acceptable to both parties was reached', this nevertheless would not support a finding that the value transfer at issue corresponded to a transaction carried out at arm's length.

825 Thus, the evidence produced by the applicants does not justify, even taken into account cumulatively, the conclusion that the value transfer at issue corresponded to a transaction carried out at arm's length.

826 In that respect, it should be noted that the Commission, relying, inter alia, on the case-law cited in paragraph 795 above (recital 1940 of the contested decision), considered that 'neither Servier nor Lupin were able to provide a plausible description of the factors determining how the final sum of EUR 40 million [had been] reached' (recital 1955 of the contested decision). The Commission also stated, in recital 1944 of the contested decision, that it was entitled to draw inferences from 'a situation where potential exculpatory evidence [could] only come from the parties themselves', and that 'the parties [were] unable to produce such evidence despite several requests [for] information'. It added, in recital 1964 of the contested decision, that 'Servier [had been] unable to produce any contemporaneous documents that would be informative as to the amount of savings expected from acquiring Lupin's technology'. Lastly, it concluded, having regard, inter alia, to 'the absence of evidence' of Servier's commercial interest in the technology transferred by Lupin, that the transfer of value under the assignment agreement represented a significant inducement (recital 1978 of the decision).

827 In view of all of the evidence discussed before the Court, it must be concluded that the Commission established the existence of a reverse payment which was not inherent in the settlement agreement at issue (see paragraph 809 above) and was therefore an inducement.

828 Lastly, it must be noted, in view of the considerations set out in paragraphs 815 to 827 above, that it has not been established that the benefit in question is insignificant, that is to say, of an amount insufficient to be regarded as a significant inducement to accept the anticompetitive clauses contained in the settlement agreement (see paragraph 810 above).

(ii) The absence of a limitation of the generic company's efforts to compete with the originator company

829 In the present case, the Lupin agreement contains non-marketing and non-challenge clauses, which, as noted in paragraph 257 above, are, by themselves, restrictive of competition.

830 The applicants submit however that the non-marketing and non-challenge clauses in the Lupin agreement are in no way restrictive of competition, in view of the manner in which other clauses in the agreement limit that restrictiveness. It is necessary to examine the validity of that assertion.

831 As a preliminary point, it must be noted that the products covered by the Lupin agreement are defined in recital A of that agreement, which refers to 'pharmaceutical products containing, as an active ingredient, perindopril tert-butylamine (also known as perindopril erbumine) and any salt thereof ("the Products")'.

832 Even though recital A of the Lupin agreement refers to ongoing litigation which, at the European level, only concerns the 947 patent, as is apparent from recitals B and D of that agreement, that clause, in view of its wording, does not appear to refer only to products containing perindopril erbumine in its alpha form, that is to say those covered by the 947 patent, but rather all products containing erbumine, regardless of its form.

833 In addition, the expression 'any salt thereof' is ambiguous. On the one hand, from a grammatical perspective, the term 'thereof' refers more obviously to perindopril tert-butylamine, that is to say erbumine, than to perindopril in its entirety, since the latter is not mentioned, as such, in that part of the sentence. On the other hand, it is not disputed that erbumine is a salt, with the result that the term 'thereof' should not refer to erbumine, but, more generally, to perindopril in its entirety.

834 Consequently, it is difficult to determine, in view of the wording of the clauses of the agreement, whether the products covered by that agreement are limited to the alpha form of erbumine or also include other forms of erbumine, or even other salts of perindopril.

835 In that context of uncertainty, it must be verified whether the scope of the non-marketing and non-challenge clauses was limited to the extent that these clauses were no longer restrictive.

836 In the first place, the restrictive nature of the non-challenge clause is clear, since Clause 1.3 of the Lupin agreement stipulates that:

'Following the date of this Agreement Lupin shall not directly or indirectly seek or assist or procure any third party to revoke, invalidate or otherwise challenge the Patents or any patent owned by Servier or its affiliates covering the Products in any country other than [a specific non-EEA Member State].'

837 In addition, it is apparent from the separate terms 'the Patents' and the 'Servier Patents', defined respectively in recital D and Clause 1.3 of the Lupin agreement, that that provision applies not only to the patents referred to in recitals B, C and D (including the 947 patent), which were the subject of litigation between Lupin and Servier, but also, at least potentially, to a series of patents which were not identified by name and which protect the products covered by the agreement.

838 In the second place, as regards the scope of the non-marketing clause, Clause 1.6 of the Lupin agreement prohibits Lupin from marketing the products referred to in the agreement.

839 It is apparent, however, from the terms of Clause 1.6 of the Lupin agreement that, where the circumstances set out in Clause 4.1 of that agreement apply, Lupin may sell or offer for sale products supplied by Servier or its own products. Clause 4.1 sets out the circumstances in which Servier is required to sell its products to Lupin. Three scenarios are envisaged in that provision.

840 In the first scenario, Lupin may enter one of the national markets covered by the agreement if some of Servier's products are marketed by a third party in that market. In the second scenario, Lupin may enter such a market if Servier's patent application is rejected or if its patent expires, is declared invalid or is revoked. Lastly, in the third scenario, Lupin may enter such a market if a generic product not produced by Servier is sold on that market — unless Servier has applied for an injunction and that application has not been rejected — and the generic medicinal product is not being sold in breach of an injunction applying in that market.

841 Thus, in essence, the market entry of Lupin, including with its own products (see paragraph 839 above), is possible in two cases.

842 First, Lupin may enter the market if Servier authorises the sale of its products by a third party, decides not to submit a patent application or decides not to apply for an injunction, that is to say in circumstances that depend on a discretion on the part of Servier over which Lupin has no influence. In this first case, the application of the circumstances set out in Clause 4.1 of the Lupin agreement cannot be regarded as calling into question, by itself, the restrictive nature of the non-marketing clause (see paragraph 257 above) or, a fortiori, as facilitating Lupin's market entry.

843 Secondly, Lupin may enter the market if Servier's patents do not allow it to oppose that entry. In that case, Clause 4.1 of the Lupin agreement does not allow Lupin to make an early market entry in relation to the effects of a patent that is still valid or enforceable. It merely reflects the absence of a valid or enforceable patent, thus avoiding a situation in which the non-marketing clause would be devoid of any link with such a patent and would then clearly show a sufficient degree of harm to the proper functioning of normal competition for it to be classified as a restriction by object (see paragraph 877 below). In this second case, the application of the circumstances set out in Clause 4.1 cannot therefore be regarded as calling into question, by itself, the restrictive nature of the non-marketing clause (see paragraph 257 above) and, a fortiori, as facilitating Lupin's market entry.

844 The non-marketing clause must therefore be held to be restrictive, despite the provisions of Clause 4.1 of the Lupin agreement.

845 The above conclusion is not called in question by the other arguments put forward by the applicants.

846 First, the applicants submit that the agreement allowed Lupin to enter the market early, that is to say before the date on which the validity of the 947 patent was expected to come to an end. According to the applicant, such early entry reduces or even neutralises the competition-restricting nature of a non-marketing clause.

847 It should be noted that, even though that interpretation is not evident due to the complex wording of Clause 1.6 of the Lupin agreement, it could be accepted that that clause, read in conjunction with Clause 4.1(c) of the same agreement, allows the market entry of Lupin with its own products where a generic 'Product' which is not produced by Servier has entered the market without breaching an injunction (and, moreover, where an application for an injunction lodged by Servier is not currently under examination).

848 Since the term 'Product', as set out in Clause 4.1(c) of the Lupin agreement, begins with an upper-case letter, it must be understood within the meaning of the definition given in recital A of that agreement, where that term is defined with an upper-case first letter (see paragraph 831 above).

849 In the light of recital A of the Lupin agreement, which seems to refer to products containing erbumine, regardless of its form (see paragraph 832 above), Clause 4.1(c) of that agreement could be interpreted, where it refers to products which are not sold in breach of an injunction, as referring to products containing forms of erbumine other than the alpha form. Thus, the agreement could be interpreted as authorising Lupin to enter the market after a third party has entered the market with generic perindopril containing a non-alpha form of erbumine.

850 In addition, the ambiguous wording of recital A of the Lupin agreement also creates uncertainty as to whether Clause 4.1(c) of that agreement could be interpreted, where it refers to products which are not sold in breach of an injunction, as also referring to products not containing erbumine (see paragraph 833 above). That could then lead to the conclusion that the agreement authorised Lupin to enter the market after a third party has entered the market with any generic perindopril in the form of a salt, including a salt other than erbumine.

851 It may therefore be concluded that the agreement provided for the market entry of Lupin, with its own products, before the expected end date of the validity of the 947 patent, since any marketing by a third party of products which do not contain the alpha form of erbumine — because it could not breach an injunction protecting that patent — would in turn allow Lupin to enter the market with its own products.

852 However, because of the uncertainties surrounding the scope of Clauses 1.6 and 4.1 of the Lupin agreement, set out in paragraphs 846 to 850 above, Lupin could fear that the non-marketing clause would continue to apply after a third party had entered the market with generic perindopril composed of a non-alpha form of erbumine or generic perindopril not composed of erbumine. That doubt was such as to deter it from entering the market. There was additional uncertainty due to the fact that, even if the term 'Product' were interpreted broadly (as covering any salt of perindopril), Servier could nevertheless apply for an injunction, even in respect of a product which clearly did not infringe any of its patents, in particular the 947 patent, which would effectively prevent the application of Clause 4.1(c) of the Lupin agreement until that application was rejected.

853 In that regard, it may also be noted that, as regards the French market, the parties exchanged several letters concerning whether Sandoz's entry to the market allowed Lupin to enter the market in turn. In a letter of 17 March 2009, Lupin thus asked Servier whether it was opposed to Lupin's entry to the French market. By a letter of 31 March 2009, Servier merely stated that Sandoz's product did not infringe any of its patents. As a result of that response, Lupin felt compelled to request, by letter of 3 April 2009, clarifications from Servier. It wrote, inter alia, the following:

'Lupin does not think that Servier has any valid reason to oppose the sale by Lupin of its perindopril erbumine product in France to its local partner(s) or the resale of that product by that/those French partner(s). Your letter of 31 March 2009 does not clearly indicate whether Servier disagrees with any of those points. If Servier disagrees, please provide a full explanation of Servier's position by 9 April 2009 by close of business.'

854 Accordingly, the very existence of Lupin's letters and the content of the last of them reveal its uncertainties as to its ability to enter the French market without infringing the agreement.

855 Consequently, the non-marketing clause must be found to be restrictive irrespective of the interpretation given to recital A of the Lupin agreement, especially since the uncertainties arising from the complexity of an agreement or the ambiguity of its wording must not allow the parties to avoid liability as regards competition law.

856 Even if the interpretation of the agreement presented in paragraph 851 were accepted, the hypothetical nature of the events mentioned at the end of paragraphs 849 and 850 above — that is to say the marketing of a generic product by a third party — precludes the conclusion that the restrictive nature of the non-marketing clause is neutralised and that therefore there is no infringement in that respect. It is necessary to distinguish between, on the one hand, the issue of the very existence of the infringement, which cannot be called into question by the mere possibility that future events may occur, and, on the other hand, that of the duration of the infringement, which may depend on the actual occurrence of such events.

857 In addition, the early entry of Lupin depends, in any event, on the marketing of a generic product by a third party, that is to say a circumstance which is both unconnected with the parties to the agreement and uncertain. That entry is therefore not the result of a clear choice of those parties on which they could rely in order to establish that the agreement between them — and, in particular, the non-marketing clause in that agreement — is not restrictive of competition.

858 Secondly, it is true that the Lupin agreement provides in Clause 4.2 for the future conclusion of a supply agreement between the parties. However, the implementation of such an agreement depends on the occurrence of one of the circumstances envisaged in Clause 4.1 of the Lupin agreement. Since, as has just been indicated, the implementation of that latter clause does not justify the conclusion that the non-marketing clause is not restrictive, the same is true of the supply agreement mentioned in Clause 4.2.

859 In addition, it may be observed that no supply agreement has been concluded between the parties. Furthermore, the Lupin agreement did not provide that failure to adopt a supply agreement would have significant legal consequences for the parties, such as, for example, termination of the Lupin agreement as a whole or of the non-marketing and non-challenge clauses in it. Thus, even if a supply agreement could be regarded as being likely to facilitate the market entry of a generic company that would be a potential competitor of the originator company, in the present case, the Lupin agreement, which merely provided for a supply agreement in principle, without providing for measures or sanctions to ensure the implementation of that agreement, could not be regarded as facilitating Lupin's market entry.

860 Admittedly, it is clear from Clause 4.2 of the Lupin agreement that the supply agreement was supposed to enable the application of Clause 4.1 of the Lupin agreement, which stipulated an 'irrevocable' commitment on Servier's part to supply the 'Products', within the meaning of the agreement, to Lupin. However, the binding nature of Servier's commitment must be put in perspective in the light of the considerations set out in paragraph 859 above.

861 Thirdly, although the applicants maintain that an interpretation of Clause 1.3 of the Lupin agreement as meaning that the non-challenge clause applies beyond the 947 patent alone must lead to the conclusion, under Clause 1.7 of that agreement, that Lupin had a free licence over all those patents, that claim is erroneous in the light of the terms of Clause 1.7, as translated into the language of the case by the applicants and according to which:

'In order to avoid any confusion, this agreement does not grant Lupin any right or licence, in any jurisdiction, over the Servier Patents, it being understood that neither Servier nor its subsidiaries, licensees and/or assignees of the Servier Patents will exercise their rights over the Servier Patents in connection with Lupin's exercise of its right to sell the Products manufactured by Lupin/Lupin (Europe) Limited granted under Clause 1.6.'

862 Indeed, the wording of that stipulation is unclear because of an at least apparent contradiction between the first part of the sentence (this agreement does not grant Lupin any right or licence, in any jurisdiction, over the Servier Patents) and the part which follows (it being understood that neither Servier nor its subsidiaries, licensees and/or assignees of the Servier Patents will exercise their rights over the Servier Patents in connection with Lupin's exercise of its right to sell the Products manufactured by Lupin/Lupin (Europe) Limited granted under Clause 1.6). Moreover, the necessity of the first part of the sentence is not clear, since no stipulation in the agreement suggests that Lupin had a licence for rights other than those relating to the technology which it had assigned to Servier. Furthermore, any understanding of the clause is further complicated by the reference in it to Clause 1.6 of the Lupin agreement, itself referring to Clause 4.1 of that agreement, which lays down the conditions under which Lupin may enter the market with its own product. Thus, in the light of its wording, Clause 1.7 was likely to give rise to uncertainty which would deter Lupin from entering the market.

863 Above all, the non-use by Servier of its patent rights against Lupin depends on fulfilment of one of the conditions laid down in Clause 4.1 of the Lupin agreement (to which Clause 1.6 of that agreement refers). To the extent that, as stated in paragraphs 844 and 855 above, the implementation of Clause 4.1 does not support the conclusion that the non-marketing clause is not restrictive, the same applies

to the implementation of Clause 1.7 of that agreement, including where the term 'Servier Patents' is understood broadly so as to include patents relating not only to the alpha form of erbumine, but also to other forms of erbumine or even to other perindopril salts.

864 It follows from the foregoing that the Commission was entitled to conclude that there was a limitation of Lupin's efforts to compete with Servier.

(iii) The absence of infringement

865 In view of the considerations set out in paragraphs 789 to 864 above, it may be observed that the Commission rightly found both an inducive benefit and a corresponding limitation of Lupin's efforts to compete with Servier.

866 As noted in paragraph 272 above, in the context of patent dispute settlement agreements, a finding of a restriction of competition by object presupposes that the settlement agreement contains both an inducive benefit to the generic company and a corresponding limitation of the generic company's efforts to compete with the originator company. Where these two conditions are met, it must be found that there has been an inducement.

867 In the case of a patent settlement agreement containing non-marketing and non-challenge clauses, the inherently restrictive nature of which has not been validly called into question, the existence of an inducement to the generic company to accept those clauses justifies a finding of a restriction by object (see paragraph 273 above).

868 In the present case, the finding of a significant inducement (see paragraph 828 above) allowed the Commission to find a restriction of competition by object.

869 Consequently, contrary to the applicants' submissions, the Commission was entitled to find a restriction by object in the contested decision.

870 However, the applicants, relying on the scope of the non-marketing and non-challenge clauses, criticise, in essence, the Commission's definition of the scope *ratione materiae* of the infringement in the contested decision.

871 As indicated in paragraph 834 above, it is difficult to determine, in the light of the wording of the clauses of the Lupin agreement, whether the products covered by that agreement were limited to the alpha form of erbumine or whether they also included other forms of erbumine, or even other salts of perindopril.

872 The scope of the non-marketing clause depends on the definition of the concept of 'Products' used, since both Clause 1.6 of the Lupin agreement and Clause 4.1 thereof, to which Clause 1.6 refers, make reference to that concept.

873 In addition, as regards the scope of the non-challenge clause, that clause applied not only to the patents referred to in recitals B, C and D of the Lupin agreement (including the 947 patent), but also to a series of patents which were not identified by name and the determination of which depended on the concept of 'Products', as defined in that agreement (see paragraph 836 above).

874 As the Commission rightly indicated in the contested decision (recital 1912), the wording of the Lupin agreement generated uncertainty as to the scope of the non-marketing and non-challenge clauses.

875 Thus, the wording of the Lupin agreement generated doubts as to whether the non-marketing clause could apply to any form of erbumine, or even to salts of perindopril other than erbumine, and whether the non-challenge clause could apply to patents other than the 947 patent, including patents covering products which do not contain erbumine. That doubt was likely to deter Lupin from, on the one hand, entering the market, including with products containing forms of erbumine other than the alpha form, or salts of perindopril other than erbumine, and, on the other hand, from challenging patents covering perindopril containing forms of erbumine other than the alpha form, or salts of perindopril other than erbumine.

876 It is also appropriate to take into account that the drafting ambiguities in question are contained in an agreement which the Commission rightly found to constitute an infringement of competition law in so far as concerns the non-marketing clause and the non-challenge clause relating to the 947 patent and the products covered by that patent (see paragraph 869 above). Finally, it is common ground that the parties to the agreement had sufficient means to employ the services of capable professionals, even if they had only a short time to do so, in order to limit such ambiguities. In the light of the foregoing considerations, the Commission was entitled to conclude that the scope of the non-marketing clause extended to products not containing erbumine and, a fortiori, containing forms other than the alpha form thereof, and that the scope of the non-challenge clause extended beyond the 947 patent to any patent relating to those products (recitals 1912 and 1918 of the contested decision).

877 In that respect, it should be noted that the existence of non-marketing and non-challenge clauses whose scope exceeds that of a specifically identified patent and the products covered by it clearly reveals a degree of harm to the proper functioning of normal competition sufficient for their inclusion to be classified as a restriction by object, without it even being necessary to prove, in addition, the existence of an inducement. Those clauses cannot, in that case, be justified in any way by the settlement of a dispute in relation to a patent and their restrictive effects do not overlap with the effects of that patent (see paragraphs 257 to 261 above).

878 Even if the Commission had wrongly found that the infringement at issue concerned forms of erbumine other than the alpha form protected by the 947 patent, or salts other than erbumine, such an error, in view of the limited and incidental role of that finding in the Commission's reasoning, would not be capable of calling into question the Commission's conclusion concerning the existence of a restriction of competition by object arising from the Lupin agreement. The Commission's reasoning is based in essence on the existence of an inducement which justifies the conclusion — even if the scope of the restrictive clauses of the settlement agreement is limited to the scope of that patent — that the patent was misused (see paragraphs 253 to 274 above).

879 It follows from all the foregoing that the applicants' plea relating both to the existence of a restriction by object and to the definition of that restriction adopted by the Commission must be rejected.

880 The foregoing conclusion cannot be called into question by the applicants' other arguments.

881 In the first place, as regards the evidence to show that the applicants' intentions, as well as those of Lupin, were legitimate, it should be recalled, on the one hand, that, in the context of patent dispute settlement agreements, a finding of a restriction of competition by object presupposes that the settlement agreement contains both an inducement in the form of a benefit for the generic company and a corresponding limitation of the generic company's efforts to compete with the originator company. Where those two conditions are met, a finding of restriction of competition by object must be made (see paragraph 272 above). On the other hand, the mere fact that an agreement also pursues legitimate objectives is not sufficient to preclude a finding of restriction of competition by object (see paragraph 222 above).

882 It follows that the applicants' arguments relied on in the context of the present plea, according to which the applicants and Lupin had legitimate reasons for concluding the Lupin agreement, are not capable of invalidating the classification of that agreement as a restriction by object, which was rightly made by the Commission and which was confirmed above (see paragraphs 869 and 879 above). Accordingly, those arguments must be rejected.

883 The same applies, in particular, first, to the argument that Lupin no longer had an interest in continuing the dispute; secondly, to the argument based on Lupin having initiated the settlement, and, thirdly, to the argument based on Servier no longer having an interest in protecting its competitive position against Lupin if it did not do so as regards Apotex.

884 In the second place, although the applicants maintain that the non-challenge clause was not likely to have restrictive effects on competition as a result, in particular, of the existence of parallel disputes and the absence of intention on the part of Lupin to bring further litigation, the fact remains that, to the extent that the Lupin agreement reveals a degree of harm sufficient to be classified as a restriction by object, examination of the specific effects of that agreement, and in particular of the non-challenge clause contained therein, is not necessary (see paragraph 219 above).

885 For the same reasons, it is appropriate to reject the applicants' argument that the non-marketing clause was, including to the extent that its scope exceeded that of the 947 patent, incapable of having restrictive effects on competition, in particular because Lupin had no real concrete possibilities of being the first to enter the market with a non-infringing product.

886 In the third place, by alleging that the restrictive effects of the non-marketing clause are hypothetical, the applicants may be regarded as in fact contesting the existence of potential competition. However, it has been found above that Lupin was a potential competitor of Servier.

887 In the fourth place, it must be borne in mind that, where an inducement has been found, the parties may no longer rely on their recognition, in the context of the settlement, of the validity of the patent. The fact that the validity of the patent is confirmed by a judicial or administrative body is, in that regard, irrelevant (see paragraph 269 above). The applicants therefore cannot rely on a scenario, that is moreover hypothetical, in which the validity of the 947 patent is confirmed by both the United Kingdom courts and the EPO.

888 It follows from all the foregoing that the present plea must be rejected.

(iv) The plea raised in the alternative by Servier concerning the error in determining the duration of the infringement

889 In the first place, the applicants submit that the Commission could not find that the infringement period started before Lupin obtained its marketing authorisation.

890 By that argument, the applicants in fact dispute the existence of potential competition. However, it was found in paragraph 751 above that, at the time the agreement was concluded, Lupin was a potential competitor of Servier.

891 In the second place, the applicants maintain that the Commission should have concluded, as it did for the French market, that the infringement ceased in Belgium, the Czech Republic, Ireland and Hungary when Sandoz entered the markets of those States with a generic form of perindopril which did not infringe patent 947, that is to say, respectively, in June 2008, July 2008, December 2008 and January 2009.

892 It must therefore be determined whether the Commission wrongly concluded that the infringement continued beyond the dates referred to in paragraph 891 above in the Member States concerned.

893 As a preliminary point, it should be stated that the generic product with which Sandoz entered the market is a form of perindopril erbumine having 'an amorphous (noncrystalline) form and hence it was free of the alpha crystals covered by the 947 patent' (recital 212 of the contested decision).

894 It is also necessary to recall (see paragraph 847 above) that, even though that interpretation is not evident due to the complex wording of Clause 1.6 of the Lupin agreement, it could be accepted that that clause, read in conjunction with Clause 4.1(c) of the same agreement, allows the market entry of Lupin with its own products where a generic 'Product' which is not produced by Servier has entered the market without breaching an injunction and where an application for an injunction lodged by Servier has not yet been dismissed.

895 Since the term 'Product', as set out in Clause 4.1(c) of the Lupin agreement, begins with an upper-case letter, it must be understood within the meaning of the definition given in recital A of that agreement.

896 The determination of the products referred to by recital A of the Lupin agreement is particularly tricky (see paragraphs 832 and 833 above), which makes it difficult to apply Clause 4.1(c) of that agreement (see paragraphs 849 and 850 above).

897 Accordingly, there was uncertainty as to the delimitation of the scope of Clause 4.1(c) of the Lupin agreement and also, therefore, as to the possibility of applying the non-marketing clause in Clause 1.6 of that agreement (see paragraph 852 above), in particular in the event of the entry onto the market of a product, such as Sandoz's product, containing a non-alpha form of erbumine.

898 Because of the uncertainties surrounding the scope of Clauses 1.6 and 4.1 of the Lupin agreement, set out in paragraphs 894 to 897 above, Lupin could fear that the non-marketing clause would continue to apply after a third party had entered the market with generic perindopril composed of a non-alpha form of erbumine or generic perindopril not composed of erbumine. That doubt was such as to deter it from entering the market.

899 That fear could be reinforced by the fact that, in any event, Servier could nevertheless apply for an injunction, even in respect of a product which clearly did not infringe any of its patents, in particular the 947 patent, which would effectively prevent the application of Clause 4.1(c) of the Lupin agreement until that application was rejected (see paragraph 852 above).

900 In that regard, Lupin's letters reveal its uncertainties as to its possibility of entering the French market without infringing the agreement (see paragraph 853 above) and, consequently, its continued application on that market of the non-marketing clause at least until that exchange of correspondence, which seems to have ended, at the earliest, at the beginning of April 2009, that is to say just a little over a month before 6 May 2009, the date fixed by the Commission as the end of the infringement as regards Belgium, the Czech Republic, Ireland and Hungary. Similarly, a letter from Servier, referred to in paragraph 853 above, does not support the conclusion that Servier, clearly and unambiguously, took the view that Lupin could enter the market.

901 A fortiori, as regards the four markets referred to in paragraph 900 above, the applicants do not adduce any evidence to show that, before 6 May 2009, Servier and Lupin had taken into account Sandoz's successive entries into those markets and that, in spite of the uncertainties linked to the ambiguity of the agreement, they considered that the non-marketing clause was no longer in force.

902 However, the fact that the non-marketing clause, because of the uncertainties linked to the ambiguity of the agreement, remained in force, thus indicating continued consensus between the parties — possibly contrary to the interpretation of the conditions of application of the contractual clause,

which, a posteriori, might be adopted, in particular, by a court —, was sufficient to allow the Commission to find that the consensus between Servier and Lupin, and thus the infringement, continued despite Sandoz's entries to the market.

903 In any event, even assuming that the agreement formally ceased to be in force as from Sandoz's entries to the market, having regard to the foregoing considerations (see paragraphs 900 and 901 above), it must be concluded that the non-marketing clause continued to be applied by Servier and Lupin following the successive entries of Sandoz to the four markets in question.

904 It is true that, as regards, as in the present case, restrictions of competition by object, there is no need to take account of their concrete effects on the market in order to establish the existence of the infringement (see, to that effect, judgment of 8 July 1999, *Commission* v *Anic Partecipazioni*, C-49/92 P, EU:C:1999:356, paragraphs 98 and 99) and accordingly its duration (see, to that effect, judgment of 19 March 2009, *Archer Daniels Midland* v *Commission*, C-510/06 P, EU:C:2009:166, paragraphs 113, 114 and 140). The same applies to consideration of the implementation of the agreement (see, to that effect, judgment of 29 June 2012, *E.ON Ruhrgas and E.ON* v *Commission*, T-360/09, EU:T:2012:332, paragraph 252).

905 However, the infringement may be found to continue beyond the period during which an agreement is formally in force, where the undertakings concerned continued to engage in prohibited conduct (judgments of 16 June 2011, *Solvay Solexis* v *Commission*, T-195/06, not published, EU:T:2011:280, paragraph 124, and of 29 June 2012, *E.ON Ruhrgas and E.ON* v *Commission*, T-360/09, EU:T:2012:332, paragraph 251).

906 That is so in the present case (see paragraph 903 above).

907 It follows from the foregoing that the present plea, raised in the alternative by Servier, must be rejected.

(c) Errors of law and of assessment in relation to the classification of the agreement concluded with Lupin as a restriction of competition by effect

908 The applicants maintain that the Commission made various errors of law and of assessment in relation to the classification of the agreement concluded with Lupin as a restriction of competition by effect.

909 It is appropriate, in applying *mutatis mutandis* the considerations set out in paragraphs 566 to 570 above, to reject the present plea as ineffective.

9. The agreements concluded with Krka

(a) Errors of law and of assessment in relation to the classification of the agreements concluded with Krka as a restriction of competition by object

910 The applicants challenge the classification as restrictions by object of, first, the settlement and licence agreements and, secondly, the assignment agreement.

(1) The settlement and licence agreements

(i) Arguments of the parties

…

(ii) Findings of the Court

943 By way of exception to the considerations relating to side deals set out in paragraphs 797 to 803 above, the linking of a normal commercial agreement to a settlement agreement containing non-challenge and non-marketing clauses no longer constitutes a strong indication of a reverse payment where the commercial agreement in question is a licence agreement concerning the patent in dispute.

944 That exception can be explained by the fact that, while it is true that a licence agreement in relation to a patent does not have as its subject matter the settlement of a dispute, but rather the grant of permission to use that patent, it may nevertheless be justifiable — in contrast to the situation as regards other commercial agreements (see paragraph 800 above) — to link that licence agreement to a settlement agreement concerning a patent which is the subject matter of the licence.

945 In principle, a patent dispute arises when the generic company's wish to enter the market comes into conflict with the patent owner's wish to safeguard the rights that he derives from that patent. Authorising such entry by concluding a licence agreement thus appears to be a particularly appropriate means of resolving the dispute, since it satisfies the wishes of both parties to the dispute.

946 It is also acknowledged that the use of a licence agreement is an appropriate means of resolving a dispute. That is apparent from paragraph 204 of the 2004 Guidelines on technology transfer, according to which 'licensing may serve as a means of settling disputes'. That paragraph is incorporated in paragraph 205 of the 2014 Guidelines on technology transfer agreements.

947 Linking a licence agreement to a settlement agreement is all the more justified since the presence, in a settlement agreement, of non-marketing and non-challenge clauses is legitimate only where that agreement is based on the parties' recognition of the validity of the patent (see paragraphs 258 to 261 above). The conclusion of a licence agreement, which, for any licensee, makes sense only if the licence is actually used, is also based on the parties' recognition of the validity of the patent. To that extent, the licence agreement thus supports the legitimacy of the settlement agreement, which fully justifies the linking of the two.

948 Since it appears justified to link a patent dispute settlement agreement to a licence agreement concerning the same patent, that linking, unlike the situation as regards the other side deals, does not constitute a strong indication of the existence of a reverse payment (within the meaning of that expression in relation to side deals, see paragraph 804 above).

949 It is therefore for the Commission to rely on indicia other than the mere linking of the licence agreement and the settlement agreement for the purpose of establishing that the licence agreement was not concluded at arm's length and that it actually masks a reverse payment inducing the generic company to accept the non-marketing and non-challenge clauses (see paragraphs 803 to 808 above).

950 It should be noted that a finding of the existence of a reverse payment is less evident in the case of a licence agreement because such an agreement does not entail a financial transfer from the originator company to the generic company, but rather from the generic company to the originator company. Thus, in a licence agreement, the licensee pays a royalty to the patent holder.

951 There is, however, a transfer of value from the originator company to the generic company, since the royalty paid to the patent holder constitutes a quid pro quo for the benefit that the generic company receives from the licence agreement, namely the authorisation to use the patent in order to enter the market without risk.

952 It is therefore for the Commission to demonstrate that that quid pro quo is abnormally low, that is to say to such an extent that it cannot be explained by considerations limited to the economic value of the asset to which the contract relates (see paragraph 806 above), and that the licence agreement thus involves a reverse payment to the generic company.

953 It must be particularly clear that the transaction in question was not concluded at arm's length in order to establish a sufficient degree of harmfulness for the purpose of classifying the settlement agreement as a restriction of competition by object, since the restriction of competition by the non-challenge and non-marketing clauses in the settlement agreement is mitigated by the licence agreement.

954 The non-marketing clause is thus rendered ineffective, at least in part. The licence agreement goes even further than a mere partial neutralisation of the effects of that clause, since it encourages the entry of generic products on the market by eliminating the litigation risk associated with the patent.

955 As regards the non-challenge clause, although its restrictive effects persist, they are limited by the fact that the licence allows market entry without a litigation risk. Although it is essential for the generic company to be able to challenge the validity of the patent when it enters the market at risk, that is less the case when it is authorised by the originator company to enter this market through a licence agreement.

956 At this stage of the analysis, it should be noted that, in the context of patent dispute settlement agreements, a finding of a restriction of competition by object presupposes that the settlement agreement contains both an inducement to the generic company and a corresponding limitation of the generic company's efforts to compete with the originator company (see paragraph 272 above). It follows from the foregoing that, where there is a licence agreement, those two elements are mitigated, or even absent, with the result that a sufficient degree of harm to the proper functioning of normal competition (see, to that effect, judgment of 11 September 2014, *CB* v *Commission*, C-67/13 P, EU:C:2014:2204, paragraphs 49 and 50 and the case-law cited) cannot easily be identified.

957 It should be added that the exception mentioned in paragraph 943 above is not contradicted by the fact that the linking of a licence agreement and a non-challenge clause are among the restrictions excluded from the exemption laid down in Article 2 of Commission Regulation (EC) No 772/2004 of 27 April 2004 on the application of Article [101(3) TFEU] to categories of technology transfer agreements (OJ 2004 L 123, p. 11), or by the case-law of the Court of Justice, first set out in the judgment of 25 February 1986, *Windsurfing International* v *Commission* (193/83, EU:C:1986:75, paragraphs 89 and 92), and clarified in the judgment of 27 September 1988, *Bayer and Maschinenfabrik Hennecke* (65/86, EU:C:1988:448).

958 First, according to Article 5 of Regulation No 772/2004, the linking of a licence agreement and a non-challenge clause is one of the restrictions excluded from the exemption provided for in Article 2 of that regulation. However, that exemption, as well as that exclusion, apply, pursuant to Articles 2 and 5 of that regulation, only in so far as the agreements in question contain restrictions of competition falling within the scope of Article 101(1) TFEU. Consequently, the fact that the linking of a licence agreement and a non-challenge clause is one of the restrictions excluded from the exemption provided for in Article 2 of Regulation No 772/2004 does not support the conclusion that such linking is, in all circumstances, a restriction of competition within the meaning of Article 101(1) TFEU and, in particular, a restriction by object.

959 In that respect, the Court of Justice held that, whilst it is true that to grant the benefit of Article 101(3) TFEU to a given agreement presupposes that this agreement falls within the prohibition imposed by Article 101(1) TFEU, the authorisation in Article 101(3) TFEU to grant that same benefit to categories of agreements does not imply that because a particular agreement comes within those categories it necessarily fits the descriptions set out in Article 101(1) TFEU. Therefore, to grant exemptions by

categories cannot amount, even by implication, to passing any pre-conceived judgment on any agreement considered individually (judgment of 13 July 1966, *Italy* v *Council and Commission*, 32/65, EU:C:1966:42, pp. 405 and 406).

960 Secondly, the Court of Justice indeed held that a clause in a licence agreement obliging the licensee not to challenge the validity of the patent was incompatible with Article 101(1) TFEU. It added that such a clause clearly does not fall within the specific subject matter of the patent, which 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 of 25 February 1986, *Windsurfing International* v *Commission*, 193/83, EU:C:1986:75, paragraphs 89 and 92).

961 However, in a judgment delivered two years later, in a case concerning a settlement agreement, the Court of Justice qualified the position it had adopted in the judgment of 25 February 1986, *Windsurfing International* v *Commission* (193/83, EU:C:1986:75), this time holding only that a non-challenge clause included in a patent licensing agreement may, in the light of the legal and economic context, restrict competition within the meaning of Article 101(1) TFEU (judgment of 27 September 1988, *Bayer and Maschinenfabrik Hennecke*, 65/86, EU:C:1988:448, paragraph 16). Although it also rejected, in that same judgment, the Commission's proposal that the inclusion of a non-challenge clause fell outside the prohibition laid down in Article 101(1) TFEU where the agreement in question was intended to settle litigation pending before a court, it did not, however, conclude that all patent settlement agreements containing such a clause fell within the prohibition laid down in Article 101(1) TFEU.

962 It is true that the licensees under a licence agreement, are, as is clear from paragraph 112 of the 2004 Guidelines on technology transfer agreements, 'normally in the best position to determine whether or not an intellectual property right is invalid' and therefore to challenge it. That is why the linking of a licence agreement and a non-challenge clause is, in principle, prohibited (Opinion of Advocate General Darmon in *Bayer and Maschinenfabrik Hennecke*, 65/86, EU:C:1987:336, point 8). However, where a licence agreement is concluded in the context of the settlement of a genuine dispute involving litigation between the parties concerned, the licensee has already had the opportunity to challenge the validity of the patent in question and if, ultimately, he agrees, without being induced, to a non-challenge clause (and a non-marketing clause), it is because he believes that the patent is valid. In that particular context of a settlement in which the parties ultimately agree that the patent is valid, the basis for prohibiting the linking of a licence agreement and a non-challenge clause no longer appears relevant, provided that the settlement agreement is based on the recognition by the parties to the agreement of the validity of the patent in question, and not on an inducement to the licensee to accept the non-challenge clause (and the non-marketing clause).

963 It follows from the foregoing that, where there is a genuine dispute involving litigation between the parties concerned and a licence agreement that is directly connected with the settlement of that dispute, the linking of that agreement to the settlement agreement does not constitute a strong indication of the existence of a reverse payment. In such circumstances, it is therefore for the Commission to demonstrate, on the basis of other evidence, that the licence agreement does not constitute a transaction concluded at arm's length and thus masks a reverse payment (within the meaning of that expression in relation to side deals, see paragraph 804 above).

964 It must be determined, in the light of the foregoing considerations, whether the Commission was entitled to conclude, in the present case, that the settlement and licence agreements concluded between Servier and Krka could be classified as a restriction by object.

965 It is necessary, in the first place, to examine whether there were genuine disputes and whether the licence agreement appeared to have a sufficiently direct connection with the settlement of those disputes to justify its linking to the settlement agreement.

966 In that regard, first, it should be noted that there were genuine ongoing disputes between Servier and Krka at the time the agreement was signed and that those disputes came to an end following the settlement agreement, which provided, in Article I(i) and (ii), that both parties were to withdraw from the ongoing proceedings between them.

967 In 2004, 10 generic companies, including Krka, had filed opposition proceedings against the 947 patent before the EPO, seeking the revocation of that patent in its entirety on grounds of lack of novelty, lack of inventive step and insufficient disclosure of the invention. On 27 July 2006, the EPO's Opposition Division confirmed the validity of that patent following minor amendments to Servier's original claims. Seven companies then brought an appeal against the EPO decision of 27 July 2006. Krka withdrew from the opposition proceedings on 11 January 2007, pursuant to the settlement agreement concluded with Servier.

968 Likewise, Servier had brought an action on 28 July 2006 for infringement of the 340 patent against Krka before the High Court of Justice (England & Wales), Chancery Division (Patents Court). On 2 August 2006, it had also brought an action for infringement of the 947 patent against Krka and applied for an interim injunction. On 1 September 2006, Krka had brought a counterclaim for annulment of the 947 patent and, on 8 September 2006, a separate counterclaim for annulment of the 340 patent. On 3 October 2006, the High Court of Justice (England & Wales), Chancery Division (Patents Court), granted Servier's application for an interim injunction and denied the motion brought by Krka on 1 September 2006. On 1 December 2006, the ongoing proceedings were discontinued as a result of the settlement reached between the parties and the interim injunction was lifted.

969 Secondly, both the settlement agreement and the licence agreement related to the disputes in question. The settlement agreement and, in particular, the non-marketing and non-challenge clauses which it contained, were limited to the scope of the patents which were the subject matter of the disputes between Servier and Krka. The licence agreement concerned the 947 patent and thus also had a direct link with those disputes.

970 Thirdly, there were, at the time the settlement and licence agreements were concluded, consistent indications capable of leading the parties to believe that the 947 patent was valid (see paragraphs 967 and 968 above).

971 Fourthly, although there were already meetings between Servier and Krka before the EPO decision of 27 July 2006 confirming the validity of the 947 patent (see, inter alia, recital 837 of the contested decision), they had not resulted in an agreement (recitals 856 to 859 of the contested decision) and it was only after that decision that new negotiations began (recital 898 of the contested decision). The EPO decision of 27 July 2006 confirmed the validity of the 947 patent and was therefore, at the very least, one of the driving factors leading to the settlement and licence agreements.

972 Thus, having regard to the scope of the terms of the settlement agreement and the licence agreement and the context in which those agreements were signed, it must be held that the linking of those two agreements was justified and therefore does not constitute a strong indication of the existence of a reverse payment from Servier to Krka giving rise to the licence agreement (see paragraph 948 above).

973 In those circumstances, it is necessary to examine, in the second place, whether, in the present case, the Commission established, on the basis of indicia or evidence other than the mere linking of the licence agreement and the settlement agreement, that the licence agreement had not been concluded at arm's length (see paragraphs 949 and 963 above).

974 In this respect, it should be noted that it is common ground that, unlike the other agreements that were the subject of the contested decision, neither the settlement agreement nor the licence agreement gave rise to a financial transfer from Servier to Krka.

975 The licence agreement even provided that Krka was to pay Servier a royalty of 3% of its net sales.

976 It is true that the royalty constitutes the quid pro quo for the benefit received by the generic company under the licence agreement, namely the authorisation to use the patent in order to enter the market without risk. However, it was for the Commission to demonstrate that that quid pro quo was abnormally low and that the licence agreement thus gave rise to a reverse payment to Krka.

977 Although the Commission presented, in the contested decision, a number of factors suggesting that the licence agreement was beneficial for Krka's commercial interests (see recitals 1738 to 1744 and, in particular, recital 1739), it did not demonstrate that the royalty rate of 3% was abnormally low, that is to say to such a degree that it could not be explained by considerations limited to the economic value of the patent to which the licence relates (see paragraph 952 above).

978 As regards the Commission's assertion that the royalty rate was much lower than Servier's operating profit for 2007 in the Czech Republic, Hungary and Poland, it is not necessarily abnormal that the rate of an operating surplus, which represents the gross profit derived from an activity, greatly exceeds the royalty rate of a licence agreement, which represents only the cost of the right of use of a patent.

979 The same reasoning can also be used to reject the Commission's argument that the royalty represented a small proportion of Krka's profit margins. A fortiori, the generic company would have no interest in concluding a licence agreement if the amount of the royalty did not enable it to generate a sufficient profit margin.

980 Finally, it is not abnormal that the royalty rate of a patent used by Krka was calculated on the basis of the sales price of Krka's product and not on the basis of the sales price of Servier's product.

981 All those elements, even taken together, can, at most, demonstrate that the price of the licence granted to Krka was favourable to its commercial interests, but do not suffice to establish that the transaction in question was not concluded at arm's length, especially since the licence agreement provided that Servier could continue to market its product in the seven Member States to which the licence applied, either directly or through one of its affiliated companies or even via a single third party per Member State. The licence granted was therefore not exclusive, which limited its advantageousness to Krka since there was a risk that Krka's product would be in competition with another generic product, whether marketed or produced by Servier or by a third party.

