JUDGMENT OF THE GENERAL COURT (Ninth Chamber)

12 December 2018 (*)

(Competition — Agreements, decisions and concerted practices — Market for perindopril, a medicinal product intended for the treatment of cardiovascular diseases, in its originator and generic versions — Decision finding an infringement of Article 101 TFEU — Patent dispute settlement agreement — Administrative procedure — Legal professional privilege protecting communications between lawyers and their clients — Potential competition — Restriction of competition by object — Objective necessity of the restriction — Balance between competition law and patent law — Conditions for exemption under Article 101(3) TFEU — Fines — 10% cap — Imputation of the unlawful conduct)

In Case T−701/14,

Niche Generics Ltd, established in Hitchin (United Kingdom), represented by E. Batchelor, M. Healy, K. Cousins, Solicitors, and F. Carlin, Barrister,

applicant,

v

European Commission, represented initially by F. Castilla Contreras, T. Vecchi and B. Mongin, and subsequently by F. Castilla Contreras, B. Mongin and C. Vollrath, acting as Agents, and by S. Kingston, Barrister-at-law,

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 applicant and, in the alternative, for annulment or reduction of the fine imposed on the applicant by that decision,

THE GENERAL COURT (Ninth Chamber),

composed of S. Gervasoni (Rapporteur), President, L. Madise and R. da Silva Passos, Judges,

Registrar: C. Heeren, Administrator,

having regard to the written part of the procedure and further to the hearing on 15 June 2017,

gives the following

Judgment

I. Background to the dispute

A. Perindopril

1 The Servier group, composed of Servier SAS and several subsidiaries (individually or jointly, ‘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').

2 The active pharmaceutical ingredient ('API') of perindopril, 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. The compound patent

3 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.

2. Secondary patents

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

5 Servier filed new patents relating to erbumine and its manufacturing processes with the EPO between 2001 and 2005, including patent EP1294689 (known as 'the beta patent'; referred to below as 'the 689 patent'), patent EP1296948 (known as 'the gamma patent'; referred to below as 'the 948 patent'), and patent EP1296947 (known as 'the alpha patent'; referred to below as 'the 947 patent'). 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.

3. Second generation perindopril

6 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.

7 Servier applied for a European patent for perindopril arginine (patent EP1354873B) on 17 February 2003. That 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.

B. The applicant

8 Niche Generics ('the applicant' or 'Niche') was established in 2002 as a joint venture owned 60% by the Indian pharmaceutical company Unichem Laboratories Ltd ('Unichem') and 40% by management shareholders from Bioglan Generics Ltd, a British generic company of which it is the successor company. Unichem's shareholding in Niche was increased to 100% in December 2006.

9 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. 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.

C. Niche's activities in relation to perindopril

10 Niche assumed all of Bioglan Generics' obligations and responsibilities under the development and licensing agreement which it had concluded on 26 March 2001 with Medicorp Technologies India Ltd ('Medicorp'), of which Matrix Laboratories Ltd ('Matrix') was the successor company, with a view to marketing a generic version of perindopril ('the Niche/Matrix agreement'). Under that agreement, the two companies were to market generic perindopril in the European Union, with Matrix responsible primarily for developing and supplying the perindopril API, while Niche was responsible primarily for taking the necessary steps to obtain marketing authorisations and for the business strategy.

11 In April 2003, Matrix provided a pilot batch of perindopril API and the corresponding drug master file in order for Niche to prepare the marketing authorisation applications.

12 Unichem was responsible for the production of perindopril in final dosage form under an agreement for the development and manufacture of perindopril tablets concluded on 27 March 2003 with Medicorp (subsequently Matrix), which was responsible for developing the perindopril IPA and providing it to Unichem ('the Unichem/Matrix agreement').

D. Disputes relating to perindopril

1. Disputes before the EPO

13 In 2004, 10 generic companies, including Niche, 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. However, Niche withdrew from the opposition procedure on 9 February 2005.

14 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. Seven companies brought an appeal against that decision. By decision of 6 May 2009, the EPO's technical board of appeal annulled the decision of the Opposition Division and revoked the 947 patent. Servier's request for a revision of that decision was rejected on 19 March 2010.

15 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.

2. Disputes before the national courts

16 The validity of the 947 patent has, moreover, been disputed by generic companies before the courts of certain Member States, notably in the United Kingdom.