982 It should be added that, during the hearing, the Commission itself indicated that it did not dispute that the royalty was consistent with market practices. By stating in the contested decision — admittedly as a subsidiary point — that 'it is not the low level of royalties but the fact that the sole licence was granted against a commitment not to enter or challenge Servier's patents in a number of other, restricted markets, that is central to this analysis' (footnote 2354), the Commission already showed that it incorrectly attached only secondary importance to the fact that the transaction might have been concluded at arm's length.

983 It follows from the considerations set out in paragraphs 977 to 982 above that the Commission has not established that the royalty rate of 3% laid down in the licence agreement was abnormally low, that is to say to such a degree that it could not be explained by considerations limited to the economic value of the patent to which the licence relates. The Commission has therefore not established that the licence agreement does not constitute a transaction concluded at arm's length.

984 Consequently, the Commission has not established the existence of a reverse payment resulting from the granting of a licence at an abnormally low price (see paragraph 803 above) and which, since it is not intended to compensate for the costs inherent in the settlement of a dispute (see paragraph 809 above), constitutes an inducement.

985 It follows that the Commission was not entitled to find in the present case that there was a restriction of competition revealing a sufficient degree of harm to be classified as a restriction by object.

986 That conclusion is not called into question by the other factors relied on by the Commission in the contested decision.

987 First, even if the licence agreement were inducive because it allowed, in the seven Member States in question — that is to say in a part of the market in respect of which the Commission did not find an infringement — the implementation of an advantageous duopoly between Servier and Krka, as the Commission indicated in the contested decision (see, inter alia, recital 1728, 1734 and 1742), that duopoly did not result from the agreement itself, but from the choices made by Servier and Krka after that agreement, namely, Servier's choice not to grant a licence to another generic company or to sell its own generic version of perindopril at a low price (recital 1727 of the contested decision) and Krka's choice not to adopt an aggressive pricing policy (recital 1744 of the contested decision).

988 The restriction by object found by the Commission, in particular the inducement which is one of the conditions of that restriction (see paragraph 272 above), concerns the settlement and licence agreements concluded between Servier and Krka, and not practices subsequent to those agreements and not determined by them.

989 Even if the duopoly in question could be regarded as an implementation of the agreements, it should be borne in mind that the Commission and the Courts of the European Union cannot, when examining whether an agreement restricts competition by object and, in particular, in assessing the economic and legal context of that agreement, completely ignore its potential effects (see case-law cited in paragraph 304 above). However, it is also apparent from the case-law that establishing the existence of a restriction of competition by object cannot, under the guise, inter alia, of the examination of the economic and legal context of the agreement at issue, lead to the assessment of the effects of that agreement, since otherwise the distinction between a restriction of competition by object and by effect laid down in Article 101(1) TFEU would lose its effectiveness (see paragraph 221 above). For the purposes of verifying the specific capability of an agreement to produce competition-restricting effects characteristic of agreements with an anticompetitive object, the analysis of the potential effects of an agreement must therefore be limited to those resulting from information objectively foreseeable at the time of the conclusion of that agreement (see, to that effect, the Opinion of Advocate General Wahl in *ING Pensii*, C-172/14, EU:C:2015:272, point 84, and also, to that effect, judgment of 11 September 2014, *CB* v *Commission*, C-67/13 P, EU:C:2014:2204, paragraphs 80 to 82).

990 In the present case, the alleged potential effects in question, that is to say the duopoly alleged by the Commission, are based on hypothetical circumstances which were therefore not objectively foreseeable at the time of the conclusion of the agreement.

991 In any event, the Commission, referring to the practice of pharmacy stock saturation and to a complaint to the Polish authorities alleging the existence of unfair competition, indicated in recital 1725 of the contested decision that 'Servier's attitude towards Krka in the seven licensed markets could hardly be described as one of cooperation'. Moreover, as is apparent from recital 1728 of the contested decision, the duopoly described by the Commission between Servier and Krka did not exclude a certain degree of competition between those companies.

992 Secondly, according to the Commission, the licence agreement was inducive, in this case, because it enabled Krka to enter certain markets without risk in return for its exclusion from other markets. From that perspective, where the scope of the non-marketing or non-challenge clauses is wider than that of the licence agreement and there is therefore a gap or an 'asymmetry' between those two agreements, according to the Commission's wording in recitals 1706 and 1736 of the contested decision, it is then possible to conclude that there is an inducement, since the licence agreement, by

allowing the generic company to enter certain parts of the market without risk, is actually intended to induce that company to agree to withdraw from other parts of the market, to the originator company's advantage.

993 Those arguments cannot be accepted.

994 First of all, the approach put forward by the Commission, whereby the mere conclusion, even on normal market conditions, of a licence agreement linked to a settlement agreement containing restrictive clauses could constitute an inducement, would lead to a paradoxical outcome because, in that case, the wider the scope of a licence agreement, the greater the inducement and thus the easier it would be to find a restriction by object, unless the scope of the licence agreement were exactly identical to that of the settlement agreement.

995 The wider the scope of a licence agreement, especially in relation to the scope of the settlement agreement to which it is linked, the more that agreement is procompetitive, in view of the procompetitive effects of the licence, which encourages the market entry of a generic company and limits the competition-restricting nature of the non-marketing and non-challenge clauses in the settlement agreement (see paragraphs 954 and 955 above).

996 In that respect, it may be noted that in his Opinion in *CB* v *Commission* (C-67/13 P, EU:C:2014:1958, point 55), Advocate General Wahl stated that the formalist approach to identifying a restriction by object was conceivable only in the case of conduct in respect of which it could be concluded that the unfavourable effects on competition outweighed the procompetitive effects.

997 In addition, the Commission's argument, which leads to the patent holder being obliged to conclude a licence agreement covering the entire territory to which the restrictive clauses in the settlement agreement apply, does not respect the intellectual property rights of the patent holder and, in particular, his margin of discretion as regards the grant of licences (see, for a case where the patent holder is in a dominant position, judgment of 17 September 2007, *Microsoft* v *Commission*, T-201/04, EU:T:2007:289, paragraph 331). That argument also disregards the margin of discretion that the parties to a dispute must have in order to reach a settlement in good faith.

998 Moreover, the conclusion of an 'asymmetric' licence agreement does not necessarily constitute — for a generic company that does not recognise the validity of the patent in question — a sufficient benefit that it would agree to the non-marketing and non-challenge clauses. For the benefit arising from such an agreement to be regarded as an inducement, it would have to offer that company compensation for the certain loss of expected profits resulting from the acceptance of a settlement with clauses prohibiting entry on certain geographic parts of the market. For a company that does not seriously believe that the patent is valid and which is able to enter the entire market covered by the non-marketing and non-challenge clauses, a licence with a geographic scope more limited than the scope of those clauses does not constitute an economically satisfactory outcome that could lead it to accept those clauses. It is true that the licence partially opens the way for that company to the market covered by the patent by offering it the possibility of obtaining the envisaged profits on that part of the market, but, if it is not established that the royalty rate of that licence is abnormally low in respect of that part of the market, that licence does not give that company any compensation for the other parts of the market, on which it could make a profit if the patent were annulled, and which it is now prevented from accessing.

999 In the present case, Krka's expected earnings in the 18 to 20 markets to which the licence agreement did not apply were far from negligible. The Commission indicates in the contested decision that the expected earnings from western European markets roughly matched those from the three largest of the seven markets covered by the licence agreement (footnote 2348). Although it must be taken into account that the licence eliminates any risk of further infringement proceedings and that the profits that Krka could obtain through the licence agreement were therefore more certain, the importance

that it could attach to such a risk depended to a large extent on its degree of conviction as to the validity of the patent. The fact that Krka recognised the validity of the 947 patent was therefore a decisive factor in its decision to choose a limited — but licence-protected — entry to the seven markets in question rather than a wider entry to all of the Member States' markets subject to a significant risk of infringement because of the validity of that patent from Krka's perspective.

1000 Thirdly, with regard to the other elements that are supposed to establish the inducive nature of the licence agreement for Krka, it should be noted first of all that the fact that the latter estimated the opportunity cost of not entering into the agreement at more than EUR 10 million of 'lost profits' in three years (recital 1738 of the contested decision) is rather an additional indication of the fact that it considered that the 947 patent was valid. The profits in question corresponded to those expected if it entered or stayed on the seven markets covered by the licence agreement. Thus, Krka seems to have considered that in the absence of an agreement with Servier, it was unlikely, if not impossible, that it would enter those markets at risk or stay on those markets, which confirms the fact that it acknowledged the validity of the 947 patent.

1001 Next, although it is apparent from recital 1740 of the contested decision, which refers to recital 913 thereof, that the 18 to 20 markets were 'traditionally less important for Krka', the expected profits on those markets were far from negligible (see paragraph 999 above).

1002 Thus, the elements set out in paragraphs 1000 and 1001 above do not establish that the licence agreement was an inducement for Krka.

1003 Fourthly, the Commission's finding in the contested decision that the settlement and licence agreements constituted market sharing between Servier and Krka (see the title of Section 5.5.3 of the contested decision and, inter alia, recital 1745 thereof) is unfounded.

1004 As regards the seven markets covered by the licence agreement, although the Commission did not find an infringement in respect of that part of the internal market, it nevertheless took account of the conduct of Servier and Krka on those seven markets, including the conclusion of the licence agreement, which the Commission classified as an inducement, in order to establish the existence of market sharing based on a distinction between the 18 to 20 other Member States, on the one hand, and those seven Member States, on the other.

1005 However, Servier was not excluded from the markets of the seven Member States where Krka and it were in competition (see paragraph 991 above).

1006 Thus, there was no part of the market which, under the agreements, was reserved for Krka. It therefore cannot be concluded that there was market sharing — in the sense of a hermetic division between the parties to the agreement — of that part of the internal market.

1007 Furthermore, it should be noted that, in those seven Member States, the licence agreement contributed to the entry or continued presence on the market of a generic competitor of the originator company. It therefore had a positive effect on competition by comparison with the previous situation in which the generic companies could only enter or remain on the market at risk, since the validity of the main patent in question — the 947 patent — had just been confirmed by the competent authorities (see paragraph 970 above) and there was a risk, which Krka perceived as a serious risk, that its product was infringing.

1008 It should be added that the fact that, at the time the agreements were concluded, the national equivalents of the 947 patent had not yet been granted to Servier in some of the seven markets in question, whereas Krka was already selling its product (recital 1755 of the contested decision), does not support the conclusion that the licence agreement had no positive effect on competition. Although it is true that Krka could already have entered the markets before the licence agreement

without facing an immediate risk of infringement proceedings and although, consequently, the licence did not play a decisive role in relation to Krka's entry of the markets in question, it nevertheless allowed Krka to remain on those markets without the risk of facing such a challenge.

1009 The licence agreement's positive effect on competition noted in paragraphs 1007 and 1008 above supports the conclusion that there was no market sharing as regards the seven Member States covered by the licence agreement.

1010 The licence agreement's positive effect on competition is further confirmed by an extract from Krka's reply to a request for information which appears in recital 913 of the contested decision. That extract states, inter alia, as follows:

'Getting a license and withdrawing oppositions was considered as the best option for Krka at that time — to be able to sell perindopril on Krka's key markets in [central and eastern Europe] immediately, it means in 2006.

According to all other scenarios, a launch was not possible earlier than in at least 2 years after July 2006, and even after such period a launch was not warranted (risk that 947 is maintained, development risks for non-alpha).'

1011 The extract cited in paragraph 1010 above supports the conclusion that Krka considered that, without the licence agreement, it would be impossible to enter or remain on the market in the seven Member States covered by that licence agreement because of the 947 patent (see paragraphs 999 and 1000 above).

1012 As regards the 18 to 20 other markets, that is to say the only part of the market in respect of which the Commission found an infringement, it should be noted that, since it has not been shown that there was an inducement (see paragraph 984 above), the non-marketing and non-challenge clauses must be regarded as arising from a legitimate patent dispute settlement agreement which is linked to a licence agreement (see paragraph 963 above). Such a contractual framework, based on the recognition of the validity of the patent, cannot, therefore, be classified as a market exclusion agreement.

1013 Accordingly, no part of the market was unlawfully reserved for Servier.

1014 The market sharing on which the Commission also based its finding of a restriction by object is therefore not established.

1015 Fifthly, the Commission failed to demonstrate that Servier or Krka had intended to conclude a market sharing or market exclusion agreement, that Servier had intended to induce Krka not to compete or that Krka had intended to agree, in exchange for an inducive benefit, not to exert competitive pressure on Servier.

1016 As a preliminary point, it should be borne in mind that it is normal for the activities which anticompetitive practices and agreements entail to take place in a clandestine fashion, for meetings to be held in secret, and for the associated documentation to be reduced to a minimum. It follows that, even if the Commission discovers evidence explicitly showing unlawful contact between traders, it will normally be only fragmentary and sparse, so that it is often necessary to reconstitute certain details by deduction (judgment of 25 January 2007, *Sumitomo Metal Industries and Nippon Steel* v *Commission*, C-403/04 P and C-405/04 P, EU:C:2007:52, paragraph 51). It must be noted, however, that the agreements at issue in the present case are genuine contracts which, moreover, were well publicised (recital 915 of the contested decision). Since the Commission could easily obtain the full content of the agreements at issue, the applicability of the case-law which has just been cited is less evident. Thus, inferences drawn from partial extracts of emails or other documents purporting to establish the

intentions of the parties cannot easily call into question a finding based on the actual content of the agreements, that is to say on the legally binding relationship which the parties have decided to establish between themselves.

1017 It should also be noted that, in the present case, documents which postdate the EPO decision of 27 July 2006, or the interim injunction of 3 October 2006 delivered in the United Kingdom against Krka, are best able to shed light on the intentions of the parties when they concluded the settlement and licence agreements. Those two events substantially altered the context in which the agreements were concluded, in particular as regards the perception that Krka, as well as Servier, could have of the validity of the 947 patent.

1018 As regards Krka, the documents on which the Commission relies in order to determine Krka's intentions (see, inter alia, recitals 849 to 854 and 1758 to 1760 of the contested decision, as well as the recitals to which they refer) concern periods before those events.

1019 The extracts cited are, in any event, too fragmentary or ambiguous to establish — contrary to what the Court has repeatedly noted (see, inter alia, paragraphs 999, 1000 and 1011 above) — that Krka did not recognise the validity of the 947 patent and, a fortiori, that, at the time the settlement and licence agreements were signed, it intended to conclude market sharing or market exclusion agreements.

1020 As regards Servier, the only extract from a document — which postdates the two events mentioned above — purportedly showing its anticompetitive intentions and which is referred to in the section of the contested decision devoted to those intentions (recitals 1761 and 1762), is the following: '4 years gained = great success'.

1021 That extract appears in the record of a meeting of the top management of Servier, which refers to the judgment of 6 July 2007 of the High Court of Justice (England & Wales), Chancery Division (Patents Court), according to which the 947 patent was invalid for lack of novelty and inventive step of that patent in relation to the 341 patent.

1022 Even assuming that it could be inferred from that extract that Servier's management had considered, following that judgment, that the interest of the 947 patent lay in allowing it to gain an additional four years of protection, it cannot be concluded from this that, on 27 October 2006, when the settlement and licence agreements were concluded, Servier intended to conclude market sharing or exclusion agreements nor, a fortiori, can it be concluded that the settlement and licence agreements were restrictive of competition by object.

1023 Furthermore, the observation made by another generic company, according to which 'it would seem the rationale for this settlement from Servier's view is that it protects the key markets where high level substitution and/or [international non-proprietary name] prescribing is prevalent' (recital 1730 of the contested decision), cannot, even taken into account with all the other evidence relied on by the Commission, establish the existence of an intention on Servier's part to adopt market sharing or market exclusion agreements with Krka.

1024 Lastly, the Commission's repeated references in the contested decision to a document entitled 'Coversyl: defense against generics' are not convincing. That document predates the EPO decision of 27 July 2006 and the interim injunction of 3 October 2006 delivered in the United Kingdom against Krka, which considerably limits its relevance (see paragraph 1017 above). Moreover, it is apparent from the contested decision itself that that document does not elaborate a strategy concerning Krka, but, at most, that it follows from 'the nature and structure of the document' and from 'the context in which reference is made to Krka' that a defence was 'considered' against it (footnote 2386). Lastly, it is not apparent from the extracts from that document cited in the contested decision that Servier expressed doubts as to the validity of the 947 patent.

1025 In any event, for the purposes of casting doubt on the conclusion reached by the Court in paragraph 985 above and establishing that the aim of the agreements at issue was — contrary to the conclusion implied by an analysis of their content and of the context in which they were concluded — the buying-off of a competitor in order to exclude it from the market, it would fall to the Commission, in light of the considerations set out in paragraph 1016 above, to produce a body of relevant and consistent evidence. The Commission has not been able to produce such evidence.

1026 Sixthly, the fact that Krka continued to challenge Servier's patents and to market its product even though the validity of the 947 patent had been upheld by the EPO Opposition Division is not a decisive factor for the purpose of establishing the existence of a restriction of competition by object, since the fact that Krka continued to exert competitive pressure on Servier can be explained by Krka's desire, despite the expected litigation risks, to strengthen its position in the negotiations that it was likely to have with Servier with a view to reaching a settlement.

1027 In addition, continuing to challenge Servier's patent did not cause Krka to run any further risks in terms of infringement. It merely increased its litigation costs. As for the fact that it continued to market its product, it limited itself to five central and eastern European markets, and the Commission indicated, in the contested decision, that Krka 'eventually ceased to consider entering at risk in the UK, France and other western European markets in the aftermath of the Opposition [Division's] Decision' (recital 1693). In addition, in five of the seven markets covered by the licence, the equivalents of the 947 patent had not yet been granted (recital 1755 of the contested decision). Thus, the risks incurred by Krka, in at least some of the markets in which it remained, were limited.

1028 Having regard to the considerations set out in paragraphs 1026 and 1027 above, the fact that Krka continued to challenge Servier's patents and to market its product even though the validity of the 947 patent had been upheld by the EPO Opposition Division does not — contrary to the Commission's submissions — support the conclusion that the EPO decision of 27 July 2006 did not have a decisive impact on Krka's perception of the 947 patent and, consequently, on its subsequent choice to agree to settle with Servier.

1029 Seventhly, although the Commission has adduced some evidence showing that the settlement and licence agreements were the subject of commercial negotiations between Servier and Krka, with Krka seeking to maximise the advantages that it could gain from the agreements and even making the licence agreement a condition of its acceptance of the non-marketing and non-challenge clauses (see, inter alia, recitals 913 and 1746 to 1748 of the contested decision), that evidence, even taken together with all of the other evidence relied on by the Commission, does not establish that the licence agreement was not a transaction concluded at arm's length, that is to say that the royalty rate of 3% stipulated in the licence agreement was not chosen on the basis of commercial considerations, but rather in order to induce Krka to accept the non-marketing and non-challenge clauses in the settlement agreement.

1030 In addition, it should be borne in mind that the conclusion of a licence agreement, which, for any licensee, makes sense only if the licence is actually used, is based on the parties' recognition of the validity of the patent (see paragraph 947 above). Thus, the fact that the generic company seeks to obtain the licence agreement which is most favourable to his commercial interests is not sufficient to show that that company did not conclude the agreement in question on the basis of its recognition of the validity of the patent.

1031 It should be added that an agreement benefiting Krka enabled it to enter the parts of the market where its position was strongest and where it could rapidly market or continue to market its product, which is beneficial to competition. Thus, the interests of a generic company such as Krka, which seeks to obtain from the originator company the licence that is most beneficial to its commercial interests, converge with those of the consumer since, due to the licence agreement, a generic company will rapidly enter the market or remain there.

1032 It follows from all the foregoing that the conclusion set out in paragraph 985 above must be affirmed, since the settlement and licence agreements at issue do not reveal a sufficient degree of harm to competition that the Commission could validly conclude that they constituted a restriction by object. The plea is therefore well founded.

(2) The assignment agreement

(i) Arguments of the parties

…

(ii) Findings of the Court

1041 It is necessary, at the outset, to note the decisive grounds on which the Commission relied, in the contested decision, in order to reach the conclusion that the assignment agreement could be characterised as a restriction of competition by object.

1042 The Commission first of all found that, under the assignment agreement, Krka had assigned two patent applications to Servier, one concerning a process for the synthesis of perindopril (WO 2005 113500) and the other concerning the preparation of perindopril formulations (WO 2005 094793), and that the technology covered by those patent applications was used for the production of Krka's perindopril (recital 1770 of the contested decision).

1043 On the basis of that finding, the Commission sought to demonstrate that the assignment agreement reinforced the competitive position of Servier and Krka which arose from the market sharing that had been established, according to the Commission, by the settlement and licence agreements (recitals 1766 and 1804 of the contested decision).

1044 As regards, in the first place, Servier, the Commission observed that the transfer of Krka's technology had taken place in specific market conditions in which there were very few alternative sources of potentially viable API technology independent of Servier (recitals 1766 and 1772 of the contested decision). According to the Commission, Krka's technology, with which the European Pharmacopoeia requirements could be satisfied (recitals 1766, 1770 and 1793 of the contested decision), constituted 'a "key" to enter the market' (recital 1803 of the contested decision).

1045 The Commission indicated the following in recital 1772 of the contested decision:

'By removing Krka's ability to freely license out or assign its technology to third parties, i.e. other generics, Servier effectively foreclosed the potential avenue of competition based on the use of Krka's technology by third parties. Such technology could, for example, serve as a platform for new patent challenges. In combination with the Krka Settlement Agreement, [the assignment and licence agreement] thus provided Servier with absolute protection from any remaining potential competition stemming from Krka's technology.'

1046 Thus, according to the Commission, by acquiring Krka's technology, Servier was certain that Krka could no longer assign a technology which could have been useful to other generic companies. The Commission therefore concluded that the assignment agreement allowed Servier to reinforce the protection that it already enjoyed because of the non-marketing and non-challenge clauses in the settlement agreement (recitals 1805 and 1806 of the contested decision).

1047 As regards, in the second place, Krka, the Commission considered not only that the latter 'was aware that acquisitions of perindopril technology by Servier could lead to foreclosure of generic competitors' (recital 1800 of the contested decision), but above all that it benefited from the licence that was granted back to it under the assignment agreement.

1048 As regards that latter aspect, the Commission indicated that Krka could continue to use its technology on the markets of the seven Member States in which it was able to market its product under the licence agreement (recital 1806 of the contested decision). According to the Commission, Krka's technology was useful, including for Krka, for the purpose of producing perindopril API with a purity level meeting the requirements of the European Pharmacopoeia. The favourable position that Krka already enjoyed on the seven markets due to the licence agreement was therefore maintained by the assignment agreement.

1049 The Commission concluded that the purpose of the assignment agreement was to reinforce the market sharing put in place by the settlement and licence agreements (recitals 1803 and 1810 of the contested decision).

1050 The Commission added that conclusion of the settlement and licence agreements and of the assignment agreement formed part of a single and continuous infringement restricting competition by sharing markets for perindopril in the European Union. The Commission relied, in that respect, inter alia, on the fact that those agreements pursued the same objective of market sharing between Servier and Krka (recital 1811 of the contested decision).

1051 The Commission concluded the section of the contested decision devoted to the analysis of the restriction by object in relation to the various agreements between Servier and Krka by indicating that those agreements 'followed [the] objective to share markets by preventing or limiting generic competition between, or to, Krka and Servier' (recital 1812).

1052 Lastly, it should be noted that the Commission considered that the assignment agreement introduced only an 'additional' distortion, as indicated by the heading of Section 5.5.3.4 of the contested decision.

1053 It follows from the foregoing considerations that the Commission's finding of a restriction by object with regard to the assignment agreement is, as the applicants correctly state, based on the previous finding of market sharing as a result of the settlement and licence agreements.

1054 However, as indicated in paragraph 1014 above, that finding is incorrect.

1055 Consequently, the Commission's finding of a restriction by object with regard to the assignment agreement must also be held to be invalid.

1056 It should be added that the assignment agreement is not a 'side deal' to the settlement agreement, within the meaning of the considerations set out in paragraphs 797 to 803 above.

1057 That assignment agreement was not concluded on the same day as the settlement agreement, there is no contractual link between the two agreements and the Commission has not established that they were indissociable (see paragraph 798 above).

1058 The Commission even stated that there was no link between, on the one hand, the EUR 30 million payment by Servier to Krka under the assignment agreement and, on the other hand, the settlement agreement, in the sense that that payment did not constitute an inducement for Krka to accept the non-marketing and non-challenge clauses in the settlement agreement. That is apparent, inter alia, from the following extracts from the contested decision:

'(1678) Two months later, Servier purchased from Krka patent applications for competing technologies to produce perindopril for EUR 30 million. Krka considered that Servier feared that this technology could otherwise be assigned or licensed to other competitors. While some elements point in the direction of the existence of a link between the Settlement Agreement and the payment of [EUR] 30 million by Servier, this decision does not draw any conclusion on this point, and the analysis of those agreements is not based on the existence of such a link.

…

(footnote 2419) Servier contests that there was a link between the payment for patent applications and the settlement agreement. (Servier's reply to the Statement of Objections, paragraph 1084, ID 10114, p. 363). As it evidently flows from Section 5.5.3.3.3, the assessment of the Krka Settlement Agreement does not consider the payment of EUR 30 million as an inducement for Krka to accept the restrictive settlement terms, and leaves open as undecided the question whether there was a link between the settlement agreement and the [assignment and licence agreement].'

1059 Thus, the assignment agreement cannot compensate for the fact that the inducement which, according to the Commission, arises from the licence agreement and allowed it to conclude that the settlement agreement was actually intended to exclude one of Servier's competitors is not established (see paragraph 984 above).

1060 It follows from all the foregoing that the Commission erred in finding, as regards the assignment agreement, a restriction of competition by object. The present plea is therefore well founded.

(b) Errors of law and of assessment in relation to the classification of the agreements concluded with Krka as a restriction of competition by effect

(1) Argument of the parties

…

(2) Findings of the Court

1075 It is appropriate to examine together the error of assessment and the error of law concerning the finding of a restriction by effect.

1076 In that regard, the Court has repeatedly held that, in order to determine whether an agreement is to be considered to be prohibited by reason of the distortion of competition which is its effect, the competition in question should be assessed within the actual context in which it would occur in the absence of the agreement in dispute (see judgments of 30 June 1966, *LTM*, 56/65, EU:C:1966:38, p. 250, and of 6 April 2006, *General Motors* v *Commission*, C-551/03 P, EU:C:2006:229, paragraph 72; see, also, judgment of 11 September 2014, *MasterCard and Others* v *Commission*, C-382/12 P, EU:C:2014:2201, paragraph 161 and the case-law cited). It is therefore necessary to show — by a comparison between the competition that existed when the agreement was in force and the competition that would have occurred if that agreement had not been concluded — that the competitive situation was worse when that agreement was in force.

1077 As a preliminary point, it is necessary to clarify the approach adopted by the Commission, in the contested decision, in examining the restriction of competition by effect with regard, in particular, to the comparative step of that examination mentioned in paragraph 1076 above.

(i) The approach adopted by the Commission

1078 It is necessary, first of all, to note some of the general considerations, applicable to all of the agreements between Servier and the generic companies at issue in the contested decision, set out by the Commission in Section 5.1.7 of the contested decision, entitled 'Assessment of patent settlement agreements with reverse payments as restrictions by effect pursuant to Article 101(1) of the Treaty'.

1079 The Commission indicated, inter alia, that the examination of conditions of competition on a given market 'must be based not only on existing competition between the undertakings already present on the relevant market but also on potential competition' (recital 1215 of the contested decision).

1080 The Commission noted, in recital 1219 of the contested decision, that, according to the Guidelines on the application of Article [101(3) TFEU] (OJ 2004 C 101, p. 97), both the 'actual and potential effects' of an agreement were to be taken into account, since the agreement only had to have 'likely anticompetitive effects'. It referred, in that regard, to paragraph 24 of those guidelines, which is based on the judgment of 28 May 1998, *Deere* v *Commission* (C-7/95 P, EU:C:1998:256, paragraph 77).

1081 The Commission then set out its method. It indicated that it would show the restrictive effects of the agreements by establishing, as a first step, that each of them had entailed the removal of a potential competitor, and then, as a second step, that the elimination of a single potential competitor was 'likely to have effects on the competitive structure' (recital 1219 of the contested decision).

1082 The Commission therefore considered that the finding of the elimination of a potential competitor allowed it to establish only anticompetitive effects that were 'likely' to occur, that is to say 'potential' effects on competition (see paragraph 1080 above).

1083 The Commission stated the following in recital 1220 of the contested decision:

'The assessment of restrictive effects should be carried out based on the facts at the time of the settlement, while also taking into account how the agreement was actually implemented. Some of the parties disagree and claim that the assessment should take into account all posterior factual developments, and not be based primarily on the situation at the time the agreements were concluded. … When elimination of potential competition is at issue, looking at what actually happened may have little to do with what would likely have happened absent the agreement, a core question for the competitive assessment. This is all the more so where the agreement significantly changes the incentives of one party, or both, to continue to compete.'

1084 In the rather ambiguously worded first two sentences of that recital, the Commission acknowledged that it would not rely, for each agreement, on all the factual developments subsequent to its conclusion; rather, it would rely, at least primarily, on the facts at the time it was concluded. In order to justify that approach, the Commission then referred to the concept of 'potential competition', stating that, where the elimination of potential competition was at issue, taking into account certain actual events, in particular events subsequent to the conclusion of the agreement, is less relevant in order to show one side of the comparison referred to in paragraph 1076 above, namely competition as it would have occurred absent an agreement.

1085 That approach is confirmed by an extract from recital 1264 of the contested decision, in which the Commission considers that, where the elimination of a potential competitor is at issue, it is necessary to analyse the 'potential future effects' of the agreements.

1086 The recital of the contested decision cited in paragraph 1085 above is contained in the section of the contested decision entitled 'Prevailing market structure at the time of the settlement agreements', which is primarily concerned with describing the gradual elimination of potential competitors to Servier by the conclusion of the various agreements at issue examined by the Commission (recitals 1244 to 1269 of the contested decision).

1087 It is true that, in that section, the Commission refers to certain events which actually occurred during the implementation of the agreements and which support the conclusion that the two companies that did not enter into an agreement with Servier continued to exert competitive pressure. The Commission thus notes that the 947 patent was invalidated in the United Kingdom as a result of the litigation pursued by one of those two companies, Apotex, in that country.

1088 However, the Commission states that there was still a strong 'possibility', after the conclusion of the agreements that Servier entered into with various generic companies, that it would again try to reach an agreement with Apotex, and with the other company representing a potential threat to it (recital 1268), even though the Commission could have observed, when it adopted the contested decision, that no such agreements had been concluded.

1089 The Commission's assertion referred to in paragraph 1088 above confirms that, in order to show the competition that would have occurred had an agreement not been concluded (one side of the comparison mentioned in paragraph 1076 above), it relied on a hypothetical approach, which was partly indifferent to the actual events that took place, in particular after the conclusion of the agreements at issue.

1090 The Commission thus relied on the premiss that it could, in the event of an agreement eliminating a potential competitor, show merely the potential effects of that agreement, that is to say those that the agreement is 'likely' to have, which allows it to base its description of competition as it would have occurred absent an agreement on hypotheses or 'possibilities' rather than on the events that actually took place, which it could have observed when it adopted its decision.

1091 In that regard, the Commission stated as follows in paragraph 152 of its defence:

> '... Servier claims that the Commission did not take into account the correct counterfactual situation. The Commission rejects that criticism. The events indicating whether a potential competitor will eventually become an actual competitor or fail to enter the market are limited in scope because the exclusion of a potential competitor at the date of the agreement in a context in which there are no actual competitors and very few potential competitors is in itself a restriction of competition by effect falling within the scope of Article 101 TFEU. The essential question is whether a generic company fulfils the requirements for classification as a potential competitor. A company may disappear from or never enter a market for a variety of reasons which do not counter the fact that it was a sufficiently serious threat at the time of the agreement.'

1092 It follows from the foregoing that the Commission considered that, where it had established that an agreement excluded a potential competitor, it was not necessary, in order to determine the competition that would have occurred had that agreement not been concluded, to rely on the actual events that occurred, in particular after the conclusion of the agreement. Rather, the Commission considered — relying on its usual practice in taking into account the potential effects of an agreement, according to which it suffices to demonstrate that that agreement is 'likely' to have anticompetitive effects (see paragraphs 1080 and 1085 above) — that it could base its description of the competition that would have occurred had an agreement not been concluded on hypotheses or 'possibilities'.

1093 The Commission's general approach having been set out, it must be determined whether, in the particular context of its analysis of the effects of the agreements between Servier and Krka on competition, the Commission took an approach consistent with that general approach.

1094 In recitals 1813 and 1814 of the contested decision, that is to say in the first recitals of the section devoted to the restriction by effect with regard to the agreements concluded with Krka, the Commission indicated that the purpose of that section was to determine whether the agreements at issue 'were likely to entail restrictive effects on competition'. Similarly, in the title of the conclusion of the section devoted to the restriction by effect with regard to the agreements concluded with Krka, the Commission indicated that those agreements 'were likely to entail restrictive effects for competition'. Finally, in its defence, the Commission confirmed that 'the decision verified whether the agreements were likely to have anticompetitive effects' (paragraph 135).

1095 It follows from the wording used by the Commission in paragraph 1094 above that its approach is based on the finding of potential effects of the agreements (see paragraph 1080 above).

1096 Moreover, in order to carry out the comparison mentioned in paragraph 1076 above, the Commission relied on the fact that, had an agreement not been concluded, Krka would have remained a 'competitive threat' to Servier (recitals 1828 and 1830 of the contested decision).

1097 On the face of it, that 'competitive threat' allegedly eliminated by the agreements relates, given its hypothetical nature, more to potential effects on competition than actual effects.

1098 The elimination of the 'competitive threat' mentioned in paragraphs 1096 and 1097 above constitutes a key element in the Commission's demonstration intended to establish that the competitive situation on the market became worse because of the settlement (see paragraph 1076 above).

1099 It is true that the Commission subsequently devotes — in relation to Servier's market power which it previously examined (recitals 1817 to 1819 of the contested decision) — a section of the contested decision to the structure of the relevant market, characterised by a lack or shortage of sources of competition (recitals 1835 to 1846).

1100 However, it is the prior finding of the existence, absent an agreement, of a 'competitive threat', made in the foregoing section of the contested decision (recitals 1825 to 1834), which constitutes the starting point for the analysis of the market structure.

1101 The Commission concludes its analysis of the structure of the market in question by indicating that there was a strong possibility that the remaining sources of competition at the time the agreements between Servier and Krka were concluded would be removed from competition by a future agreement or otherwise, but it does not specify whether that actually occurred during the period when the agreements concluded with Krka were in force (recital 1846 of the contested decision).

1102 The element mentioned in paragraph 1101 above confirms the findings set out in paragraph 1092 above. Thus, the Commission considered that, since it had established that the settlement agreement excluded Krka and that Krka was at least a potential competitor to Servier, it was not required, in order to demonstrate the competition that would have occurred had an agreement not been concluded (one side of the comparison, mentioned in paragraph 1076 above), to take into account the events that actually occurred, which it could have observed at the time it adopted its decision. Rather, the Commission considered — relying on its usual practice in taking into account the potential effects of an agreement, according to which it suffices to demonstrate that that agreement is 'likely' to have anticompetitive effects — that it could base its description of the competition that would have occurred had an agreement not been concluded on hypotheses or 'possibilities'.

1103 The Commission's analysis of the agreements concluded between Servier and Krka was therefore consistent with the general approach it had set out for examining the various settlement agreements found to be infringing in the contested decision.

1104 Having noted the Commission's approach to the comparative step of the examination of the restriction by effect mentioned in paragraph 1076 above, it is necessary to determine whether the Commission was entitled to find that the agreements concluded between Servier and Krka restricted competition by effect.

1105 That examination requires, as a preliminary point, a review of the relevant case-law.

1106 In particular, in view of the approach taken by the Commission and the key role played in its reasoning by the multiple references to the 'potential effects' of the agreements and to the fact that they were 'likely to entail restrictive effects on competition', it is necessary to review the case-law, already referred to in paragraph 1080 above and mentioned at the hearing, according to which account should be taken of the potential effects of an agreement, a concerted practice or a decision by an association of undertakings for the purpose of determining whether such measures fall within the scope of Article 101(1) TFEU.

(ii) The relevant case-law in the present case

1107 Whilst the Court of Justice, in the context of references for a preliminary ruling, has often reiterated the principle that Article 101(1) TFEU does not restrict the assessment of an agreement or practice to actual effects alone, since that assessment must also take account of the agreement's potential effects on competition within the internal market (judgments of 21 January 1999, *Bagnasco and Others*, C-215/96 and C-216/96, EU:C:1999:12, paragraph 34; of 23 November 2006, *Asnef-Equifax and Administración del Estado*, C-238/05, EU:C:2006:734, paragraph 50; of 28 February 2013, *Ordem dos Técnicos Oficiais de Contas*, C-1/12, EU:C:2013:127, paragraph 71; and of 26 November 2015, *Maxima Latvija*, C-345/14, EU:C:2015:784, paragraph 30), it has rarely had the opportunity to examine itself whether a practice or agreement has potential effects such that a restriction of competition may be found.

1108 The Court of Justice first examined the taking into account of the potential effects of an agreement in the judgment of 17 November 1987, *British American Tobacco and Reynolds Industries* v *Commission* (142/84 and 156/84, EU:C:1987:490). In the case that gave rise to that judgment, the Commission had rejected a complaint and found that the agreements to which that complaint related did not constitute an infringement of the Treaty rules on competition (judgment of 17 November 1987, *British American Tobacco and Reynolds Industries* v *Commission*, 142/84 and 156/84, EU:C:1987:490, paragraph 1). The Court of Justice held in that case that, where the Commission finds that an agreement does not breach competition law, it is required not only to take account of the effects that the clauses of that agreement had at the time of their examination by the Commission but also the effects that they could have in the future in the light of the as yet unrealised possibilities they open to the parties. For example, in that case, an agreement relating to acquisitions of shareholdings in a competing undertaking gave the investing undertaking the possibility of reinforcing its position at a later stage by taking effective control of the other undertaking, which could have consequences on the competitive situation examined (judgment of 17 November 1987, *British American Tobacco and Reynolds Industries* v *Commission*, 142/84 and 156/84, EU:C:1987:490, paragraphs 37, 39, 54, 57 and 58).

1109 Thus, according to the judgment referred to in paragraph 1108 above, the Commission must take into account, in the examination of the effects of an agreement, not only the actual effects of clauses which are already being implemented when it adopts its decision, but also the potential effects of clauses which have not yet been implemented.

1110 The Court of Justice subsequently acknowledged the taking into account of potential effects of an agreement in the judgment of 28 May 1998, *Deere* v *Commission* (C-7/95 P, EU:C:1998:256). The case that gave rise to that judgment concerned a Commission decision following the notification of an agreement aimed at obtaining, under Article 2 of Regulation No 17, a negative clearance, by which the Commission could certify, upon application by the undertakings concerned, that there were no grounds for action on its part in respect of an agreement. In its decision, the Commission had found that the agreement notified to it constituted a restriction of competition by effect.

1111 In that case, the General Court, and subsequently the Court of Justice, upheld that finding, which was based on the existence of potential effects.

1112 The applicant in that case relied on the fact that the information exchange system established by the agreement had been applied for several years before the notification of the request for negative clearance to support its argument that the Commission's assessment should be limited to taking into account the actual effects of the exchange of information. However, the General Court considered that that argument was not relevant, since the Treaty prohibited both actual and potential effects of agreements (judgment of 27 October 1994, *Deere* v *Commission*, T-35/92, EU:T:1994:259, paragraphs 59 and 61).

1113 It is necessary, however, to qualify the conclusion that the argument based on the fact that the agreements or practices in question had been implemented was ineffective.

1114 First, the circumstances of the case were unusual, because the agreement for which negative clearance was requested had replaced a previous agreement which had not been notified to the Commission. The Commission therefore had to decide on the compliance of that new agreement with the competition rules, and not on that of the previous agreement. It is therefore not certain that the Commission would have been able to draw definitive conclusions as regards that new agreement from the application of the previous agreement, despite their similarity. As regards the new agreement, it had been applied for only a few months before the participants decided to suspend it. The Commission thus did not have the necessary perspective to examine its actual effects on competition (judgment of 27 October 1994, *Deere* v *Commission*, T-35/92, EU:T:1994:259, paragraphs 2 and 4).

1115 Secondly, the General Court, when examining the potential effects on competition of an agreement in the judgment of 27 September 2006, *GlaxoSmithKline Services* v *Commission* (T-168/01, EU:T:2006:265, paragraph 163), indicated that the fact that the agreement in question had been suspended only a few months after its entry into force, until the adoption of the Commission decision contested in that case, led it to interpret the Commission's examination of the agreement as being mainly devoted to its potential effects.

1116 The General Court, in that judgment, therefore established an explicit link between the fact that an agreement has not been implemented and the examination of its potential effects.

1117 Thirdly, in the judgment of 30 June 2016, *CB* v *Commission* (T-491/07 RENV, not published, EU:T:2016:379, paragraphs 243, 247, 248 and 250), the General Court examined the potential effects on competition of a decision of an association of undertakings by taking into account the effects that the measures in question would produce if they were applied, which again establishes a link between the examination of the potential effects of the association's decision and the fact that it has not yet been implemented. It should be highlighted that the Commission had distinguished, in the decision in question (Commission Decision C(2007) 5060 final of 17 October 2007 relating to a proceeding under Article [101 TFEU] (COMP/D 1/38606 — Groupement des cartes bancaires 'CB')), between the analysis of potential effects, that is to say those that the measures would produce if they were no longer suspended (recital 261 et seq.), and the analysis of the effects that had occurred in the course of the period during which the measures at issue had been applied (recital 310 et seq.).

1118 It should be noted that, in the cases that gave rise to the judgments of 27 September 2006, *GlaxoSmithKline Services* v *Commission* (T-168/01, EU:T:2006:265), and of 30 June 2016, *CB* v *Commission* (T-491/07 RENV, not published, EU:T:2016:379), the Commission did not penalise the undertakings concerned, but ordered them to bring an immediate end to the infringement in question.

1119 It should also be added that, in the cases mentioned in paragraph 1118 above, it was the undertakings concerned that had referred the measures in question to the Commission (see, to that effect, judgments of 27 September 2006, *GlaxoSmithKline Services* v *Commission*, T-168/01, EU:T:2006:265, paragraph 10, and of 30 June 2016, *CB* v *Commission*, T-491/07 RENV, not published, EU:T:2016:379, paragraph 8).

1120 Thus, in most of the cases in which the EU Courts have applied to an agreement, a concerted practice or a decision of an association of undertakings the case-law according to which a finding of restriction by effect may arise from the potential effects of those measures, the Commission decision at issue did not penalise past conduct constituting a restriction by effect, but rather prevented the occurrence of such conduct by envisaging the effects that the measures in question could have if they were applied. That was the situation, inter alia, in the case which gave rise to the judgment of 17 November 1987, *British American Tobacco and Reynolds Industries* v *Commission* (142/84 and 156/84, EU:C:1987:490), in which the Commission rejected a complaint by examining the effects that a clause of the agreement might have if the possibility that it provided were implemented.

1121 There is therefore no previous case-law, concerning agreements, decisions and concerted practices, in which the Court of Justice or the General Court has accepted that the Commission may rely only on the potential effects of the measure at issue in order to find that an infringement has been committed and impose a fine on the infringers on the basis of that finding.

1122 It appears paradoxical — where the clauses of an agreement have been implemented and their impact on competition can be measured by taking into account the relevant factual developments, including those subsequent to the conclusion of the agreement, which took place before the Commission issued its decision — to allow the Commission to demonstrate merely the anticompetitive effects that such clauses are likely to have and, to that end, to make the comparison mentioned at paragraph 1076 above without taking those developments into account (see paragraphs 1084, 1092 and 1102 above).

1123 It also appears paradoxical to allow the Commission, in order to find that an infringement in the form of a restriction of competition by effect was committed (and can therefore be penalised by a fine), to rely on the mere fact that clauses of an agreement that were implemented are likely to have anticompetitive effects and not on whether they had such effects, even though the Court of Justice has held that the burden of proving the anticompetitive effects of an agreement can be waived only in the case of a restriction of competition by object, which should concern only agreements 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 (judgment of 11 September 2014, *CB* v *Commission*, C-67/13 P, EU:C:2014:2204, paragraph 51). If it were possible for the Commission to rely, in relation to agreements which have been implemented, solely on the effects that they are likely to have, in order to demonstrate that they had an anticompetitive effect, the distinction between restrictions of competition by object and by effect, established by Article 101(1) TFEU, would lose its relevance.

1124 It follows from the foregoing that, since the agreements at issue were implemented and since, by the contested decision, the Commission found that an infringement had been committed, which enabled it to impose a fine on the parties to the agreements, the case-law just referred to in paragraphs 1107 to 1120 above, as regards taking the potential effects of agreements into account in relation to restrictions by effect, is not applicable.

1125 It must also be noted, moreover, that the case-law mentioned in paragraph 1124 above must be distinguished from that concerning the taking into account of the effects on competition of a limitation of competition, including where that competition is only potential.

1126 In that regard, in the judgment of 12 June 1997, *Tiercé Ladbroke* v *Commission*, T-504/93, EU:T:1997:84, paragraphs 157 to 160), which is cited in recital 1217 of the contested decision, the General Court examined the legality of a Commission decision whereby the Commission had rejected a complaint on the ground, inter alia, that, in the absence of present competition on the relevant market, the agreement in question did not fall within the scope of Article 85(1) of the Treaty, now Article 101(1) TFEU. The General Court held that the Commission had not examined with the required diligence all the matters of fact and of law brought to its attention by the applicant, because the agreement was likely to restrict potential competition. It therefore annulled the decision before it on that point.

1127 It cannot be inferred from that case-law, which concerned a rejection of a complaint, that the mere fact that an agreement is 'likely' to restrict potential competition must necessarily lead to a finding of a restriction of competition by effect, but rather that the Commission cannot exclude from the outset the possibility of a restriction by effect where an agreement is only likely to restrict potential competition and not present competition.

1128 Thus, when the Commission adopts a decision finding an infringement of Article 101(1) TFEU, which allows it to impose a fine on the infringers on the basis of that finding, the mere fact that the Commission has established the existence of potential competition and a limitation of the autonomy of a potential competitor, or even the elimination of that autonomy, does not release it from its obligation to demonstrate an analysis of the actual effects of the measure in question on competition if the case-law cited in paragraphs 1107 to 1120 above is not applicable.

1129 It must be borne in mind in that regard that the finding of anticompetitive effects of an agreement requires evidence that competition has, 'in fact', been prevented, restricted or distorted (judgment of 30 June 1966, *LTM*, 56/65, EU:C:1966:38, p. 249).

1130 Thus, demonstrating that an agreement has anticompetitive effects requires that the Commission, in the light of the need to be realistic that arises from the case-law of the Court of Justice, take into account, in the context of the comparison referred to in paragraph 1076 above, all the relevant factual developments, including those subsequent to the conclusion of the agreement, which took place before it adopts its decision.

1131 In that regard, the Court of Justice has held that, when appraising the effects of an agreement between undertakings in the light of Article 101 TFEU, it is necessary to take into consideration the actual context in which the agreement in question is situated, in particular the economic and legal context in which the undertakings concerned operate, the nature of the goods or services affected, as well as the real conditions of the functioning and the structure of the market or markets in question (judgment of 11 September 2014, *MasterCard and Others* v *Commission*, C-382/12 P, EU:C:2014:2201, paragraph 165).

1132 It follows that the scenario envisaged on the basis of the hypothesis that the agreement in question was not concluded must, according to the Court of Justice, be 'realistic' (see, to that effect, judgment of 11 September 2014, *MasterCard and Others* v *Commission*, C-382/12 P, EU:C:2014:2201, paragraph 166).

1133 The Court of Justice indicated that taking into account developments that were likely to have occurred on the market in the absence of that agreement was necessary when examining the agreement's restrictive effects on competition (see, to that effect, judgment of 11 September 2014, *MasterCard and Others* v *Commission*, C-382/12 P, EU:C:2014:2201, paragraphs 167 to 169).

1134 Moreover, the requirement of likelihood and realism applying to the description of the competition that would have occurred had an agreement not been concluded (one side of the comparison mentioned in paragraph 1076 above) is consistent with the approach adopted by the Commission in several guidelines, which requires it to establish the sufficiently likely nature of the restrictive effects of the measures that it examines.

1135 Thus, first, paragraph 24 of the Guidelines on the application of Article [101(3) TFEU], to which the Commission refers in recital 1219 of the contested decision, states that 'for an agreement to be restrictive [of competition] by effect it must affect actual or potential competition to such an extent that on the relevant market negative effects on prices, output, innovation or the variety or quality of goods and services can be expected with a reasonable degree of probability'.

1136 Secondly, in paragraph 19 of the 2001 Guidelines on horizontal cooperation agreements, it is indicated that many horizontal cooperation agreements do not have as their object a restriction of competition and that an analysis of the effects of each agreement is therefore necessary. It is added that, for that analysis, it is not sufficient that the agreement limits competition between the parties, but that the agreement must also be likely to affect competition in the market to such an extent that it is possible to expect negative market effects as to prices, output, innovation or the variety or quality of goods and services.

1137 Thirdly, the Commission confirmed that it maintained that approach in the 2011 Guidelines on horizontal cooperation agreements. It thus states, in paragraph 28 of those guidelines, to which it refers in footnote 1733 of the contested decision, that restrictive effects on competition within the relevant market are likely to occur where it can be expected with a reasonable degree of probability that, due to the agreement, the parties would be able to profitably raise prices or reduce output, product quality, product variety or innovation.

1138 Moreover, in the contested decision itself (recital 1218), the Commission noted that restrictive effects on competition must be established with a sufficient degree of probability.

1139 In the light of all the foregoing, it must be determined whether, in the present case, the Commission — despite the hypothetical approach that it adopted as regards the comparative step of the examination of restriction of competition by effect (see paragraphs 1076 to 1102 above) — established the sufficiently realistic and probable nature of the restrictive effects of the agreements concluded between Servier and Krka.

(iii) The error of assessment

1140 The Commission analysed the effects of the non-marketing and of the non-challenge clause contained in the settlement agreement between Servier and Krka, as well as the licensing of Krka's technology to Servier, by examining, for each of those three measures, the competition that would have occurred in its absence (see, inter alia, recitals 1825 to 1829 of the contested decision).

1141 It is necessary to determine, for each of the three measures, whether the Commission was entitled to find a restriction of competition by effect.

– *The non-marketing clause in the settlement agreement*

1142 It must be borne in mind that, in order to determine whether an agreement is to be considered to be prohibited by reason of the distortion of competition to which it gives rise, the competition in question should be assessed within the actual context in which it would occur in the absence of the agreement at issue (see paragraph 1076 above).

1143 In the present case, the scope of the non-marketing clause is limited to that of the 947 patent, which is the subject of proceedings between Servier and Krka.

1144 The actual context of the competition, absent the settlement agreement, consisted of the attempts of generic companies, including Krka, to enter the market by overcoming obstacles linked to Servier's patents, in particular the 947 patent, and the patent litigation between those companies and Servier.

1145 As noted in paragraph 234 above, the specific purpose of awarding a patent 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, *Centrafarm and de Peijper*, 15/74, EU:C:1974:114, paragraph 9). When granted by a public authority, a patent is normally assumed to be valid and an undertaking's ownership of that right is assumed to be lawful. The mere possession by an undertaking of such an exclusive right normally results in keeping competitors away, since public regulations require them to respect that exclusive right (judgment of 1 July 2010, *AstraZeneca* v *Commission*, T-321/05, EU:T:2010:266, paragraph 362).

1146 It is true that the at risk market entry of a generic company is not unlawful in itself (see, to that effect, judgment of 8 September 2016, *Lundbeck* v *Commission*, T-472/13, under appeal, EU:T:2016:449, paragraph 122). However, such entry is much less likely where the generic company recognises the validity of the patent or believes that its chances of having that patent declared invalid are low.

1147 A generic company's recognition or non-recognition of the validity of the patent in question or its perception of the strength of that patent is therefore decisive when determining whether it is likely to enter the market at risk.

1148 The Commission did not properly take into account the effects that the 947 patent and Krka's recognition of its validity could have on the assessment, for the purpose of the comparison referred to in paragraph 1076 above, of Krka's likely behaviour in the absence of an agreement, in the section of the contested decision devoted to the examination of that conduct (recitals 1825 to 1834).

1149 Events decisive for assessing whether Krka recognised the validity of the 947 patent, or its perception of its prospects of success in having that patent declared invalid, such as the EPO decision of 27 July 2006 confirming the validity of the patent and the interim injunction against Krka issued by a court in the United Kingdom, are not mentioned in that section of the contested decision, despite the fact that they occurred even before the conclusion of the settlement agreement between Servier and Krka.

1150 In addition, the Commission, in recitals 1828 to 1834 of the contested decision, in the analysis of Krka's likely behaviour absent the agreements, does not refer to the circumstance — which is significant in this context — that several pieces of evidence in the case file supported the finding that Krka might be infringing the 947 patent.

1151 That confirms that the hypothetical approach adopted by the Commission (see paragraphs 1077 to 1103 above) led it not only to disregard the events that occurred after the conclusion of the agreements but, more generally, to disregard the actual course of events as it could have been observed when it adopted its decision.

1152 The Commission's reluctance to take into account in particular the effects of the 947 patent can be explained by the fact that, in its analysis of the restriction by object, it considered that the real basis for the settlement agreement between Servier and Krka was the inducement of the latter to comply with the restrictive clauses of that agreement and not a genuine recognition of the validity of the 947 patent. From that perspective, Krka could not in any way, according to the Commission, rely on the recognition of the validity of the 947 patent, since that recognition was vitiated in its very principle.

1153 However, the finding of an inducement and of a restriction by object made by the Commission has been invalidated by the General Court as regards the settlement and licence agreements between Servier and Krka, which gives renewed relevance to the taking into account of Krka's perception of the strength of the 947 patent or its recognition of the validity of that patent.

1154 It must be borne in mind that there were, at the time the settlement and licence agreements were concluded, strong indications capable of leading the parties to believe that the 947 patent was valid (see paragraphs 967 and 968 above). In the United Kingdom, that is to say one of the three countries (with France and the Netherlands) in which the Commission analysed and found a restriction by effect, Krka and Apotex, another competitor of Servier, were even the subject of an interim injunction.

1155 Although the request for an interim injunction prohibiting the marketing of a generic version of perindopril placed on the market by Krka because of the infringement of the 947 patent, which was introduced by Servier in Hungary, was rejected in September 2006, it was a procedure which, unlike those mentioned in paragraph 1154 above, did not concern any of the countries in which the Commission found a restriction by effect.

1156 Moreover, although there were already meetings between Servier and Krka before the EPO decision of 27 July 2006 (see, inter alia, recital 837 of the contested decision), they had not resulted in an agreement (recitals 856 to 859 of the contested decision) and it was only after that decision that new negotiations began (recital 898 of the contested decision). The EPO decision of 27 July 2006 confirming the validity of the 947 patent was therefore, at the very least, one of the catalysts which led to the settlement and licence agreements, which is further evidence that those agreements were based on the parties' recognition of the validity of the patent (see paragraph 971 above).

1157 It should also be added that, as noted above (see paragraph 947 above), the conclusion of a licence agreement, which, for any licensee, makes sense only if the licence is actually used, is based on the parties' recognition of the validity of the patent. Thus, the very conclusion of the licence agreement, supported by a number of pieces of evidence (see paragraphs 999 and 1001 above), confirms that Krka ultimately recognised the validity of the 947 patent.

1158 It is even apparent from documents in the file that Krka seemed to consider that, in the absence of a licence agreement with Servier, entry at risk to the 18 to 20 markets in question was very unlikely, or even impossible (see paragraphs 1001 and 1012 above).

1159 Lastly, the Commission indicated, in the contested decision (recital 1693), that Krka had 'eventually ceased to consider entering at risk in the UK, France and other western European markets in the aftermath of the Opposition [Division's] Decision'.

1160 In the light of the factors set out above, it must be concluded that it has not been established that, in the absence of an agreement, Krka would probably have entered at risk the markets of the 18 to 20 Member States in question, in particular the markets of France, the Netherlands and the United Kingdom.

1161 The above conclusion is not called into question by the other elements in the file which might be relevant for the purposes of establishing that Krka would have entered the market had an agreement with Servier not been concluded. Those elements are contained primarily in the part of the contested decision devoted to the Commission's demonstration that Krka was a potential competitor of Servier.

1162 First, it must be borne in mind (see paragraph 1026 above) that the fact that Krka continued to challenge Servier's patents and to market its product even though the validity of the 947 patent had been upheld by the EPO's Opposition Division can obviously be explained by Krka's desire to strengthen its position in the negotiations that it might engage in with Servier with a view to reaching a settlement.

1163 In addition, continuing to challenge Servier's patent did not cause Krka to run any further risks in terms of infringement. It merely increased its litigation costs. With regard to the continued marketing of its product, the Commission confined itself to the five central and eastern Europe markets, in respect of which the Commission did not find a restriction of competition by effect. In addition, in five of the seven markets covered by the licence, the equivalents of the 947 patent had not yet been granted (recital 1755 of the contested decision). Thus, the risks incurred by Krka, in at least some of the markets in which it remained, were limited (see paragraph 1027 above).

1164 Krka's decision to continue challenging Servier's patent and to continue marketing its product therefore do not support the conclusion that Krka did not recognise the validity of the 947 patent and would therefore have probably entered at risk the markets of the 18 to 20 Member States in question or, at the very least, the three markets in respect of which the Commission found a restriction of competition by effect.

1165 Secondly, although the comments made by Krka's representatives show their surprise and discontent following the EPO decision of 27 July 2006 (recital 1688 of the contested decision), those comments cannot establish that, despite that decision, Krka would probably have entered the three national markets in respect of which the Commission found a restriction by effect.

1166 Thirdly, the Commission devotes a section of the contested decision to Krka's 'intention to enter' the market. That very short section is composed of only one recital, which is itself rather short: recital 1699. In that recital, the Commission states that, 'even' after the EPO decision of 27 July 2006, Krka 'appeared' willing to support launches at risk by its partners and that it remained committed to supply its product 'in case the patent barriers were overcome'. It is added in that recital that one of Krka's commercial partners urged it to supply its product 'in case the 947 patent was invalidated' and that some of Krka's partners entered the market with that product 'once the 947 patent was invalidated in the [relevant] markets'.

1167 The extracts cited in paragraph 1166 above attest less to Krka's intention to enter the three national markets in respect of which the Commission found a restriction by effect than to the importance attached to the 'patent barrier' represented by the 947 patent after the EPO decision of 27 July 2006, both for Krka and its commercial partners.

1168 In view of all the elements set out above, it has not been established that, had the settlement and licence agreements not been concluded, Krka would probably have entered the three national markets in respect of which the Commission found a restriction of competition by effect.

1169 Nor was it established by the Commission in the contested decision that, absent those agreements, Krka would have probably entered the markets concerned before the date on which the infringement came to an end, namely before 6 July 2007 for the United Kingdom, 12 December 2007 for the Netherlands and 16 September 2009 for France.

1170 The hypothetical approach adopted by the Commission (see paragraphs 1079 to 1103 above) led it to pay little attention to the actual course of events — in particular those that occurred after the conclusion of the agreements — and therefore to possible changes in Krka's perception of the validity of the 947 patent as a result of those events.

1171 However, it is not for the Court, as regards the appraisal of the constituent elements of an infringement — which do not fall within the scope of its unlimited jurisdiction, but rather the review of legality — to substitute its own reasoning for that of the Commission (see, to that effect, judgment of 21 January 2016, *Galp Energía España and Others* v *Commission*, C-603/13 P, EU:C:2016:38, paragraphs 73 and 75 to 77).

1172 Therefore, it is not for the Court to examine, for the first time, on the basis of the evidence in the file, whether a restriction of competition by effect could have arisen during the period after the conclusion of the agreements as a result of a decline in Krka's recognition of the validity of the 947 patent.

1173 In any event, the evidence in the file does not support the conclusion that, had the agreements not been concluded, Krka would probably have entered the three national markets concerned during the period between the conclusion of the agreements and the end of the infringement.

1174 Moreover, it should be emphasised that the Commission does not even allege that Krka would have probably entered the market in the absence of an agreement. In the section of the contested decision entitled 'Likely behaviour absent the Krka Agreements', the Commission does not rely, at least explicitly, on a hypothesis of an early market entry by Krka on the three markets concerned in the absence of an agreement, but only on the hypothesis that it would have remained a 'competitive threat' on those markets (see paragraph 1096 above).

1175 Thus, according to the Commission, 'Krka would have remained a competitive threat as a potential generic entrant with perindopril in the UK, France and the Netherlands' (recital 1825 of the contested decision). The Commission notes that Krka would, inter alia, have continued to be a threat as a supplier to local distribution partners (recital 1828 of the contested decision).

1176 The Commission also indicates that the parties to the agreement, in the absence of an inducement, could have negotiated a less restrictive agreement granting Krka earlier entry or a licence for the entire EU territory (recital 1831 of the contested decision).

1177 The Commission concludes by indicating that, 'in the absence of the restrictions in the … Agreements, Krka would have remained a prominent potential competitor to Servier' (recital 1834 of the contested decision).

1178 It should be noted that, by merely invoking the 'competitive threat' that Krka would have continued to represent for Servier, even though the procompetitive effects of a mere 'threat' are not — unlike those of the market entry of a generic company — evident and, moreover, the effects of that 'threat' were, in the present case, largely mitigated by the presence of the 947 patent and the confirmation of its validity by the competent authorities (see paragraphs 1142 to 1169 above), the Commission failed to establish that the competition that would have occurred in the absence of the settlement agreement would probably have been more open.

1179 It may be noted, in that respect, that the Commission should have specified the probable effects, in particular on prices, production, quality, diversity of products or innovation (see paragraphs 1135 to 1137 above), of the 'competitive threat' that Krka would have continued to represent for Servier in the absence of the settlement agreement, which it could have done, for example, by demonstrating that, because of the absence of a threat, Servier had limited its research and development expenditure.

1180 It should be noted that, although the Commission's analysis of Servier's market power, and the structure of the relevant market, characterised by a lack or shortage of sources of competition, could have supported a finding of restrictive effects of an agreement preventing the market entry of a potential competitor, it is not enough to make probable and concrete the restrictive effects of an agreement undermining the existence of a 'competitive threat'.

1181 Irrespective of the structure of the market, the anticompetitive effects of the non-marketing clause remain largely hypothetical if it is likely, given the actual course of events as it could have been observed when the Commission adopted its decision, that, even in the absence of that clause, the potential competitor concerned might have behaved similarly to how it did in the presence of the clause, that is to say, in the present case, that Krka would have remained outside the three markets in respect of which the Commission found a restriction by effect.

1182 The credibility of the hypothesis that, in the absence of the settlement and licence agreements between Servier and Krka, and, in particular, of the inducement that, according to the Commission, they contained, another agreement allowing the early entry of Krka or granting it a licence for the European Union in its entirety would have been concluded (see paragraph 1176 above and recital 1142 of the contested decision), is in no way established, especially since, as is apparent from the examination of the plea alleging the absence of restriction of competition by object, the existence of an inducement has not been established by the Commission.

1183 Lastly, it must be highlighted that the specific context of the settlement and licence agreements between Servier and Krka, which was characterised by the presence of a patent the validity of which was confirmed by the EPO (see paragraph 1144 above), is different from that at issue in the case that gave rise to the judgment of 14 April 2011, *Visa Europe and Visa International Service* v *Commission* (T-461/07, EU:T:2011:181, paragraphs 187 and 191), which is cited by the Commission, in particular, in recital 1219 of the contested decision. In the absence of background factors comparable to those, relating to the existence of a patent and the recognition of its validity, which have been set out (inter alia, in paragraphs 1145 to 1159 above) and which are decisive in the present proceedings, the Court considered, in that judgment, on the basis of the sole fact that an undertaking subject to an exclusion clause by the measure at issue was a potential competitor, that the Commission had been entitled to conclude that that undertaking would have entered the market in the absence of the exclusion clause.

1184 It should also be noted that, in the judgment of 14 April 2011, *Visa Europe and Visa International Service* v *Commission* (T-461/07, EU:T:2011:181), the Court did not confirm a decision-making practice of the Commission whereby it could, in cases involving the elimination of a potential competitor, ignore the actual course of events as it could have been observed when it adopted its decision.

1185 Moreover, such a practice, if it were valid, could lead to an inconsistent outcome in some cases, for example, where the only potential competitor, which is eliminated by an agreement, has been wound up by the time it is implemented, as a result of insolvency for example, which would obviously neutralise the exclusionary effects of the agreement, except if those effects were envisaged in a hypothetical manner, and not realistically, as required by the case-law (see paragraphs 1129 and 1132 above).

1186 A restriction of competition by effect therefore cannot be found in the present case by reference to the judgment of 14 April 2011, *Visa Europe and Visa International Service* v *Commission* (T-461/07, EU:T:2011:181).

1187 It follows from the foregoing that the competition-restricting effects of the non-marketing clause in the settlement agreement have not been established by the Commission.

– *The non-challenge clause in the settlement agreement*

1188 As a preliminary point, it should be observed that, in the section of the contested decision entitled ‘Likely behaviour absent the Krka Agreements’, the Commission does not mention anything relating to Krka’s likely behaviour as regards the 340 patent, in respect of which the settlement agreement also contains a non-challenge clause.

1189 Consequently, in the stage of the analysis of restriction by effect consisting in a comparison between the competition in the presence of the agreements and the competition that would have existed in their absence (see paragraphs 1076 above), the Commission limited its analysis to the 947 patent.

1190 The failure to take into account the 340 patent may be explained by the fact that, according to the Commission, that patent affords only minor protection to Servier against the market entry of generic companies (recital 114 of the contested decision).

1191 Furthermore, the Commission indicated, also in the section of the contested decision entitled 'Likely behaviour absent the Krka Agreements', that 'it appears plausible that, absent the non-challenge obligation, Krka would have remained a challenger to the validity of the '947 [patent] before the UK courts and the EPO' (recital 1827 of the contested decision).

1192 The Commission therefore based its finding of a restriction by effect on the fact that, in the absence of the non-challenge clause, Krka would have continued the proceedings in which it was engaged before the United Kingdom courts and the EPO.

1193 In that respect, it should be noted that a non-challenge clause is, by itself, restrictive of competition, since it undermines the public interest in eliminating any obstacle to economic activity which may arise where a patent was granted in error (see, to that effect, judgment of 25 February 1986, *Windsurfing International* v *Commission*, 193/83, EU:C:1986:75, paragraph 92).

1194 It is therefore necessary to determine whether the application of the non-challenge clause and, in particular, Krka's withdrawal from the proceedings in which it was engaged, had an effect as regards the elimination of the 947 patent.

1195 It should be borne in mind that, at the time the agreements were concluded, Krka and Servier were engaged in two sets of proceedings against one another and that it was the settlement agreement that led Krka not to pursue those proceedings.

1196 Thus, in the United Kingdom, on 2 August 2006, Servier had brought an action for infringement of the 947 patent against Krka before the High Court of Justice (England & Wales), Chancery Division (Patents Court). It had also made an application for an interim injunction. On 1 September 2006, Krka had lodged a counterclaim for the annulment of the 947 patent. On 3 October 2006, the High Court of Justice (England & Wales), Chancery Division (Patents Court), had upheld Servier's application for interim relief and had refused the motion for summary judgment lodged by Krka on 1 September 2006, seeking a declaration of invalidity of the 947 patent. On 1 December 2006, the ongoing proceedings were discontinued as a result of the settlement reached between the parties and the interim injunction was lifted.

1197 As regards the proceedings before the EPO, in 2004, 10 generic companies, including Krka, filed opposition proceedings against the 947 patent before the EPO seeking the revocation of that patent on grounds of lack of novelty, lack of inventive step and insufficient disclosure of the invention. On 27 July 2006, the EPO's Opposition Division had confirmed the validity of that patent following minor amendments to Servier's original claims. Seven companies had brought an appeal against that decision of the Opposition Division. Krka withdrew from the opposition procedure on 11 January 2007, pursuant to the settlement agreement reached between the parties.

1198 It must be borne in mind, however, that, on 1 August 2006, Servier had also brought an action for infringement before the High Court of Justice (England & Wales), Chancery Division (Patents Court), against the company Apotex, claiming infringement of the 947 patent, since Apotex had launched a generic version of perindopril in the United Kingdom on 28 July 2006. Apotex had brought a counterclaim for annulment of that patent. An interim injunction prohibiting Apotex from importing, offering to sell or selling perindopril had been obtained on 8 August 2006.

1199 On the basis of the counterclaim lodged by Apotex, the High Court of Justice (England & Wales), Chancery Division (Patents Court), ruled, on 6 July 2007, that the 947 patent was invalid because it lacked novelty and inventive step over the 341 patent. Consequently, the injunction was lifted immediately and Apotex was able to resume selling its generic version of perindopril on the United Kingdom market.

1200 The Commission considered that the infringement concerning the agreements concluded between Servier and Krka had ended on that date in the United Kingdom.

1201 Furthermore, as regards the litigation before the EPO, on the basis of the proceedings initiated by Krka, amongst others, the EPO's Technical Board of Appeal, by decision of 6 May 2009, annulled the EPO decision of 27 July 2006 and dismissed the 947 patent.

1202 The Commission found that the infringement concerning the agreements concluded between Servier and Krka, in so far as it was still taking place in certain Member States, had ended on that date.

1203 In the light of the proceedings relating to the 947 patent, which continued after Krka's withdrawal from the proceedings to which it was a party, as mentioned above, it cannot be considered that, in the absence of the settlement agreement reached between the parties, Krka's continuation of the proceedings would probably, or even plausibly, have allowed a faster or more complete invalidation of the patent.

1204 However, the Commission has not established, or even alleged, in the contested decision, that the invalidation of the 947 patent would have been more rapid or more complete if Krka had not agreed to the non-challenge clause in the settlement agreement.

1205 The fact that 'Krka previously considered that its patent case was amongst the best ones, and that it was a particular threat to the 947 patent' or that the courts of the United Kingdom, despite their rejection of the motion for summary judgment lodged by Krka, had considered that it had a 'powerful base' to challenge the validity of the 947 patent (recital 1827 of the contested decision) does not support the conclusion that Krka's participation in the proceedings in question would have led to the faster or more complete invalidation of the patent.

1206 Likewise, to note, as the Commission does in recital 1712 of the contested decision, that 'eliminating a strong challenger may impact the final outcome of the litigation/opposition' does not justify a finding that the effects of the non-challenge clause that applied to Krka are probable, or plausible.

1207 It was for the Commission to demonstrate, in a sufficiently precise and substantiated manner, how Krka's arguments or its particular position as regards the litigation could, if it had continued the proceedings in which it was engaged, have had a decisive impact, not on the outcome of disputes, since two of those cases — namely that before the EPO, which continued after Krka's withdrawal and that between Servier and Apotex before the High Court of Justice (England & Wales), Chancery Division (Patents Court) — in any event, resulted in the invalidation of the 947 patent, but on the period in which that invalidation occurred or its scope.

1208 Moreover, it is not for the Court, as regards the appraisal of the constituent elements of an infringement — which do not fall within the scope of its unlimited jurisdiction, but rather the review of legality — to substitute its own reasoning for that of the Commission (judgment of 21 January 2016, *Galp Energía España and Others* v *Commission*, C-603/13 P, EU:C:2016:38, paragraphs 73 and 75 to 77).

1209 Therefore, it is not for the Court to examine for the first time, on the basis of elements in the file other than those relied upon by the Commission in order to establish the restrictive effects of the non-challenge clause, whether Krka's continued participation in the ongoing litigation would have resulted in the faster or more complete invalidation of the 947 patent.

1210 It should also be added that, irrespective of the structure of the relevant market, including where, as in this case, it is characterised, according to the Commission, by a lack or shortage of sources of competition, the anticompetitive effects of a non-challenge clause remain largely hypothetical if it is likely, given the actual course of events as it could have been observed when the Commission adopted its decision, that, in the absence of that clause, the patent in question, namely, in the present case, the 947 patent, would have been invalidated at the same time and in equal measure (see paragraph 1181 above).

1211 Moreover, the Commission has not demonstrated, contrary to what recital 1712 of the contested decision suggests, that the proceedings between Servier and Krka before the courts of the United Kingdom could have established that Krka's technology was non-infringing. The proceedings concerning Krka and Apotex consisted of actions for infringement brought by Servier and counterclaims for annulment of the 947 patent lodged by those two generic companies in response. These proceedings were therefore similar. The proceedings concerning Apotex were brought to an end in their entirety by the invalidation of the 947 patent and, thus, without it being necessary to determine whether its technology was infringing. It is plausible, given the similarity of the proceedings and in the absence of evidence to the contrary adduced by the Commission, that the same would have happened to Krka.

1212 A fortiori, it has not been shown that the procedure before the EPO could have established that Krka's technology was a non-infringing technology since that procedure concerned only the validity of the 947 patent.

1213 It follows from the foregoing that the restrictive effects on competition of the non-challenge clause in the settlement agreement have not been established by the Commission.

– *The licensing of Krka's technology*

1214 As regards the licence agreement by which Krka sold its technology to Servier, the Commission merely noted that, absent that agreement, 'Krka would have retained the freedom to sell or license out the rights to its perindopril technology' (recital 1829 of the contested decision), which is not sufficient — in relation to a mere transfer of property accompanied by a licence agreement and not an exclusionary measure as a non-marketing clause may be — to establish the existence of probable effects, in particular on prices, production, quality, diversity or innovation (see paragraphs 1135 to 1137 above). The existence of anticompetitive effects is even less established since Krka's technology did not make it possible to circumvent the 947 patent, which, in view of the serious indications suggesting that that patent was valid, renders implausible the assumption that generic companies competing with Servier would, absent the assignment agreement, have sought to acquire Krka's technology.

1215 It follows from the foregoing that the restrictive effects on competition of the licensing of Krka's technology have not been established by the Commission.

1216 It follows from all the foregoing that the Commission has not established the existence of a restrictive effect on competition resulting from the settlement agreement or the assignment agreement which is sufficiently realistic and likely as to be able to support the finding of a restriction by effect. It should be added that such a restrictive effect is no more likely to be found if the two agreements are considered as a whole.

1217 The complaint alleging an error of assessment must therefore be upheld, and the applicants' plea alleging that the Commission erred in finding a restriction by effect as a result of the agreements between Servier and Krka, may, on that basis alone, be declared well founded in its entirety.

1218 It is also necessary to determine whether the Commission has, in addition, vitiated its decision by errors of law.

(iv) Error of law

1219 As mentioned (see paragraphs 1092 and 1102 above), the Commission considered that, since it had established that the settlement agreement excluded a potential competitor of Servier, it was not required, in order to demonstrate the competition that would have occurred had an agreement not been concluded (one side of the comparison mentioned in paragraph 1076 above), to take into account the actual course of events which it could have observed at the time it adopted its decision. Rather, the Commission considered — relying on its usual practice in taking into account the potential effects of an agreement, according to which it suffices to demonstrate that that agreement is 'likely' to have anticompetitive effects (see paragraphs 1080 and 1085 above) — that it could base its description of the competition that would have occurred had an agreement not been concluded on hypotheses or possibilities.

1220 As is apparent from the above examination of the complaint alleging an error of assessment, some of the events that the Commission did not take into account were not only relevant, but also decisive for the purposes of the comparison referred to in paragraph 1076 above.

1221 Thus, as regards the non-marketing clause, although the Commission took into account the EPO decision of 27 July 2006 and the interim injunctions issued by the United Kingdom courts against Krka and Apotex in order to establish that Krka was a potential competitor, it did not take due account of those events for the purpose of determining whether Krka would probably have entered the market absent an agreement, merely stating in that regard that, absent an agreement, the 'competitive threat' from Krka would have persisted.

1222 As regards the non-challenge clause, the Commission did not take into account the outcome of the proceedings brought against the 947 patent by other generic companies, which continued despite the fact that Krka had ceased any challenge.

1223 As regards, lastly, the market structure, a cross-cutting issue which concerns both the non-marketing clause and the non-challenge clause, the Commission merely identified the remaining sources of competition at the time the last of the settlement agreements referred to in the contested decision was concluded and indicated that there was a 'strong possibility' that those sources would be removed from competition by an agreement or otherwise, without taking account of the fact that that possibility did not occur during the infringement period (recital 1846 of the contested decision).

1224 That reasoning is expressly apparent from footnote 2445 of the contested decision, in which the Commission relies — in order to prove that the non-challenge clause had restrictive effects — on the fact that there were few companies competing with Servier likely to pursue the ongoing proceedings or to launch new ones and that 'it was plausible that Servier would consider reaching settlements with these companies', which would have eliminated any possibility that proceedings against the 947 patent would continue or be launched. While it is true that Servier approached those companies, it did not reach a settlement with them and in particular with one of them which ultimately obtained the annulment of the 947 patent at the very time the non-challenge clause was applied by Krka.

1225 The limited nature of the review undertaken by the Commission cannot be justified in the light of the case-law of the EU Courts. The case-law on taking into account the potential effects of agreements, examined in paragraph 1107 to 1120 above, was not applicable in the present case (see paragraph 1124 above).

1226 The same is true, for the reasons indicated in paragraphs 1183 to 1186 above, as regards the applicability of the solution adopted, in relation to agreements eliminating potential competition, in the judgment of 14 April 2011, *Visa Europe and Visa International Service* v *Commission* (T-461/07, EU:T:2011:181) (see paragraphs 1183 to 1186 above).

1227 It must therefore be concluded that the Commission carried out an incomplete examination of the situation that it was required to assess in order to determine whether the agreements between Servier and Krka were restrictive of competition by effect, and that the incompleteness of the Commission's examination shows a misapplication of the case-law of the EU courts and thus an error of law.

1228 Moreover, according to the Commission's approach, it had only to demonstrate the elimination of a potential competitor in order to be able to find — in the context of a market structure characterised by a lack or shortage of sources of competition and by market power on the part of the originator company — a restriction of competition by effect.

1229 If it were accepted, that approach would allow the Commission, in cases such as the present case concerning restrictive clauses linked to a settlement agreement in relation to medicinal product patents, to find a restriction of competition by effect by, in essence, ensuring that only two of the three conditions required in order to find a restriction by object, namely the existence of potential competition and the presence of clauses restrictive of competition, are met.

1230 Since demonstrating that the third condition, namely the existence of an inducement, is met is, as is clear from the examination of the plea on restriction by object, particularly difficult, the Commission's task would be made significantly easier.

1231 In the light of the higher evidential requirements that apply to the demonstration of a restriction of competition by effect (see paragraphs 1123 and 1128 to 1139 above), that solution — which runs counter to the spirit of the distinction established by the Treaty between restrictions of competition by object and restrictions of competition by effect — cannot be accepted.

1232 It follows from the foregoing that the complaint alleging an error of law must be upheld, and the applicants' plea alleging that the Commission erred in finding a restriction by effect resulting from the agreements between Servier and Krka may, on that basis alone, be declared well founded in its entirety.

1233 Since the plea relating to the absence of a restriction by object has also been found to be well founded, it must be concluded that the Commission erred in finding an infringement under Article 101(1) TFEU as regards the agreements between Servier and Krka.

1234 It is therefore appropriate, without there being any need to examine the other complaints relied on by the applicants in the present plea or the plea relating to the status of Krka as a potential competitor, to annul Article 4 of the contested decision in so far as, by that provision, the Commission found that Krka had participated in an infringement of Article 101(1) TFEU as regards the agreements between Servier and Krka.

10. The plea relating to the definition of the concept of restriction of competition by effect

(a) Arguments of the parties

…

(b) Findings of the Court

1247 For the reasons already referred to in paragraphs 566 to 570, 743 and 909 above, regarding other pleas raised against the finding of a restriction by effect resulting from the agreements concluded by Servier with Niche and Unichem, Matrix, Teva and Lupin, this plea must be rejected as ineffective.

11. Errors of law and of assessment in relation to the classification as separate infringements

(a) The classification of the five agreements as separate infringements

(1) Arguments of the parties

…

(2) Findings of the Court

1254 It is apparent from the contested decision and is not disputed by the applicants that they concluded separate agreements, signed on different dates (with the exception of the agreements concluded with Niche and with Matrix), with different parties, in different economic and legal contexts and with different scopes. The applicants maintain, however, that, in spite of those differences, the conclusion of those agreements constitutes a single infringement, on account of the identity of the product concerned, a certain spatial and temporal identity of the agreements, the identity of the method and arrangements for implementing the agreements and the identity of the natural person involved, for their part, in the conclusion of the agreements.

1255 It should be noted, as a preliminary point, that the present plea in law, criticising the failure to recognise that there was a single infringement in the present case, is raised in the alternative (see paragraph 1248 above), in the event that the pleas alleging errors of law and of assessment in classifying the agreements at issue as restrictions by object and by effect are rejected. Accordingly, and since the pleas directed against the classification of the agreements concluded by the applicants with Krka as restrictions of competition have been upheld, the present plea will be examined only in so far as it challenges the classification of the agreements concluded by the applicants with Niche, Matrix, Teva and Lupin as separate infringements.

1256 As regards the effectiveness of the plea, the Commission argues, in essence, that it must be rejected as ineffective, since, in any event, the applicants have not established that the fine would necessarily have been lower if the Commission had considered that the agreements at issue constituted a single infringement.

1257 It must be borne in mind, first, that the effective or ineffective nature of a plea which has been raised refers to its capacity, in the event that it is well founded, to lead to the annulment sought by an applicant; it does not refer to the interest which that applicant may have in bringing such an action or even in raising a specific plea, since those are issues relating to the admissibility of the action and the admissibility of the plea respectively (judgment of 21 September 2000, *EFMA* v *Council*, C-46/98 P, EU:C:2000:474, paragraph 38).

1258 Next, since, inter alia, if the Commission establishes the existence of a legitimate interest in making such a finding, it has the power to adopt a decision finding an infringement without imposing a fine with that decision (see, to that effect, judgments of 6 October 2005, *Sumitomo Chemical and Sumika Fine Chemicals* v *Commission*, T-22/02 and T-23/02, EU:T:2005:349, paragraph 31, and of 16 November 2006, *Peróxidos Orgánicos* v *Commission*, T-120/04, EU:T:2006:350, paragraph 18), the lawfulness of a decision finding that an undertaking participated in an infringement cannot depend on the legality of the fine imposed on that undertaking. That is why the pleas relating to the imposition of penalties can by definition concern only the imposition of the fine and not the finding of infringement itself (see, to that effect, judgment of 27 June 2012, *Bolloré* v *Commission*, T-372/10, EU:T:2012:325, paragraph 81). On the other hand, the pleas relating to the finding of infringement itself are, in principle, capable of bringing about the annulment not only of the decision finding that an undertaking participated in an infringement, but also, as a consequence, the fine imposed on that undertaking.

1259 It follows, in the present case, that if the Court were to consider that the Commission wrongly identified separate infringements on the basis of each of the agreements at issue instead of a single infringement, the contested decision should be annulled in so far as it finds, as against the applicants, separate infringements and, as a result, in so far as it imposes fines on them on the basis of those infringements, irrespective of whether the annulment would have a favourable impact for the applicants on the total amount of the separate fines which were imposed on them and which, where appropriate, should be recalculated if a single fine is imposed on them in the context of a new decision. It should be recalled that the unlimited jurisdiction enjoyed by the General Court on the basis of Article 31 of Regulation No 1/2003 concerns solely the assessment by that Court of the fine imposed by the Commission, to the exclusion of any alteration of the constituent elements of the infringement lawfully determined by the Commission in the decision under examination by the General Court (judgment of 21 January 2016, *Galp Energía España and Others* v *Commission*, C-603/13 P, EU:C:2016:38, paragraph 77).

1260 For the sake of completeness, in any event, it must be considered that, if the Court were to hold that the Commission wrongly identified separate infringements instead of a single infringement, that would have an effect on the amount of the fine.

1261 It must be borne in mind that describing certain unlawful acts as constituting one and the same infringement or as a number of separate infringements is not, in principle, without consequence as regards the penalty that may be imposed, since a finding that a number of separate infringements have been committed may lead to the imposition of several separate fines, each time within the limits laid down in Article 23(2) of Regulation No 1/2003 and thus within the upper limit of 10% of turnover in the business year preceding the adoption of the decision. Thus the Commission may find, in a single decision, two separate infringements and impose two fines the total amount of which exceeds the upper limit of 10% laid down in Article 23(2) of Regulation No 1/2003, provided that the amount of each fine does not exceed that upper limit. It is irrelevant, for the application of that upper limit of 10%, whether fines are imposed for the various infringements of the EU competition rules in a single set of proceedings or in separate proceedings at different points in time, as the maximum limit of 10% applies to each infringement of Article 101 TFEU (see judgment of 6 February 2014, *AC-Treuhand* v *Commission*, T-27/10, EU:T:2014:59, paragraphs 230 to 232 and the case-law cited). In the present case, however, it must be stated, as the applicants acknowledge in the application, that the total amount of the fines imposed on them for the infringements of Articles 101 and 102 TFEU is lower than the ceiling of 10% of turnover in the business year preceding the adoption of the decision, laid down in Article 23(2) of Regulation No 1/2003. Consequently, the applicants cannot criticise the Commission for having decided to impose on them separate fines in order to be able to exceed that 10% ceiling when those fines are taken as a whole.

1262 However, recitals 3120, 3121 and 3128 of the contested decision show that, since the Commission imposed separate fines on the applicants for each infringement of Article 101 TFEU, it applied to those amounts a downward correction factor to avoid a potentially disproportionate outcome due to the parallel imposition of multiple fines. It is because it decided to impose on the applicants several separate fines that the Commission applied an average reduction of 54.5% to the amount of the value of the applicants' sales taken into account in order to determine the amount of each of the fines, reflecting the degree of temporal and geographic overlap of the corresponding infringements. In any event, in order to show that the plea is ineffective, the Commission must therefore establish that the fine imposed on the applicants would have been as high in the case of a single infringement, which seems unlikely.