(a) Dispute between Servier and Niche

17 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 the generic version of perindopril, developed in partnership with Matrix and Unichem (see paragraphs 10 to 12 above). On 9 July 2004 Niche served on Servier a counterclaim for a declaration of invalidity of the 947 patent.

18 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, Niche and Unichem on 8 February 2005, which put an end to the litigation between those parties

(see paragraphs 21 to 23 below).

(b) Dispute between Servier and Apotex

19 On 1 August 2006, Servier 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 brought a counterclaim for annulment of the 947 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). On 9 October 2008, the High Court of Justice (England & Wales), Chancery Division (Patents Court), awarded damages to Apotex in the amount of 17.5 million pounds sterling (GBP) on account of the loss of revenue suffered during the period when the injunction was in force.

E. The agreement concluded between Niche, Unichem and Servier

20 Servier entered into a series of settlement agreements with a number of generic companies with which it was involved in patent disputes.

21 On 8 February 2005, Servier concluded a settlement agreement ('the Agreement') with Niche and Unichem. The territorial scope of the Agreement covered all the countries in which the 339, 340, 341 and 947 patents existed (Clause 3 of the Agreement).

22 Under that 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 of the Agreement) ('the non-marketing clause'). However, they would be free, under the Agreement, to market perindopril made using the process at issue without infringing the patents after the expiry of those patents (Clauses 4 and 6 of the Agreement). 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 of the Agreement). 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 of the Agreement). 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 of the Agreement) ('the non-challenge clause'). Niche also agreed to withdraw its oppositions to the 947 and 948 patents before the EPO (Clause 7 of the Agreement).

23 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 Agreement (Clause 5 of the Agreement) and, secondly, to pay Niche and Unichem the sum of GBP 11.8 million in two instalments (Clause 13 of the Agreement). 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]'.

F. Developments after the conclusion of the Agreement

24 In a letter sent to Niche dated 22 June 2005, Matrix declared that the Niche/Matrix agreement was to be suspended with immediate effect until the expiry of the 339, 340 and 341 patents in 2008. The Unichem/Matrix agreement, however, was not formally suspended or terminated.

G. The Sector Inquiry

25 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.

26 The Commission published a preliminary report on the results of its inquiry on 28 November 2008 as a basis for 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.

H. The administrative procedure and the contested decision

27 On 24 November 2008, the Commission carried out unannounced inspections at the premises of the companies concerned. The Commission sent requests for information to several companies in January 2009.

28 On 2 July 2009 the Commission decided to open proceedings against Servier and the applicant as well as other generic companies.

29 In August 2009 and then between December 2009 and May 2012, the Commission sent several requests for information to the applicant. Between 2009 and 2012, the applicant was invited to attend a number of state of play meetings.

30 On 27 July 2012, the Commission issued a Statement of Objections to several companies including the applicant, which submitted its reply on 16 November 2012.

31 Following the hearing of the companies concerned between 15 and 18 April 2013, further state of play meetings were arranged and additional requests for information sent.

32 On 18 December 2013, the Commission granted access to evidence gathered or more widely disclosed after the Statement of Objections and sent a Letter of Facts, to which the applicant replied on 21 January 2014. On 4 April 2014, the Commission also sent Letters of Facts concerning solely the issue of parent-company liability to the applicant amongst others, to which the applicant replied on 22 April 2014.

33 The Hearing Officer issued his final report on 7 July 2014.

34 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’).

35 Under Article 1 of the contested decision, Niche and Unichem infringed Article 101 TFEU by participating in a reverse payment patent dispute settlement agreement covering all Member States, except Croatia and Italy, for the period starting 8 February 2005, except as regards Latvia (period starting 1 July 2005), Bulgaria and Romania (period starting 1 January 2007) and Malta (period starting 1 March 2007), and ending on 15 September 2008, except as regards the Netherlands (period ending 1 March 2007) and the United Kingdom (period ending 6 July 2007).

36 The Commission imposed a EUR 13 968 773 fine jointly and severally on Niche and Unichem (Article 7(1)(a) of the contested decision). Niche is also to refrain from repeating the infringement penalised and from any act or conduct having the same or similar object or effect (Article 8 of the contested decision).

II. Procedure and forms of order sought

37 By application lodged at the Court Registry on 22 September 2014, the applicant brought the present action.

38 Acting on a proposal from the Judge-Rapporteur, the Court decided to open the oral part of the procedure and, after hearing the parties, to join the present case with Case T−705/14, *Unichem Laboratories* v *Commission*, for the purposes of that oral procedure. In the context of the measures of organisation of procedure laid down in Article 89(3) of the Rules of Procedure of the General Court, it also asked the Commission to submit two documents, which were submitted within the prescribed period, and put two written questions to the parties, requesting them to answer those questions at the hearing.

39 At the hearing on 15 June 2017, the parties presented oral argument and their answers to the written and oral questions put by the Court. At the hearing, the Court asked the applicant to produce the full version of an annex to the application, which the applicant did within the prescribed period.

40 The applicant claims that the Court should:

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

– in the alternative, annul or reduce the fine imposed on the applicant;

– order the Commission to pay the costs;

41 The Commission contends that the Court should:

– dismiss the action;

– order the applicant to pay the costs.

42 In the reply, the applicant requested that the defence be declared inadmissible on the ground that it was not signed by the Commission's representative, and that the Court deliver a judgment by default. On the contrary, the Commission maintains that the defence had been duly signed by its representative.

III. Law

A. The admissibility of the defence

43 The applicant submits that the defence is inadmissible, on the ground that it was not signed by the Commission's representative.

44 It should be noted that the first subparagraph of Article 43(1) of the Rules of Procedure of the General Court of 2 May 1991, which apply in the present case, indeed provides that '[t]he original of every pleading must be signed by the party's agent or lawyer'. However, Article 43 of the Rules of Procedure of 2 May 1991 also provides, in paragraph 7, that '[w]ithout prejudice to the first subparagraph of paragraph 1 or to paragraphs 2 to 5, the General Court may by decision determine the criteria for a procedural document sent to the Registry by electronic means to be deemed to be the original of that document' and that '[t]hat decision shall be published in the *Official Journal of the European Union*'. By decision of 14 September 2011 on the lodging and service of procedural documents by means of e-Curia (OJ 2011 C 289, p. 9), the General Court thus established a way of lodging and serving procedural documents by electronic means and Article 3 of that decision provides:

'A procedural document lodged by means of e-Curia shall be deemed to be the original of that document for the purposes of the first subparagraph of Article 43(1) of the Rules of Procedure where the representative's user identification and password have been used to effect that lodgment. Such identification shall constitute the signature of the document concerned.'

45 In the present case, the defence was lodged by means of the e-Curia application by F. Castilla Contreras, the Commission's representative, in accordance with the abovementioned provisions (see, to that effect, order of 12 March 2014, *Xacom Comunicaciones* v *OHIM — France Telecom España (xacom Comunicaciones)*, T−252/13, not published, EU:T:2014:163, paragraph 17, and judgment of 16 July 2014, *Langguth Erben* v *OHIM* (Shape of an alcoholic beverage bottle), T−66/13, not published, EU:T:2014:681, paragraphs 11 to 16).

46 Since the defence therefore meets the conditions laid down in Article 43(1) of the Rules of Procedure of 2 May 1991, the plea of inadmissibility raised by the applicant and its request that the Court deliver a judgment by default must be rejected.

B. Substance of the action

1. The plea alleging a breach of the obligation to consult the Advisory Committee on Restrictive Practices and Dominant Positions

47 At the hearing, the applicant relied on a new plea in law alleging a breach of the obligation to consult the Advisory Committee on Restrictive Practices and Dominant Positions ('the Advisory Committee'), as provided for in Article 14 of Regulation No 1/2003, and requested the Court to raise that plea of its own motion.

48 The Commission submits that that plea is inadmissible and could not be raised by the Court of its own motion.

49 It should be noted, in that respect, that 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 '[t]he 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)'. Article 14(2) of Regulation No 1/2003 provides that, '[f]or 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 '[t]he 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'.

50 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).

51 Thus, even if, as an essential procedural requirement, the breach of the rules on consulting the Advisory Committee may, or even must, be raised by the Court of its own motion, it follows from the case-law cited in paragraph 50 above that the question whether or not the obligations under the provisions governing that consultation constitute essential requirements depends on information specific to each case, of which the court hearing the case is not necessarily informed. In those circumstances — which, moreover, correspond to those of the present case, since it is not apparent from the documents in the case file, or from the applicant's assertions at the hearing, that rules on consultation enabling the Advisory Committee to reach a decision in full knowledge of the facts could have been breached — it cannot be considered that the plea raised by the applicant is based on the infringement of an essential procedural requirement and therefore constitutes a matter of public policy which may, or even must, be raised by the Court of its own motion.