1263 Accordingly, it is necessary to examine the substance of the plea.

1264 According to settled case-law, an infringement of Article 101(1) TFEU can result not only from an isolated act, but also from a series of acts or from continuous conduct, even if one or more aspects of that series of acts or continuous conduct could also, in themselves and taken in isolation, constitute an infringement of that provision. Accordingly, if the different actions form part of an 'overall plan', because their identical object distorts competition within the internal market, the Commission is entitled to impute responsibility for those actions on the basis of participation in the infringement considered as a whole (judgments of 6 December 2012, *Commission* v *Verhuizingen Coppens*, C-441/11 P, EU:C:2012:778, paragraph 41, and of 24 June 2015, *Fresh Del Monte Produce* v *Commission* and *Commission* v *Fresh Del Monte Produce*, C-293/13 P and C-294/13 P, EU:C:2015:416, paragraph 156).

1265 An undertaking which has participated in such a single and complex infringement through its own conduct, which fell within the definition of an agreement or a concerted practice having an anticompetitive object for the purposes of Article 101(1) TFEU and was intended to help bring about the infringement as a whole, may accordingly be liable also in respect of the conduct of other undertakings in the context of the same infringement throughout the period of its participation in the infringement. That is the position where it is shown that the undertaking intended, through its own conduct, to contribute to the common objectives pursued by all the participants and that it was aware of the offending conduct planned or put into effect by other undertakings in pursuit of the same objectives or that it could reasonably have foreseen it and was prepared to take the risk (judgments of 6 December 2012, *Commission* v *Verhuizingen Coppens*, C-441/11 P, EU:C:2012:778, paragraphs 42 and 60, and of 24 June 2015, *Fresh Del Monte Produce* v *Commission* and *Commission* v *Fresh Del Monte Produce*, C-293/13 P and C-294/13 P, EU:C:2015:416, paragraph 157).

1266 Thus, according to the case-law of the Court of Justice, application of the concept of 'single infringement' makes it possible, under certain circumstances, to impute responsibility for a series of unlawful acts to every participant in any one of the acts in that series. That possibility arises, however, only if, inter alia, it is possible to identify an objective common to all the participants.

1267 The need for a common objective, purpose or goal follows not only from the judgments cited in paragraphs 1264 and 1265 above, but also from earlier case-law.

1268 Accordingly, in the judgment of 8 July 1999, *Commission* v *Anic Partecipazioni* (C-49/92 P, EU:C:1999:356, paragraphs 82 and 83), the Court of Justice confirmed the reasoning of the General Court that, first, because of their identical object, the agreements and concerted practices found to exist, formed part of systems of regular meetings, target-price fixing and quota-fixing, and that those schemes were part of a series of efforts made by the undertakings in question in pursuit of a single economic aim, namely to distort the normal movement of prices, and, secondly, it would be artificial to split up such continuous conduct, characterised by a single purpose, by treating it as consisting of several separate infringements, when what was involved was a single infringement which progressively manifested itself in both agreements and concerted practices.

1269 Similarly, the Court of Justice held, in the judgment of 7 January 2004, *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, EU:C:2004:6, paragraphs 258 and 259), that, when the different actions form part of an 'overall plan', because their identical object distorts competition within the internal market, the Commission is entitled to impute responsibility for those actions on the basis of participation in the infringement considered as a whole. The Court of Justice stated in that regard that it was artificial to subdivide into a number of distinct actions an agreement, which is characterised by a series of efforts pursuing a single economic end, namely non-transhipment to home markets.

1270 Moreover, it must be pointed out that the existence of a common objective is inherent in the concept of 'overall plan' to which the case-law of the Court of Justice refers, since such a plan could not exist without a common objective to which all participants adhere.

1271 Finally, it should be noted that links of complementarity between agreements or concerted practices may constitute objective indicia supporting the existence of an overall plan aimed at attaining a single anticompetitive objective. Such links exist if those agreements or concerted practices are intended to deal with one or more consequences of the normal pattern of competition and, through their interaction, contribute to the attainment of a single anticompetitive objective (see, to that effect, judgments of 28 April 2010, *Amann & Söhne and Cousin Filterie* v *Commission*, T-446/05, EU:T:2010:165, paragraph 92 and the case-law cited, and of 16 September 2013, *Masco and Others* v *Commission*, T-378/10, EU:T:2013:469, paragraphs 22, 23 and 32 and the case-law cited). It is on the basis of the foregoing general considerations that the facts specific to the present case must be examined.

1272 In that regard, it must first be pointed out that the applicants were parties to separate settlement agreements each concluded with one or more generic companies, which differed depending on the agreements, and that — as is clear from the examination of the pleas specific to each of those agreements — those agreements constituted, in themselves and considered in isolation, an infringement of Article 101 TFEU.

1273 In that context, the Commission could consider, in the light of the case-law referred to above, that the settlement agreements at issue constituted a single and continuous infringement of Article 101 TFEU only if it was in a position to establish, in particular, that those agreements formed part of an overall plan.

1274 Therefore, the finding of a single infringement presupposed that Servier and all the generic companies concerned had concluded the agreements at issue in pursuit of at least one common objective.

1275 The applicants do not argue, at least explicitly, that there existed such an objective which they specifically identify.

1276 Moreover, the existence of such an objective is not apparent from the documents in the file.

1277 In that regard, it must be made clear that the concept of a common or single objective cannot be determined by a general reference to the distortion of competition on the market concerned by the infringement, since a restriction on competition, whether it is the object or the effect of the conduct in question, constitutes an element consubstantial with any conduct covered by Article 101(1) TFEU. Such a definition of the concept of a single objective is likely to deprive the concept of a single and continuous infringement of part of its meaning, since it would have the consequence that different instances of conduct which relate to a particular economic sector and are prohibited under Article 101(1) TFEU would have to be systematically characterised as constituent elements of a single infringement (see judgment of 28 April 2010, *Amann & Söhne and Cousin Filterie* v *Commission*, T-446/05, EU:T:2010:165, paragraph 92 and the case-law cited).

1278 However, it does not appear from the documents in the file that there was an objective common to Servier and to the generic companies which may be defined more precisely than by a simple general reference to the distortion of competition on the market concerned by the infringement.

1279 Moreover, the generic companies did not conclude settlement agreements which were binding upon each of them in relation to one another, but only agreements binding upon each of them in relation to Servier. Furthermore, with the exception of the Matrix agreement, the agreements thus concluded followed, in particular, national disputes specific to each generic company between it and Servier, and the other generic companies in question were not involved in those disputes. Finally, those agreements, which were concluded at different times, differed in their content, the Niche and Matrix agreements involving a simple reverse payment, the Teva agreement providing for an exclusive purchasing clause and the Lupin agreement being linked to the conclusion of an agreement for Lupin to assign patent applications to Servier.

1280 It should be added that the entry into force of each agreement was not subject to the entry into force of the other agreements and no clause in the agreements provided for or gave rise to a coordination of behaviour between the various generic companies. Moreover, it is not apparent from the documents in the file that those companies have, in one way or another, coordinated their efforts to restrict competition. In the absence of such links between the agreements or of evidence that there was, at the time of the conclusion of the agreements, collusion between the generic companies, the only coordination apparent from the documents in the file is that on the part of Servier in concluding the various agreements.

1281 In the light of the foregoing considerations, it cannot be concluded that the generic companies in question participated in an overall plan. On the contrary, it must be found that they confined themselves, as the Commission rightly points out in its defence, to seizing the opportunity presented to each of them by the proposed draft agreement with Servier. Each of the generic companies thus participated in an autonomous market exclusion agreement without contributing to a set of agreements having a common objective.

1282 In the absence of an objective common to Servier and to each of the generic companies and therefore of an overall plan, the Commission was correct in not finding that the settlement agreements at issue constituted a single infringement.

1283 The foregoing finding cannot be called into question by the applicants' other arguments.

1284 In the first place, although the applicants were parties to all the settlement agreements at issue and the Commission could consider that some generic companies had been informed that the applicants had concluded other settlements with generic companies, the fact remains that mere knowledge of other anticompetitive practices is not sufficient to establish the existence of a single infringement. Although such knowledge is a requirement for holding an undertaking liable for the behaviour of other undertakings in the context of a single infringement (see paragraph 1265 above), it does not, as such, prove the existence of a subjective common element and, in particular, the pursuit of a purpose or objective common to all the participants, which alone are capable of demonstrating the existence of a single infringement (see, to that effect, judgments of 12 December 2007, *BASF and UCB* v *Commission*, T-101/05 and T-111/05, EU:T:2007:380, paragraph 205, and of 28 April 2010, *Amann & Söhne and Cousin Filterie* v *Commission*, T-446/05, EU:T:2010:165, paragraph 108).

1285 In the second place, the applicants complain that, in recital 3120 of the contested decision, the Commission referred to three precedents in case-law which were irrelevant or could not be relied upon, since some of the decisions in question had not been published. However, it must be pointed out, in any event, that for objective reasons the Commission may initiate separate procedures, find a number of separate infringements and impose a number of separate fines (see judgment of 28 April 2010, *Amann & Söhne and Cousin Filterie* v *Commission*, T-446/05, EU:T:2010:165, paragraph 93 and

the case-law cited). Consequently, in the present case, whether or not the Commission cited relevant precedents and whether or not they were published cannot render the contested decision unlawful, since the Commission is required, in each case, to ascertain whether there are objective reasons for establishing the existence of a single infringement. It may also be added, for the sake of completeness, that the Commission in the present case referred to the criticised precedents only as an illustration of the imposition of separate fines for separate infringements, after having recalled that it followed from Article 23(2) of Regulation No 1/2003 and was consistent with the Guidelines on the method of setting fines that separate fines should be imposed for each infringement.

1286 In the third place, the applicants criticise the Commission for vitiating its analysis with contradictory reasoning. In their view, the Commission could not rule out the classification of the settlement agreements as a single infringement, under Article 101 TFEU, since it considered, in the part of the contested decision relating to abuse of a dominant position, that those same agreements constituted a single infringement of Article 102 TFEU.

1287 However, that line of argument cannot be accepted.

1288 The concept of a single infringement for the purposes of Article 101 TFEU concerns the bilateral or multilateral conduct of several undertakings, whereas the concept of abuse by an undertaking of its dominant position covers that undertaking's unilateral conduct, such as the conduct found to exist by the Commission in the section of the contested decision relating to the application of Article 102 TFEU. Since those two concepts are distinct and based on different criteria, a finding of the existence of a single infringement for the purposes of Article 101 TFEU cannot arise as a result of the fact that the conduct of one of the undertakings party to that infringement is classified as abuse of a dominant position. That applies a fortiori where, as in the present case, the classification of abuse of a dominant position is, in part, based on the taking into account of conduct which has not been examined in the context of Article 101 TFEU, namely the acquisition by the applicants of the Azad technology.

1289 Moreover, it should be noted that the Commission did not find in the section of the contested decision relating to the application of Article 102 TFEU that the applicants, in the implementation of their strategy of foreclosure of their competitors by means of the conclusion of settlement agreements and the acquisition of the Azad technology, pursued a common objective with the generic companies, a requirement for a finding of a single infringement for the purposes of Article 101 TFEU. Furthermore, the applicants do not claim that the Commission made such a finding. Consequently, they cannot reasonably rely on that section of the contested decision to conclude that the Commission should have considered that the settlement agreements constituted a single infringement.

1290 It follows from all the foregoing that the present plea must be rejected.

(b) The classification of the agreements concluded with Niche and Matrix as separate infringements

(1) Arguments of the parties

…

(2) Findings of the Court

1293 It is apparent from paragraph 5 and recital 3120 of the contested decision that the Commission considered that the two agreements concluded by the applicants (and Biogaran) with Niche (settlement agreement and licensing and supply agreement) and the settlement agreement concluded with Matrix constituted two separate infringements of Article 101 TFEU. The applicants maintain that those agreements constitute a single infringement.

1294 The Commission argues that the plea must be rejected as ineffective, since, in any event, the applicants have not established that the fine would necessarily have been lower if the Commission had considered that the agreements concluded with Niche and with Matrix constituted a single infringement. It is apparent, however, from paragraphs 1256 to 1263 above that, if this plea is well founded, the contested decision must be annulled and the fine recalculated. Consequently, like the plea criticising in general terms the classification of the various agreements concluded by the applicants as separate infringements, the present plea must be regarded as effective.

1295 As to the merits of this plea, it must be borne in mind that, in order to find a single infringement, it is for the Commission to establish that the agreements at issue form part of an overall plan knowingly implemented by the undertakings in question with a view to achieving a single anticompetitive objective and that the Commission is required to examine in that regard all the facts capable of establishing or of casting doubt on that overall plan (see, to that effect, judgment of 16 September 2013, *Masco and Others* v *Commission*, T-378/10, EU:T:2013:469, paragraphs 22 and 23; see, also, paragraphs 1264 to 1269 above).

1296 In the present case, it may indeed be inferred from the arguments put forward by the applicants that the latter were driven by 'similar motives' in concluding the agreements in question, as the Commission rightly pointed out in recital 1472 of the contested decision, and pursued in that respect an identical objective, namely definitively to settle the ongoing dispute and to avoid any future litigation concerning the Niche/Matrix product and to eliminate that product as a source of potential competition in return for payment. In particular, the fact that the applicants actually pursued that same objective when they concluded the agreements with Niche and Matrix is evidenced by the fact that those agreements were signed on the same day and at the same place by the same representative of the applicants, the fact that their temporal and geographic scope was identical, the fact that the agreements related in particular to the same product — imposing similar obligations on Niche and Matrix — and, finally, the undisputed fact that it was in the applicants' interest to conclude agreements with the stakeholders in the relevant joint perindopril project (see, in that regard, recital 2940 of the contested decision).

1297 However, such factual evidence does not establish that Niche and Matrix were together pursuing the same objective, thus attesting to a common plan, by concluding the agreements at issue, nor a fortiori that they participated in that common plan with the applicants.

1298 Indeed, the conclusion of the agreements on the same day and in the same place attests to their links and to the common objective pursued by Servier, a signatory of both agreements, but does not in itself allow the finding of a common plan between the others signatories, Niche and Matrix. Similarly, the representation of Niche and Matrix by the same lawyer — which also explains the payment of the two transfers of value into the same account, that of their common representative — reveals the absence of a conflict of interest between them, but does not in itself make it possible to establish a community of interest, especially since the representative in question was Niche's representative, who represented Matrix only for the signing of the Matrix agreement (recitals 575 and 576 of the contested decision). Moreover, although the two agreements effectively prohibit the marketing of the Niche/Matrix product, it should be noted that the Niche agreement covers, in general, all the potentially infringing products which Niche might develop, alone or with other partners, just as the Matrix agreement covers, in general, all the potentially infringing products which Matrix might develop, alone or with

other partners (in accordance with the definition of 'process' used in each agreement), which, furthermore, places in context the similarity between the clauses of the agreements. It should also be added, in that respect, that the clauses of the Niche and Matrix agreements are not strictly identical, notably in the light of the different litigation between Servier and Niche, on the one hand, and between Servier and Matrix, on the other. Thus, only the Niche agreement contains clauses providing for the termination of ongoing litigation before the United Kingdom courts and the EPO (Clauses 2 and 7 of the Niche agreement), since Matrix was not directly involved in any of those disputes (see also Clause 9 of the Niche agreement, which has no equivalent in the Matrix agreement).

1299 Nor can the existence of a plan common to Niche and Matrix be demonstrated by their alleged arrangement concerning implementation of the agreements they concluded with the applicants. Such an arrangement cannot be regarded as having been adequately established by the mere mention of an oral agreement jointly to compensate Niche's customers and of a request from Niche to Matrix for written confirmation of that agreement. It is even contradicted by the actual implementation of the agreements, which resulted in particular in Matrix's unilateral suspension of the Niche-Matrix agreement.

1300 Nor is it apparent from the course of the negotiations for the agreements in question that Niche and Matrix pursued the same objective in concluding the agreements. Indeed, several uncontested pieces of evidence in the file and in the contested decision (recitals 574 to 577 of the contested decision) show that the conclusion by Matrix of its agreement with Servier is indicative of its intention to seize an opportunity offered by the applicants (see also paragraph 1281 above) rather than of a common plan with its partner Niche to terminate their joint perindopril project. In particular, first, Matrix was informed of the existence of negotiations between Niche and the applicants only two days before the conclusion of its own agreement with the applicants and was briefly informed of the state of those negotiations only the day before. Secondly, it may be inferred from recital 577 of the contested decision that Matrix's participation in the negotiations mainly concerned the amount of the transfer of value.

1301 Finally, it may be pointed out that the classification of the Niche and Matrix agreements as a single infringement would lead to the inclusion in that infringement of the agreement concluded between Niche and Biogaran, which the Commission regarded, without this being disputed by the applicants, as forming part of the infringement alleged against them on the basis of the Niche agreement (see in particular recital 3006 of the contested decision). However, such an agreement — negotiated between Biogaran and Niche without the knowledge of Matrix, unrelated to the Niche/Matrix product and having an objective different from that of the Matrix agreement (licensing and supply agreement relating to other medicinal products) — cannot be regarded as forming part of a plan which could be common to both Niche and Matrix and a fortiori to those two undertakings and the applicants.

1302 It must therefore be held that the Commission did not commit an error of law or an error of assessment in classifying the agreements respectively concluded by the applicants (and Biogaran) with Niche and with Matrix as separate infringements. It also follows that the applicants cannot criticise the Commission for having penalised them twice for the same acts. Since the Commission found two separate infringements, it was entitled to impose two separate fines on the applicants. However, the particular circumstances of the conclusion of the Matrix agreement and the specific scope of that agreement mean, as will be set out in paragraphs 1692 to 1699 below, that due account must be taken of those characteristics in assessing the proportionality of the fine imposed in connection with that agreement in relation to that imposed in relation to the Niche agreement.

1303 It follows from all the foregoing that it is necessary to reject in their entirety the present plea and the pleas alleging errors of law and of assessment in relation to the classification as separate infringements.

12. Errors of law and of assessment in relation to the definition of the relevant finished product market

(a) Arguments of the parties

…

(b) Findings of the Court

1367 The applicants, supported by the intervener, raise, in essence, three complaints.

1368 First of all, by their first complaint, the applicants criticise the Commission for having disregarded the particular features of the pharmaceutical sector in that it based its analysis of the relevant market primarily on the price of medicinal products and not on therapeutic substitutability. There are two parts to that complaint, the first alleging that the Commission did not take into account the overall economic context and the second that the Commission attached excessive importance to the price factor.

1369 Next, by their second complaint, the applicants challenge the Commission's view that ACE inhibitors were not sufficiently substitutable from a therapeutic point of view. They call into question the distinction between perindopril and other ACE inhibitors in terms of efficacy and side effects, the phenomenon of doctors' 'inertia' with respect to new patients, the low propensity to switch of continued-use patients and the Commission's analysis of promotional activities.

1370 Finally, by their third complaint, the applicants contest, in the alternative, the methodological shortcomings of the Commission's econometric analysis of natural events seeking to demonstrate that ACE inhibitors did not exert significant competitive constraints on perindopril.

1371 Before proceeding to the examination of each of those three complaints, it is appropriate to recall, in the context of a series of preliminary remarks, on the one hand, the extent of the review carried out by the EU courts in matters of competition law and, on the other hand, the factors of analysis established in the case-law relating to the definition of the relevant product market, in particular in the pharmaceutical sector, in the light, also, of the parties' responses to the questions from the Court concerning the respective place of therapeutic substitutability and price factors in that analysis.

(1) Preliminary remarks

(i) The extent of review carried out by the EU Courts

1372 It must be recalled that EU law provides for a system of judicial review of Commission decisions relating to proceedings under Article 102 TFEU (see judgment of 10 July 2014, *Telefónica and Telefónica de España* v *Commission*, C-295/12 P, EU:C:2014:2062, paragraph 42 and the case-law cited). That system of judicial review consists in a review of the legality of the acts of the institutions for which provision is made in Article 263 TFEU, which may be supplemented, pursuant to Article 261 TFEU, by the exercise of unlimited jurisdiction with regard to the penalties provided for by the legislation (judgment of 21 January 2016, *Galp Energía España and Others* v *Commission*, C-603/13 P, EU:C:2016:38, paragraph 71).

1373 As the Court of Justice has stated, the scope of judicial review provided for in Article 263 TFEU extends to all the elements of Commission decisions relating to proceedings applying Articles 101 TFEU and 102 TFEU which are subject to in-depth review by the General Court, in law and in fact, in the light of the pleas raised by the applicants and taking into account all the elements submitted by

the latter, whether those elements pre-date or post-date the contested decision, whether they were submitted previously in the context of the administrative procedure or, for the first time, in the context of the proceedings before the General Court, in so far as those elements are relevant to the review of the legality of the Commission decision (judgment of 21 January 2016, *Galp Energía España and Others* v *Commission*, C-603/13 P, EU:C:2016:38, paragraph 72).

1374 In that regard, it must be borne in mind that, according to settled case-law, although the EU judicature undertakes a comprehensive review of the question as to whether or not the conditions for the application of the competition rules are met, the review of complex economic appraisals made by the Commission is necessarily limited to checking whether the relevant rules on procedure and on stating reasons have been complied with, whether the facts have been accurately stated and whether there has been any manifest error of assessment or a misuse of powers (judgments of 11 July 1985, *Remia and Others* v *Commission*, 42/84, EU:C:1985:327, paragraph 34; of 17 November 1987, *British American Tobacco and Reynolds Industries* v *Commission*, 142/84 and 156/84, EU:C:1987:490, paragraph 62; and of 10 April 2008, *Deutsche Telekom* v *Commission*, T-271/03, EU:T:2008:101, paragraph 185).

1375 The Court of Justice has held that whilst, in areas giving rise to complex economic assessments, the Commission has a margin of discretion with regard to economic matters, that does not mean that the Courts of the European Union must refrain from reviewing the Commission's interpretation of information of an economic nature. Those Courts must establish, among other things, not only whether the evidence relied on is factually accurate, reliable and consistent but also whether that evidence contains all the information which must be taken into account in order to assess a complex situation and whether it is capable of substantiating the conclusions drawn from it (judgments of 15 February 2005, *Commission* v *Tetra Laval*, C-12/03 P, EU:C:2005:87, paragraph 39; of 8 December 2011, *Chalkor* v *Commission*, C-386/10 P, EU:C:2011:815, paragraph 54; and of 10 July 2014, *Telefónica and Telefónica de España* v *Commission*, C-295/12 P, EU:C:2014:2062, paragraph 54). Where, in order to classify a practice in the light of the provisions of Article 102 TFEU, the Commission attaches real importance to an economic analysis of whether rebates were capable of excluding as efficient a competitor ('the as efficient competitor test', 'the AEC test'), the EU judicature is required to examine all the arguments put forward by the penalised undertaking concerning that test (see, to that effect, judgment of 6 September 2017, *Intel* v *Commission*, C-413/14 P, EU:C:2017:632, paragraphs 141 to 144).

1376 Moreover, it should be pointed out that, according to settled case-law of the Court of Justice, in the field of competition law, where there is a dispute as to the existence of an infringement, it is for the Commission to prove the infringements found by it and to adduce evidence capable of demonstrating to the requisite legal standard the existence of the circumstances constituting an infringement. Where the Court still has a doubt, the benefit of that doubt must be given to the undertakings accused of the infringement (judgments of 22 November 2012, *E.ON Energie* v *Commission*, C-89/11 P, EU:C:2012:738, paragraphs 71 and 72, and of 16 February 2017, *Hansen & Rosenthal and H&R Wax Company Vertrieb* v *Commission*, C-90/15 P, not published, EU:C:2017:123, paragraphs 17 and 18).

1377 Although it is for the authority alleging an infringement of the competition rules to prove it, it is for the undertaking raising a defence against a finding of an infringement of those rules to demonstrate that the conditions for applying the rule on which such defence is based are satisfied, so that the authority will then have to resort to other evidence. Moreover, even if the burden of proof rests, according to those principles, on the Commission or on the undertaking concerned, the evidence on which a party relies may be of such a kind as to require the other party to provide an explanation or justification, failing which it is permissible to conclude that the rules on the burden of proof have been satisfied (see judgment of 17 June 2010, *Lafarge* v *Commission*, C-413/08 P, EU:C:2010:346, paragraphs 29 and 30 and the case-law cited).

1378 Accordingly, when the Commission relies on evidence which is in principle sufficient to demonstrate the existence of the infringement, it is not sufficient for the undertaking concerned to raise the possibility that a circumstance arose which might affect the probative value of that evidence so that the Commission bears the burden of proving that that circumstance was not capable of affecting the probative value of that evidence. On the contrary, except in cases where such proof could not be provided by the undertaking concerned on account of the conduct of the Commission itself, it is for the undertaking concerned to prove to the requisite legal standard, on the one hand, the existence of the circumstance relied on by it and, on the other, that that circumstance calls in question the probative value of the evidence relied on by the Commission (judgment of 22 November 2012, *E.ON Energie* v *Commission*, C-89/11 P, EU:C:2012:738, paragraph 76).

1379 It should be noted, finally, that the Court of Justice and the General Court cannot, in the context of the review of legality referred to in Article 263 TFEU, substitute their own reasoning for that of the author of the contested measure (judgments of 27 January 2000, *DIR International Film and Others* v *Commission*, C-164/98 P, EU:C:2000:48, paragraph 38; of 24 January 2013, *Frucona Košice* v *Commission*, C-73/11 P, EU:C:2013:32, paragraph 89; and of 21 January 2016, *Galp Energía España and Others* v *Commission*, C-603/13 P, EU:C:2016:38, paragraph 73). Since the review of the legality of the contested decision covers the reasons given in that decision, the Court cannot, either of its own motion or at the request of the administrative authority, add further reasons to those used by the administrative authority in that decision.

(ii) The definition of a relevant product market in the pharmaceutical sector

1380 In the first place, the definition of the relevant market is carried out in order to define the boundaries within which it must be assessed whether a given undertaking is able to behave, to an appreciable extent, independently of its competitors, its customers and, ultimately, consumers (judgment of 9 November 1983, *Nederlandsche Banden-Industrie-Michelin* v *Commission*, 322/81, EU:C:1983:313, paragraph 37).

1381 According to settled case-law, for the purposes of investigating the possibly dominant position of an undertaking on a particular market, the possibilities of competition must be judged in the context of the market comprising the totality of the products which, with respect to their characteristics, are particularly suitable for satisfying constant needs and are only to a limited extent interchangeable with other products (judgments of 9 November 1983, *Nederlandsche Banden-Industrie-Michelin* v *Commission*, 322/81, EU:C:1983:313, paragraph 37, and of 21 October 1997, *Deutsche Bahn* v *Commission*, T-229/94, EU:T:1997:155, paragraph 54). The Commission cannot limit itself to examining only the objective characteristics of the goods and services in question. Indeed, the competitive conditions and the structure of supply and demand on the market must also be taken into consideration in order to assess whether the undertaking concerned is in a position to prevent effective competition from being maintained. and behave, to an appreciable extent, independently of its competitors, its customers and consumers (judgments of 9 November 1983, *Nederlandsche Banden-Industrie-Michelin* v *Commission*, 322/81, EU:C:1983:313, paragraph 37, and of 17 December 2003, *British Airways* v *Commission*, T-219/99, EU:T:2003:343, paragraph 91).

1382 As is apparent inter alia from paragraph 7 of the Notice on the definition of the relevant market, the relevant product market comprises all those products or services which are regarded as substitutable by the consumer, by reason of the products' characteristics, their prices and their intended use.

1383 As is further stated in paragraph 25 of the Notice on the definition of the relevant market, the definition of the market is the result of a body of evidence permitting an assessment of the extent to which substitution would take place. The definition of the boundaries of the market must be made by examining empirical evidence, aimed at making an effective use of all information which is relevant in an individual case.

1384 In paragraphs 15 to 19 of the Notice on the definition of the relevant market, the Commission states that the exercise of market definition focuses on prices for operational and practical purposes, and more precisely on demand substitution arising from small, permanent changes in relative prices. The Commission states that it seeks to assess demand substitutability in the light of a theoretical approach which presupposes a small (in the range 5% to 10%) but permanent relative price increase in the product on the basis of which the relevant market is defined, and to evaluate whether that hypothetical increase could be applied profitably by the hypothetical monopolist of the relevant product. According to that economic test, as set out in paragraph 17 of the Notice on the definition of the relevant market, if substitution were enough to make such a price increase unprofitable because of the resulting loss of sales, substitutes must be regarded as exercising a significant competitive constraint over the relevant product.

1385 In the second place, it should be noted that competitive relationships in the pharmaceutical sector respond to mechanisms which differ from those determining competitive interactions normally present in markets which are not so heavily regulated (judgment of 1 July 2010, *AstraZeneca* v *Commission*, T-321/05, EU:T:2010:266, paragraph 183). Indeed, as described, moreover, in the communication from the Commission entitled 'Executive Summary of the Pharmaceutical Sector Inquiry Report' of 8 July 2009, the pharmaceutical sector is 'unusual' in that the demand for prescription medicines is guided by the prescribing doctor and not the ultimate consumer (the patient). Similarly, doctors are primarily guided by the therapeutic effect of medicines when choosing what to prescribe. Consequently, in so far as they determine doctors' choices, non-price factors, such as therapeutic use, constitute, alongside price-based indicators, relevant factors for the purposes of market definition (see, to that effect, judgment of 1 July 2010, *AstraZeneca* v *Commission*, T-321/05, EU:T:2010:266, paragraph 187).

1386 It is also clear from the case-law that the specific features which characterise competitive mechanisms in the pharmaceutical sector do not negate the relevance of price-related factors in the assessment of competitive constraints, although those factors must be assessed in their specific context (judgment of 1 July 2010, *AstraZeneca* v *Commission*, T-321/05, EU:T:2010:266, paragraph 183).

1387 In the context of proceedings brought for abuse of a dominant position in the pharmaceutical sector, the Commission may, for the purposes of definition of the relevant market, base its assessment inter alia on the greater efficacy of the pharmaceutical product concerned, a therapeutic use which differs from those of other pharmaceutical products, the trend of asymmetrical substitution that characterised the growth in sales of that product and the corresponding decrease or the stagnation in sales of the other products and price indicators, such as they resulted from the regulatory framework in force (see, to that effect, judgment of 1 July 2010, *AstraZeneca* v *Commission*, T-321/05, EU:T:2010:266, paragraphs 61, 153, 182, 183, 203 and 219 to 222).

1388 As regards therapeutic use, for the purposes of the definition of the relevant market, it is necessary to assess the differences and similarities in use of pharmaceutical products or categories of pharmaceutical products. The Commission may reasonably consider that a difference in the therapeutic use of two pharmaceutical products intended for the treatment of the same conditions is an element supporting the conclusion that the relevant market includes only one of those products (see, to that effect, judgment of 1 July 2010, *AstraZeneca* v *Commission*, T-321/05, EU:T:2010:266, paragraph 153).

1389 At the hearing, the Court invited the parties to comment on the respective significance of therapeutic substitutability and price in the definition of the relevant market in the pharmaceutical sector, particularly in the light of the judgment of 1 July 2010, *AstraZeneca* v *Commission* (T-321/05, EU:T:2010:266).

1390 As the Commission rightly pointed out at the hearing, the fact that competitive price pressure is largely mitigated in the pharmaceutical sector — on account of the importance which prescribers attach to the therapeutic aspects of medicinal products intended for the treatment of the same condition and the regulatory framework governing pricing and the arrangements for the reimbursement of medicinal products by the social security system — is an important factor in the analysis of the relevant market, which may justify a narrow market definition.

1391 The fact that that mitigation results, in part, from the regulatory framework is not capable of changing that finding. Indeed, the fact that the absence or insignificance of competitive constraints is due to the regulatory framework which determines the conditions of the competitive interactions between products and the extent to which those interactions take place does not affect the relevance, in the context of market definition, of the finding that those competitive constraints are non-existent or insignificant. Where it is established that a group of products is not subject to a significant extent to competitive constraints from other products, so that that group may be considered to form a relevant product market, the type or nature of the factors that shield that group of products from any significant competitive constraint is of only limited relevance, since the finding of an absence of such competitive constraints leads to the conclusion that an undertaking in a dominant position on the market thus defined would be able to affect the interests of consumers on that market by preventing, through abusive behaviour, the maintenance of effective competition (see, to that effect, judgment of 1 July 2010, *AstraZeneca* v *Commission*, T-321/05, EU:T:2010:266, paragraphs 97, 174 and 175).

1392 The regulatory framework in the pharmaceutical sector, while often mitigating the competitive constraints by means of prices between substitutable medicinal products, nonetheless has mechanisms which accentuate those constraints, by facilitating the granting of marketing authorisations for generic medicinal products, by allowing the prices of those medicinal products to be set at levels far lower than those of the reference originator medicinal products and by strongly encouraging or even compelling prescribing doctors and pharmacists to substitute the generic version of a medicinal product for the originator medicinal product. It is therefore very easy to identify the competitive constraints on the price and sales of an originator medicinal product resulting from the entry to the market of its generic version. In the present case, for example, it is common ground that the entry of generic perindopril in the United Kingdom led to a fall of the order of 90% in the price of perindopril. However, that substitution, where it is provided for by the legislation, can take place only between the reference originator medicinal product and generic versions of it and cannot apply between different compounds, including where the medicinal products concerned belong to the same therapeutic class and have the same mode of action.

1393 However, while the definition of the relevant market in the pharmaceutical sector must take due account of the relative weakness of price pressure, linked in particular to the regulatory framework, it must also take into account another essential factor in the analysis of competitive interactions, specific to that sector, that is to say the choice of treatment by prescribers, which is primarily determined not by the cost of the available medicinal products, or even in the light of a conventional assessment of the value for money of those medicinal products, but on the basis of prescribers' perceptions of the therapeutic advantages and disadvantages of those medicinal products (see, by analogy, as regards the definition of the relevant market for the purposes of the application of Article 101(1) TFEU, judgment of 23 January 2018, *F. Hoffmann-La Roche and Others*, C-179/16, EU:C:2018:25, paragraph 65).

1394 Medicinal products issued on prescription are not like other products, which are freely traded on a market between sellers and consumers and whose prices are set at the point where supply and demand align, but products which patients access through health professionals such as doctors and pharmacists and for which the financial liability is, in large part, collective. The rules governing the price of medicinal products and the conditions for their reimbursement by the social security system reflect the specific nature of those products, as do the rules limiting their advertising or restricting their sale to pharmacies, under the responsibility of pharmacists.

1395 Doctors' freedom of choice, between the originator medicinal products available on the market or between originator medicinal products and generic versions of other compounds, and the priority focus of prescribers on therapeutic aspects permit, where appropriate, the operation of significant qualitative and non-price competitive constraints in addition to the usual mechanisms of price pressure. Such constraints may also exist where the therapeutic value of a medicinal product is clearly superior to that of other medicinal products available for treatment of the same condition and where the available medicinal products are recognised or perceived as equivalent by prescribers.

1396 Indeed, when a medicinal product proves to be clearly superior to others in therapeutic terms, or even represents the only therapeutic option recommended by the scientific community, it may be chosen by prescribers regardless of its price, even if that price is significantly higher than that of the other available medicinal products. The low level of prices of other medicinal products, which would, in a conventional market, nonetheless constitute a strong competitive constraint, therefore does not have a decisive effect. The price difference between those products is of even less importance since the level of reimbursement reduces the financial burden on the patient of the chosen treatment. As a result, a pharmaceutical company whose medicinal product is no longer recognised or perceived favourably by practitioners and which seeks to lower the price of that product in the hope of maintaining its market shares would have little chance of success. In other words, a medicinal product which is recognised as superior can exert significant competitive pressure on the other medicinal products available for the treatment of the same condition, even though it is more expensive. Thus, in the case which gave rise to the judgment of 1 July 2010, *AstraZeneca* v *Commission* (T-321/05, EU:T:2010:266), it was found by both the Commission and the Court that the therapeutic superiority of proton pump inhibitors (PPIs) to H2 blockers had allowed PPIs to gradually eliminate H2 blockers from the market, despite the much higher price of PPIs. Conversely, medicinal products which are not or are no longer in a position to compete therapeutically with the 'blockbuster' medicinal product can no longer exert competitive pressure on it. Such factors may justify the medicinal product on its own constituting a market, limited to its compound, in both its originator and generic versions.

1397 Where, for the treatment of the same condition, prescribers have a choice between medicinal products of which none is recognised or perceived as superior to the others, in particular because their mode of action is the same or because their therapeutic benefits or their adverse or side effects do not make it possible to distinguish between them, the analysis of the competition between those medicinal products also relies, in large part, on a qualitative comparison. In general, the practitioner's choice depends primarily not on the respective cost of those treatments, but on the degree to which they differ therapeutically, on their suitability to the profile of patients, on the doctor's knowledge of the various medicinal products or even on his personal experience and that of his patients. There is in principle no clear correlation between the price level of a medicinal product and its therapeutic value: a medicinal product is not better because it is more expensive than its competitors and is not inferior to its competitors because of its lower price. The higher price of a more recent medicinal product does not necessarily depend on the therapeutic innovations which that medicinal product offers, especially if it belongs to the same therapeutic class as other medicinal products and has the same mode of action as those products, and may be explained in particular by the amortisation of higher research or manufacturing costs or of promotion costs more significant than those of an older medicinal product.

1398 It is true, as the Commission pointed out at the hearing, that between medicinal products recognised or perceived as fully equivalent, the variable of price may be important. A significant decrease in the price of a medicinal product, in particular through the introduction of its generic version on the market, may justify that medicinal product being favoured by doctors and the prescription of its generic version being encouraged by those managing the social security system and the regulatory authorities. Likewise, the entry of the generic version of another medicinal product recognised or perceived as equivalent or substitutable may weaken the position of the originator medicinal product concerned on the market. Competitive constraint by means of price may then be exerted and maintenance of the price of the medicinal product concerned could be indicative of the weakness of the competitive pressure on that medicinal product.

1399 However, as the applicants rightly argued at the hearing, it cannot be inferred solely from the maintenance of the price of a medicinal product on the market that it is not exposed to significant competitive constraints, exerted by medicinal products perceived or recognised as equivalent or substitutable, in both their originator and generic versions.

1400 Since doctors are able to choose freely between those medicinal products for reasons unrelated to their cost, it is possible for large variations to appear in the frequency of use of those products, in the degree of loyalty to those products that doctors demonstrate and in the perception which doctors have of their benefits at a given moment in their choices of prescription. The decisions taken by doctors are thus able to change considerably the respective market shares of the various medicinal products available and to place pharmaceutical companies in a dependent situation vis-à-vis the choices of prescribers, as with any producer of goods in relation to consumers in a situation where goods are easily substitutable.

1401 That is why the companies manufacturing those medicinal products, which, incidentally, put little emphasis on the price of their product in their commercial strategy, often make significant efforts to promote their product in order to increase prescriber loyalty or attract new prescribers, either by carrying out scientific studies which they finance and which attempt to distinguish their product from those of their competitors, or by direct promotion to prescribing doctors, which takes the most diverse forms. Those promotional activities represent a considerable percentage of the net sales of the products concerned, sometimes close to 30%, which distinguishes the pharmaceutical sector from other sectors in which promotional activities are not as intensive. As the applicants have argued, such efforts may constitute an indication of the existence of a situation of effective competition between the undertakings concerned.

1402 In such a situation, where medicinal products are recognised or perceived as equivalent or substitutable, the market analysis must pay particular attention to the factors making it possible to identify qualitative or non-price competitive constraints, reflected, inter alia, in efforts to make a medicinal product the initial choice of treatment for new prescribers, in switching by continued-use patients to other competing medicinal products and in the intensity of promotional activities carried out for a medicinal product where equivalent or less expensive alternatives exist.

1403 If it is not possible to establish the existence of evidence indicating non-price competitive pressure such as that referred to in paragraph 1402 above, in particular because of a high level of inertia among doctors in their prescription choices, as a result of loyalty effects leading to market foreclosure, the medicinal product concerned may be shielded from effective competitive pressure, as long as its generic version does not enter the market, a fortiori because the regulatory framework mitigates the role of competition factors based on pricing. This may then justify definition of the relevant market at the level of the compound of that medicinal product, in both its originator and generic versions.

1404 It follows from the foregoing that, in the present case, it will be necessary, in response to the arguments of the applicants and the Commission, first, to consider whether there were during the relevant period, as the applicants maintain, any medicinal products recognised or perceived as equivalent to perindopril, and thus easily substitutable for it, or whether the therapeutic merits of perindopril had sufficiently distinguished it from the competition and, secondly, to identify whether there was evidence of non-price competitive pressure exerted on perindopril by other medicinal products, which may justify a broader market definition than that of that single medicinal product, despite the relative price inelasticity of demand for perindopril, as emphasised by the Commission.

1405 It is in the light of all those considerations, set out in paragraphs 1380 to 1404 above, that it is necessary to examine the three main complaints raised by the applicants seeking to challenge the Commission's analysis in the contested decision of the relevant market for the product.

(2) The first part of the first complaint, alleging a failure to take into account the overall economic context

1406 In the first complaint, the applicants argue, in essence, that the Commission infringed the fundamental principle that the definition of the market in pharmaceutical products must take account of the overall economic context. The Commission relied excessively on price, without taking sufficient account of the therapeutic substitutability of the products in question.

1407 More specifically, the applicants criticise the Commission, by the first part of that complaint, for not having taken into account all the elements of the context in defining the market. By the second part of the complaint, the applicants take the view that the Commission attached excessive importance to the price factor.

1408 It is necessary at the outset to examine the merits of the first part of the complaint, alleging that the Commission did not take into account the overall economic context in defining the relevant market. However, in order to be able to assess the relative weight attached by the Commission to the price factor, the Court will examine the second part of the complaint after assessing the legality of the contested decision as regards all the non-price factors capable of playing a role in defining the relevant market.

1409 It is therefore necessary to consider in the present case whether the Commission took into account the overall economic context, in particular factors other than price, in defining the relevant product market.

1410 As a preliminary point, as is apparent from the considerations set out in paragraphs 1380 to 1404 above, the pharmaceutical sector is an 'unusual' sector, the specific features of which require the market to be defined through an approach based on a number of criteria, in particular the therapeutic use of the products.

1411 First of all, as regards taking into account the therapeutic use of the products in question, it should be noted that the Commission found, in recitals 2432 to 2459 of the contested decision, that perindopril belonged to the ACE inhibitor class, listed at the ATC 3 level of the WHO classification. However, on the basis of the evidence on which it relied, the Commission considered that medicinal products belonging to the ACE inhibitor class were not homogeneous products, since perindopril is, in the Commission's view, scientifically recognised as having certain characteristics differentiating it from other ACE inhibitors.

1412 As is apparent in particular from recitals 2496 to 2513 of the contested decision, concerning switching patterns, the Commission also took into account, on the one hand, the existence of a mechanism of doctors' 'inertia' and of a growing group of 'loyal' perindopril prescribers capable of limiting competitive constraints as regards new patients and, on the other hand, the low propensity of patients treated with perindopril to switch medicinal products.

1413 Moreover, the Commission referred, in its analysis of the relevant market, to the promotional activities of Servier, considering inter alia that the stability of the promotional expenditure suggested the absence of exposure to strong competitive pressures.

1414 Finally, in carrying out an analysis of natural events relating to price, the Commission considered that the generic perindopril constraint should be regarded as critical for the analysis of the relevant market and that the fact that the generic constraint outweighed all other potential constraints naturally led to a restriction of the relevant market solely to the perindopril compound (recital 2546 of the contested decision). Moreover, with regard to the impact of the regulatory framework, the Commission noted that the regulatory systems limited to a large extent Servier's exposure to price constraints, thus allowing Servier to act free of competitive pressure (recital 2527 of the contested decision).

1415 Consequently, it is clear from the contested decision that the Commission did not restrict itself solely to the price factor in order to define the relevant market. In particular, the therapeutic use of perindopril was considered a relevant element of the market analysis. Therefore, although, as is clear from the framework for analysis set out in paragraphs 1380 to 1404 above, the applicants are justified in pointing out that the therapeutic characteristics of the medicinal products must be taken into account in order to define the relevant market, they cannot reasonably argue that the Commission did not take into consideration, in the present case, the overall economic context, in particular the therapeutic use of the medicinal products.

1416 The Commission therefore did not make the error of law attributed to it by the applicants in that regard.

1417 The first part of the first complaint must therefore be rejected.

(3) The second complaint, alleging that the Commission failed to take into account the therapeutic substitutability of ACE inhibitors

1418 By their second complaint, the applicants maintain, in essence, that the Commission failed to take into account the therapeutic substitutability between ACE inhibitors. They argue, first, that the Commission wrongly considered that perindopril has particular qualities which differentiated it from other ACE inhibitors; secondly, that there was lively competition between ACE inhibitors with regard to new patients; thirdly, that the Commission underestimated the propensity of patients treated with perindopril to switch medicines and, finally, that promotional activities are one of the key aspects of competition in the relevant market.

(i) The distinction between perindopril and other ACE inhibitors in terms of efficacy and side effects

1419 In the contested decision, in particular in recitals 2449, 2499 and 2519, the Commission considered, in essence, that ACE inhibitors were a class of therapeutically heterogeneous medicinal products, that that heterogeneity could be linked to differences in efficacy and tolerance at the individual level and that perindopril had a therapeutic use which differed from that of other ACE inhibitors. It noted that, although ACE inhibitors formed a class of medicinal products in accordance with the third level of the ATC classification system used by the WHO, it would nevertheless be incorrect to regard ACE inhibitors as a simple homogeneous class. According to the Commission, perindopril was scientifically recognised for certain characteristics that differentiated it from other ACE inhibitors. In support of those considerations, the Commission relied, in particular, on medical guidelines, a range of scientific studies, internal documents from Servier and a survey of perindopril prescribers.

1420 The applicants dispute the Commission's assessment that other ACE inhibitors cannot be substituted therapeutically for perindopril, having regard inter alia to its particular characteristics in terms of efficacy and side effects. They argue that ACE inhibitors form part of a homogeneous class within which there is no significant difference justifying a finding that the perindopril compound, by itself, constitutes a separate market.

1421 It is necessary to examine all the relevant elements making it possible to assess whether perindopril was perceived by prescribing doctors as being such that other ACE inhibitors could be substituted therapeutically for it. In the present case, account will be taken, in turn, of the following: the basic information concerning that medicinal product set out in the contested decision, the ATC classification system, medical guidelines, medical studies, policies implemented by certain local authorities in the United Kingdom, internal documents from Servier, the Commission's survey of prescribers and the responses of producers of other ACE inhibitors to the questions asked by the Commission.

1422 In the first place, the contested decision sets out as a preliminary matter, in recitals 2143 to 2164, basic information concerning perindopril, in particular as regards the mode of action, main indications, contraindications and side effects of that medicinal product.

1423 It should be noted that no factor differentiating between perindopril and other ACE inhibitors is apparent from that description of basic information concerning perindopril.

1424 As regards side effects, the contested decision indeed states, in recital 2149, that according to the medical literature, perindopril is generally well tolerated, with an adverse effect profile similar to that of other ACE inhibitors, and that Servier, in its internal documents, praised its product for its high level of tolerance and compliance. It should nevertheless be pointed out that it is apparent from the actual wording of the medical literature cited by the Commission in recital 2149 of the contested decision that the adverse effect profile of perindopril is similar to that of other ACE inhibitors. In the defence, the Commission now expressly acknowledges that ACE inhibitors have similar side effects, which is not stated in the contested decision.

1425 It follows from the presentation of the basic information relating to perindopril in the contested decision that the mode of action, main indications, contraindications and side effects of the ACE inhibitors are similar.

1426 In the second place, the ATC classification system, which the competition authorities take into account for the purposes of assessing therapeutic substitutability between medicinal products and determining the relevant market, divides pharmaceutical products into five different levels and classifies them according to the organs on which they act and their chemical, pharmacological and therapeutic properties. The third ATC classification level groups pharmaceutical products according to their therapeutic indications, the fourth takes into consideration the mode of action and the fifth defines the narrowest classes, including active substances taken individually.

1427 It is clear from the Commission's decision-making practice in the pharmaceutical sector, concerning market definition, that the analysis generally starts from the third level. However, the other ATC classification levels may also be taken into consideration where it appears that sufficiently strong competitive constraints operate at other levels and that, consequently, the third level does not seem to allow a correct market definition (judgment of 1 July 2010, *AstraZeneca* v *Commission*, T-321/05, EU:T:2010:266, paragraph 154).

1428 In the present case, the Commission did not end its analysis at the third level of the ATC classification, but defined the relevant market at the fifth level of that classification, namely the perindopril compound, the active ingredient of Coversyl. Although the definition of the relevant market at the fifth level of the ATC classification is not open to criticism in itself, it should be noted that all ACE inhibitors, of which there are 16, are grouped together both at the third level of the ATC classification, corresponding to therapeutic indications, and at the fourth level of that classification, corresponding to the mode of action, in the same group called 'ACE inhibitors, plain'.

1429 Thus, the ATC classification system does not permit a distinction of any kind between perindopril and other ACE inhibitors with respect to therapeutic use. It confirms, which is not disputed moreover, that there are no differences between ACE inhibitors in terms of indications and mode of action.

1430 In the third place, as the Commission rightly points out in recital 2172 of the contested decision, the analysis of the relationships between the various antihypertensive medicinal products takes into account the relevant medical guidelines.

1431 Medical guidelines are intended to provide balanced information to practitioners to help them make decisions in everyday practice. Those guidelines are based on all the available sources of scientific evidence, including large clinical trials and their meta-analysis. Such guidelines offer a summary of the medical knowledge that was available during the period under investigation.

1432 In the contested decision, the Commission analysed joint guidelines issued by the WHO and the International Society of Hypertension in 1999, guidelines issued by the European Society of Hypertension and the European Society of Cardiology in 2003 and 2007, guidelines issued by the British Hypertension Society in 1999 and 2004 and guidelines issued by the National Institute for Health and Clinical Excellence (NICE, UK) in 2004 and 2006.

1433 However, the joint guidelines of the WHO and the International Society of Hypertension of 1999 mention, as regards ACE inhibitors, the same primary and secondary indications and the same primary and secondary contraindications. The contested decision does not identify, in those guidelines, any element of differentiation between ACE inhibitors.

1434 The guidelines of the European Society of Hypertension and the European Society of Cardiology of 2003 and 2007, which were approved by national cardiology societies, in particular in France, the Netherlands and Poland, provide an overall analysis of the properties, effects and indications of all ACE inhibitors and contain no recommendations specifically covering any one of the compounds in that class of medicinal products. There is in those guidelines no subdivision between medicines in the ACE inhibitor class, unlike, for example, in the case of medicines in the class of calcium channel blockers and of diuretics. Those guidelines recommend changing the class of medicinal product if a medicine is not effective or not tolerated.

1435 The guidelines of the European Society of Hypertension and the European Society of Cardiology state, it is true, that even different products in the same class of medicinal product differ in relation to the types and frequency of side effects. However, that consideration does not refer specifically to the ACE inhibitor class and is not accompanied by any clarification as to the medicinal products concerned or the nature of the side effects in question. Consequently, a mere reference in the guidelines to a difference in the side effects caused by different products in the same class of medicinal product does not establish the actual existence of a difference between perindopril and the other ACE inhibitors as regards side effects.

1436 Similarly, the Commission states, in recital 2181 of the contested decision, that, according to the guidelines of the European Society of Hypertension and the European Society of Cardiology, the selection of a hypertension medicine needs to be based on the individual patient and that this point is of considerable importance in the assessment of the relevant market. However, the fact that those guidelines state that different individuals may be differently prone to develop a given adverse effect does not suggest that there is a difference between ACE inhibitors as regards side effects. It follows that the European guidelines for the management of hypertension do not contain any information making it possible to differentiate perindopril from other ACE inhibitors in terms of therapeutic use.

1437 The guidelines of the British Hypertension Society of 1999 and 2004 mention the existence of indications, contraindications and side effects, including coughing, which are common to all medicinal products in the ACE inhibitor class. The NICE guidelines of 2004 and 2006 include recommendations on which medicinal products should be prescribed as the first and second line of treatment, but do not, in that respect, make any distinction between ACE inhibitors.

1438 Accordingly, the medical guidelines analysed in the contested decision, which provide balanced information to practitioners based on all the available sources of scientific evidence, including large clinical trials and their meta-analysis, do not distinguish between medicinal products in the ACE inhibitor class. Those guidelines confirm, like the ATC classification, the homogeneity of the ACE inhibitor class in terms of therapeutic use.

1439 In the fourth place, the Commission examined in the contested decision medical studies relating to perindopril: both studies available at the beginning of the period under investigation and studies published in the 2000s.

1440 As regards the medical studies relating to perindopril available in the early 2000s, the contested decision relies on two articles published in 2001.

1441 The first article states, in particular, that perindopril is a well-tolerated ACE inhibitor, which, for patients with mild to moderate hypertension, is significantly better in terms of clinical response than captopril and as effective as other ACE inhibitors. The second article indicates that the ability of perindopril to lower blood pressure is comparable to or better than that of other antihypertensive agents in its therapeutic class and that first-dose hypotension caused by an acute reduction in blood pressure occurs less frequently with perindopril than with other ACE inhibitors, an advantage with certain categories of patients.

1442 The contested decision concludes from this that, as of the date of publication of those articles, there was already an important body of scientific evidence suggesting that perindopril should be regarded as a leading ACE inhibitor. However, it should be noted that, although those 2 articles do indeed consider that perindopril is as effective or better than other therapies in terms of reducing blood pressure, perindopril is claimed to be superior in that regard, in just 1 of the 2 articles, only to 1 of the 16 ACE inhibitors, captopril. Moreover, those articles do not suggest that perindopril offers advantages, in terms of reducing blood pressure, over other ACE inhibitors, in particular the medicinal products which Servier regards as competitors of perindopril, such as ramipril, lisinopril or enalapril.

1443 Furthermore, while the second article states that perindopril offers advantages over other ACE inhibitors as regards first-dose hypotension caused by an acute reduction in blood pressure, it gives no view on the weight to be given to that relative superiority of perindopril and fails to examine the therapeutic benefits which other ACE inhibitors, for their part, have in relation to perindopril.

1444 With regard to the medical studies published in the 2000s, that is to say during the period under investigation, the Commission states, in recital 2208 of the contested decision, that it analysed the major studies involving the use of perindopril which are referred to in Servier's internal strategy documents.

1445 Accordingly, the Progress study (published in 2001), the Europa study (published in 2003), the ASCOT-BPLA study (published in 2005), the Preami and CAFE studies (published in 2006), the Advance study (published in 2007) and the HYVET study (published in 2008) show that there is scientific evidence of perindopril's efficacy, whether or not associated with other medicinal products, in reducing the risk of stroke, preventing risks of major cardiovascular events causing coronary heart disease and reducing progressive left ventricular remodelling.

1446 However, none of the medical studies referred to in paragraph 1445 above compares the efficacy of perindopril to that of other ACE inhibitors or asserts that the relative efficacy of perindopril is superior to that of the other ACE inhibitors. In those circumstances, the studies analysed by the Commission do not suggest that perindopril differs from other ACE inhibitors in terms of efficacy.

1447 Moreover, the contested decision did not analyse all the studies involving the use of perindopril in the 2000s, in particular one which does not appear favourable to that medicinal product. The PEP-CHF study (published in 2006), which aimed to demonstrate the efficacy of perindopril in the treatment of heart failure, was not analysed by the Commission. According to Professor V.'s report, drawn up at the request of Servier and submitted by it as part of its observations in reply to the statement of objections, the results of that study, which were published notwithstanding the interruption of the

study, failed to demonstrate any efficacy of perindopril in heart failure. That medical study puts into perspective the scientific evidence of efficacy existing for perindopril during the period under investigation

1448 Moreover, the contested decision did not analyse the medical studies published in the 2000s involving the use of other ACE inhibitors, even though those studies were included in Servier's internal strategy documents. The Commission did not examine the medical studies relating to ramipril (ASCOT-BPLA, HOPE), enalapril (SOLVD and ANBP2) and trandolapril (TRACE), referred to in recital 2234 of the contested decision. The Cochrane study, to which Servier referred in the context of its observations in reply to the statement of objections and which analyses the relative efficacy of 14 ACE inhibitors in terms of antihypertensive efficacy, is not referred to in the contested decision.

1449 The absence of analysis by the Commission of studies involving the use of other ACE inhibitors prevents, for the sake of completeness, the medical studies presented in the contested decision from being regarded as demonstrating that perindopril is of particular efficacy among the ACE inhibitors.

1450 Of those studies, the HOPE study (published in 2000) was not analysed by the Commission, whereas it is cited on numerous occasions in Servier's internal strategy documents and constitutes, according to Servier's orientation plan, a significant study which allowed ramipril to benefit from a new indication contributing to considerable commercial success and which was used by Sanofi-Aventis in the context of a communication highlighting the ability of ramipril to save lives. Contrary to what the Commission maintains, the content of the HOPE study was not analysed in the contested decision, which merely states, in recital 2493, that the potential interpretation that is given to that study depends to a large degree on the way in which studies are communicated to prescribers as a part of producers' promotional activities, a consideration which does not constitute an analysis of the content of that study.

1451 The Cochrane medical study (published in April 2009) is a meta-analysis which assesses the relative efficacy of ACE inhibitors in reducing blood pressure based on 92 previous studies involving 14 ACE inhibitors. It should be noted that the ability to reduce blood pressure is clearly an essential element in assessing the relative efficacy of ACE inhibitors. The Cochrane study, as the applicants rightly point out, concludes that no ACE inhibitor appears better or worse than the others in terms of antihypertensive efficacy. Although the Cochrane study was published at the end of the period under investigation, it is nevertheless relevant for assessing the relative efficacy of ACE inhibitors, in so far as it is based on a large number of previous studies, including those which were not analysed by the Commission in the contested decision.

1452 The Commission argues that the conclusion of the Cochrane study is that it is not possible to rule out that there may be a difference between one or more of the medicinal products concerned with regard to their ability to lower blood pressure and that, for the purpose of analysing whether or not such differences exist between the various medicinal products, comparative trials of the various ACE inhibitors at equivalent doses for lowering blood pressure are necessary. That argument must be rejected, since the study's consideration of the existence of uncertainty as to the differences in the ability of ACE inhibitors to lower blood pressure is included in the 'Discussion' section of the study and is not one of its conclusions. The relevant paragraph of the 'Discussion' section of the study concludes with the observation that it is very likely that the near-maximal effect on blood pressure reduction of the various ACE inhibitors is the same.

1453 The Commission also states that the Cochrane study could not properly analyse, on the basis of the data available to its authors, the issue of side effects. However, that fact is, in any event, irrelevant to the conclusion of the study concerning the absence of a significant difference between the ACE inhibitors in terms of reducing blood pressure. Moreover, with regard to the Commission's argument that the study highlights differences between ACE inhibitors as regards dose-response relationship, the availability of the various dosages and the time to take effect, it should be pointed out that the study

does not indicate the existence of significant therapeutic differences between ACE inhibitors and concludes instead that prescribing the cheapest ACE inhibitor at the lowest dosage will result in substantial savings.

1454 Accordingly, the Commission's arguments cannot call into question one of the main conclusions of the Cochrane study, explicitly stated in its conclusions and summary, that no ACE inhibitor appears better or worse than the others in terms of antihypertensive efficacy.

1455 The lack of differentiation of perindopril with respect to other ACE inhibitors, in particular in terms of efficacy, is confirmed by Professor V.'s report, drawn up at the request of Servier, which is not contested by the Commission. That report, which examines the results of medical studies involving the use of perindopril as well as the results of medical studies from the 1980s, 1990s and 2000s involving the use of other ACE inhibitors, including the SAVE study on captopril, the AIRE and HOPE studies on ramipril and the Consensus and SOLVD studies on enalapril, states that, with the exception of captopril and, to a far lesser extent, enalapril, all ACE inhibitors are compatible with single daily administration for the two main indications of that class, namely high blood pressure and heart failure. The report points out, like the Cochrane study, that the medical studies do not reveal any difference in the antihypertensive efficacy of the various ACE inhibitors. It states that, in the context of heart failure, the beneficial effects of that therapeutic class are, according to the available studies for captopril, enalapril, ramipril, quinapril and lisinopril, shared by all ACE inhibitors. Although there is evidence of the efficacy of perindopril in cardiovascular disease prevention, there is no such evidence in the context of heart failure.

1456 Professor V.'s report concludes that, for each of the five therapeutic classes used in the treatment of high blood pressure, in particular the ACE inhibitors, the therapeutic effects are attributable to class effects and not to the individual properties of the prescribed compounds. Ramipril is, according to that report, the second-generation ACE inhibitor for which it is possible to obtain the most evidence-based data derived from randomised clinical trials and which has become, on the basis of its excellent pharmacological profile and the high quality of the evidence supporting it, especially in the context of heart failure, the undisputed leader in the antihypertensive medicinal product market. Perindopril is, according to that report, an ACE inhibitor like any other, which is neither the most powerful one nor the one with the best pharmacological profile. For perindopril, evidence-based data can be found in the context of cardiovascular disease prevention, although the results obtained do not necessarily indicate that the observed effect is attributable to perindopril. On the other hand, evidence-based data is not available in the areas of heart failure and diabetic nephropathy.

1457 It follows from the foregoing that the published medical studies do not establish that perindopril differs therapeutically from the other ACE inhibitors, particularly in terms of efficacy. The analysis of the medical studies shows, moreover, that, although evidence of the efficacy of perindopril is available, that is also true of other ACE inhibitors, such as enalapril, lisinopril or ramipril, and there is, incidentally, more evidence of the efficacy of the latter in heart failure.

1458 In the fifth place, the applicants claim that the policies implemented by local health authorities in the United Kingdom support the fact that it is possible to substitute perindopril for other ACE inhibitors from the therapeutic point of view. They provide, in support of their arguments, several annexes relating to the policy implemented by Primary Care Trusts (PCTs).

1459 In that regard, the Commission contends, first, that Annex C 29, relating to the PCTs for Scotland and Northern Ireland and presented by the applicants, must be rejected as inadmissible and, secondly, that the applicants' use of Annexes A 286, A 287 and C 29 as a whole, relating to the policies implemented by the local authorities of the United Kingdom, is contrary to Article 21 of the Statute of the Court of Justice of the European Union and Article 76 of the Rules of Procedure of the General Court.

1460 Pursuant to Article 85(2) of the Rules of Procedure, the main parties may produce or offer further evidence in the reply and the rejoinder in support of their arguments, provided that the delay in the submission of such evidence is justified. However, according to the case-law, evidence in rebuttal and the amplification of the offers of evidence submitted in response to evidence in rebuttal from the opposite party in the defence are not covered by the time-bar laid down by that provision. That provision concerns offers of fresh evidence and must be read in the light of Article 92(7) of those rules, which expressly provides that evidence may be submitted in rebuttal and previous evidence may be amplified (judgments of 17 December 1998, *Baustahlgewebe* v *Commission*, C-185/95 P, EU:C:1998:608, paragraphs 71 and 72, and of 5 December 2006, *Westfalen Gassen Nederland* v *Commission*, T-303/02, EU:T:2006:374, paragraph 189).

1461 In the present case, the evidence relating to the PCTs of Scotland and Northern Ireland submitted by the applicants in Annex C 29 cannot be declared inadmissible on the ground that it was produced in the reply in breach of Article 85(2) of the Rules of Procedure. As the applicants state in paragraph 417 of the reply, the evidence set out in Annex C 29 responds to the criticism in the Commission's defence concerning the individual nature and purely theoretical impact of the policies implemented by the PCTs. Consequently, the time-bar rule in Article 85(2) of the Rules of Procedure does not apply to it, so that the evidence in question is admissible.

1462 Turning next to the use of Annexes A 286 and A 287, attached to the application lodged on 21 September 2014 and relating to the guidelines and policies implemented by the local authorities in the United Kingdom, it must be noted that their use is consistent with Article 21 of the Statute of the Court of Justice of the European Union and Article 44(1) of the Rules of Procedure of the General Court of 2 May 1991, then applicable. Similarly, the use of Annex C 29, attached to the reply lodged on 29 July 2015 and relating to the documents from the PCTs of Scotland and Northern Ireland, is consistent with Article 21 of the Statute of the Court of Justice of the European Union and Article 76 of the Rules of Procedure of the General Court. According to consistent case-law it is necessary, for an action to be admissible, that the basic matters of law and fact relied on be indicated, at least in summary form, coherently and intelligibly in the application itself. That interpretation of Article 21 of the Statute of the Court of Justice of the European Union and Article 44(1) of the Rules of Procedure of the General Court of 2 May 1991 also applies to the conditions for admissibility of a reply, which is intended to supplement the application (judgment of 17 September 2007, *Microsoft* v *Commission*, T-201/04, EU:T:2007:289, paragraphs 94 and 95 and the case-law cited). In the present case, even though Annexes A 286, A 287 and C 29 are large and contain a succession of documents, the applicants set out in the body of the application, and then in the reply, the arguments of fact and law on which they rely. The applicants support, through the production of those annexes containing documents from the PCTs of the United Kingdom, including Scotland and Northern Ireland, their arguments seeking to show, first, that the PCTs have taken views on the therapeutic equivalence between perindopril and other ACE inhibitors and have encouraged general practitioners to replace perindopril with other ACE inhibitors and, secondly, that those policies, which are not individual in nature, have had a real impact on local demand.

1463 The Commission therefore has no basis for maintaining that Annexes A 286, A 287 and C 29, produced by the applicants, must be excluded from the proceedings.

1464 Moreover, it is apparent from the documents in the file, in particular from recital 2280 of the contested decision, that certain PCTs expressly considered, as from 2005, that perindopril was no more effective than any other ACE inhibitor and recommended, for cost reasons, the use of ACE inhibitors other than perindopril, or even the substitution of another ACE inhibitor for perindopril, in particular lisinopril or ramipril. The Commission is wrong to argue that the documents relating to the PCTs produced by the applicants contain individual considerations and opinions. Indeed, those policies implemented by competent authorities, which were also drawn up by a non-negligible number of PCTs located in several regions of the United Kingdom, cannot be regarded as mere expressions of

individual opinions. Regardless of the actual effects of the initiatives of the PCTs, the assessment of those entities concerning the possibility of substituting other ACE inhibitors for perindopril tends to contradict the Commission's analysis of the heterogeneity of the ACE inhibitor class.

1465 Consequently, the policies implemented by local health authorities in the United Kingdom support the fact that perindopril is indistinguishable from other ACE inhibitors from a therapeutic point of view.

1466 In the sixth place, the Commission wrongly relied on Servier's internal documents to establish that perindopril had particular therapeutic qualities as compared with the other ACE inhibitors.

1467 As a preliminary point, it should be recalled that, according to the generally applicable rules on evidence, the reliability and, therefore, the probative value of a document depends on its origin, the circumstances in which it was drawn up, the person to whom it is addressed and the reputed and reliable nature of its content (see, to that effect, judgments of 24 October 1991, *Atochem* v *Commission*, T-3/89, EU:T:1991:58, paragraphs 31 to 38, and of 11 March 1999, *Ensidesa* v *Commission*, T-157/94, EU:T:1999:54, paragraph 312; Opinion of Judge Vesterdorf, acting as Advocate General in *Rhône-Poulenc* v *Commission*, T-1/89, EU:T:1991:38).

1468 In the present case, Servier's internal documents, in so far as they contain assessments of the therapeutic use of ACE inhibitors intended for the promotion of perindopril, do not constitute, unlike the medical guidelines, a balanced summary of scientific knowledge. Unlike the medical studies, they are not based on a methodology designed to ensure the reliability of the results obtained. Extracts from those internal documents must therefore be analysed taking into account the fact that they have, in some cases, a promotional purpose.

1469 Thus, it is clear from the internal strategy documents that Servier presented the characteristics of perindopril favourably in the context of promotional messages intended for doctors. The documents summarising Servier's promotional activities emphasise the positive results of perindopril and even refer, based on medical studies, to a unique mode of action, the possibility of differentiating perindopril from its competitors in a positive way, or even the superiority of perindopril to other ACE inhibitors with respect to such matters as the trough-to-peak ratio, efficacy in reducing blood pressure, synergy in combination with a diuretic or cardiovascular protection.

1470 However, as stated above, the content of those messages must be analysed in the light of their promotional purpose. In that regard, it should be noted, first of all, that the Commission does not dispute the applicants' assertion that all the ACE inhibitors were presented in their respective promotional messages as being the best. Moreover, Servier's internal strategy documents, as well as the orientation plans, launch plans and promotional messages for the other ACE inhibitors in the file, show that the promotional campaigns for other ACE inhibitors, such as those for ramipril, lisinopril or trandolapril, are also very laudatory in presenting the therapeutic characteristics of those medicinal products. The promotional campaigns for other ACE inhibitors frequently describe their medicinal product as a leading product and a unique medicinal product among the ACE inhibitors and describe it as a reference product or a better choice. Those communication campaigns highlight the alleged benefits of the medicinal product in question within the ACE inhibitor class in terms of indications, efficacy or tolerance. They sometimes include direct comparisons with perindopril and, in some cases, claim that the medicinal product is superior to perindopril. In those circumstances, the content of the messages seeking to promote perindopril in Servier's internal strategy documents does not support the conclusion that that medicinal product differs from the other ACE inhibitors in therapeutic terms.

1471 Moreover, Servier's internal strategy documents, taken as a whole, do not show the therapeutic superiority of perindopril over other ACE inhibitors. Those documents show that other ACE inhibitors, such as ramipril, lisinopril and enalapril, have strengths in terms of evidence of indications

and efficacy, thanks to studies such as TRACE, AIRE or HOPE. In particular, ramipril is mentioned as a medicinal product for which there is evidence of efficacy in heart failure, for patients at high cardiovascular risk and for diabetic patients.

1472 Finally, the Commission states, inter alia in recitals 2224 to 2236 of the contested decision, that, according to Servier's internal documents, the purpose of the promotional campaigns was in particular to differentiate perindopril from other ACE inhibitors. However, it is clear from those documents that communication campaigns have not been sufficient, from the point of view of doctors, to allow perindopril to be differentiated from other ACE inhibitors. Those documents refer, for example, to a qualitative study conducted in July 2007 among general practitioners and cardiologists, among whom perindopril and ramipril were perceived as similar. The 2009-2010 orientation plan highlights, at the end of the period under investigation, the lack of differentiation with respect to ramipril. With regard to the Netherlands, the 2006-2007, 2007-2008 and 2008-2009 orientation plans indicate that many general practitioners considered lisinopril as equivalent to perindopril.

1473 Therefore, Servier's internal documents do not demonstrate that perindopril was recognised for particular therapeutic qualities that differentiated it from other ACE inhibitors. While the undertaking attempted, like other undertakings marketing ACE inhibitors, to promote and differentiate perindopril in a positive way by means of laudatory communications, that strategy was, according to those documents, incapable of sufficiently differentiating perindopril from other ACE inhibitors.

1474 In the seventh place, the Commission based its assessment of the therapeutic substitutability of perindopril on a survey of prescribers.

1475 In order to determine the recipients of the questionnaires, the Commission relied on a list of perindopril prescribers — supplied by Servier — which was to include, in particular, all the cardiologists and general practitioners with whom Servier had professional and commercial relationships. While some of those lists contained almost all prescribers, that is not the case with the list of general practitioners from France and from the United Kingdom. In those circumstances, there is, as Servier argues, a selection bias relating to those two categories of recipients. It is clear that that bias may have had an effect on the results of the survey for those two categories, in so far as it is possible that doctors having professional relationships with Servier favoured, more than other prescribers not in that situation, the prescription of perindopril in their professional practice.

1476 Moreover, the presentation of some survey results does not correspond to the questions put to the prescribing doctors. Thus, in recital 2392 of the contested decision, the Commission presented the percentage of respondents for whom perindopril was a preferred first- or second-line treatment for essential (primary) hypertension, for chronic ischemic heart disease and for heart failure. However, the applicants point out, without being challenged, that the survey itself does not mention any 'preferred' treatment, but asks for which cardiovascular conditions perindopril is prescribed as a 'first-/second-line treatment in preference to other treatments'. A positive answer to that question does not imply that perindopril is prescribed in preference to other ACE inhibitors and does not indicate the extent to which perindopril is prescribed as a first-line treatment for high blood pressure. Similarly, a positive response to the questions concerning the specific efficacy of perindopril in certain categories of patients and its rarer side effects in certain categories of patients does not necessarily imply, given the wording of the questions, that perindopril differed from other ACE inhibitors, according to the prescribing doctor.

1477 Furthermore, the results of that survey show that, according to 51% of responding prescribers, there was an equivalent medicinal product for 81 to 100% of patients who started treatment with perindopril. It follows that, for a majority of the doctors surveyed, it was possible from a therapeutic point of view to substitute another medicinal product for perindopril for the majority of patients who started treatment. The Commission also acknowledges, in recital 2454 of the contested decision, that a

majority of the responding prescribers considered other medicines as equivalent alternative therapies to perindopril. The Commission also states that the alternative most often used by practitioners is ramipril in France, Poland and the United Kingdom and enalapril and lisinopril in the Netherlands.

1478 It follows from the foregoing that the Commission's survey does not support the argument that perindopril differs from other ACE inhibitors.

1479 In the eighth place, it is clear from the replies to the questions put by the Commission to the producers of other ACE inhibitors, analysed in recital 2255 et seq. of the contested decision, that AstraZeneca, a producer of lisinopril, regarded perindopril as being among five other ACE inhibitors which were substitutes for its lisinopril until the expiry date of its patent. Similarly, Merck Sharp & Dohme (MSD), which produces enalapril and lisinopril, stated that Servier is one of the undertakings competing with it in the field of hypertension and that its product, perindopril, is one of the treatments which may be used as an alternative treatment for its antihypertensive treatments. Moreover, although Sanofi-Aventis takes the view, as the Commission stated in the contested decision, that perindopril and ramipril should not be regarded as 'substitute to each another', it does so on account, on the one hand, of the significantly larger population likely to benefit from ramipril given its broader indications for use in reducing cardiovascular mortality and, on the other hand, of the wider range of starting doses for ramipril. Although those elements, if proved, are likely to limit the possibilities of substituting perindopril for ramipril, they are not, in any event, such as to limit the possibilities of substituting ramipril for perindopril. They therefore do not prevent ramipril from being regarded as a product that is therapeutically substitutable for perindopril.

1480 It follows from the foregoing that the responses from the originator producers to the questions put by the Commission tend to confirm that the other ACE inhibitors may be therapeutically substituted for perindopril.

1481 In the light of all the documents in the file, it must be concluded that there is no significant difference between perindopril and the other ACE inhibitors in therapeutic terms, including in terms of efficacy and side effects. There is in the file no objective scientific evidence of the therapeutic superiority of perindopril over other ACE inhibitors. ACE inhibitors are widely perceived as substitutable by prescribers and there are numerous medicinal products regarded by doctors as therapeutic equivalents to perindopril. Accordingly, the Commission erred in considering that the ACE inhibitor class was heterogeneous and that perindopril exhibited particular therapeutic characteristics within that class of medicinal products.

1482 It is therefore appropriate to uphold the applicants' argument that the Commission erred in the analysis of the therapeutic substitutability of ACE inhibitors.

(ii) The phenomenon of doctors' 'inertia' with respect to new patients

1483 It is apparent from recitals 2388, 2511 et seq. and 2539 et seq. of the contested decision that the Commission regarded perindopril as an 'experience good' subject to limited competitive pressure with respect to new patients because of a well-known phenomenon of doctors' 'inertia'. Indeed, even if doctors have access to several therapies, they naturally tend to prescribe to new patients medicinal products which have proven effective in the past.

1484 According to the Commission, perindopril had, even before the period under investigation, built up a large base of continued-use patients. The phenomenon of doctors' 'inertia', which restricts substitutability between available therapies, is a mechanism which allowed the consolidation of perindopril's customer base. The existence of a growing group of loyal prescribers among doctors explains the continued growth of perindopril's patient base.

1485 The applicants dispute that assessment by the Commission, arguing, in essence, that there was strong competition between ACE inhibitor producers for new patients and that there was no significant doctors' 'inertia', but merely a lack of price-sensitivity among prescribers.

1486 As a preliminary point, it should be pointed out that the phenomenon of doctors' 'inertia', which the Commission defines as the 'natural' tendency to prescribe to new patients medicinal products which have proven to be successful for their previous patients, is, as the Commission itself notes in recital 2540 of the contested decision, a factor which may differ over time and depends on the type of pathology. This is an empirical question which requires due consideration on a case-by-case basis.

1487 As the General Court held in the case which gave rise to the judgment of 1 July 2010, *AstraZeneca* v *Commission* (T-321/05, EU:T:2010:266), the 'inertia' characterising prescribing practices may, in particular, stem from the caution that normally characterises doctors' attitudes towards a new product with whose properties they are not yet very familiar and, more specifically, from their significant concerns as to the possible side effects of that product, for example possible carcinogenic effects (see to that effect, judgment of 1 July 2010, *AstraZeneca* v *Commission*, T-321/05, EU:T:2010:266, paragraphs 91, 92 and 98).

1488 In the circumstances of the present case, it is therefore appropriate to assess the extent to which a phenomenon of doctors' 'inertia' was able to restrict substitutability between the available therapies and explain the changes in perindopril's patient base, described as continuous growth by the Commission.

1489 In the first place, it is not apparent from the documents in the file, as previously stated, that ACE inhibitors were therapeutically heterogeneous. On the contrary, there is no significant therapeutic difference between perindopril and the other ACE inhibitors, including in terms of efficacy and side effects. In the absence of heterogeneity of the ACE inhibitor class, there was consequently no factor that limited the leeway available to doctors to prescribe ACE inhibitors other than perindopril. The documents in the file do not suggest, in particular, that the other ACE inhibitors gave rise to any particular concerns as to their possible side effects. In those circumstances, there are in the present case no particular concerns regarding the therapeutic use or possible side effects of ACE inhibitors which might have given rise to a high degree of 'inertia' of doctors who had already had occasion to prescribe perindopril, when those doctors were choosing to prescribe any one of the ACE inhibitors for new patients.

1490 It should be emphasised that the situation of perindopril in relation to other ACE inhibitors is distinct from the situation of PPIs in relation to H2 blockers in the case giving rise to the judgment of 1 July 2010, *AstraZeneca* v *Commission* (T-321/05, EU:T:2010:266). In that case, PPIs and H2 blockers were used differently, since PPIs were essentially prescribed to treat the severe forms of gastrointestinal acid-related conditions and H2 blockers were prescribed to treat the less severe, or mild, forms of those conditions (see, to that effect, judgment of 1 July 2010, *AstraZeneca* v *Commission*, T-321/05, EU:T:2010:266, paragraph 72). H2 blockers could not exert a significant competitive constraint on PPIs, especially given the importance accorded by doctors and patients to the therapeutic superiority of PPIs (see, to that effect, judgment of 6 December 2012, *AstraZeneca* v *Commission*, C-457/10 P, EU:C:2012:770, paragraph 58). In the present case, there is no evidence of any therapeutic superiority of perindopril to the other ACE inhibitors capable of preventing the ACE inhibitors from exerting significant competitive pressure on perindopril with respect to new patients.

1491 Moreover, perindopril was launched after several other ACE inhibitors, notably after lisinopril and enalapril on the markets of France, the Netherlands and the United Kingdom, and after enalapril on the Polish market. Perindopril was therefore not likely to benefit, by comparison with the ACE inhibitors placed on the market before it, from a phenomenon of 'inertia' linked to the caution normally characterising doctors' attitudes towards a new product with whose properties they are not very familiar.

1492 Thus, it is not apparent from the documents in the file that perindopril could benefit, by comparison with other ACE inhibitors, from a particular degree of 'inertia' in doctors' prescribing practices in the light of the therapeutic properties of ACE inhibitors and the date on which that medicinal product was placed on the market.

1493 In the second place, the ground of the contested decision according to which perindopril had already built up, prior to the period under investigation, a large base of continued-use patients must be significantly qualified.

1494 It is apparent from the documents in the file that, in January 2000, perindopril had, in all the countries concerned, a much smaller patient base than other ACE inhibitors such as ramipril, enalapril or lisinopril. In terms of sales of tablets and capsules, perindopril ranked fourth in the United Kingdom, behind lisinopril, enalapril and ramipril, with sales volumes more than three times lower than those of lisinopril; third in the Netherlands, behind enalapril and lisinopril, with sales volumes more than 10 times lower than those of enalapril; second in France, behind ramipril, and second in Poland, behind Enalapril, with sales volumes nearly six times lower than those of enalapril.

1495 In those circumstances, assuming that there exists a mechanism of 'inertia' in doctors' prescribing practices, such a phenomenon was not likely to be of particular benefit to perindopril in the light of the relative size of its continued-use patient base as compared with that of other ACE inhibitors with a stronger position in terms of sales volumes.

1496 In the third place, the finding by the contested decision of the continued growth of perindopril's patient base and, more generally, the finding of the commercial success of perindopril must also be qualified in the light of the situation of other ACE inhibitors.

1497 It is apparent from the documents in the file that, among the ACE inhibitors, perindopril was not the most successful medicinal product in the ACE inhibitor class during in the relevant period. Although the contested decision states, in recital 2129, that worldwide sales of products containing Servier's perindopril reached over EUR 800 million in the peak year, there is in that decision no indication of the order of magnitude of the worldwide turnover achieved by the other ACE inhibitor producers. In that regard, the applicants stated at the hearing, without being challenged, that, at the material time, perindopril was ranked as the 143rd bestselling compound in the world, whereas, for example, Sanofi-Aventis' ramipril was ranked 72nd in the world. Present on some national markets, perindopril is almost absent from markets as significant as the German market, on which perindopril, at the material time, accounted for less than 1% of sales of medicinal products in the ACE inhibitor class. Ramipril was, as the applicants maintain, the world leader in the ACE inhibitor class of medicines during the period in question.

1498 On the four national geographic markets chosen by the Commission, it is apparent from the documents in the file that Servier's perindopril, despite the growth in its sales, was never in a leading position among the ACE inhibitors in terms of sales of tablets and capsules, during the period of the practices referred to in the contested decision. According to the sales data for tablets and capsules in the contested decision, perindopril was in third position in the Netherlands (in November 2007) and in the United Kingdom (in June 2007), in second position in France (in August 2008) and in Poland (in May 2006), with, on each national market except France, sales volumes very far below those of the leader.

1499 In terms of growth, while perindopril sales increased on the four national markets taken as a whole during the period in question, the same is true of other ACE inhibitors, such as ramipril and lisinopril. In the light of the sales data for tablets and capsules in the contested decision, it must be concluded that the growth in lisinopril sales was sustained in the 2000s, while the growth of ramipril sales was clearly higher than the growth of perindopril sales over that period.

1500 Given the changes in the sales of the other ACE inhibitors, the significance of the phenomenon of continuous growth in perindopril sales referred to in the contested decision must be placed in context.

1501 In the fourth place, the significant fluctuations in the relative sales of ACE inhibitors during the 2000s tend to call into question the existence of a high degree of 'inertia' in doctors' ACE inhibitor prescribing practices.

1502 First of all, according to the CRA's report, commissioned by Servier and dated January 2013, the relative sales of ACE inhibitors were subject to significant fluctuations between 2001 and 2010, since the respective positions of the medicinal products changed in contrasting ways. For example, between 2001 and 2010, the share of perindopril sales in total ACE inhibitor sales, expressed in defined daily doses, increased little in the United Kingdom (remaining between 5 and 10%), while the share of ramipril sales almost doubled (from between 30 and 40% to between 60 and 70%) and the share of lisinopril sales declined sharply. In Poland, during the same period, perindopril saw its share of sales fall sharply (from a share of between 15 and 20% to a share between 10 and 15%), while that of ramipril grew considerably (from a share of between 0 and 5% to a share of between 60 and 70%). In the Netherlands, perindopril and ramipril made little progress, with the share of sales of each of those two medicinal products reaching between 10 and 20% in 2010, while enalapril still accounted for between 40 and 50% of the share of sales at that date. In France, lisinopril declined sharply (from a share of sales of between 30 and 40% in 2001 to a share of between 5 and 10% in 2010), while the share of sales of perindopril increased substantially (from a share of between 10 and 15% to a share of between 20 and 30%), though less significantly than that of ramipril (increasing from a share of between 20 and 30% to a share of between 50 and 60%).

1503 The Commission argues that the calculation of the share of sales of each ACE inhibitor in the total sales of that class of medicinal products is incorrect, in so far as that calculation is based on sales expressed in defined daily doses, which overestimates the growth in sales of other ACE inhibitors, including ramipril.

1504 In that regard, it should be noted that the Commission itself primarily analysed the sales volumes of the ACE inhibitors using defined daily doses and cannot therefore, in principle, consider that such a calculation is irrelevant for analysing the change over time of sales of ACE inhibitors, unless it is calling into question its own analysis. Moreover, the Commission does not provide any alternative analysis of the change in the relative sales of the various ACE inhibitors based on more reliable data. Furthermore, while the Commission states that that method of calculation leads to an inflation of the value of ramipril sales by a factor of two or more, it does not put forward any explanation in support of the argument that that method of calculation also results in an overestimate of the share of sales of ACE inhibitors other than ramipril. Finally, in any event, it is apparent from the limited sales data for ACE inhibitors expressed in terms of tablets and capsules contained in the contested decision that, in each of the countries examined by the contested decision, significant changes, the existence of which is also not disputed by the Commission, took place in the respective positions of the various ACE inhibitors between January 2000 and the years 2006 to 2008.

1505 In addition, the Commission states, on the one hand, that the comparison between the market shares of ACE inhibitors is based on the premiss of a market comprising all the ACE inhibitors whereas the market definition is specifically intended to define the relevant market and, on the other hand, that the analysis does not make it possible directly to assert that the increase in sales of ramipril occurred at the expense of sales of perindopril.