52 It also follows that that plea, which the applicant raised for the first time at the hearing, must be rejected as inadmissible since it is out of time.

53 It may be added that, in any event, that plea would have to be rejected even if it were considered in the present case that the breach of the obligation to consult the Advisory Committee in question constitutes a matter of public policy.

54 It must be borne in mind that any obligation to raise matters of public policy of its own motion could exist only where the evidence in the file allows the EU judicature to detect and identify an infringement of an essential procedural requirement (judgments of 8 July 1999, *Hüls* v *Commission*, C-199/92 P, EU:C:1999:358, paragraph 134, and of 19 October 2017, *Possanzini* v *Frontex*, T-686/16 P, not published, EU:T:2017:734, paragraph 71), which, as can be seen from paragraph 51 above, is not the case here.

55 Moreover, even if that plea were admissible, despite the fact that it is out of time, it cannot be regarded as meeting the formal requirements for the presentation of pleas, since the applicant merely provides an abstract statement of the plea, which does not enable the Commission to defend itself effectively, and does not allow the Court to exercise its powers of review.

2. The plea alleging infringement of the rights of the defence and the principle of sound administration

(a) Arguments of the parties

56 The applicant submits that the Commission infringed its rights of defence and the principle of sound administration by failing to warn it of its misunderstanding of the concept of legal professional privilege and of the implications of withdrawing its claim for legal professional privilege over a number of documents, including an email dated 5 February 2005 from its intellectual property counsel regarding the merits of a settlement agreement, which is covered by

legal professional privilege. Having been asked by the Commission to identify the documents for which it would still seek to assert legal professional privilege, the applicant responded that, since it no longer had legal representation, it had no choice but to abandon its claim for legal professional privilege. The applicant adds that, had the Commission not been able to access the legally privileged information at issue, it would not have been able to class the Agreement as a restriction by object.

57 The Commission contends that the email at issue was not covered by legal professional privilege, that the Commission was not under any obligation to advise undertakings subject to proceedings under Article 101 TFEU of the rules on legal professional privilege, and that it had, nonetheless, informed the applicant of the implications of withdrawing its claim for legal professional privilege. The Commission points out that the law firm which previously represented the applicant had provided it with legal advice as to the legally privileged nature of the documents concerned and that the applicant had not established that it was unable to obtain legal representation or advice. Lastly, the Commission adds that, even if the email at issue could not be relied upon, the validity of the contested decision, which relies on a large amount of other evidence, would not be affected.

(b) Findings of the Court

58 It is settled case-law that the rights of the defence in any proceedings in which penalties, especially fines or penalty payments, may be imposed, such as those provided for in Regulation No 1/2003, are fundamental rights forming an integral part of the general principles of law, whose observance the Courts of the European Union ensure (see judgment of 8 July 2008, *AC-Treuhand* v *Commission*, T−99/04, EU:T:2008:256, paragraph 46 and the case-law cited).

59 It also follows from the case-law that the principle of the protection of the confidentiality of written communications between lawyer and client is an essential corollary to the effective exercise of the rights of the defence (judgments of 18 May 1982, *AM & S Europe* v *Commission*, 155/79, EU:C:1982:157, paragraph 23, and of 17 September 2007, *Akzo Nobel Chemicals and Akcros Chemicals* v *Commission*, T−125/03 and T−253/03, EU:T:2007:287, paragraph 120). The protection of the confidentiality of written communications between lawyer and client precludes the Commission reading the content of such communications and — were the Commission to have read them — the protection of confidentiality would preclude the Commission using such communications as the basis for a decision imposing a fine for an infringement of European Union competition law (judgment of 29 February 2016, *Deutsche Bahn and Others* v *Commission*, T−267/12, not published, EU:T:2016:110, paragraph 49; see also, to that effect, judgment of 17 September 2007, *Akzo Nobel Chemicals and Akcros Chemicals* v *Commission*, T−125/03 and T−253/03, EU:T:2007:287, paragraph 86).