1506 Nevertheless, while it is true that the calculation of the perindopril market shares requires the prior definition of the market and that, consequently, the concept of market shares of the various ACE inhibitors cannot be accepted in the present case, the analysis of the change in the relative sales of the ACE inhibitors, which does not, for its part, presuppose the existence of an ACE inhibitor market, is not irrelevant for the purposes of defining the relevant market.

1507 Moreover, the applicants do not claim that changes in the relative sales of the ACE inhibitors make it possible directly to assert that perindopril is subject to competitive pressure from other ACE inhibitors. They argue that changes in the relative sales of ACE inhibitors within a single country do not support the existence of a high degree of doctors' 'inertia' in ACE inhibitor prescribing practices. In that regard, the Commission does not put forward any explanation as to the compatibility between the doctors' 'inertia' mechanism, which it emphasises in the contested decision, and the fluctuations over time in the relative sales of the ACE inhibitors. In those circumstances, it must be held, as the applicants rightly argue, that the significant changes in the relative sales of ACE inhibitors during the period under investigation tend to call into question the importance of the alleged mechanism of doctors' 'inertia' in their ACE inhibitor prescribing practices.

1508 In the fifth place, the documents in the file — in particular the Thalès study, commissioned by Servier as part of its strategic planning, the Commission's survey of prescribers and the answers of the ACE inhibitor producers to the Commission's questions — do not establish the existence of a significant degree of 'inertia' in the behaviour of doctors in their perindopril prescribing practices.

1509 The Thalès study, conducted from December 2003 to February 2004, focuses on changes in French general practitioners' perindopril prescribing practices. That study places perindopril prescribers into 3 categories: 'big prescribers' with over 10 prescriptions per trimester, 'medium prescribers' with 6 to 10 prescriptions per trimester and 'small prescribers' with 1 to 5 prescriptions per trimester. The study analyses changes in the categorisation of prescribers between the period from April to June 2003 (T 0) and the period from December 2003 to February 2004 (T 2). The Commission notes, in support of its proof of the existence of a growing group of 'loyal' perindopril prescribers, that 80 to 90% of 'big prescribers', 50 to 60% of 'medium prescribers' and 60 to 70% of 'small prescribers' in T 0 still belong to the same category in T 2.

1510 However, those changes do not demonstrate a high degree of doctors' 'inertia' in the prescription of perindopril, since, on the one hand, they were observed over a limited time period of 8 to 10 months and, on the other hand, the proportion of doctors who changed category over that limited time period is significant. It should be pointed out, moreover, that the Thalès study relied upon by the Commission classifies general practitioners into one of four groups of doctors, 'loyal', 'lapsed', 'new customer' or 'occasional', on the basis of the changes in their prescribing habits between period T 0 and period T 2. The study indicates that the proportions of 'loyal', 'lapsed', 'new customer' or 'occasional' general practitioners are, respectively, 30 to 40%, 5 to 10%, 10 to 15% and 40 to 50% of all general practitioners. It is thus clear from the results of the Thalès study that the proportion of 'loyal' general practitioners is a minority and less than the proportion of 'occasional' general practitioners. The results of the Thalès study, limited solely to French general practitioners, therefore establish neither the significance of the mechanism of doctors' 'inertia' as regards the prescription of perindopril nor the high proportion of prescribing doctors 'loyal' to perindopril.

1511 Furthermore, the Commission does not dispute the applicants' assertion that 52% of the doctors interviewed in the Commission's survey of prescribers of perindopril responded that they prescribed more alternative medicinal products than they did perindopril. However, the fact that a majority of doctors prescribe more medicinal products which are alternatives to perindopril than they do perindopril also tends to call into question the existence of a mechanism of 'inertia' which might particularly benefit perindopril.

1512 Finally, it follows from the responses of the three ACE inhibitor producers surveyed by the Commission that those ACE inhibitor producers consider perindopril as a competitor of their own medicinal product. In particular, Sanofi-Aventis, in its response to the Commission, expressly states that perindopril is its largest competitor in the Netherlands, in Poland and, as from 2001, in France, and its second largest competitor in the United Kingdom. There is no evidence in the responses of the originator producers of ACE inhibitors surveyed that the competitive pressure between ACE inhibitors was limited by a significant phenomenon of doctors' 'inertia' with respect to new patients.

1513 In the light of the foregoing, it must be concluded that the Commission has not established that a phenomenon of doctors' 'inertia' and the existence of a growing group of 'loyal' perindopril prescribers had significantly restricted the competitive pressure exerted on perindopril by other ACE inhibitors with respect to new patients.

(iii) The propensity of continued-use patients to switch

1514 The Commission considered, in particular in recitals 2496 to 2510 of the contested decision, that continued-use patients treated with perindopril were unlikely to switch to alternative medicines once they had settled on the use of perindopril. Due to the nature of perindopril as an 'experience good', Servier enjoyed an information advantage in the sense that the continued-use perindopril patients knew more about that product than about other treatments that had not yet been tried.

1515 On account of the heterogeneity between the medicinal products in the ACE inhibitor class, which may be linked to differences in efficacy and tolerance at the individual level, therapy switching between medicinal products in the same therapeutic class would, according to the Commission, have to be regarded as unlikely to occur. Indeed, such therapy switching could be associated with costs resulting from additional medical consultations and potentially very serious risks relating to the onset of side effects and sub-optimal control of blood pressure.

1516 The improbability of treatment switching among continued-use patients receiving a treatment which meets their needs is supported, according to the Commission, by a series of longitudinal studies, the results of the prescriber survey and Sanofi-Aventis' response to the Commission's questionnaire to the effect that switching between ramipril and perindopril was very limited. The Commission argues that the average duration of perindopril treatment may be estimated at seven to eight years and that the 90% 'loyalty' rate measured by repeat prescriptions for perindopril confirms the lock-in effects of perindopril's patient base.

1517 The applicants, bringing to the attention of the Court a number of items of evidence, argue that the Commission underestimated the propensity of continued-use patients to switch.

1518 In the first place, it should be noted that the Commission's analysis of the switching patterns of continued-use patients is based on the heterogeneity of medicinal products belonging to the ACE inhibitor class. It is clear from the grounds of the contested decision, in particular recitals 2496 and 2499, that the Commission relied on the heterogeneity of the ACE inhibitor class in its analysis of the patterns of switching between perindopril and other antihypertensive medicinal products. It is in the light of the alleged heterogeneity of medicinal products in the ACE inhibitor class that the Commission considered that therapy switching between medicinal products in the same therapeutic class could be associated with potentially very serious risks accompanying the treatment switch.

1519 However, as has been stated previously, the Commission has not demonstrated the heterogeneity of the medicinal products belonging to the ACE inhibitor class. On the contrary, there is no significant therapeutic difference between perindopril and the other ACE inhibitors, including in terms of efficacy and side effects. In particular, it is not apparent from the documents in the file that the other ACE inhibitors raised, on the part of prescribers, particular concerns relating to their side effects or

reduced efficacy. It follows that, since doctors did not regard ACE inhibitors as heterogeneous, the Commission's analysis as regards the association of switching between medicinal products of the same therapeutic class with potentially very serious risks is called into question. In the absence of differences in efficacy and tolerance between ACE inhibitors, it has not been established that switching between ACE inhibitors raised particular concerns on the part of doctors.

1520 In the second place, the Commission's assessment of the low propensity to switch of patients treated with perindopril was based on longitudinal studies prepared by Thalès. Those studies analyse the prescribing habits of general practitioners between July 2005 and June 2006 in France and the United Kingdom. According to those studies, more than 90% of perindopril prescriptions were repeat prescriptions. The Commission infers from this that the level of 'loyalty' to perindopril was very high at 90%. It takes the view that analysing patients' propensity to switch based on the number of prescriptions issued is a better reflection of the nature of demand for perindopril than relying on the number of patients.

1521 However, the proportion of repeat prescriptions in the total number of prescriptions gives only partial information on the propensity for patients treated with perindopril to switch. Indeed, the rate of repeat prescriptions depends in particular on the frequency of patients' visits to doctors' surgeries, which may vary considerably and is also not referred to in the contested decision. Moreover, the number of repeat prescriptions in relation to the total number of prescriptions does not measure the level of patient loyalty, in the sense of the proportion of patients treated with perindopril in period N who are still being treated with perindopril in period N + 1.

1522 In those circumstances, the Thalès studies are insufficient to establish the loyalty to perindopril of patients commencing treatment with that medicinal product.

1523 In the third place, the Cegedim and IMS Health studies provide information, in relation to France and the United Kingdom, on the propensity of patients treated with perindopril to switch treatment over a five-year period.

1524 The Cegedim study, dated October 2012 and produced by Servier in the context of its observations in reply to the statement of objections, analyses, over a period of five years, the treatment continuance of patients with perindopril by general practitioners in France. The analysis concerns patients treated with perindopril who consulted the same general practitioner for a period of five years. It shows that 20 to 30% of patients commencing perindopril treatment stop the treatment within six months and that, among patients maintained on perindopril beyond six months, 30 to 40% are switched to other antihypertensive medicinal products and no longer follow that treatment after a period of five years. The switching to other antihypertensive medicinal products after a period of six months primarily involves switches to treatments with sartans, while about 40% of patients are switched to a treatment with another ACE inhibitor used alone or in combination. Ultimately, more than 50% of patients starting perindopril treatment are no longer treated with that medicinal product after a period of five years. As a result, for patients under the regular supervision of a single French general practitioner, treatment switching for patients starting treatment with perindopril is significant over a period of five years. It is also clear from the Cegedim study that, in 2005, the flows of incoming and outgoing patients (that is, respectively, a proportion of 30 to 40% and of 15 to 20%) accounted for half the patients treated with Coversyl.

1525 The IMS Health study, dated December 2013 and produced by Servier, analyses the prescriptions of ramipril, lisinopril and perindopril during the period from 2003 to 2008, for patients under the supervision of general practitioners in the United Kingdom.

1526 The Commission objects to the IMS Health study being taken into consideration by the Court, since that study was communicated by the applicants to the Commission late in the administrative procedure. However, as recalled in paragraph 1373 above, the Court ensures an in-depth review of

legality taking into account all the elements submitted by the applicants, whether those elements pre-date or post-date the contested decision, in so far as those elements are relevant to the review of the legality of the Commission decision. In the present case, the IMS Health study of December 2013, submitted by Servier to the Commission during the administrative procedure, in response to the Letter of Facts of 18 December 2013, addresses the Commission's argument that patients treated with perindopril are unlikely to switch treatment. That study therefore cannot be regarded as constituting evidence submitted out of time which cannot be taken into consideration at the stage of the review of legality of the contested decision.

1527 As to the credibility of the study, the Commission cannot reject the IMS Health study on the ground that it was 'tailor-made' for the applicants. The fact that the applicants themselves requested IMS Health to produce that study does not necessarily affect its probative value, particularly since it was not drawn up on the basis of information provided by the applicants themselves. As the Court has already held (judgment of 3 March 2011, *Siemens* v *Commission*, T-110/07, EU:T:2011:68, paragraph 137), an analysis is devoid of credibility and, therefore, of probative value beyond that of a mere statement from the applicants when it is drawn up on the basis of information provided by the applicants, without the accuracy or the relevance of that information being subject to any kind of independent assessment. In the present case, the study commissioned by Servier was drawn up on the basis of information from a third party, IMS Health, which, the Commission does not dispute, as is clear in particular from footnote 2843 of the contested decision, was a reference institution in the supply of data in the pharmaceutical sector. The Commission has itself relied on IMS Health data on a number of occasions in the context of defining the relevant market.

1528 Moreover, the fact that the commissioning of the study was not provided to the Commission and that the Commission was unable fully to reproduce the results of the study is not sufficient to call into question, in the circumstances of the present case, the credibility of that study. Indeed, in its reply to the Commission's questionnaire of 17 February 2014, Servier gave a detailed description of the instructions given to IMS Health. IMS Health described, in the study, the methodology, assumptions and definitions used and provided the raw data as well as the algorithm allowing replication of the study. While it is true that IMS Health did not provide the new patients tab, it should be noted that, following the transmission of the algorithm and the databases, the Commission did not draw Servier's attention to the existence of a methodological obstacle likely to undermine the credibility of the study. Moreover, IMS Health stated in the study that new patients were those who had not received the medicinal product in question within the 12 months preceding that prescription and indicated, in a letter of 1 September 2014, that Servier had not been involved in the analysis of the study, that the study was conducted by IMS Health using the methodology and definitions described in the study, that the new patients tab corresponded to a standard definition used in similar studies and that the new patients data had been obtained from a database using integrated reporting accessible from a workstation within the undertaking or where a customer has subscribed to that database. In those circumstances, having regard in particular to the adequate explanations provided by Servier and IMS Health, the Commission is not justified in maintaining that the IMS Health study cannot be accepted as reliable evidence.

1529 The IMS Health study shows, with regard to the patients under the supervision of English general practitioners during the years 2003 to 2008, that, in a given year, new perindopril patients represented a third of the total number of patients following that treatment. It also shows that the substitutes for perindopril are primarily other classes of antihypertensive medicinal products, but also other ACE inhibitors. It indicates that among patients commencing perindopril treatment, the average length of treatment, excluding treatment interruptions, is less than six months for 24% of patients, less than three years for 57% of patients and less than five years for 76% of patients.

1530 The Commission submits that the switching process is regressive, that is to say that patients were less and less likely to discontinue perindopril the more extended the length of the treatment. However, it should be noted that, according to the Cegedim study, the average net loss of patients treated with

perindopril over the course of the fourth and fifth years of treatment is close to 5% per year for patients under the supervision of French general practitioners. According to the IMS Health study, the proportion of patients under the supervision of English general practitioners whose average length of treatment, excluding interruptions of treatment, is between three and four years, on the one hand, and four and five years, on the other hand, amounts respectively to 12% and 7%. Therefore, it is apparent from the documents in the file that the proportion of patients likely to discontinue their perindopril treatment during the fourth and fifth year of treatment with perindopril is significant.

1531 Thus, the Cegedim and IMS Health studies show that patients treated with perindopril and under the supervision of general practitioners in France and the United Kingdom during the period under investigation had an average length of treatment of less than five years. A significant proportion switched their treatment not only within the first six months of treatment, but also within five years of commencing treatment.

1532 In the fourth place, the PCT documents support the existence, as regards the United Kingdom, of switching by patients treated with perindopril to other ACE inhibitors.

1533 As stated above, a number of PCTs considered, as of 2005, that perindopril was no more effective than the other ACE inhibitors and recommended the use of ACE inhibitors other than perindopril, or even the substitution of another ACE inhibitor for perindopril. Those policies, which have on occasion taken the form of guidelines, formularies or standard letters to patients to switch their treatment from perindopril to ramipril or lisinopril, are significant, given the number of PCTs involved and the fact that those PCTs were from various regions of the United Kingdom.

1534 It is apparent from the documents in the file that those policies, identified as threats in Servier's internal strategy documents as of 2005, had a real negative effect on perindopril sales at the local level. It is true, as the Commission points out, that there is no evidence that the policies implemented by the PCTs had a significant impact at national level. Although the figure in recital 2286 of the contested decision shows a virtual stagnation of sales of perindopril expressed in defined daily doses as from September 2006, the documents in the file do not establish the reality of a causal link between the recommendations of the PCTs and changes in the relative sales of perindopril and other ACE inhibitors across the United Kingdom as a whole. However, those recommendations are not irrelevant, in that they illustrate in practical terms the possibilities of switching between ACE inhibitors in one of the geographic markets selected by the Commission in its analysis.

1535 The Commission cannot claim that the applicants' argument relying on the policies implemented by the PCTs contradicts their assertion that the price factor plays a limited role in the relationships between the various ACE inhibitors. As is clear from the considerations set out in paragraphs 1380 to 1404 above, the pharmaceutical sector is an 'unusual' sector, the specific features of which require the market to be defined through an approach based on a number of criteria, in particular the therapeutic use of the products. In the present case, the PCT policies do not call that finding into question. Although those policies support the existence of therapeutic substitutability between ACE inhibitors and the possibilities of switching treatment for patients treated with perindopril, it does not follow that the price factor plays a decisive or predominant role in the analysis of the competitive pressures between those medicinal products.

1536 In the fifth place, the Commission submits, based in particular on the results of the survey of prescribers, that treatment switching of patients treated with perindopril is unlikely where the patients are 'successfully' treated with perindopril.

1537 However, the results of the Commission's survey of prescribers — according to which a large majority of doctors (76%) considered that patients who were treated 'successfully' during the initial period and for whom that treatment was not changed were likely to continue perindopril treatment for more than five years — do not call into question the findings of the Cegedim and IMS Health studies

relating to the average length of treatment of patients treated with perindopril and to treatment switching by them. Indeed, the question put to the prescribers is based on an estimate of the likelihood that perindopril treatment will continue and not on an estimate of the actual proportion of patients who continue treatment beyond five years. Moreover, the question put to the prescribers concerns only patients treated 'successfully' and for whom the treatment was not changed, while the Cegedim and IMS Health studies provide information on the average length of treatment of patients treated with perindopril and on all treatment switches occurring, regardless of the doctors' assessment of the results of the perindopril treatment. Finally, even as regards patients 'successfully' treated with perindopril and for whom that treatment was not changed, only a minority of doctors surveyed consider that those patients are likely to continue treatment with perindopril for more than 10 years.

1538 Although patients 'successfully' treated with perindopril naturally have a lower propensity to switch treatment than those who do not fall into that category, the findings of the Cegedim and IMS Health studies remain relevant for quantitatively assessing the extent to which patients who commence treatment remain 'loyal' to perindopril over a five-year period. Those studies show the existence of significant treatment switching, which calls into question the assertions made by the Commission in the contested decision concerning the lock-in effects of perindopril's patient base.

1539 In the sixth place, the Commission relies, in the contested decision, on the fact that Sanofi-Aventis stated in the response to its questionnaire that treatment switching between ramipril and perindopril was very limited and that for both products their growth was based on newly-acquired patients commencing treatment. However, apart from the fact that that assertion concerns only the French market, Sanofi-Aventis explains in its response, as previously stated, that the patient population which could be treated with ramipril was wider than that for perindopril and that the dose range of ramipril was broader than that of perindopril until 2007, factors which are more likely to limit patient switching from ramipril to perindopril than vice versa. Moreover, Sanofi-Aventis did not comment on treatment switching in the Netherlands and the United Kingdom and stated, with regard to the Polish market, that it regarded perindopril as a product at whose expense ramipril had obtained patients. It follows that Sanofi-Aventis' responses to the Commission's questionnaire do not call into question the extent of treatment switching for patients treated with perindopril.

1540 It follows from the foregoing that the Commission underestimated the propensity of patients treated with perindopril to switch treatment, relying, moreover, on the erroneous assumption of the heterogeneity of medicinal products in the ACE inhibitor class. It is apparent from the documents in the file that treatment switching of patients commencing treatment with perindopril is significant over a period of five years, which calls into question the average length of treatment as assessed by the Commission and the significance of the lock-in effects of perindopril's patient base.

(iv) Promotional activities

1541 The Commission considered, in recitals 2515 to 2521 of the contested decision, that promotion could extend the degree of competition if, as a consequence, the medical community was informed about additional therapeutic alternatives, in particular new products or new important indications for existing products. However, it considered that, in the present case, competition in promotion should not be regarded as a source of significant competitive constraints from the specific perspective of the relationship between perindopril and its potential competitors, in so far as any new promotional activities, for medicinal products which had been marketed for some time, would only add to the existing goodwill capital already accumulated with 'loyal' prescribers. The Commission noted that, in view of the barriers to treatment switching and the predominance of the continued-use patients, the potential impact of promotional activities undertaken by the producers of other ACE inhibitors on the sales of perindopril were limited. The Commission added that the lack of competitive constraints from

other ACE inhibitor producers was also demonstrated by the categories of patients targeted by Servier as part of its promotional policy, by the analysis of the promotions contained in Servier's internal strategy documents and by the stability of its promotional expenditure.

1542 The applicants argue, in essence, that the Commission erred by failing to take due account of the companies' significant promotional activities, which constitute one of the key aspects of competition and a necessity, in the absence of 'inertia' of patients and doctors, in facing the competition.

1543 In the first place, the Commission based its analysis of the promotional activities on the phenomenon of doctors' 'inertia' and the existence of barriers to treatment switching.

1544 As previously stated, the prescribing behaviour of doctors was not characterised by a high degree of 'inertia' and treatment switching by continued-use patients was significant. It is therefore on the basis of erroneous assumptions liable to vitiate its analysis that the Commission considered that the potential impact which the promotional activities of producers of other medicinal products had on sales of perindopril should be regarded as particularly limited.

1545 In the second place, the Commission's analysis of the promotional activities was based on the categories of patients targeted by Servier as part of its promotions and on the alleged particular qualities of perindopril in terms of therapeutic use. It noted, in recitals 2366 and 2519 of the contested decision, that Servier's promotional expenditure was focused on potential new patients, comprising newly diagnosed hypertensive patients and patients whose high blood pressure was not being controlled satisfactorily by other antihypertensive medicines, and on specific groups of patients for whom perindopril had been shown to have particular qualities.

1546 In that regard, it should be pointed out that promotion may be an instrument of competition, particularly where products are broadly similar. The absence of any positive differentiation of perindopril with regard to other ACE inhibitors is consistent with the need for Servier to undertake significant promotional activities to stay in the market and win over prescribing doctors. Indeed, in the absence of any therapeutic superiority of perindopril, prescribers have no incentive, on that basis alone, to prescribe perindopril rather than another medicinal product.

1547 Moreover, it is clear from the actual wording of recitals 2366 and 2519 of the contested decision that Servier carried out promotional activities aimed at both new patients and patients who had already used another antihypertensive medicinal product. Furthermore, the Commission has not demonstrated, as previously stated, that perindopril had particular qualities which differentiated it therapeutically from other ACE inhibitors. Although Servier sought to differentiate perindopril from other ACE inhibitors, those efforts by Servier were not as successful as had been hoped and were incapable of sufficiently differentiating perindopril from the other ACE inhibitors.

1548 The promotional strategy of perindopril, in so far as it targets certain categories of patients, therefore does not allow the conclusion that the impact of competition between ACE inhibitors through promotion was limited.

1549 In the third place, Servier's internal documents, the responses of the producers of the other ACE inhibitors and the other documents in the file tend to show, contrary to the Commission's arguments, that the promotional activities of the other ACE inhibitor producers were able to exert competitive pressure on perindopril.

1550 Thus, it is clear from Servier's internal strategy documents, in particular the document entitled '2005/2006 orientation plan' and the document entitled 'Coversyl 2006/2007 orientation plan', that Servier considered, in the years 2000 to 2009, that competition on the high blood pressure and heart failure markets was strong. It also appears from those documents that Servier considered other ACE inhibitors as competitors, in particular ramipril, captopril, lisinopril, enalapril, fosinopril and

trandolapril. On several occasions, ramipril is included in the section of the strategic documents concerning threats to the development of perindopril. For example, the launch in 2005 of a new product, Cotriatec, making it possible to ensure continuity of communication of the ramipril product range, is presented as a threat.

1551 The three originator producers of ACE inhibitors surveyed by the Commission also regard perindopril as a competitor or rival to their own medicinal product. Admittedly, as the Commission has pointed out, the fact that other undertakings take a certain product to be the main competitive target does not mean that the product in question is subject to a significant competitive constraint on the part of those other undertakings. However, that body of evidence may be useful in that it allows for consideration of how undertakings assess their own position in the market. In that regard, it is clear from the responses of the undertakings questioned by the Commission on their perception of competition that Sanofi-Aventis, the producer of ramipril, AstraZeneca AB, the producer of lisinopril, and MSD, the producer of enalapril and lisinopril, regarded perindopril as a competitor to their own medicinal product. The documents provided by Sanofi-Aventis, namely presentations concerning the Polish market and the business plans for 2008-2009, show in particular that perindopril and enalapril were, according to that undertaking, the first and second closest rivals of ramipril and that ramipril generally enjoyed the best perception as a brand.

1552 Moreover, the documents in the file suggest that the promotional materials of the other ACE inhibitors could have had a significant impact on the sales of perindopril.

1553 Servier's internal strategy documents and the documents relating to the promotion of the other ACE inhibitors show that the other ACE inhibitors were presented as the best in that class of medicinal products, or even presented as superior to the other ACE inhibitors. Some promotional plans for other ACE inhibitors directly targeted Servier's perindopril.

1554 Although the strong promotional pressure of sartans coupled with the reduction in ACE inhibitor promotion is presented as a threat by Servier's internal documents, the promotion of ramipril is presented as a threat to perindopril, while the reduction in that promotion is perceived as a favourable prospect. Servier's internal documents stress that the promotion of ramipril is based on the HOPE study, presented as a major event in 2001, which allowed ramipril to achieve strong growth and obtain new indications. It is stated in Servier's strategy documents that the results of the HOPE study and the positioning of ramipril had a strong impact on sales of Servier's Coversyl 4 mg.

1555 It is also apparent from the documents in the file, in particular the information provided by IMS Health contained in the contested decision and Sanofi-Aventis' response to the Commission's request for information, that the promotional expenditure incurred by the other ACE inhibitor producers was significant during certain periods, in particular the expenditure relating to ramipril in the Netherlands and the United Kingdom until 2003 or in France until the beginning of 2006.

1556 Consequently, the documents in the file, in particular Servier's internal strategy documents and the responses of the other ACE inhibitor producers, tend to show that the promotional activities of the other ACE inhibitors were likely to have a significant impact on the sales of Servier.

1557 In the fourth place, the significance of Servier's promotional expenditure during the period under investigation is also consistent with the fact that competition through promotion could have constituted a source of competitive pressure in the relationships between ACE inhibitors, without this being called into question by the alleged stability of that promotional expenditure.

1558 The significance of Servier's promotional expenditure, which is not contested, is apparent in particular from the data relating to the main cost items contributing to the total cost of variants of perindopril. That expenditure was significant, in particular in France, the Netherlands and the United Kingdom, as indicated in the information provided by IMS Health contained in the contested decision. For example,

in 2000, EUR 70 to 80 million was spent by Servier in France to promote perindopril, while total net sales of the product were between EUR 180 and 200 million. In 2004, promotional expenditure in that country reached EUR 100 to 120 million, or approximately one third of the total net sales of the product (300 to 350 million euros).

1559 It must be added that the fact that, despite the very significant level of Servier's promotional expenditure for perindopril, the profitability of perindopril remained high during the period under investigation does not imply that perindopril was not subject to significant competitive pressure from other ACE inhibitors. Moreover, although the Commission notes the generally high level of profitability of perindopril in recitals 2369 to 2371 of the contested decision, it draws no conclusions from this in the context of the definition of the relevant market and does not rely on that profitability in concluding, in recitals 2403 to 2546 of the contested decision, that the relevant product market is limited to the originator and generic versions of perindopril.

1560 Servier's internal strategy documents highlight the link between the competitive environment and Servier's promotional expenditure, and indicate that the competitive environment requires a very significant promotional effort, primarily through medical sales visits. Those documents express the intention of Servier to acquire new customers, to the detriment of other antihypertensive medicinal products, inter alia ACE inhibitors, and refer to Servier's difficulty in engaging with general practitioners especially in view of the financial and human investments made by other producers of antihypertensive products.

1561 The Commission argues that the stability of Servier's promotional expenditure during the period under investigation suggests the largely independent nature of perindopril promotion and the absence of exposure to strong competitive pressures.

1562 However, the stability of Servier's promotional expenditure is not apparent from the documents in the file, in particular from the data of the IMS Health study, since the level of expenditure varied significantly during the period under investigation. Moreover, the stability of promotional expenditure, even if it were established, does not necessarily imply a lack of significant competitive pressure from other ACE inhibitors. The maintenance of such a high level of promotional expenditure may demonstrate the undertaking's intention to maintain sales when faced with therapeutically substitutable products exerting significant competitive pressure on perindopril. The Commission does not explain the reasons why an operator in a dominant position like Servier needed, in the absence of significant competitive pressure, to spend such a proportion of its total turnover on promotional expenditure over such a long period.

1563 Nor does the discontinuity in Servier's promotional activities at the time of generic entry indicate the absence of significant competitive pressure prior to the entry of generics onto the market. Although an expected absence of profits is likely to deter a producer from engaging in promotional activities, the prospect of making profits is such as to encourage that producer to invest in promoting the product. However, it is possible that, before the entry of generics onto the market, Servier could reasonably expect to benefit from its promotional investment. Prior to the market entry of generics, Servier might have been prompted to undertake promotional activities in the context of competition between ACE inhibitors, stemming in particular from the absence of heterogeneity of the medicinal products in that class.

1564 Therefore, Servier's promotional expenditure during the period under investigation does not indicate that Servier was not subject to significant competitive pressures from other ACE inhibitors.

1565 Accordingly, it follows from the foregoing that the Commission did not give due consideration to the companies' promotional activities and their significance in the analysis of the competitive relationships between perindopril and the other ACE inhibitors.

1566 It follows from all the considerations set out in paragraphs 1418 to 1565 above that the second complaint raised by the applicants is well founded.

(4) The second part of the first complaint, alleging that excessive importance was attached to the price criterion in the market analysis, and the third complaint, raised in the alternative, alleging that the Commission's econometric analysis is flawed

1567 In recitals 2460 to 2495 of the contested decision, the Commission, for the purposes of defining the market for the products at issue, carried out an analysis of the 'natural' events occurring on the markets in France, the Netherlands, Poland and the United Kingdom.

1568 The Commission considered that, where two products are close substitutes, a substantial decrease in the price of one should lead to a decrease in the turnover from the other. The Commission attempted to assess, by means of a preliminary visual assessment and then an econometric calculation, the impact of a reduction in the prices of other antihypertensive medicinal products on perindopril sales. In order to do so, the Commission inter alia compared the effect of the entry of perindopril generics on the sales of perindopril to the effect of the entry of other ACE inhibitor generics on the sales of perindopril. According to the Commission, the fact that the sales of perindopril were less affected by the entry of other ACE inhibitor generics than by the entry of its own generics shows that the ACE inhibitors did not exert significant price constraints on perindopril (recital 2494 of the contested decision).

1569 At the end of its analysis of natural events, the Commission considered that perindopril was not subject to substantial price constraints from other products, in particular from other ACE inhibitors, except for the constraints exerted by generic perindopril. According to the Commission, the reductions in the price of other ACE inhibitors did not have a significant adverse impact on perindopril sales and turnover.

1570 By the second part of their first complaint, the applicants maintain that the Commission attached excessive importance to the price factor in its analysis of the relevant product market. They submit, in the alternative, in the context of their third complaint, that the Commission's econometric analysis is flawed.

1571 In the first place, as was stated at the outset in paragraphs 1385 to 1404 above, it is clear from the case-law that the specific features which characterise competitive mechanisms in the pharmaceutical sector do not negate the relevance of price-related factors in the assessment of competitive constraints, although those factors must be assessed in their specific context (judgment of 1 July 2010, *AstraZeneca* v *Commission*, T-321/05, EU:T:2010:266, paragraph 183).

1572 In the present case, the Commission could therefore examine, in the definition of the relevant market, whether perindopril was subject to significant competitive pressures resulting from the relative price changes of other ACE inhibitors and take into account the outcome of that examination.

1573 The Commission inferred from its analysis of the price changes of other ACE inhibitors that perindopril was not subject to significant competitive pressures resulting therefrom. The low sensitivity of perindopril to the price changes of other ACE inhibitors is apparent from several documents in the file, inter alia Servier's internal documents or the survey of prescribers carried out by the Commission. Nor is that conclusion challenged as such by the applicants. The applicants themselves indicate that doctors are generally not very price-sensitive, that doctors' choices are primarily guided by the therapeutic relevance and efficacy of different medicinal products rather than by their price and that competition between companies mainly involves aspects other than prices, such as innovation, product quality and promotion.

1574 However, as the applicants rightly point out, the analysis of natural events, as understood by the Commission, that is through the prism of price changes, does not support the conclusion that there was an absence of qualitative and non-price competitive pressure.

1575 As stated in paragraphs 1395 and 1397 above, doctors' freedom of choice, between the originator medicinal products available on the market or between originator medicinal products and generic versions of other compounds, and the priority focus of prescribers on therapeutic aspects permit, where appropriate, the operation of significant qualitative and non-price competitive constraints in addition to the usual mechanisms of price pressure. Such constraints may also exist where the therapeutic value of a medicinal product is clearly superior to that of other medicinal products available for treatment of the same condition and where the available medicinal products are recognised or perceived as equivalent by prescribers.

1576 Where, for the treatment of the same condition, prescribers have a choice between medicinal products of which none is recognised or perceived as superior to the others, in particular because their mode of action is the same or because their therapeutic benefits or their adverse or side effects do not make it possible to distinguish between them, the analysis of the competition between those medicinal products also relies, in large part, on a qualitative comparison. In general, the practitioner's choice depends primarily not on the respective cost of those treatments, but on the degree to which they differ therapeutically, on their suitability to the profile of patients, on the doctor's knowledge of the various medicinal products or even on his personal experience and that of his patients.

1577 Moreover, as follows from the response to the second complaint, perindopril could, in view of the absence of significant therapeutic differentiation between perindopril and the other ACE inhibitors, be exposed to non-price and qualitative competitive pressures, which the Commission should have taken into due consideration. Those competitive pressures, which could in particular be exerted through the promotional activities of the producers of other ACE inhibitors, concerned both new patients and patients who had already commenced treatment with perindopril.

1578 The fact that perindopril is not very sensitive to changes in the prices of the other ACE inhibitors did not therefore necessarily imply that that medicinal product was not subject to significant competitive pressure from those medicinal products. That fact does not support the inference that perindopril was shielded from significant competitive pressure resulting, as the applicants argue, from aspects other than prices, such as innovation, product quality and promotion. In that regard, the Commission itself notes, in recital 2543 of the contested decision, that economic substitutability may exist where changes affecting important economic variables other than prices shift a significant proportion of the sales from one product to another.

1579 Consequently, the fact that the sales and prices of perindopril fell only after the entry of generic perindopril and remained stable or were less affected by the occurrence of natural events relating to changes in the price of other compounds does not support the conclusion that there was an absence of competitive constraints until the entry of the perindopril generics.

1580 In the second place, it is apparent from the documents in the file that the Commission, as the applicants rightly point out, attached excessive importance to the price factor in the definition of the product market, by inferring from the analysis of natural events an absence of significant competitive pressure on perindopril exerted by ACE inhibitors.

1581 It is apparent from the documents in the file that the price factor played, in the Commission's analysis, a decisive role in the exclusion of other ACE inhibitors from the relevant market. It is clear from the actual wording of the contested decision that the Commission relied essentially on the analysis of natural events relating to price in order to exclude from the relevant market ACE inhibitors, such as ramipril, enalapril or lisinopril, presented by Servier as its close competitors. The Commission emphasised, for example in recital 2460 and footnote 3245 of the contested decision, the importance

of the results of its econometric analysis seeking to ascertain whether or not the fall in the price of certain medicinal products in the ACE inhibitor class, following the introduction of generic medicinal products, had an effect on the sales of perindopril. In the contested decision, the Commission stated on several occasions, in particular in recitals 2527 and 2534, that the absence of price constraints resulting from the regulatory framework and revealed by the analysis of natural events supported the conclusion that no other compound had exerted a significant competitive constraint on perindopril. In recital 2546 of the contested decision, the Commission considered that the fact that the generic competitive constraint outweighs by an order of magnitude all other potential competitive constraints facing perindopril led naturally to the finding of a narrow market comprising only the medicine in question.

1582 The importance, in the Commission's definition of the market, of the analysis of natural events relating to price changes is, moreover, emphasised in the Commission's defence, which states that that analysis indicates, for the four Member States concerned, that the applicants did not face significant competitive pressure from the producers of other ACE inhibitors. The defence states, as regards Poland, that the analysis of natural events shows that the other medicinal products in the same class did not exert competitive constraints on perindopril.

1583 At the hearing, the Commission further pointed out that the finding of the absence of a decline in sales of perindopril with the entry onto the market of generic versions of other ACE inhibitors, far less expensive than perindopril, was central to its analysis and supported the conclusion that no significant competitive pressure was exerted by the other ACE inhibitors.

1584 By attaching decisive importance to the results of its analysis of natural events, which is essentially based on the impact of price changes, the Commission has not fully taken into account the specific context of the pharmaceutical sector and has not paid sufficient attention to evidence supporting the existence of qualitative or non-price competitive pressures.

1585 In those circumstances, it is appropriate to uphold the second part of the first complaint raised by Servier, concerning the excessive importance which the Commission attached to changes in the relative prices of medicinal products. The Commission could not infer from the analysis of natural events and the low sensitivity of perindopril to changes in the price of other ACE inhibitors that Servier was not subject to any kind of competitive constraints from other products, except for the constraints exerted by generic perindopril.

1586 In so far as the Court upholds the second part of the first complaint, concerning the analysis of prices and raised by the applicants as their principal argument, there is no need to respond to the third complaint raised by the applicants, by which they argue, in the alternative, that the Commission's econometric analysis of prices is vitiated by a methodological flaw.

(5) Conclusion

1587 As a preliminary point, it must be borne in mind, as was stated in paragraphs 1373 to 1375 above, that the scope of judicial review provided for in Article 263 TFEU extends to all the elements of Commission decisions relating to proceedings applying Articles 101 and 102 TFEU which are subject to in-depth review by the General Court, in law and in fact, in the light of the pleas raised by the applicants and taking into account all the elements submitted by the latter (judgment of 21 January 2016, *Galp Energía España and Others* v *Commission*, C-603/13 P, EU:C:2016:38, paragraph 72).

1588 Moreover, whilst, in areas giving rise to complex economic assessments, the Commission has a margin of discretion with regard to economic matters, that does not mean that the Courts of the European Union must refrain from reviewing the Commission's interpretation of information of an economic nature. Those Courts must establish, among other things, not only whether the evidence relied on is

factually accurate, reliable and consistent but also whether that evidence contains all the information which must be taken into account in order to assess a complex situation and whether it is capable of substantiating the conclusions drawn from it (judgments of 15 February 2005, *Commission* v *Tetra Laval*, C-12/03 P, EU:C:2005:87, paragraph 39; of 8 December 2011, *Chalkor* v *Commission*, C-386/10 P, EU:C:2011:815, paragraph 54; and of 10 July 2014, *Telefónica and Telefónica de España* v *Commission*, C-295/12 P, EU:C:2014:2062, paragraph 54). Where, in order to classify a practice in the light of the provisions of Article 102 TFEU, the Commission attaches real importance to an economic analysis of whether a rebate was capable of excluding as efficient a competitor (the AEC test), the EU judicature is required to examine all the arguments put forward by the penalised undertaking concerning that test (see, to that effect, judgment of 6 September 2017, *Intel* v *Commission*, C-413/14 P, EU:C:2017:632, paragraphs 141 to 144).

1589 In the present case, at the end of the overall assessment of the elements on which the Commission based its assessment and of the examination of the applicants' complaints, it must be concluded that the Commission made a series of errors in the analysis of the definition of the relevant market. The Commission:

– wrongly considered, with regard to therapeutic use, that ACE inhibitors were a class of heterogeneous medicinal products and that perindopril had particular characteristics within that class of medicinal products;

– wrongly concluded that a mechanism of doctors' 'inertia' had significantly restricted the competitive pressure exerted on perindopril by the other ACE inhibitors with respect to new patients;

– underestimated the propensity of patients treated with perindopril to switch treatment;

– failed to give due consideration to the companies' promotional activities and their significance in the analysis of competitive relationships;

– disregarded the particular characteristics of competition in the pharmaceutical sector, erroneously inferring from an analysis of natural events based primarily on price changes that perindopril was not subject to significant competitive pressures from other ACE inhibitors.

1590 By relying on an analysis vitiated by the errors referred to above, the Commission restricted the relevant market to the perindopril compound alone, while the documents in the file show that perindopril may have been exposed to significant non-price competitive pressures from the other ACE inhibitors. In those circumstances, it must be held that the Commission's errors are such as to vitiate the result of its analysis.

1591 It must therefore be concluded, following an assessment made by the Court in accordance with the limits on judicial review referred to in paragraphs 1587 and 1588 above, that it has not been established that the relevant product market is limited solely to originator and generic perindopril.

1592 In the light of the foregoing, the 14th plea in law, directed against the definition of the finished product market as the market for originator and generic perindopril, must be upheld.

13. Errors of assessment concerning the existence of a dominant position on the finished product market

(a) Arguments of the parties

…

(b) Findings of the Court

1595 It should be recalled at the outset that it is settled case-law that a dominant position under Article 102 TFEU concerns a position of economic strength held by an undertaking which enables it to prevent effective competition from being maintained on the relevant market by giving it the power to behave to an appreciable extent independently of its competitors, its customers and, ultimately, consumers (judgments of 14 February 1978, *United Brands and United Brands Continentaal* v *Commission*, 27/76, EU:C:1978:22, paragraph 65, and of 13 February 1979, *Hoffmann-La Roche* v *Commission*, 85/76, EU:C:1979:36, paragraph 38).

1596 In the present case, the Commission concluded, in recital 2593 of the contested decision, that Servier had held a dominant position within the meaning of Article 102 TFEU on the market for originator and generic perindopril in the United Kingdom from January 2000 to June 2007, in the Netherlands from January 2000 to December 2007, in France from January 2000 to December 2009 and in Poland from January 2000 to December 2009.

1597 In reaching the conclusion that Servier held a dominant position on the market for originator and generic perindopril, the Commission relied on the market shares of Servier on the relevant market, on the existence of barriers to entry to the market, on the existence of substantial economic rents as well as the lack of countervailing buying power exercised by the public authorities. In recitals 2594 to 2600 of the contested decision, the Commission added that, irrespective of the definition of the market which it had adopted, there was strong evidence, namely the existence of substantial economic rents, which gave a direct indication of the market power enjoyed by Servier.

1598 The applicants dispute the existence of a dominant position and argue in particular that the product market is not limited to originator and generic perindopril.

1599 Since the market definition is, as stated in response to the preceding plea, erroneous in so far as it restricts the product market solely to originator and generic perindopril, it is appropriate to conclude, as a consequence, that the examination of the economic power of Servier on the market is also flawed.

1600 Moreover, the Court notes that, at the very least, two of the main criteria for assessing Servier's economic power, that is to say market shares and the existence of substantial economic rents, are called into question by the erroneous definition of the relevant market.

1601 As regards market shares, the Commission stated, in recital 2561 of the contested decision, that modest market shares were generally a good indicator of the absence of strong market power. It also considered that market shares of more than 50% constituted very large market shares and were in themselves, save in exceptional circumstances, evidence of the existence of a dominant position, and that market shares of between 70 and 80% were a clear indication of a dominant position.

1602 The Commission took the view, in recitals 2563 to 2567 of the contested decision, that Servier had very large market shares on the relevant market (in particular a market share of 90 to 100% in France, Poland and the United Kingdom, from 2000 to 2005), in any event continually larger than 50% even taking into account the role of parallel traders in the Netherlands.

1603 Since the Commission erred in holding that the relevant product market was limited solely to originator and generic perindopril, the Commission's calculation of market shares is necessarily erroneous.

1604 The Court notes that it is not disputed that, if the relevant market had been defined by the Commission at the level of all the ACE inhibitors and not at the level of the perindopril compound, Servier's average market share in the four Member States analysed by the Commission would have been lower than 25%, under the thresholds for market shares which, according to the contested decision, constitute evidence of the existence of a dominant position.