60 In the present case, it cannot be considered that the Commission breached the applicant's rights of defence by failing to respect the protection of the confidentiality of its written communications with its lawyer, as regards in particular the email of 5 February 2005 sent to the applicant by its intellectual property counsel and submitted to the Commission in response to a request for information, which is the only document specifically mentioned by the applicant as having been unlawfully used by the Commission even though it was covered by legal professional privilege and was, accordingly, confidential.

61 Without it being necessary to rule on whether the email of 5 February 2005 was actually covered by legal professional privilege, it must be pointed out that, also according to the case-law, if the holder of evidence obtained by the Commission decides, in full knowledge of his rights, not to object to its use by the Commission even though he could have done so, he clearly cannot take issue with the Commission for having used that evidence in its investigation (see, to that effect, judgments of 18 May 1982, *AM & S Europe* v *Commission*, 155/79, EU:C:1982:157, paragraph 28, and of 12 December 2012, *Almamet* v *Commission*, T−410/09, not published, EU:T:2012:676, paragraph 43).

62 In the present case, contrary to the applicant's assertions, it may be regarded as having decided, in full knowledge of its rights, not to object to the use of that email by the Commission.

63 In its replies of 7 March 2011 to the Commission's request for information, the applicant waived the confidential treatment it had initially requested in October 2009. Although the Commission did not take note of that waiver in its letter of 6 May 2011, it nevertheless alerted the applicant to the fact that its replies could be understood as a waiver of confidentiality, while repeatedly emphasising the 'important legal consequences' of such a waiver and asking it to submit non-confidential versions of the documents in question. Furthermore, when, following that letter, the applicant asked it to provide it with wording for a confidentiality waiver, the Commission, in its reply of 20 July 2011, once again drew the applicant's attention to the important legal consequences of that waiver, specifying that the Commission could, as a result, use the information contained in the documents in question against the applicant in support of a possible Statement of Objections and in a final decision on a potential infringement of competition law. The Commission, in that letter, even gave the applicant the opportunity to reconsider its waiver.

64 Contrary to the applicant's assertions, it cannot therefore be maintained that the Commission did not warn it of the consequences of waiving its request for confidentiality. The fact that that warning was worded in general terms and did not refer to the specific reason for the applicant's waiver of confidentiality is not capable of calling into question the fact that the Commission repeatedly drew the applicant's attention to the consequences of that waiver.

65 In addition, having been informed that the applicant did not have any legal representation during the period concerned — and it should be borne in mind that legal representation is not obligatory during the administrative procedure before the Commission — the Commission not only advised the applicant to seek legal advice, but also, failing this, repeatedly explained the concept and the different types of confidential information, as well as how to prepare non-confidential versions, while remaining at the applicant's disposal to assist it in producing non-confidential version of the documents concerned (see the email from the Commission to the applicant dated 1 August 2011).

66 In those circumstances, it cannot be maintained that the Commission did not warn the applicant of its alleged misunderstanding of the concept of confidentiality. Contrary to the applicant's assertions, it is clear from the abovementioned correspondence and, in particular, from the letter of 20 July 2011, not that the applicant had erroneously considered that the recognition of the confidential nature of a document depended on its representation by a lawyer, but that it faced difficulties in preparing the requested non-confidential versions without the assistance of a lawyer, difficulties which the Commission took into account, as can be seen from paragraph 65 above.

67 It follows that the Commission also did not breach the principle of sound administration, since it is clear from the foregoing that it exercised all due diligence in order to ensure that the applicant was aware of the confidentiality issues in relation to certain documents and was able to make confidentiality requests.

68 In any event, even if the Commission had in the present case taken into consideration the aforementioned email of 5 February 2005 in breach of its obligations, that unlawful consideration could not lead to the annulment of the contested decision. That email merely sets out the reasons that could justify the conclusion of the Agreement and thus could be interpreted as demonstrating the applicant's anticompetitive intent in concluding the Agreement with Servier. According to settled case-law, which the Commission referred to and applied in the present case (see paragraphs 228, 230 and 305 to 307 below), the intent of the parties to the agreement may indeed be taken into consideration for the purpose of determining whether an agreement constitutes a restriction of competition by object (see recitals 1356 to 1362 of the contested decision), but it does not allow such a determination by itself, since, in order to assess whether an agreement between undertakings reveals a sufficient degree of harm to constitute a restriction of competition by object,

regard must be had to the content of its provisions, its objectives and the economic and legal context of which it forms part (see recitals 1281 to 1354 of the contested decision). In addition, it appears from the documents in the file, as the examination of the substance of the action will underline, that the Commission correctly took account of other evidence in order to establish the applicant's anticompetitive intent.

69 Accordingly, it cannot be considered that, if it had not taken account of the aforementioned email, the Commission could not have classed the Agreement as a restriction of competition by object.

70 It follows from all the foregoing considerations that the plea alleging infringement of the rights of defence and of the principle of sound administration must be rejected.

3. The plea alleging errors of law and of assessment in the analysis of potential competition on the market

(a) The criteria for assessing potential competition

(1) Arguments of the parties

71 Relying on the case-law, the applicant maintains that the potential competitor test is objective, since it requires that, in order for a company to be considered a potential competitor, there must be a real, concrete possibility of it entering the market as an economically viable strategy supported by evidence or an analysis of market structure. Market entry should, moreover, occur sufficiently quickly, and therefore the Commission was wrong to consider that entry within three years is a sufficiently short period and to downplay the significance of deferrals of entry, misapplying the judgment of 3 April 2003, *BaByliss* v *Commission* (T-114/02, EU:T:2003:100, paragraph 102), which, moreover, relates to circumstances different from those in the present case. The parties' perceptions and intentions, however, are irrelevant according to the case-law.

72 The Commission contends that it applied the Court's case-law on potential competition by establishing whether the generic company exerted competitive pressure on the originator company. According to that case-law, there is a need for the potential entry to take place sufficiently quickly. In that regard, the Commission states, first, that its reference in the contested decision to a three-year period is an indicative time frame, as is clear, moreover, from the provisions providing for that time frame and, secondly, that it complied fully with the judgment of 3 April 2003, *BaByliss* v *Commission* (T-114/02, EU:T:2003:100). Furthermore, the perceptions of the incumbent operators could be relevant in order to determine whether there is a real, concrete possibility of market entry, as could the intention of the parties to enter that market, although such an intention is not a necessary precondition for the purposes of demonstrating the existence of potential competition.

(2) Findings of the Court

73 It should be noted that, according to settled case-law, also cited by the applicant, 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-461/09, EU:T:2011:181, paragraphs 166 and 167 and the case-law cited). As the parties rightly emphasised, if a market is characterised by barriers to entry, an examination of whether those barriers are insurmountable is a useful adjunct to the examination of whether there are real concrete possibilities of entering the market in question, based on the ability and intention of that undertaking (judgment delivered today, *Servier and Others* v *Commission*, T-691/14, paragraph 321).

74 It follows from the case-law on the assessment of real concrete possibilities of market entry 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; of 29 June 2012, *E.ON Ruhrgas and E.ON* v *Commission*, T−360/09, EU:T:2012:332, paragraph 87; and judgment delivered today, *Servier and Others* v *Commission*, T−691/14, paragraph 318). Whether potential competition — which may be no more than the existence of an undertaking outside that market — is restricted cannot depend on whether it can be demonstrated that that undertaking intends to enter that market in the near future (judgment of 14 April 2011, *Visa Europe and Visa International Service* v *Commission*, T−461/07, EU:T:2011:181, paragraph 169).

75 It follows that, contrary to the applicant's assertions, while it is true that the intention to enter the market is neither necessary in order to find that there is potential competition on that market, 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 (judgment delivered today, *Servier and Others* v *Commission*, T−691/14, paragraph 382).

76 In the same manner, and contrary to the applicant's further assertions, the perception of the incumbent operators is a relevant criterion in assessing potential competition. It is true that, 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, it follows from the case-law that 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).

77 In particular, 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 applicant, 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 applicant's assertions, it was 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.

78 In the judgment of 12 July 2011, *Hitachi and Others* v *Commission* (T−112/07, EU:T:2011:342), which was also cited by the applicant, the Court clearly took account of the criterion of the incumbent operator's perception in order to establish the existence of potential competition. It follows 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). Contrary to the applicant's assertions, in that judgment the Court also carried out an objective analysis of the competitive situation, 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, 160 and 319 to 332).

79 It follows that the subjective criterion of the incumbent operator's perception is only one criterion amongst others for assessing the existence of potential competition and it is on that basis that the Commission took it into account in the contested decision (see recital 1163 of the contested decision and paragraphs 101 to 107 below).