1605 In that regard, the Commission states, in the contested decision, that Servier's calculations of ACE inhibitor market shares are based not on the value of sales but on the volume of sales expressed in defined daily doses, which leads to an overestimate of the value of ramipril sales. However, apart from the fact that the Commission provides no alternative analysis of the relative sales of the various ACE inhibitors, it is clear from paragraphs 1494 and 1498 above that, in January 2000, perindopril had in all the countries concerned a far smaller patient base than other ACE inhibitors such as ramipril, enalapril or lisinopril. Irrespective of the geographic market, Servier's perindopril was never the leading ACE inhibitor in terms of sales of tablets and capsules, during the period of the practices covered by the contested decision.

1606 As regards economic rents, the Commission considered that Servier enjoyed substantial economic rents. It defined economic rents as persistent significantly high returns relative to those which would prevail in a competitive market for the product in question. It estimated the rents Servier had received prior to the entry of generics by multiplying the difference in prices before and after the entry of generics by the amounts sold by the originator producer. However, that reasoning is based on the premiss that the market is limited solely to originator and generic perindopril and that, as a result, there was no competitive market prior to the entry of generic perindopril. Since the Commission has not shown that the market was limited solely to originator and generic perindopril, it could not, on the basis of such a calculation, estimate the level of Servier's economic rents. In those circumstances, the existence of substantial economic rents for Servier is not established.

1607 Accordingly, the Commission's assessment concerning two essential elements of its reasoning, that is to say the market shares and the existence of economic rents, is called into question by the erroneous definition of the market. Consequently, without it being necessary to assess the existence of barriers to entry and the countervailing buying power of the public authorities, the Commission could not, in any event, conclude by the grounds which it has stated that Servier held a dominant position and was able to behave, to an appreciable extent, independently of its competitors, its customers and consumers

1608 Accordingly, the present plea, alleging the absence of a dominant position on the finished product market, must be upheld.

14. Errors of law and errors of assessment concerning the existence of a dominant position on the technology market

(a) Arguments of the parties

…

(b) Findings of the Court

1611 The Commission considered, in recitals 2667 and 2758 of the contested decision, that the relevant technology market was limited to perindopril API technology and that Servier held a dominant position on that market within the meaning of Article 102 TFEU.

1612 The applicants dispute the Commission's conclusions and argue, in particular, that the Commission's errors in the definition of the finished product market also vitiate the definition of the technology market and the analysis of Servier's dominant position on that market.

1613 In that regard, the Court asked the parties, at the hearing, to state their views on the consequences to be drawn concerning the lawfulness of the decision in so far as it is based on Article 102 TFEU, in the event that the plea alleging the incorrect definition of the finished product market is upheld.

1614 The Commission considered that any error in the definition of the finished product market did not call into question Servier's dominant position on the technology market. The Commission argues that the finding that Servier held a dominant position is based on the assessment of a set of relevant criteria, in particular the demand for perindopril API, which is not dependent on the definition of the finished product market.

1615 As regards the definition of the technology market, it is clear from the contested decision that, in concluding that the relevant technology market was that for the perindopril API technology, the Commission relied in particular on the fact that the finished product market, vertically linked to the technology market, was limited solely to originator and generic perindopril. It thus considered that the demand for API technology derives from the demand for the finished medicinal product of perindopril (recitals 2648 to 2651 of the contested decision). The Commission therefore used the erroneous definition of the relevant market which it adopted for the finished product market in its analysis of the technology market, in particular with regard to the assessment of demand on the technology market.

1616 Nevertheless, as the Commission argues, it also used, in its analysis of the technology market, other elements to define that market, in particular an analysis of supply-side substitutability (recital 2657 et seq. of the contested decision).

1617 In the present case, however, it is not necessary to rule on whether or not the definition of the technology market is erroneous in order to assess the plea alleging errors in the Commission's finding that Servier held a dominant position on that market.

1618 It is clear from recitals 2668 and 2669 of the contested decision that the Commission considered that Servier was in a dominant position on the technology market in the light of the manifestations of its dominant position on the finished product market.

1619 In particular, the Commission assessed Servier's position in the API technology market by relying, in recital 2735 et seq. of the contested decision, on Servier's market shares on the finished product market. The Commission expressly stated, in recital 2738 of the contested decision, that the market position of a given API technology crucially depended on whether the final pharmaceutical product can be viably marketed or not. Accordingly, the Commission considered, in recitals 2743, 2746, 2751 and 2755 of the contested decision, that Servier was, with certain exceptions, the only undertaking marketing perindopril, from which it inferred that it was in a dominant position on the perindopril technology market. As analysed by the Commission, Servier's position on the upstream market in terms of market shares is therefore essentially the reflection of Servier's position on the finished product market.

1620 It follows that the Commission relied decisively on the definition of the finished product market in order to conclude that Servier was in a dominant position on the technology market.

1621 Since the definition of the finished product market is erroneous, the Commission could not establish, on that basis, that Servier held a dominant position on the technology market.

1622 In the light of the foregoing, the plea alleging errors in the Commission's finding that Servier held a dominant position on the technology market must be upheld, without it being necessary to respond to the applicants' complaint concerning the erroneous nature of the definition of that market.

15. Errors of law and of fact relating to the existence of an abuse of a dominant position

(a) Arguments of the parties

…

(b) Findings of the Court

1625 The Commission considered, in recital 2997 of the contested decision, that Servier's strategy combining the acquisition of API technology with the conclusion of patent settlement agreements with reverse payments constituted a single and continuous infringement of Article 102 TFEU.

1626 However, having regard to all the considerations set out in response to the three preceding pleas, it must be concluded that the errors made by the Commission in the examination of Servier's dominant position on the finished product market and on the technology market necessarily call into question the existence of an abuse of a dominant position. Indeed, in the absence of a dominant position, the issue of abuse of that position becomes entirely irrelevant.

1627 For the sake of completeness, the Court notes that Servier's lack of a dominant position on the finished product market calls into question, in itself, the existence of the abuse of a dominant position alleged against Servier in the contested decision.

1628 In that regard, the Court, as stated in paragraph 1613 above, asked the parties, at the hearing, to state their views on the consequences to be drawn concerning the existence of an infringement of Article 102 TFEU, if the plea alleging the incorrect definition of the finished product market is upheld

1629 The Commission argued in that regard that, even if the definition of the finished product market was criticised by the Court, the existence of the infringement of Article 102 TFEU would not be called into question. In particular, the Commission explained that the two abuse practices covered by the abuse of a dominant position alleged against Servier, namely the acquisition of the Azad technology and the series of patent settlements with generic companies, were related to the technology market.

1630 Nevertheless, it must be pointed out that the Commission found that there was an abuse of a dominant position seeking essentially, according to recital 2765 of the contested decision, to protect Servier's perindopril market position against generic entry, in order to protect Servier's income from perindopril. The Commission thus alleged that Servier had committed a single and continuous infringement seeking essentially to protect Servier's position and income on the finished product market for perindopril by delaying the entry of generics. The Commission therefore relied, for the purposes of explaining and characterising the alleged practice of Servier, on that undertaking's imputed willingness to defend its position on the finished product market.

1631 Moreover, the Commission, which referred essentially to the finished product market for the purposes of characterising the practice, classified the acts as a single and continuous infringement covering both the upstream technology market and the finished product market. Although the contested decision draws a distinction, as the Commission points out, between the acquisition of the Azad technology and the settlement agreements, it nevertheless fails to draw a distinction, in the context of the single and continuous infringement, between Servier's conduct relating only to the technology market and other conduct of Servier founded on its dominant position on the finished product market. Neither

the acquisition of the Azad technology nor the patent settlement agreements are classified by the contested decision as infringements of Article 102 TFEU solely on the basis of Servier's dominant position on the technology market. Since Servier does not have a dominant position on the finished product market, the finding of the existence of the single and continuous infringement is therefore deprived of one of its essential grounds, and it is not possible to identify any of Servier's conduct which is separable and the infringing nature of which does not depend on the undertaking's dominant position on the perindopril market and which relates solely to the technology market.

1632 Accordingly, the present plea must be upheld.

1633 It follows from the examination of the preceding four pleas that the contested decision must be annulled in part, in so far as it found the existence of an infringement of Article 102 TFEU. Consequently, Article 6 of that decision must be annulled.

16. The alternative claims, seeking cancellation of the fines or a reduction in the amount of those fines

1634 The applicants seek the cancellation of the fines imposed on them or a reduction in the amount of those fines.

1635 In order to obtain the cancellation of those fines or a reduction in the amount of those fines, the applicants rely on seven pleas which must be examined in turn.

1636 In order to take account of the annulment of Article 4 of the contested decision in so far as the Commission found in that provision that the applicants had participated in an infringement of Article 101(1) TFEU relating to the agreements concluded between Servier and Krka (see, above, the section concerning the agreements concluded with Krka), it is necessary, at the outset, to annul Article 7(4)(b) of the contested decision, by which the Commission imposed a fine totalling EUR 37 661 800 on Servier in respect of that infringement.

1637 In the light of the cancellation of that fine, it is not necessary to examine the merits of the pleas or complaints raised in support of the claim relating to the fine referred to in paragraph 1636 above.

1638 Similarly, in order to take account of the annulment of Article 6 of the contested decision, by which the Commission found an infringement of Article 102 TFEU (see, above, the sections concerning the definition of the relevant market, the existence of a dominant position on the two relevant markets and the abuse of a dominant position), it is necessary to annul Article 7(6) of the contested decision, by which the Commission imposed a fine totalling EUR 41 270 000 on Servier in respect of that infringement.

1639 In the light of the cancellation of that fine, it is not necessary to examine the merits of the pleas or complaints raised in support of the claim relating to the fine referred to in paragraph 1638 above.

1640 Consequently, in the discussion below, the complaints or arguments relating to the agreements concluded with Krka or to the abuse of a dominant position will not, in principle, be examined or even referred to. Where, exceptionally, they are, that examination will be carried out for the sake of completeness.

(a) The unforeseeability of the interpretation adopted in the contested decision

(1) Arguments of the parties

…

(2) Findings of the Court

1655 As a preliminary point, it should be observed that the effective penalisation of infringements of competition law cannot go so far as to disregard the principle that offences and penalties must have a proper legal basis as enshrined in Article 49 of the Charter of Fundamental Rights (see, by analogy, as regards criminal penalties and the Member States' obligation to counter illegal activities affecting the financial interests of the Union, judgment of 5 December 2017, *M.A.S. and M.B.*, C-42/17, EU:C:2017:936, paragraph 61).

1656 It must next be observed that, according to the case-law of the Court of Justice, the principle that offences and penalties must have a proper legal basis implies that legislation must define clearly offences and the penalties which they attract. That requirement is satisfied where the individual concerned is in a position to ascertain from the wording of the relevant provision and, if need be, with the assistance of the courts' interpretation of it, what acts and omissions will make him criminally liable (see judgment of 22 October 2015, *AC-Treuhand* v *Commission*, C-194/14 P, EU:C:2015:717, paragraph 40 and the case-law cited).

1657 The principle that offences and penalties must have a proper legal basis cannot be interpreted as precluding the gradual, case-by-case clarification of the rules on criminal liability by judicial interpretation, provided that the result was reasonably foreseeable at the time the offence was committed, especially in the light of the interpretation put on the provision in the case-law at the material time (see judgment of 22 October 2015, *AC-Treuhand* v *Commission*, C-194/14 P, EU:C:2015:717, paragraph 41 and the case-law cited).

1658 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 (see judgment of 22 October 2015, *AC-Treuhand* v *Commission*, C-194/14 P, EU:C:2015:717, paragraph 42 and the case-law cited).

1659 It should be added that the need for professional advice appears all the more evident where, as was the case here, it is necessary to prepare and draft agreements intended to prevent or to settle disputes.

1660 In that context, even though, at the time of the infringements found in the contested decision, the Courts of the European Union had not yet had the opportunity to rule specifically on a settlement agreement of the type concluded by Servier, Servier should have expected, if necessary after taking appropriate legal advice, its conduct to be declared incompatible with the EU competition rules, especially in the light of the broad scope of the terms 'agreement' and 'concerted practice' established by the case-law of the Court of Justice (see, to that effect, judgment of 22 October 2015, *AC-Treuhand* v *Commission*, C-194/14 P, EU:C:2015:717, paragraph 43).

1661 In particular, Servier could assume that by inducing generic companies to accept non-marketing and non-challenge clauses, by themselves restrictive of competition, it rendered the inclusion of such clauses in a patent settlement agreement entirely illegitimate. Indeed, their inclusion was no longer based on recognition by the parties to the agreements of the validity of the patent and thus indicated a misuse of the patent, unrelated to its specific purpose (see paragraph 267 above). Servier could therefore reasonably have foreseen that its conduct was caught by the prohibition laid down in Article 101(1) TFEU (see, to that effect, judgments of 22 October 2015, *AC-Treuhand* v *Commission*, C-194/14 P, EU:C:2015:717, paragraph 46, and of 8 September 2016, *Lundbeck* v *Commission*, T-472/13, under appeal, EU:T:2016:449, paragraph 764).

1662 In addition, as the General Court has already noted, well before the date of conclusion of the agreement at issue, there was case-law on the application of competition law in fields characterised by the presence of intellectual property rights (see, to that effect, judgment of 8 September 2016, *Xellia Pharmaceuticals and Alpharma* v *Commission*, T-471/13, not published, under appeal, EU:T:2016:460, paragraphs 314 and 315).

1663 Thus, the Court of Justice held, as early as 1974, that although the existence of rights recognised under the industrial property legislation of a Member State is not affected by Article 101 TFEU, the conditions under which those rights may be exercised may nevertheless fall within the prohibitions contained in that article and that 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 of 31 October 1974, *Centrafarm and de Peijper*, 15/74, EU:C:1974:114, paragraphs 39 and 40).

1664 Next, since the judgment of 27 September 1988, *Bayer and Maschinenfabrik Hennecke* (65/86, EU:C:1988:448), it is clear that patent dispute settlements may be categorised as agreements within the meaning of Article 101 TFEU.

1665 Moreover, it must be pointed out that, by the agreements at issue, Servier and the generic companies concerned actually decided to conclude market exclusion agreements (see, inter alia, paragraphs 271, 562 and 704 above). Although it was only in a judgment delivered after the conclusion of the agreements at issue that the Court of Justice held that market exclusion agreements, in which the stayers are to compensate the goers, constitute a restriction on competition by object, it nonetheless made clear that that type of agreement conflicts patently with the concept inherent in the provisions of the Treaty relating to competition, according to which each economic operator must determine independently the policy which it intends to adopt on the market (judgment of 20 November 2008, *Beef Industry Development Society and Barry Brothers*, C-209/07, EU:C:2008:643, paragraphs 8 and 32 to 34). In concluding such agreements, Servier could not, therefore, have been unaware of the anticompetitive nature of its conduct.

1666 Indeed, although, because the agreements at issue were concluded in the form of patent settlements, the unlawful nature of those agreements might not have been evident to an outside observer such as the Commission or lawyers specialising in the fields in question, the same could not be said for the parties to the agreement.

1667 The difficulties likely to be encountered by the Commission in identifying an infringement were, moreover, capable of justifying, at least in part, the length of the proceedings or the length of the contested decision.

1668 The conclusion in paragraph 1661 above is not called in question by the other arguments submitted by the applicants.

1669 In the first place, the argument alleging that the Commission has a practice of not imposing fines or imposing merely symbolic fines when it examines new legal issues cannot be accepted in the present case, since, in spite of the novelty of the questions raised in the present case, Servier could reasonably

have foreseen that, in acting as it did, that is to say by paying generic companies to stay out of the market, its conduct was caught by the prohibition laid down in Article 101(1) TFEU (see paragraph 1661 above). In that regard, it should be noted that, in one of the Commission decisions cited by the applicants, it is apparent that 'it was not sufficiently clear to [the party concerned] that its behaviour would constitute an infringement'. Accordingly, the Commission was faced with a situation different from that in the present dispute.

1670 Moreover, it was stated in paragraph 1665 above that Servier could not in the present case have been unaware of the anticompetitive nature of its conduct.

1671 In any event, according to the case-law, the Commission has a margin of discretion when setting the amount of fines, in order that it may channel 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 the implementation of EU 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 (judgment of 8 September 2016, *Lundbeck* v *Commission*, T-472/13, under appeal, EU:T:2016:449, paragraph 773).

1672 In the second place, although the applicants refer to the existence of a legal opinion that had been sought by one of the generic companies in question and which is mentioned in recital 3074 of the contested decision, they have not adduced sufficient evidence to support a conclusion that there was genuine uncertainty concerning the infringing nature of the agreements at issue in the light of the EU competition rules.

1673 In the third place, although the applicants maintain that the solution adopted by the Commission in the contested decision conflicts with the principles set out in the 2004 Guidelines on technology transfer agreements, that argument must be rejected.

1674 Indeed, even if the applicants had intended to rely in that way on an infringement of paragraph 209 of the 2004 Guidelines on technology transfer agreements, it is clear from that paragraph that non-challenge clauses are 'generally' considered to fall outside Article 101(1) TFEU. Accordingly, in view of the use of that word, that provision does not preclude that non-challenge clauses may, in certain circumstances, constitute an infringement of the competition rules.

1675 In addition, paragraph 209 of the 2004 Guidelines on technology transfer agreements provides that non-challenge clauses may fall outside Article 101(1) TFEU in so far as the 'very purpose' of those clauses, by preventing future challenges to the intellectual property rights covered by the agreements, is 'to settle existing disputes and/or to avoid future disputes'.

1676 Where, as in the present case, it is a reverse payment, and not the recognition by each of the parties of the validity of the patent, which led to the adoption of the agreements at issue, it cannot be considered that the 'very purpose' of those agreements — which are actually market exclusion agreements with anticompetitive objectives — is 'to settle existing disputes and/or to avoid future disputes'.

1677 Moreover, contrary to what the applicants seem to claim, there is no evidence to support the conclusion that the solution adopted by the Commission in the contested decision was unforeseeable to the extent that the Commission considered it necessary to amend the provisions of the 2004 Guidelines on technology transfer agreements.

1678 It is true that paragraph 243 of the 2014 Guidelines on technology transfer agreements provides that a non-challenge clause may infringe Article 101(1) TFEU if the licensor, besides licensing the technology rights, induces, financially or otherwise, the licensee to agree not to challenge the validity of the technology rights.

1679 However, that new provision merely clarified the provisions previously contained in the 2004 Guidelines on technology transfer agreements.

1680 In the fourth place, as regards the argument alleging contradictions in the contested decision concerning the interpretation of the concept of potential competition, it is necessary to point out that that argument has already been rejected and to refer to the considerations already set out in that regard (see paragraphs 374 to 377 above).

1681 It follows from the foregoing that the plea, in so far as it relates to the infringements found in the contested decision under Article 101 TFEU, must be rejected.

(b) The error of law relating to the imposition of cumulative fines

1682 The applicants rely on two complaints, alleging, first, the existence of a single infringement comprising all the settlement agreements at issue concluded by Servier, which prevents the Commission from imposing five separate fines on Servier and, secondly, the unlawfulness of imposing the fine under Article 101 TFEU cumulatively with that imposed under Article 102 TFEU.

(1) Infringement of the concept of single infringement

(i) Arguments of the parties

…

(ii) Findings of the Court

1685 The applicants put forward two arguments, both relating to the concept of a single infringement and alleging, first, the existence of a single infringement comprising all the settlement agreements at issue concluded by Servier and, secondly, in the alternative, the existence of a single infringement comprising the Niche and Matrix agreements.

1686 As regards the first argument, as is clear from paragraph 1282 above, the existence of an objective common to Servier and to each of the generic companies and therefore of an overall plan could not be established by the Commission.

1687 In the absence of such a common objective as well as an overall plan, the Commission was not in a position to conclude that there was a single infringement. It was therefore entitled to impose a separate fine on Servier for each of the infringements found.

1688 Thus, the Commission's imposition of cumulative fines in the contested decision, which is based on the justified finding of the existence of separate infringements, cannot, contrary to the applicants' argument, be regarded as being 'unfair and disproportionate'.

1689 On the contrary, it would be unfair to the generic companies for Servier, like them, to be penalised only once, even though, unlike them, Servier participated in several separate agreements.

1690 Moreover, the imposition of cumulative fines is, in principle, even less disproportionate since the Commission took into account, in the contested decision (recital 3128), the fact that Servier committed several infringements which — although different — relate to the same product, perindopril, and largely to the same geographic areas and periods of time. In that particular context, in order to avoid a potentially disproportionate result, the Commission decided to limit, in respect of each infringement, the proportion of the value of sales made by Servier taken into account for the

purpose of determining the basic amount of the fine. It thus applied a correction which led to an average reduction of 54.5% in the overall values of the sales relating to the various infringements of Article 101 TFEU.

1691 The present argument must therefore be rejected.

1692 As regards the specific argument relating to the Niche and Matrix agreements, as is apparent from the considerations set out in paragraphs 1295 to 1302 above, those agreements constituted two separate infringements of Article 101 TFEU.

1693 However, as stated in paragraph 1296 above, it may be inferred from the analysis of the context and the terms of those agreements that Servier was driven by 'similar motives' in concluding the agreements in question and pursued in that respect an identical objective, namely definitively to settle the ongoing dispute and to avoid any future litigation concerning the Niche/Matrix product and to eliminate that product as a source of potential competition in return for payment. In particular, the fact that Servier actually pursued that same objective when it concluded the Niche and Matrix agreements is evidenced by the fact that those agreements were signed on the same day and at the same place by the same representative of the applicants, the fact that their temporal and geographic scope was identical, the fact that the agreements related in particular to the same product — imposing similar obligations on Niche and Matrix — and, finally, the undisputed fact that it was in Servier's interest to conclude agreements with the two stakeholders in the relevant joint perindopril project.

1694 Although the factual information set out in paragraph 1693 above does not establish that Niche and Matrix were together pursuing the same objective — attesting to a common plan — in concluding that the agreements in question, or a fortiori that they shared that common plan with Servier, that information does show that Servier was pursuing the same objective when concluding the Niche and Matrix agreements (see paragraphs 1296 to 1301 above).

1695 Moreover, the harmful effects of the agreements in question related in part to the product developed jointly by Niche and Matrix, the marketing of which was prohibited during the same period and in the same territory. The degree of overlap between the anticompetitive effects of those agreements was therefore particularly high.

1696 In the light of the elements referred to in the preceding paragraphs, which are specific to the Niche and Matrix agreements and thus distinguish them from the settlement agreements which Servier concluded with other generic companies, it must be held that the reduction used by the Commission on the basis of overlapping infringements (see paragraph 1690 above), since it failed to apply special treatment to the Matrix agreement, did not take sufficient account of the links between that agreement and the Niche agreement.

1697 Moreover, the amount of the fine imposed by the Commission does not adequately reflect the degree of gravity of the infringement consisting in the Matrix agreement, which, as regards Servier, is lower than the degree of gravity of the infringement consisting in the Niche agreement, because the Matrix agreement was concluded by Servier for the purpose of strengthening the effects of the Niche agreement (see paragraph 1300 above) and because, in the light of the Biogaran agreement, the overall transfer of value to Niche and Unichem is greater than that to Matrix.

1698 Therefore, in the exercise its unlimited jurisdiction, the Court has decided, for the purpose of observing the principle of proportionality (see, to that effect, judgment of 4 September 2014, *YKK and Others* v *Commission*, C-408/12 P, EU:C:2014:2153, paragraph 66), to reduce the amount of the fine imposed on Servier on the basis of the Matrix agreement by 30%, that is to say EUR 23 736 510.

1699 Consequently, the amount of the fine imposed on Servier in respect of the infringement referred to in Article 2 of the contested decision, as set out in Article 7(2)(b) thereof, is set at EUR 55 385 190 instead of EUR 79 121 700.

(2) The imposition of cumulative fines under Articles 101 and 102 TFEU

(i) Arguments of the parties

…

(ii) Findings of the Court

1702 In the light of the annulment of Article 7(6) of the contested decision (see paragraph 1638 above), Servier is now penalised only under Article 101 TFEU. In the absence of any cumulation of penalties under Articles 101 and 102 TFEU, it is not necessary, in any event, to examine the merits of the present complaint, which must be rejected.

(c) The calculation of the value of sales

1703 The applicants rely on three discrete complaints which must be examined separately.

(1) The taking into account of hospital sales

(i) Arguments of the parties

…

(ii) Findings of the Court

1706 It should be noted that the applicants refer, in support of the present complaint, to recitals 2408 to 2412 of the contested decision, in which the Commission states that it excluded the hospital sector from its market analysis.

1707 Recitals 2408 to 2412 of the contested decision are set out in Section 6.5 of that decision, which deals with the assessment of Servier's dominance on the finished product market.

1708 The Commission stated in recital 2412 of the contested decision that perindopril was predominantly distributed in the retail channel and that, accordingly, the sales taking place at hospitals could not affect the overall prices and volumes obtained in the retail sales. The Commission therefore considered that the competitive constraints resulting from the hospital sector could not prevent Servier from behaving independently of competitive pressure. It therefore excluded the hospital sector from the analysis of the finished product markets.

1709 The Commission also stated, in recital 2595 of the contested decision, that the finding of independence of competitive pressure made it possible to establish the existence of market power.

1710 It follows from the foregoing that the Commission intended to exclude the hospital sector from the market analysis, on the ground that it considered that that portion of the market was not relevant for the purpose of determining whether or not Servier had market power.

1711 When examining the agreements at issue under Article 101 TFEU, the Commission referred to Section 6.5 of the contested decision in the context of the analysis of the restriction by effect for which determining whether Servier had market power was relevant, as is apparent, in particular, from recitals 1397, 1503, 1656, 1847 and 2048 of the contested decision and, above all, from recital 1224 thereof, in which the Commission stated that the notion of market power was central to the analysis of the restrictive effects of agreements.

1712 The Commission therefore intended to exclude the hospital sector from the analysis of the restriction by effect.

1713 As regards its analysis of the restriction by object, the Commission made no reference to Section 6.5 of the contested decision and at no time did it state that it was excluding the hospital sector from its analysis. Moreover such exclusion was of no relevance to the Commission, because the analysis of the restriction by object did not lead it to determine whether or not Servier had market power.

1714 Furthermore, in order to establish the existence of a restriction by object, the Commission relied on the presence of restrictive clauses in the agreements at issue. It is therefore the existence of those clauses and, consequently, their scope which enabled the Commission to determine the scope of the restriction by object. For example, as regards the geographic scope of the restriction by object found, with respect to each agreement, by the Commission, the Commission included only the Member States in which the restrictive clauses applied, as is apparent from Table 50, set out in recital 3134 of the contested decision.

1715 However, the non-marketing clauses in the agreements at issue did not exclude the hospital sector from their scope. Similarly, even if such an exclusion is possible for a non-challenge clause, the non-challenge clauses in those agreements did not exclude that sector from their scope.

1716 In the light of the foregoing considerations, it must be concluded that the Commission did not exclude the hospital sector when it found that there was a restriction of competition by object.

1717 In order to determine whether, on account of the exclusion of the hospital sector from the analysis of the restriction by effect noted above, the applicants could nonetheless obtain a reduction in the amount of the fines imposed under Article 101 TFEU, it is necessary to ensure that the taking into account of the finding made by the Commission of a restriction by effect did not allow it to impose on Servier a penalty going beyond what the mere finding of a restriction by object allowed it to impose.

1718 In that regard, it must be pointed out that at no time did the Commission state in the contested decision that it was extending the material, temporal or geographic scope of the infringement beyond what the finding of a restriction by object permitted it to do.

1719 On the contrary, the Commission found the existence of a restriction by effect only in four Member States, namely France, the Netherlands, Poland and the United Kingdom, whereas, for the purposes of calculating the amount of the fine, as regards the infringements concerning Niche and Unichem, Matrix, Krka and Lupin, it extended the geographic scope of the infringements to all the Member States in which the agreements were applied.

1720 Moreover, it may be noted that it is only in the alternative, ‘for the sake of completeness’ (recital 1213 of the contested decision), that the Commission analysed the restrictive effects of the agreements at issue on competition.

1721 Finally, the applicants themselves state that the calculation of the amount of the fine ‘is based solely on the premiss that the agreements constitute restrictions by object’.

1722 Accordingly, the taking into account of the finding made by the Commission of a restriction by effect did not allow it to impose on Servier a penalty going beyond what the mere finding of a restriction by object allowed it to impose.

1723 It follows from the foregoing that the Commission was right not to exclude the hospital sector from the calculation of the amount of the fine with respect to the part of that fine relating to Article 101 TFEU.

1724 It follows from all the foregoing that the present complaint must be rejected.

(2) The failure to state sufficient reasons for the calculation of the value of sales

(i) Arguments of the parties

…

(ii) Findings of the Court

1727 It is clear from the settled case-law that, in the determination of the amount of the fine in a case of infringement of the competition rules, the Commission fulfils its obligation to state reasons when it indicates in its decision the factors which enabled it to determine the gravity of the infringement and its duration, and it is not required to indicate the figures relating to the method of calculating the fines (see judgment of 22 October 2015, *AC-Treuhand* v *Commission*, C-194/14 P, EU:C:2015:717, paragraph 68 and the case-law cited).

1728 In the present case, the applicants criticise only the correction coefficient which the Commission applied to the value of sales.

1729 In that regard, the Commission stated, in recital 3128 of the contested decision, that, in view of the fact that Servier committed several infringements which — although different — relate to the same product, perindopril, and largely to the same geographic areas and periods of time, it applied a correction factor making it possible to limit, in respect of each infringement, the proportion of the value of sales made by Servier taken into account for the purpose of determining the basic amount of the fine. The Commission also stated that that correction factor led, on average, in respect of each of the five infringements of Article 101 TFEU, to the application of a reduction of 54.5% in the values of sales.

1730 Accordingly, in the light of the case-law cited in paragraph 1727 above and the fact that the application of the correction coefficient in question, even though it is not provided for in the Guidelines on the method of setting fines, benefits the applicants, the Commission stated sufficient reasons for its decision, and the fact that the applicants are not in a position to reproduce all the calculations which led, on the one hand, to the rate of 54.5% referred to above and, on the other hand, to the amount of the fine ultimately imposed in respect of each infringement of Article 101 TFEU cannot lead to a different conclusion.

1731 Admittedly, it may be noted that, following a measure of organisation of procedure conducted by the Court in order to facilitate, where appropriate, the exercise of its unlimited jurisdiction, the Commission forwarded more precise information on the calculations allowing it to obtain the rate of 54.5% referred to above and the amount of the fine ultimately imposed in respect of each infringement of Article 101 TFEU, and that that information permitted the Court and the applicants to understand in greater detail how the Commission had determined that rate and those amounts.

1732 However, the fact that more specific information concerning the calculation of the amount of the fine for infringement of the competition rules is communicated subsequently, in the course of the judicial proceedings, is not such as to show that the contested decision was in that regard, vitiated by inadequate reasoning. Where the author of a contested decision provides explanations to supplement a statement of reasons which is already adequate in itself, that does not go to the question whether the duty to state reasons has been complied with, though it may serve a useful purpose in relation to review by the EU Court of the adequacy of the grounds of the decision, since it enables the institution to explain the reasons underlying its decision (see, to that effect, judgment of 16 November 2000, *Weig* v *Commission*, C-280/98 P, EU:C:2000:627, paragraph 45).

1733 Moreover, contrary to the applicants' submissions, the partial nature of the reduction applied as a result of the correction coefficient is justified by the fact that, as was stated in response to the plea relating to the existence of a single and continuous infringement, the various agreements in question constitute not a single infringement but separate infringements in respect of each of which the Commission was entitled to apply a separate fine.

1734 It follows from all the foregoing that the present complaint must be rejected.

(3) The geographic scope of the value of sales

(i) Arguments of the parties

…

(ii) Findings of the Court

1738 The applicants submit that in the contested decision, in particular in Table 50, contained in recital 3134 thereof, the Commission erroneously defined the geographic scope of the infringements of Article 101 TFEU, since, on the one hand, the 947 patent was granted in Poland only after all the infringements had come to an end, and, on the other hand, Bulgaria, the Czech Republic, Estonia, Cyprus, Latvia, Lithuania, Hungary, Malta, Poland, Romania, Slovenia, Slovakia and Finland were not covered by the 939 to 941 patents.

1739 It should be pointed out that the aforementioned Table 50 shows the dates of the beginning and end of each infringement by Member State.

1740 As a preliminary point, the infringement concerning Teva should be excluded from the analysis. Indeed, that infringement concerns only the United Kingdom. However, none of the applicants' arguments concerns that Member State. Those arguments therefore have no bearing on the geographic scope of that infringement.

1741 As regards the other infringements, it should be noted that the scope, in particular the geographic scope, of each infringement necessarily depends on the scope of the non-marketing and non-challenge clauses in the agreement in question. It is those clauses which restrict competition and which, when they are entirely illegitimate, reveal a sufficient degree of harm to the proper functioning of normal competition that a restriction by object may be found (see paragraph 270 above).

1742 In that regard, the applicants merely infer from the absence of one or more patents in a given Member State that there is no infringement in respect of that State, without drawing any distinction between infringements and, above all within each infringement, between the potentially different effects of the absence of a patent on the geographic scope of the non-marketing clause and on the geographic scope of the non-challenge clause.

1743 Accordingly, the applicants do not specify, or even refer to, the consequences which a difference between the respective geographic scopes of the non-marketing clause and the non-challenge clause might have on the assessment of the gravity of the infringement.

1744 The applicants' line of argument seeks therefore only to exclude, for a given Member State, the existence of any infringement.

1745 However, it is sufficient for either the non-marketing clause or the non-challenge clause to have applied in a Member State for a particular period for the Commission to be entitled to include that State within the geographic scope of that infringement for the period in question.

1746 The plea, as relied upon by the applicants, can therefore succeed only in so far as it is possible to conclude that neither the non-marketing clause nor the non-challenge clause applied in a given Member State during a period in respect of which the Commission nonetheless found an infringement in that Member State.

1747 It is necessary first of all to examine, in the light of the various arguments put forward by the applicants, the geographic scope of the non-marketing clause for each of the agreements other than the Teva agreement.

1748 The applicants put forward two arguments, the first relating to the 947 patent and the second to the 339, 340 and 341 patents.

1749 With regard to the Lupin agreement, Clause 1.6 thereof provides that Lupin may not sell the 'product' in any Member State. The term 'product' refers, in particular, to medicinal products containing erbumine. In that agreement, the non-marketing clause is therefore not subject to the existence of a patent, whether the 947 patent or the 339, 340 and 341 patents. Accordingly, it applied to all the Member States without it being necessary to determine whether, in each of them, the patents just referred to existed at the time of the infringement. Since the Commission did not erroneously define the geographic scope of the infringement as regards the non-marketing clause, the applicants' plea may therefore be rejected in so far as it concerns the Lupin agreement (see paragraphs 1741 to 1746 above).

1750 As regards the Niche and Matrix agreements and the settlement agreement concluded with Krka, the scope of the non-marketing clause is, on the contrary, subject to the existence of Servier's patents. The applicants' arguments may therefore reasonably be relied upon.

1751 It is necessary, first, to examine the argument relating to the 947 patent.

1752 The applicants maintain that that patent had not been granted in Poland at the time of the infringement.

1753 As regards, in any event (see paragraphs 1636, 1637 and 1640 above), the settlement agreement concluded with Krka, as is clear from Table 50 — set out in recital 3134 of the contested decision, which is not disputed on that point — the Commission has not found the existence of an infringement concerning Poland. It is therefore irrelevant whether that Member State was or was not covered by the 947 patent during the period of the infringement.

1754 As regards the Niche agreement, the non-marketing clause provided for in Clause 3 applies in countries in which there exists, inter alia, an 'alpha patent right', which includes the 947 patent and all equivalent patents or patent applications, as provided for in Clause 1(ii), contained in Section 1, entitled 'Definitions'.

1755 Similarly, as regards the Matrix agreement, the non-marketing clause provided for in Clause 1 applies to 'the territory', that is to say in all countries in which there exists, inter alia, an 'alpha patent right', which includes the 947 patent and all equivalent patents or patent applications, as provided for in Clause 1(ii), contained in Section 1, entitled 'Definitions'.

1756 However, it is not disputed, as is clear from recital 120 and footnote 155 of the contested decision, that Servier had applied for a patent covering 'its alpha-crystalline form of perindopril erbumine (corresponding to the 947 patent)' in Poland on 6 July 2001.

1757 Consequently, the applicants' argument relating to the 947 patent (see paragraph 1752 above) must be rejected with regard to the Niche and Matrix agreements.

1758 It follows from the foregoing that that argument must be rejected for all the agreements.

1759 It is appropriate, secondly, to examine the applicants' argument concerning the 339, 340 and 341 patents.

1760 The applicants submit that, at the time of the infringements, Bulgaria, the Czech Republic, Estonia, Cyprus, Latvia, Lithuania, Hungary, Malta, Poland, Romania, Slovenia, Slovakia and Finland were not covered by the patents in question.

1761 As regards the settlement agreement concluded with Krka, it is sufficient, in any event (see paragraphs 1636, 1637 and 1640 above), to note that the scope of the non-marketing clause is not subject to the existence of patents 339 to 341. It is therefore irrelevant that those patents or an application relating to them were not granted in each of the Member States for which the applicants claim that those patents did not apply.

1762 With respect to the Niche and Matrix agreements, the non-marketing clause in those agreements applies in countries in which the 339 to 341 patents 'and/or' the 947 patent exist, as provided for in Clause 3 of the Niche agreement and Clause 1(xiii) of Section 1 of the Matrix agreement and Clause 1 of Section 2 of that agreement.

1763 With the exception of the argument relating to Poland, which has already been rejected above, the applicants do not claim and, a fortiori, do not establish that the 947 patent was absent from one of the Member States referred to in paragraph 1760 above.

1764 Since the applicants had precise knowledge of the scope of the agreements because of their status as co-author of those agreements, it was incumbent upon them to adduce evidence establishing, or at the very least to claim, such an absence.

1765 Thus, even assuming that the Member States referred to in paragraph 1760 above were not covered by the 339, 340 and 341 patents, that fact would not, in the light of the arguments put forward by the applicants, support the conclusion that the non-marketing clauses in the Niche and Matrix agreements were not applicable in those States, since the applicants do not dispute that the 947 patent covered them.

1766 It follows from the foregoing that the arguments and evidence put forward by the applicants do not support the conclusion that the Commission erroneously defined the geographic scope of the infringement as regards the non-marketing clause.

1767 In view of the considerations set out in paragraphs 1741 to 1746 above, the present plea may be rejected without it being necessary to determine whether the Commission erroneously defined the geographic scope of the infringement as regards the non-challenge clause.

(d) The gravity of the infringements

(1) Arguments of the parties

…

(2) Findings of the Court

1784 It is necessary to examine, in the first place, the applicants' complaint concerning the lack of anticompetitive intent.

1785 The applicants are, in fact, criticising recital 3064 et seq. of the contested decision, in which the Commission confined itself to finding that the infringements in question had been committed either intentionally or negligently, which allowed it, as provided for in Article 23(2) of Regulation No 1/2003, to impose fines on the undertakings in question.

1786 In that respect, 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 (judgments of 18 June 2013, *Schenker & Co. and Others*, C-681/11, EU:C:2013:404, paragraph 37; of 10 July 2014, *Telefónica and Telefónica de España* v *Commission*, C-295/12 P, EU:C:2014:2062, paragraph 156; and of 8 September 2016, *Lundbeck* v *Commission*, T-472/13, under appeal, EU:T:2016:449, paragraph 762).

1787 However, it follows from the examination of the various agreements at issue, with the exception of the agreements concluded with Krka, that Servier paid generic companies to stay out of the market. It therefore could not have been unaware of the anticompetitive nature of that conduct. The exclusion of competitors from the market constitutes an extreme form of market sharing and of limitation of production (see, to that effect, judgment of 8 September 2016, *Lundbeck* v *Commission*, T-472/13, under appeal, EU:T:2016:449, paragraph 435), which, according to the case-law, is 'patently' unlawful (see paragraph 1665 above).

1788 Although, because the agreements at issue were concluded in the form of a patent settlement, the unlawful nature of those agreements might not have been evident to an outside observer, the same could not be said for the parties to those agreements (see paragraph 1666 above).

1789 Moreover, it must be pointed out that the agreements at issue, with the exception of the agreements concluded with Krka, pursued anticompetitive objectives.

1790 In the event that — as is the case with each of the agreements at issue — a reverse payment and not recognition by each of the parties of the validity of the patent leads to the adoption of a settlement agreement, that is to say when the generic company is induced to accept non-marketing and non-challenge clauses, the restrictions on competition introduced by those clauses are no longer linked to the settlement of litigation, whether it be real or notional, relating to a patent. It is then the inducement, and not the recognition of the validity of the patent at issue by the parties to the agreement, which is the real cause of the restrictions of competition introduced by those clauses. In such a situation, that agreement as a whole may properly be regarded as a market exclusion agreement pursuing anticompetitive objectives.

1791 Thus, the existence of an anticompetitive objective is established and it is in that respect irrelevant whether or not Servier concluded an agreement with all the generic companies contesting its patents, whether or not it took the initiative in the agreements and whether or not the agreements in question were secret.

1792 Those elements will, however, be taken into consideration subsequently in order to determine whether the rates used by the Commission were disproportionate.

1793 It is necessary to examine, in the second place, the applicants' complaint that the Commission failed to take into account the existence of Servier's patents.

1794 In that regard, contrary to what the applicants claim, the Commission did not overlook the fact that the agreements related to intellectual property rights.

1795 The finding of an inducement implies that the market exclusion entailed by the agreement results, not from the effects of the patents at issue and from their legitimate use, in particular in the context of a settlement, but rather from a value transfer, representing the financial consideration for that exclusion (see paragraphs 253 to 276 above).

1796 It should also be underlined that the Commission complied with the conditions for the application of competition law to intellectual property rights and the presumption of validity enjoyed by those rights, since it classified as restrictions by object only those agreements which constituted abnormal use of the patent in that they were based on an inducement and not on the recognition of the validity of the patent (see paragraphs 266 and 267 above).

1797 Finally, where, as is the case for all the agreements at issue with the exception of the agreements concluded with Krka, the existence of an inducement is established, the parties can no longer rely on their recognition, in the context of the settlement, of the validity of the patent. The fact that the validity of the patent is confirmed by a court or administrative body is, in that respect, immaterial. The same applies to the validation of the 947 patent by the EPO Opposition Division or the findings, favourable to the applicants, made by the United Kingdom courts (see paragraph 269 above).

1798 Moreover, the applicants' argument that it is 'paradoxical and unlawful' for the duration of the infringements to depend on the length and outcomes of the litigation concerning Servier's patents must be rejected.

1799 The duration of the infringements alleged against the applicants depends on the temporal scope of the non-marketing and non-challenge clauses in the agreements at issue, which in turn depends on the existence of Servier's patents and therefore on the outcomes of proceedings seeking to challenge those patents.