80 It also follows that, among the factors capable of demonstrating the incumbent operator's perception that there is potential competition, the very fact that an undertaking already present on the market seeks to enter into agreements with undertakings with similar activities in the same sector but which are not present on that market, and a fortiori the conclusion of such agreements, is particularly strong evidence (see, to that effect, judgment of 8 September 2016, *Lundbeck* v *Commission*, T−472/13, under appeal, EU:T:2016:449, paragraph 144). Thus, since Servier concluded such an agreement with the applicant, the assertion that it is apparent from one of the applicant's internal notes of November 2004 that Servier did not perceive the generic companies as competitive constraints cannot succeed.

81 In addition, contrary to the applicant' assertions, the analysis, from a temporal perspective, of potential competition carried out by the Commission in the contested decision is consistent with the applicable principles.

82 According to settled case-law cited by the Commission in the contested decision (recital 1158), an operator cannot be classified 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). That case-law refers to 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 Guidelines on the applicability of Article 101 [TFEU] to horizontal co-operation agreements (OJ 2011 C 11, p. 1; '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.

83 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).

84 In the present case, first, 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 perindopril market (recital 1182 and footnote 1669 to the contested decision). Contrary to the applicant's assertions, the existence of different steps that must be taken in order to enter the market does not imply that only those operators which are close to completing those steps are potential competitors. Besides the fact that such an assertion amounts to denying the distinction between potential competition, corresponding to the exertion of competitive pressure, and actual competition, corresponding to market entry, 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 company, before, or even well before, the expiry of the patents and the actual market entry of the generic companies (see paragraph 123 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).

85 Furthermore, the Commission indeed noted, in footnote No 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.

86 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 applicant's assertions, the Commission therefore did not infer from this that it was free to disregard those delays in its assessment of potential competition. The Commission also relied, correctly, on the judgment of 3 April 2003, *BaByliss* v *Commission* (T−114/02, EU:T:2003:100, paragraphs 102 to 106), 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, that the deferrals of market entry did not call into question BaByliss' status as a potential competitor, relying on several factors showing its ability to enter the market in question.

87 It follows from all the foregoing that the Commission did not apply any incorrect criteria for the assessment of potential competition.

(b) Errors of assessment in respect of potential competition

(1) Arguments of the parties

88 The applicant submits, in the first place, that insurmountable barriers to market entry precluded potential competition. These barriers may include, as is clear from the case-law and the Commission's decision-making practice, patents and regulatory and financial barriers. As regards patents, the applicant disputes, in particular, the Commission's suggestion that patent rights are uncertain or potential rights as well as the fact that the Commission takes into account the parties' subjective perceptions of their chances of success in patent litigation and that it asserts that there are alternative routes to market. In that regard, the applicant also refers to the arguments set out in a 'Patent Issues Memorandum' annexed to the application.

89 The applicant submits, in the second place, that, in this case, it had no real or concrete possibility, or indeed that it had no possibility at all, of entering the market within a reasonable time frame. There were four types of barriers to market entry, and the contested decision did not show that these barriers could be overcome.

90 As regards the financial barriers, the applicant argues that its financial situation was deteriorating rapidly at the end of 2004 and that, according to external experts, it would be insolvent as of March 2005, even without taking into account the legal fees it would have incurred in the patent disputes

and the compensation it might have had to pay to its customers following the probable termination of its contracts with them. The applicant maintains that the reference to expected profits in the contested decision is irrelevant since that projection was based on an intended perindopril launch date which did not materialise. The applicant submits, in that regard, that its only pipeline product under development was perindopril. It adds that the contested decision offers no credible evidence that its financial situation could be remedied. Based on an expert report which it deems to be balanced and complete, the applicant argues in particular that its invoicing agreement, Servier's non-refundable deposit, the guarantee of its parent company and the sharing of legal costs were all either hypothetical or insufficient. In that connection, the applicant criticises the Commission for having infringed its rights of defence and failed to state reasons for the contested decision by contending that further sources of funding existed — resulting, in the present case, from the licence and supply agreement between Niche and Biogaran and the financing from Unichem — which were not referred to in themselves during the administrative procedure or in the contested decision. It makes the same criticism with regard to the Commission's contention regarding the works being carried out at its Irish facility, at which no perindopril is produced, in an attempt to establish that perindopril was not its lead product.