1800 It should be added that Servier is all the more incapable of contesting the link between the length of the litigation relating to its patents and the duration of the infringements, since the interdependence referred to in paragraph 1799 above, which creates such a link, arises from contractual clauses that it co-authored.

1801 It is necessary to examine, in the third place, the applicants' complaint concerning the absence of any actual impact of the infringements on the market.

1802 In that regard, it must first be recalled that Article 23(3) of Regulation No 1/2003 provides that, in determining the amount of the fine, it is necessary to consider the duration of the infringement and its gravity, but does not specify that the infringement has to be assessed by reference to the actual results which occur on the market (Opinion of Advocate General Mischo in *Mo och Domsjö* v *Commission*, C-283/98 P, EU:C:2000:262, point 96).

1803 It is true that the Guidelines on the method of setting fines imposed pursuant to Article 15(2) of Regulation No 17 and Article 65(5) of the ECSC Treaty (OJ 1998 C 9, p. 3) provide that, in assessing the criterion of the infringement's gravity, account must be taken of, inter alia, its actual impact on the market, where this can be measured.

1804 However, no reference is made to such a requirement in the Guidelines on the method of setting fines imposed pursuant to Article 23(2)(a) of Regulation No 1/2003.

1805 In that regard, it may be noted that the factor relating to 'whether or not the infringement has been implemented', referred to in point 22 of the Guidelines on the method of setting fines, concerns the conduct of the participants in the infringement and not its effects on the market.

1806 Accordingly, the Commission was under no obligation, pursuant to the Guidelines on the method of setting fines, to take into consideration the actual impact of the infringement on the market in order to determine the percentage of the value of sales used for gravity in accordance with points 19 to 24 of the Guidelines on the method of setting fines (see, to that effect, judgments of 14 March 2013, *Fresh Del Monte Produce* v *Commission*, T-587/08, EU:T:2013:129, paragraphs 773 to 775, and of 16 June 2015, *FSL and Others* v *Commission*, T-655/11, EU:T:2015:383, paragraph 539).

1807 Secondly, the case-law of the EU Courts does not require the Commission to take into consideration the actual impact of the infringement on the market.

1808 It is clear from the case-law of the Court of Justice that the gravity of infringements must be determined by reference to numerous factors such as, in particular, the particular circumstances of the case, its context and the dissuasive element of fines, although no binding or exhaustive list of the criteria to be applied has been drawn up (order of 25 March 1996, *SPO and Others* v *Commission*, C-137/95 P, EU:C:1996:130, paragraph 54; judgments of 17 July 1997, *Ferriere Nord* v *Commission*, C-219/95 P, EU:C:1997:375, paragraph 33, and of 28 June 2005, *Dansk Rørindustri and Others* v *Commission*, C-189/02 P, C-202/02 P, C-205/02 P to C-208/02 P and C-213/02 P, EU:C:2005:408, paragraph 241).

1809 The effects on the market may indeed be taken into account amongst the very numerous factors referred to in paragraph 1808 above, but they are crucial only when one is dealing with agreements, decisions or concerted practices which do not directly have as their object the prevention, restriction or distortion of competition and which are not therefore liable to fall within the scope of application of Article 101 TFEU except as a result of their actual effects (Opinion of Advocate General Mischo in *Mo och Domsjö* v *Commission*, C-283/98 P, EU:C:2000:262, point 101).

1810 To require that the Commission, at the stage of calculating the amount of the fine, take into consideration the actual impact of the infringement on the market would have the effect of imposing on the Commission an obligation to which, according to settled case-law, it is not subject for the purposes of applying Article 101 TFEU where the infringement in question has an anticompetitive object (see judgment of 3 September 2009, *Prym and Prym Consumer* v *Commission*, C-534/07 P, EU:C:2009:505, paragraph 64 and the case-law cited).

1811 It is true, as the applicants point out, that the Commission did not rely in the contested decision solely on the finding of the existence of restrictions of competition by object, but also found the existence of restrictions by effect.

1812 However, it is only in the alternative, 'for the sake of completeness' (recital 1213 of the contested decision), that the Commission analysed the restrictive effects of the agreements at issue on competition. Moreover, it may be noted that the Commission considered that it had established the existence of a restriction by effect only in four Member States, namely France, the Netherlands,

Poland and the United Kingdom. For the purpose of calculating the amount of the fine, a geographic scope of the infringements which included all the Member States in which the agreements had applied was taken into account by the Commission.

1813 Furthermore, the applicants themselves state that the calculation of the amount of the fine 'is based solely on the premiss that the agreements constitute restrictions by object'.

1814 It follows from the foregoing that the Commission was not required to take into account the alleged absence of any actual impact of the infringements on the market when it determined the amount of the fine for the infringements of Article 101 TFEU.

1815 In any event, even assuming that the Commission had to establish that the infringements in question had an actual impact on the market and failed adequately to do so, this would have no effect on the rates the Commission used, in so far as it is possible to conclude, even in the absence of such an impact, that those rates are not disproportionate.

1816 In that regard, it should be noted that the agreements at issue are market exclusion agreements pursuing anticompetitive objectives (see paragraph 1790 above). The exclusion of competitors from the market constitutes an extreme form of market sharing and of limitation of production (see paragraph 271 above). Thus, under point 23 of the Guidelines on the method of setting fines, such agreements are, in principle, to be heavily fined.

1817 It should also be added that the restrictive clauses contained in the agreements at issue were implemented.

1818 In view of those factors, the proportion of the value of sales used by the Commission, that is 10 or 11%, depending on the circumstances, which is only approximately a third of the maximum proportion that may be used, does not appear disproportionate. On the contrary, those percentages adequately reflect both the gravity of the infringements found, which were particularly harmful because of their anticompetitive objective, and the specific context in which they occurred, characterised by the defence of intellectual property rights and the uncertainty surrounding the outcome of litigation relating to Servier's patents.

1819 In that regard, it should be noted that the applicants are even less justified in relying on the absence of actual effects on competition of the agreements at issue, since those agreements, based on an inducement and not on the recognition by the parties of the validity of the patent at issue, specifically allowed the applicants to replace the vicissitudes of patent litigation and the uncertainties surrounding the conditions and possibilities of market entry by generic companies with the certainty of excluding from the market those companies in respect of which an agreement was concluded.

1820 Similarly, the conclusion set out in paragraph 1818 above could not be called into question even if the existence of the elements relied on by the applicants and referred to in paragraph 1791 above were established.

1821 Moreover, the failure to state adequate reasons which the applicants rely on, with no clarification, cannot be upheld. Servier was actually in a position — in the light of all the findings made by the Commission in the contested decision, in particular in recital 3130 thereof, and in view of the context in which that decision was adopted — to understand the reasons for using the rates of 10 and 11% of the value of sales.

1822 The Commission has, in particular, adequately justified applying different proportions of the value of sales depending on the agreements. It stated that the rate used for the Niche, Matrix and Lupin agreements was higher than that used for the Teva and Krka agreements, because the geographic scope of the first group of agreements was wider than that of the second group of agreements (recital 3131 of the contested decision).

1823 It follows from all the foregoing that the present plea must be rejected.

(e) The duration of the infringements

1824 The applicants rely on two complaints, alleging, first, errors relating to the determination of the starting point of the infringements and, secondly, errors relating to the determination of the end of the infringements.

(1) The starting point of the infringements

(i) Arguments of the parties

…

(ii) Findings of the Court

1833 It is necessary to examine, in the first place, the argument that the challenge to Servier's patents did not end and was not even delayed.

1834 In that regard, it should be noted that the applicants do not establish, or even claim, that one of the generic companies which concluded the agreements at issue challenged one of Servier's patents, in spite of being subject to a non-challenge clause.

1835 The applicants therefore rely not on non-implementation of the agreements, but rather on the fact that generic companies other than those which concluded the agreements at issue challenged Servier's patents.

1836 The applicants' argument therefore consists essentially in relying on the absence of actual effects on competition of the agreements at issue.

1837 In that regard, it should be recalled that, as regards restrictions of competition by object, there is no need to take account of their concrete effects on the market in order to establish the existence of the infringement (see, to that effect, judgment of 8 July 1999, *Commission* v *Anic Partecipazioni*, C-49/92 P, EU:C:1999:356, paragraphs 98 and 99) and, consequently, define the temporal scope of that infringement and thereby determine its duration (see, to that effect, judgment of 19 March 2009, *Archer Daniels Midland* v *Commission*, C-510/06 P, EU:C:2009:166, paragraphs 113, 114 and 140).

1838 The fact that the agreements at issue had no effect on competition cannot therefore be validly relied upon for the purpose of calling into question the duration of the infringements, since that duration is adequately established on the basis of the finding of a restriction by object.

1839 In any event, if the applicants' challenge is to be regarded as relating not to the finding of the infringements, in that the duration of those infringements was incorrectly determined, but to the assessment of the gravity of the infringements found by the Commission in the contested decision, it

should be recalled that the complaint relating to the absence of actual effects of the agreements and to the consequences of that absence on the assessment of the gravity of the infringements has already been rejected (see paragraphs 1801 to 1820 above).

1840 In the second place, as regards the arguments that some of the infringements could not be found until Teva and Lupin had a marketing authorisation, those arguments have already been examined in the context of the response to the pleas relating to the lack of potential competition (see paragraphs 604 and 743 above). It is clear from that response that the Commission rightly considered that Teva and Lupin were, at the date of the conclusion of the agreements, potential competitors of Servier. The Commission therefore did not incorrectly use that date as the starting date of the infringements in question.

1841 As regards the argument that the SPC relating to the patent protecting the perindopril compound had not expired, it may be disregarded on the basis of the considerations set out in the response to the plea concerning the lack of potential competition.

1842 Indeed, as stated in paragraph 359 above, it is possible for an operator to take the risk of entering the market with a product, including by potentially infringing the patent in force, and that 'at risk' entry or launch could be successful, if the patent holder decides not to bring an infringement action or, in the event that such an action is brought, if that infringement action is dismissed. That possibility of 'at risk' entry helps to show that patents do not pose insurmountable barriers to the market entry of generic companies.

1843 Moreover, a patent does not prevent operators from carrying out the operations required for the manufacture and marketing of a non-infringing product. They are therefore regarded as potential competitors of the patent holder until they enter the market, after which they become the patent holder's actual competitors (see paragraph 357 above).

1844 In that regard, the Commission stated in recital 3137 of the contested decision that generic companies sometimes started to prepare their entry to the market several years before the expiry of the SPC relating to a patent and that, as regards perindopril, this period was on average two to three years. Those considerations supported the finding that the infringements in question had started before the expiry date of the SPC relating to the patent protecting the perindopril compound.

1845 The Commission added, however, that, where the SPC had expired in a Member State after the launch of generic perindopril had taken place in other Member States, it preferred, 'in view of … the existence of accelerated mutual recognition procedures under which the Member States agree to recognise the validity of the [marketing authorisation] issued by another Member State' (footnote 4073 of the contested decision), to adopt a conservative approach and to fix the starting date of the infringement at the time of expiry of the SPC. The Commission went on to say that it had adopted such an approach in relation to Italy. It stated that, in France, by contrast, no generic product had been launched in any other Member State before the expiry of the SPC (footnote 4073 of the contested decision).

1846 The evidence set out in paragraphs 1844 and 1845 above is not disputed by the applicants.

1847 Having regard to the considerations set out in paragraphs 1842 to 1846 above, it must be concluded that the Commission was correct to consider that certain infringements had started in France on 8 February 2005, before the expiry of the SPC.

1848 Moreover, the applicants' complaint is effective only with respect to the infringements corresponding to the Niche and Matrix agreements, which are the only agreements at issue concluded before the expiry in France of the SPC.

1849 However, those agreements were concluded only on 8 February 2005, that is to say a little over a month prior to the expiry in France of the SPC on 22 March 2005.

1850 It is therefore particularly easy to note that, on 8 February 2005, the generic companies concerned were in a position to prepare a market entry which could take effect as soon as the SPC expired and therefore to exert competitive pressure.

1851 Moreover, even assuming that the applicants may be regarded as relying on an infringement of the principle of equal treatment and that the reference to that plea is not out of time, the fact that Servier was able, as regards the determination of the start of the infringement in respect of Italy, to receive favourable treatment which was unnecessary (having regard, in particular, to the considerations set out in paragraph 1842 above) does not justify Servier's receiving such treatment in respect of all the other Member States, unless it is established that such a difference in treatment is arbitrary (see paragraphs 1868 to 1871 below).

1852 However, that is not the case here. There was an objective difference between France and Italy which was not unrelated to the possibility of finding an infringement (see paragraph 1845 above).

1853 For the sake of completeness, the difference between the situations of France and Italy on which the Commission relied (see paragraphs 1844 and 1845 above) could justify the application of different treatment.

1854 It follows from all the foregoing that the present complaint must be rejected in its entirety.

(2) The end date of the infringements

(i) Arguments of the parties

…

(ii) Findings of the Court

1859 In the context of the present complaint, the applicants rely on the entry onto several Member States' markets of generic companies which are not party to any of the agreements at issue and on the subsequent fall in the prices of perindopril.

1860 Their line of argument essentially amounts to an assertion that the agreements at issue had no actual effect on competition as from the market entry of those generic companies.

1861 In that regard, it is necessary to recall, with regard to restrictions of competition by object, the case-law cited in paragraph 1837 above.

1862 An absence of effect of the agreements at issue on competition cannot therefore be reasonably relied upon in order to call into question the duration of the infringements since that duration is sufficiently established on the basis of the finding of a restriction by object.

1863 In any event, if the applicants' challenge is to be regarded as relating not to the finding of the infringement, in that the duration of that infringement was incorrectly determined, but to the assessment of the gravity of the infringement found by the Commission in the contested decision, it should be recalled that the complaint relating to the absence of actual effects of the agreements and to the consequences of that absence on the assessment of the gravity of the infringement has already been rejected (see paragraphs 1801 to 1820 above).

1864 However, the applicants also rely on an infringement of the principle of equal treatment.

1865 In that regard, the applicants rely on the fact that the Commission reduced the duration of the infringements in the Netherlands and the United Kingdom to take account of the entry of generic products onto those two markets, whereas it did not do so in other markets for which the Commission relied, as a general rule, on the expiry or invalidation dates of Servier's patents (recital 3133 of the contested decision).

1866 However, it must be pointed out that, as regards the United Kingdom, the accepted end date of the infringement indeed corresponds to the entry onto the market of a generic product (recital 776 of the contested decision), but also to a judgment of a court of that State invalidating the 947 patent (recitals 180, 776 and 2125 of the contested decision).

1867 The relevance of the applicants' argument, alleging different treatment depending on the Member States in which the infringements were committed, is therefore not established with regard to the United Kingdom.

1868 Moreover, the fact that Servier was able, in respect of certain Member States as regards the determination of the end of the infringement, to receive more favourable treatment which was unnecessary — since it was based on an absence of restrictive effects which is irrelevant where the Commission finds, as in the present case, the existence of a restriction by object (see paragraph 1862 above) — does not justify Servier's receiving such treatment in respect of all the other Member States concerned. The principle of equal treatment is not intended to secure for an undertaking receiving favourable treatment, which was necessary under neither legislation nor case-law, a right not to be penalised when the Commission correctly establishes the existence of an infringement.

1869 It is true, however, that the Commission cannot apply, including to the same undertaking, methods of calculating the amount of the fine which vary arbitrarily in that such variations are devoid of any relevant justification.

1870 In the present case, however, the existence of such variation is not established. Indeed, the Commission stated that it adopted for the Netherlands and the United Kingdom a specific approach, which it described as 'conservative', that approach leading it to reduce the duration of the infringement periods to take account of the dates of full-scale entries into those two Member States of generic products which had a significant impact on the sales of Servier's perindopril (recital 3133 of the contested decision).

1871 However, the only evidence relied on by the applicants in this connection, that is to say the existence of a significant reduction in the price of Servier's perindopril and a continuing decline in its market shares following the introduction of a generic product in France, is not sufficient to establish that the situations in the Netherlands and in the United Kingdom, on the one hand, and in France, on the other hand, were so similar that a difference in treatment was arbitrary. A fortiori, the evidence relied on does not establish that a difference in treatment between the Netherlands and the United Kingdom, on the one hand, and Belgium, the Czech Republic and Ireland, on the other hand, is arbitrary in nature, since that evidence does not concern the situation of those three Member States.

1872 For the sake of completeness, although it is clear from Tables 43 and 44 of the contested decision that the entry of generic products led to a massive and sudden fall in the value of Servier's perindopril sales in the Netherlands and the United Kingdom, it is not apparent from Table 45 of the contested decision that such a fall was noted in France following that entry. The difference between the situations of the Netherlands and the United Kingdom, on the one hand, and France, on the other hand, thus allowed the Commission rightly to apply a difference in treatment in finding, solely for the Netherlands and the United Kingdom, that the infringement ended upon the entry of the generic products onto those markets.

1873 The existence of a difference in situation, noted in paragraph 1872 above, is not called into question by the fact that the entry onto the French market of a generic product led to a 30% fall in the price of perindopril and 'Servier's market share diminishing continuously'. Indeed, that evidence does not demonstrate a fall in the value of sales of Servier in France as massive and sudden as that observed in the Netherlands and the United Kingdom.

1874 As regards Belgium, the Czech Republic and Ireland, there is in the file no evidence on which the applicants rely that, on the markets of those Member States, a massive and sudden fall in the value of Servier's sales of perindopril — equivalent to that observed for the Netherlands and the United Kingdom — had been noted upon the entry of the generic products.

1875 It follows from all the foregoing that the present complaint and, consequently, the plea as a whole must be rejected.

(f) The application of an additional amount

(1) Arguments of the parties

…

(2) Findings of the Court

1883 It must be borne in mind that the agreements at issue are agreements allowing Servier to exclude competitors from the market, and the fact that the latter were potential competitors does not alter that assessment. Such agreements, concluded between competitors, constitute horizontal agreements. Moreover, the exclusion of competitors from the market constitutes an extreme form of market sharing and of limitation of production (judgment of 8 September 2016, *Lundbeck* v *Commission*, T-472/13, under appeal, EU:T:2016:449, paragraph 435). Accordingly, the Commission was entitled to apply point 25 of the Guidelines on the method of setting fines, which provides for the application of an additional amount for horizontal output-limitation agreements.

1884 The foregoing finding cannot be called into question by the applicants' other arguments.

1885 In the first place, contrary to the submissions of the applicants, the Commission did not disregard the fact that the agreements at issue related to intellectual property rights (see paragraphs 1794 to 1797 above).

1886 In the second place, contrary to the submissions of the applicants and as has already been noted in the various sections relating to the response to the pleas alleging the lack of potential competition, the generic companies were potential competitors of Servier when each of them signed the agreement or agreements at issue relating to that company.

1887 In the third place, contrary to the submissions of the applicants, Servier could reasonably have foreseen that its conduct was caught by the prohibition laid down in Article 101(1) TFEU (see paragraph 1661 above). Moreover, Servier could not have been unaware of the anticompetitive nature of its conduct (see paragraph 1665 above).

1888 In the fourth place, as regards the absence of 'actual effects' of the infringements which is invoked by the applicants, it must be pointed out that the applicants merely rely, with no clarification, on that supposed absence to conclude that the additional amount applied by the Commission was disproportionate. That argument is therefore not accompanied by sufficient information to assess its merits and must therefore be rejected.

1889 In any event, the Commission was no more obliged at that stage of calculating the amount of the fine than it was at the stage of determining the proportion of the value of sales which it used (see paragraphs 1802 to 1810 above) to take into account any absence of actual impact on the market. It was required to do so neither by Regulation No 1/2003 nor by the Guidelines on the method of setting fines or the case-law of the EU Courts.

1890 In the fifth place, the fact that the Commission did not apply to the generic companies an additional amount does not justify the conclusion that the principle of equal treatment was infringed.

1891 In that regard, there are fundamental differences between the method set out in the Guidelines on the method of setting fines which the Commission applied to Servier and the method which the Commission applied to the generic undertakings (see, to that effect, judgment of 8 September 2016, *Xellia Pharmaceuticals and Alpharma* v *Commission*, T-471/13, not published, under appeal, EU:T:2016:460, paragraph 423).

1892 In the method set out in the Guidelines on the method of setting fines, the objective of taking into account the value of sales as provided for in point 13 is to adopt as the starting point for the setting of the fine to be imposed on an undertaking an amount which reflects the economic significance of the infringement and the relative size of the undertaking's contribution to it. Next, pursuant to points 19 and 21 of those guidelines, the Commission, according to the gravity of the infringement, will set the proportion of that value of sales to be used for determining the basic amount. That proportion may, as a rule, be set at up to 30% and must be multiplied by a coefficient based on the duration of the infringement, in accordance with point 24 of the 2006 Guidelines. Next, pursuant to point 25 thereof, 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 entering into horizontal price-fixing, market-sharing and output-limitation agreements, or even other infringements (judgment of 8 September 2016, *Xellia Pharmaceuticals and Alpharma* v *Commission*, T-471/13, not published, under appeal, EU:T:2016:460, paragraph 424).

1893 However, the method adopted with regard to the generic companies, given that it allows the Commission to use directly as a basic amount the value transfers made by Servier to the generic company in question, does not provide for all those stages, in particular the application of an additional amount pursuant to point 25 of the Guidelines on the method of setting fines (see, to that effect, judgment of 8 September 2016, *Xellia Pharmaceuticals and Alpharma* v *Commission*, T-471/13, not published, under appeal, EU:T:2016:460, paragraph 425).

1894 The application of the first method to Servier and the second to the generic companies was justified.

1895 First, by reason of the very purpose of the agreements at issue, which are market exclusion agreements, the generic companies, unlike Servier, were not present, during the period of the infringements, on the markets on which those infringements were committed.

1896 Accordingly, the Commission was not able to use the values of the sales made by the generic companies in the relevant geographic area during the last full business year of their participation in the infringements, as provided for in point 13 of the Guidelines on the method of setting fines.

1897 The Commission was therefore not in a position to apply to the generic companies the method of calculating the amount of the fine set out in the Guidelines on the method of setting fines and, in particular, to impose on them an additional amount calculated on the basis of the value of sales made by the undertaking in relation to the infringement concerned.

1898 The foregoing considerations apply to all the generic companies, since none of them was able to enter the markets in which the infringement relating to it had been found by the Commission.

1899 With regard in particular to Krka, even if it is assumed that the applicants may reasonably rely, in support of the complaint alleging infringement of the principle of equal treatment, on the method of calculating the amount of the fine imposed on that generic company although Servier cannot be held liable under the agreements with Krka (see paragraph 1636 above), such a complaint must be rejected.

1900 It is true that the applicants' complaint is based not on a comparison, on the basis of each agreement at issue, between Servier's situation and that of the generic company concerned, but on a comparison, for all the agreements, between Servier's situation and the situation of all the generic companies in question. Accordingly, the fact that an additional amount was not applied to Servier on the basis of the agreements concluded with Krka does not necessarily prevent the situation of Krka from being taken into account in order to examine the applicants' complaint.

1901 Next, it is true that one of the agreements which Krka had concluded with Servier provided for the granting of a licence for the 947 patent which applied in seven Member States. As a result, Krka was able to sell its products in those Member States for the duration of the infringement.

1902 However, the Commission did not find an infringement with respect to the Member States in which the licence applied. It criticises the parties to the agreement not because of the entry of Krka onto the seven markets in which the licence applied, but because Krka refrained from entering the markets of the other Member States in which the non-marketing and non-challenge clauses applied without a licence agreement.

1903 However, the concept of the value of sales referred to in point 13 of the Guidelines on the method of setting fines cannot extend to encompassing sales made by the undertaking in question which do not fall within the scope of the alleged cartel (judgment of 12 November 2014, *Guardian Industries and Guardian Europe* v *Commission*, C-580/12 P, EU:C:2014:2363, paragraph 57).

1904 Accordingly, the seven markets covered by the licence agreement could not be regarded as included in 'the relevant geographic area' within the meaning of point 13 of the Guidelines on the method of setting fines.

1905 It should be added that, even though the benefit of a licence agreement could, under certain circumstances, be described as an inducement, the fact that a generic company, through such an agreement, is permitted to enter or remain on a market without risk is, as a rule, favourable to competition, since the market entry of a generic company is likely to lower prices significantly. However, it would be inappropriate to take into account the value of sales made on markets in which competition has increased, for the purpose of imposing a fine on a generic company alleged to have participated in a restriction of competition on other markets.

1906 The Commission was therefore not in a position to apply to Krka and, a fortiori, to the other generic companies party to the agreements at issue the method of calculating the amount of the fine set out in the Guidelines on the method of setting fines and, in particular, to impose on them an additional amount calculated on the basis of the value of sales made by the undertaking in relation to the infringement concerned.

1907 However, that was not the case as regards Servier, which sold perindopril in the geographic areas concerned by the infringements.

1908 Secondly, the method of calculating the amount of the fine used by the Commission for the generic companies was adapted to the specific features of the context, since the amount of the transfer of value used in the agreement took into account the profit which each generic company derived from the infringement relating to it. Such a method was not suitable for Servier, which was supposed to benefit from maintaining a high price for perindopril.

1909 Such differences in situation justified the application to the generic companies of treatment different from that of Servier, that is to say a specific calculation method distinct from the method set out in the Guidelines on the method of setting fines and thus not requiring the application of the additional amount provided for in those guidelines.

1910 It follows from the foregoing that the Commission was entitled to apply an additional amount in calculating the amount of the fine imposed on Servier for the first infringement of Article 101 TFEU, that is to say that concerning Niche and Unichem (recital 3139 of the contested decision).

1911 In connection with the separate complaint alleging the inadequacy of the statement of reasons for the contested decision as regards the non-application of an additional amount in calculating the amount of the fine for the generic companies, it should be noted that the Commission stated as follows in recital 3146 of the contested decision:

'The generic undertakings agreed not to sell generic perindopril in the geographic area concerned by each agreement and therefore did not have any sales in the geographic areas concerned. Point 37 of the Guidelines on [the method of setting] fines should therefore be applied to the generic undertakings in this case. Point 37 of the Guidelines on [the method of setting] fines allows the Commission to depart from the normal methodology of the Guidelines on [the method of setting] fines because of the particularities of a given case or the need to achieve deterrence in a particular case.'

1912 In recital 3152 of the contested decision, the Commission stated inter alia that:

'According to Regulation No 1/2003 and the Guidelines on [the method of setting] fines, the fine should relate to the following factors: (i) the gravity of the infringement, (ii) its duration, (iii) any aggravating or attenuating circumstances and (iv) the need to achieve deterrence. The Commission, in exercising its margin of discretion, considers that in the present case, given its particularities, the amount of the value transfer received by the generic companies provides important indications as to these factors.'

1913 It is clear from the abovementioned extracts from the contested decision that (i) the Commission did not apply the method laid down in the Guidelines on the method of setting fines, which is based on the value of sales during the last full business year of the undertaking's participation in the infringement, but rather a method which used the amount of the value transfer received by the generic companies as the basic amount for the calculation of the fine, (ii) it did so based on the very purpose of the agreements, which were market exclusion agreements by reason of which the generic companies were not present on that market at the time of the infringement, and (iii) it took the view that the method chosen enabled it to take into account, inter alia, the gravity and the duration of the infringement.

1914 That reasoning allowed the applicants to understand the reasons why the Commission used a different method for the generic companies, in particular in that that method did not involve the application of an amount additional to that provided for in the Guidelines on the method of setting fines. It also places the Courts of the European Union in a position to exercise their power of review of legality and fulfil their role as courts having unlimited jurisdiction.

1915 The complaint alleging the failure to state adequate reasons in that regard must therefore be rejected.

1916 In conclusion, it should be noted that the application, with respect to the first infringement of Article 101 TFEU, of an additional amount calculated on the basis of a rate of 11% of the value of sales, which is below the range of rates provided for in point 25 of the guidelines and which is

applied, moreover, only to one of the infringements of Article 101 TFEU found against Servier, cannot be regarded as disproportionate in the light of all the relevant circumstances of the present case, as set out in paragraphs 1816 to 1818 above.

1917 It follows from all the foregoing that the present plea must be rejected.

(g) Infringement of the principle of proportionality and of the principle that the penalty must be specific to the offender

1918 The applicants put forward two complaints, based, first, on the failure to take into account the particular features of Servier and, secondly, on the length of the administrative procedure.

(1) Failure to take into account the particular features of Servier

(i) Arguments of the parties

…

(ii) Findings of the Court

1922 In the first place, even if it had been established that Servier is a 'single-product' undertaking, that circumstance did not, as such, require the Commission to reduce the amount of the fines. In that regard, it should be noted that the applicants do not rely, in support of that argument, on any binding provision of EU law or any precedent in case-law.

1923 Moreover, an undertaking such as the applicant, which derives a particularly large part of its total turnover from the product encompassed by the cartel, therefore derives particularly significant profits from that cartel (see, to that effect, Opinion of Advocate General Kokott in *Pilkington Group and Others* v *Commission*, C-101/15 P, EU:C:2016:258, point 100). Thus, the fact that Servier is a 'single-product' undertaking does not justify, in itself, a reduction in the amount of the fines.

1924 As regards the reference to the Commission's decision-making practice whereby the Commission has reduced the amount of fines on the basis of the existence of a 'single-product' undertaking, it should be noted that the precedent relied on by the applicants, as presented by them, involved circumstances different from those in the present case, since the Commission had reduced the amount of the fine in question in order to prevent it from reaching the ceiling of 10% of turnover referred to in Article 23(2) of Regulation No 1/2003.

1925 Moreover, according to the case-law, the Commission has a margin of discretion when setting the amount of fines, in order that it may channel 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 the implementation of EU competition policy. The proper application of the EU competition rules in fact requires that the Commission may at any time adjust the level of fines to the needs of that policy (see, to that effect, judgment of 8 September 2016, *Lundbeck* v *Commission*, T-472/13, under appeal, EU:T:2016:449, paragraph 773).

1926 Moreover, in accordance with settled case-law, the right to rely on the principle of the protection of legitimate expectations extends to any person in a situation where an EU institution has caused him or her to have justified expectations. Three conditions must be satisfied in order for a claim to entitlement to the protection of legitimate expectations to be well founded. First, precise,

unconditional and consistent assurances originating from authorised and reliable sources must have been given to the person concerned by the EU administration. Secondly, those assurances must be such as to give rise to a legitimate expectation on the part of the person to whom they are addressed. Thirdly, the assurances given must comply with the applicable rules (see judgment of 5 September 2014, *Éditions Odile Jacob* v *Commission*, T-471/11, EU:T:2014:739, paragraph 91 and the case-law cited).

1927 However, the evidence relied on by the applicants, namely a Parliament resolution and a statement by the Commissioner for Competition, supports, at most, the conclusion that it is possible that the Guidelines on the method of setting fines may be amended in future to take into account the specific characteristics of 'single-product' undertakings. Accordingly, they were not precise, unconditional and consistent assurances of such a nature as to give rise to a legitimate expectation on the part of Servier.

1928 In the second place, the circumstance, even if it were established, that Servier is managed by a non-profit foundation paying no dividends to natural persons and that it is therefore able to devote a significant portion, or even all, of its profits to research, in no way required the Commission to reduce the amount of the fines.

1929 Moreover, the Commission has a margin of discretion when setting the amount of fines (see paragraph 1925 above).

1930 Even if the applicants intended to dispute Servier's status as an undertaking, within the meaning of competition law, it should be noted that the three undertakings to which the contested decision is addressed, which are also applicants, are not foundations.

1931 Moreover, the Court of Justice has stated that the fact that the offer of goods or services is made without profit motive does not prevent the entity which carries out those operations on the market from being considered an undertaking, since that offer exists in competition with that of other operators which do seek to make a profit (see, to that effect, judgment of 1 July 2008, *MOTOE*, C-49/07, EU:C:2008:376, paragraph 27).

1932 In the third place, the applicants rely on a failure to have regard to the principle that the penalty must be specific to the offender.

1933 In that regard, it should be recalled that the principle that the penalty must be specific to the offender and the offence requires, in accordance with Article 23(3) of Regulation No 1/2003, that the amount of the fine to be paid jointly and severally must be determined by reference to the gravity of the infringement for which the undertaking concerned is held individually responsible and the duration of the infringement (judgments of 10 April 2014, *Commission and Others* v *Siemens Österreich and Others*, C-231/11 P to C-233/11 P, EU:C:2014:256, paragraph 52, and of 19 June 2014, *FLS Plast* v *Commission*, C-243/12 P, EU:C:2014:2006, paragraph 107).

1934 The applicants' argument is not concerned with challenging the finding of joint and several liability made by the Commission in imposing a single fine on separate undertakings.

1935 Moreover, the fact that the Commission did not reduce the amount of the fines imposed on Servier to take into account the fact that Servier was a non-profit foundation paying no dividend to any natural person and that it was therefore able to devote a significant portion, or even all, of its profits to research does not establish that the Commission did not determine the overall amount of the fine imposed on Servier on the basis of the gravity of the individual infringement alleged against it and the duration of that infringement, as provided for in the case-law cited in paragraph 1933 above.

1936 It follows from the foregoing that the present complaint must be rejected.

(2) The duration of the administrative procedure

(i) Arguments of the parties

…

(ii) Findings of the Court

1941 It should be noted that, although the infringement of the principle of observance of a reasonable period is capable of justifying the annulment of a decision taken following an administrative procedure based on Article 101 or 102 TFEU inasmuch as it also constitutes an infringement of the rights of defence of the undertaking concerned, the Commission's infringement of a reasonable period for such an administrative procedure, if established, is not capable of leading to a reduction of the amount of the fine imposed (see judgment of 9 June 2016, *PROAS* v *Commission*, C-616/13 P, EU:C:2016:415, paragraph 74 and the case-law cited).

1942 In the present case, the applicants do not claim that the alleged infringement of the principle of observance of a reasonable period resulted in an infringement of Servier's rights of defence. Accordingly, that infringement, even if established, is not capable of justifying the annulment of the contested decision. Nor is it capable, pursuant to the case-law cited in paragraph 1941 above, of allowing the applicants to obtain a reduction of the amount of the fine imposed on them.

1943 In any event, the Commission states as follows in paragraph 1037 of the defence:

'The Commission considers that it has complied with all its legal obligations relating to the duration of the administrative procedure. In the present case, the Commission initiated its *ex officio* investigation on 24 November 2008. The Decision was adopted on 9 July 2014. The Decision has already highlighted the numerous measures taken in the course of the investigation … According to the Commission, the scope and importance of the case — both in terms of the various practices being investigated and the number of undertakings and authorities involved — help to explain the length of the investigation. The Commission points out that the Decision was addressed to 13 undertakings, concerned the application of Articles 101 and 102 TFEU, 6 separate infringements and 2 market definitions and required the analysis of a significant amount of documentation. The Commission sent more than 200 [requests for information], inspected 6 undertakings, organised more than 15 working meetings with the undertakings concerned and created a file comprising more than 11 000 entries …'

1944 However, those factors, which are not disputed by the applicants, together with the factual and legal complexity of the case in question, which results, at least in part, from the wording of the agreements which the applicants co-authored, support the conclusion that the duration of the administrative procedure did not exceed a reasonable period of time in the present case.

1945 It should be added that the finding of complexity made in paragraph 1944 above does not contradict the Commission's statement in recital 3110 of the contested decision, in which the Commission indicated that:

'… In any event, the practices in the present case, which were aimed at market exclusion in exchange for a value transfer, cannot be considered, for the purpose of imposition of the fine, as legally complex, and their illegality was foreseeable for the parties.'

1946 It should be recalled that, although, because the agreements at issue were concluded in the form of patent settlements, the unlawful nature of those agreements might not have been evident to an outside observer such as the Commission, the same could not be said for the parties to the agreement.

1947 It follows from the foregoing that the present complaint and therefore the plea as a whole must be rejected.

(h) Summary concerning the cancellation and reduction of the fines

1948 It should be recalled that the agreements at issue are, with the exception of the agreements concluded with Krka, market exclusion agreements pursuing anticompetitive objectives. However, the exclusion of competitors from the market constitutes an extreme form of market sharing and of limitation of production (see paragraph 1816 above). Thus, under point 23 of the Guidelines on the method of setting fines, such agreements are, in principle, to be heavily fined (see paragraph 1816 above).

1949 Moreover, those agreements, based on an inducement and not on the recognition by the parties of the validity of the patent at issue, allowed Servier to replace the vicissitudes of patent litigation and the uncertainties surrounding the conditions and possibilities of market entry by generic companies with the certainty of excluding from the market those companies in respect of which an agreement was concluded (see paragraph 1819 above).

1950 Finally, it should be noted that those agreements were implemented.

1951 Moreover, it should be recalled that the Commission took into account, in the contested decision (recital 3128), the fact that Servier committed several infringements which — although different — relate to the same product, perindopril, and largely to the same geographic areas and periods of time. In that particular context, in order to avoid a potentially disproportionate result, the Commission decided to limit, in respect of each infringement, the proportion of the value of sales made by Servier taken into account for the purpose of determining the basic amount of the fine. It thus applied a correction which led to an average reduction of 54.5% in the overall values of the sales relating to the various infringements of Article 101 TFEU.

1952 Furthermore, the proportion of the value of sales used for the purposes of calculating the amount of the fine by the Commission, that is 10 or 11%, depending on the circumstances, is only approximately a third of the maximum proportion that may be used.

1953 Finally, the Court, taking into account the links between the Matrix agreement and the Niche agreements, reduced the amount of the fine imposed on Servier on the basis of the Matrix agreement.

1954 In the light of the factors referred to in paragraphs 1948 to 1953 above and all the considerations set out in the present judgment, it must be concluded that the amounts of the fines imposed on Servier under Article 101 TFEU are not, in view of the reductions already made by the Court in the exercise of its unlimited jurisdiction, disproportionate, even though the Commission, in paragraph 3130 of the contested decision, wrongly considered, as is apparent from the response to the plea alleging errors of assessment as regards the definition of the relevant market, that Servier 'possessed a very high market share of the relevant markets established for the purpose of the present Decision and affected by the infringements of Article 101 [TFEU]'.

1955 It must also be pointed out that, since the Commission correctly considered that the infringements found were separate infringements (see paragraphs 1685 to 1691 above), the fact that the cumulative amount of the fines represents a non-negligible percentage of Servier's worldwide turnover does not support the conclusion that those fines are disproportionate. It is all the more apparent that they are not disproportionate, since that percentage was substantially reduced by the Court in the exercise of its unlimited jurisdiction.

1956 It follows from all the foregoing that the applicants' alternative claim must be rejected in so far as it concerns the fines imposed on Servier for the infringements relating to Article 101 TFEU, with the exception of that part of the claim seeking, first, annulment of the fine imposed on Servier in respect of the infringement relating to the agreements concluded with Krka and, secondly, a reduction in the amount of the fine imposed on Servier in respect of the infringement relating to the Matrix agreement. As regards the applicants' alternative claim in so far as it concerns the infringement relating to Article 102 TFEU, it must therefore be upheld, since Article 6 of the contested decision, whereby the Commission found an infringement of Article 102 TFEU, is annulled (see paragraph 1638 above).

1957 Finally, it must be added that the Commission, in the context of the method of calculating the amount of each of the fines relating to the various infringements of Article 101 TFEU which it found, introduced a correction factor based on the number of infringements taking place concurrently in a Member State. Thus, the conclusion that one of the infringements of Article 101 TFEU has not been established could lead the Court to raise the question of whether it might be appropriate to increase the fines imposed on Servier in respect of the other infringements of Article 101 TFEU.

1958 However, in the light of all the circumstances of the present case, in particular those referred to at the end of paragraph 1954 above, it is not necessary to apply such an increase, which, moreover, has not been requested by the Commission.

IV. Overall conclusion

1959 In the first place, as regards Article 101 TFEU, it follows from all the foregoing considerations that the Commission was fully entitled to find a restriction of competition by object in respect of the Niche, Matrix and Teva and Lupin agreements. In those circumstances, it is not necessary, in any event, to examine whether the finding of a restriction of competition by effect relating to those agreements is well founded.

1960 However, first, as regards the infringement found on the basis of the agreements concluded with Krka, the Court concludes that the Commission has not established the existence of a restriction of competition by object. The Court also concludes, from its examination of the finding made by the Commission of the existence of a restriction of competition by effect, that such a restriction has not been established. Article 4 of the contested decision must therefore be annulled in that, by that article, the Commission found that Servier participated in an infringement under Article 101(1) TFEU as regards the agreements concluded between Servier and Krka. Consequently, Article 7(4)(b) of the contested decision, by which the Commission imposed a fine of EUR 37 661 800 on Servier in respect of that infringement, must also be annulled.

1961 Secondly, in the exercise of its unlimited jurisdiction, the Court considers that the amount of the fine imposed on Servier in respect of the infringement relating to the Matrix agreement found in Article 2 of the contested decision is too high. Consequently, that amount, set out in Article 7(2)(b) of the contested decision, must be reduced and fixed at EUR 55 385 190.

1962 For the remainder, as regards the fines imposed by the Commission on Servier in respect of the Niche, Teva and Lupin agreements, the amount of those fines must be confirmed.

1963 In the second place, as regards Article 102 TFEU, the Court considers that it has not been established that the relevant finished product market was limited to perindopril. Since it has not been established that Servier had a dominant position either on that market or on the technology market, the existence of an abuse of such a position is called into question, with the result that Article 6 of the contested

decision, relating to the finding of that infringement, must be annulled. Consequently, Article 7(6) of the contested decision, by which the Commission imposed a fine of EUR 41 270 000 on Servier in respect of that infringement, must also be annulled.

V. Costs

1964 Under Article 134(1) 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.

1965 Under the first sentence of Article 134(3) of the Rules of Procedure, the parties are to bear their own costs where each party succeeds on some and fails on other heads.

1966 As the applicants and the Commission have succeeded on some and failed on other heads, each party must bear its own costs.

1967 Under Article 138(3) of the Rules of Procedure, the Court may order an intervener other than those referred to in Article 138(1) and (2) to bear its own costs.

1968 As the provision referred to in paragraph 1967 above is applicable to the EFPIA, it must be ordered to bear its own costs.

On those grounds,

THE COURT (Ninth Chamber, Extended Composition)

hereby:

1. **Annuls Article 4 of Commission Decision C(2014) 4955 final of 9 July 2014 relating to a proceeding under Article 101 and Article 102 TFEU (Case AT.39612 — Perindopril (Servier)) in so far as it finds that Servier SAS and Les Laboratoires Servier SAS participated in the agreements referred to in that article;**

2. **Annuls Article 6 of Decision C(2014) 4955 final;**

3. **Annuls Article 7(4)(b) and (6) of Decision C(2014) 4955 final;**

4. **Sets the amount of the fine imposed on Servier and Les Laboratoires Servier in respect of the infringement referred to in Article 2 of Decision C(2014) 4955 final, as set out in Article 7(2)(b) thereof, at EUR 55 385 190;**

5. **Dismisses the remainder of the application;**

6. **Orders Servier, Servier Laboratories Ltd and Les Laboratoires Servier, on the one hand, and the European Commission, on the other hand, to bear their own costs;**

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

Gervasoni Bieliūnas Madise

da Silva Passos Kowalik-Bańczyk

Delivered in open court in Luxembourg on 12 December 2018.

[Signatures]

Table of contents