91 As regards the patent-related barriers, the applicant maintains that the process patents (patents 339, 340 and 341) and the 947 patent, in combination, created an insurmountable barrier to its market entry. It produced an alpha beta mix in order to reduce the risk of infringement of the 947 patent and invested substantially in a new process which did not infringe the process patents, discovering, nonetheless, in November 2004 that that process could be infringing the 947 patent — a discovery that, moreover, rendered irrelevant its previous statements regarding its confidence in the successful outcome of the patent litigation. As regards the process patents, the evidence relied on by the Commission confirms that the applicant had a number of concerns about the infringement risk, particularly since that risk was made apparent by one of its customers.

92 As regards technical and regulatory barriers, the applicant submits that the aforementioned change in the manufacturing process resulted in technically defective API and tablets (particle size, presence of impurities, stability problems). These defects, identified in particular by Unichem, prompted the applicant to ask that production be ceased and, according to an expert report, prevented, or at least delayed, a marketing authorisation from being obtained, in particular in the United Kingdom. It is apparent in particular from that report that there were various technical difficulties and that these were far reaching and fundamental, and that the efforts made to resolve them were haphazard and misdirected. In response to the claim disputing the probative value of that report, the applicant adduced, in an annex to its reply, another expert report which confirmed the quality, objectivity and content of the previous report.

93 The applicant also submits that the marketing authorisation granted to one of its business partners in the Netherlands is not proof of its imminent market entry, since that marketing authorisation was unusable on account of the subsequent change to the manufacturing process. It is also irrelevant that Matrix had begun commercial-scale API production and that the applicant concluded agreements with several customers, since those agreements predated the aforementioned, in particular, technical difficulties, or were unrelated to those difficulties and could be accounted for by the fact that the applicant wanted to maintain its customers' confidence. The applicant also argues that Matrix's supposed confidence in overcoming barriers is irrelevant in so far as the statement at issue was not based on any first-hand evidence.

94 As regards commercial barriers, the applicant states that, as a result of Matrix's refusal to supply it with API and to assist it in completing its regulatory submissions, and because there was no alternative supply of API, it was prevented from entering the market at all.

95 The Commission contends, in the first place, that it has never been held, nor is it apparent from the Commission's decision-making practice, that the existence of a patent constitutes an insurmountable

barrier to market entry. A patent does not provide an absolute right to exclude potential competitors, since a company is still free to enter the market with a non-infringing product or to challenge the validity of that patent. The Commission contends that it is consistent with the case-law to take into account, in that regard, the subjective perceptions of the parties, and that an originator company could begin to feel competitive pressure from generic companies even prior to the expiry of the compound patent, otherwise the distinction between actual and potential competition would be blurred. Lastly, it argues that the arguments set out in the 'Patent Issues Memorandum' to which the applicant refers should be rejected as inadmissible and, in any event, as having little probative value. Similarly, the fact that a company may be in financial difficulty does not mean that this situation constitutes an insurmountable barrier to its market entry.

96 In the second place, the Commission draws attention to the various facts, as substantiated by evidence and set out in the contested decision, showing, in its submission, that there was a real and concrete possibility of Niche entering the market within a relatively short period of time and exerting competitive pressure on Servier in the run-up to the signing of the Agreement. It argues that the applicant's version of events is inconsistent with that evidence, and is based on factual inaccuracies and unsubstantiated blatant exaggerations. The Commission adds, citing the case-law, that given that large volume of contemporaneous evidence at its disposal, it did not need to request additional expert opinions.

97 As to the alleged financial barriers to market entry, the Commission submits that the financially very attractive nature of the value transfer provided for in the Agreement does not mean that Niche faced insurmountable financial difficulties. It argues that none of the alleged financial losses or the risk of such losses were supported by conclusive evidence, pointing out in particular that the expert report referred to by the applicant was produced eight years after the event, that the legal costs should have been anticipated and then shared and, in any event, borne by the losing party, that its commercial activity was not based only on perindopril, that its trading results did not suggest impending disaster and that its customers would not have cancelled their contracts and demanded compensation. On the contrary, the Commission maintains that Niche had secured, or at least was capable of securing, considerable additional finance, and mentions in particular the financing available from its parent company and upfront payments in respect of agreements under negotiation. In response to the claim that it infringed the rights of defence and the obligation to state reasons, the Commission adds that the evidence at issue had been submitted in order to respond to the arguments set out in the application.

98 As regards the alleged patent-related barriers to entry, the Commission states that there was ongoing litigation and that Niche and Matrix were confident that Servier's process patents were not being infringed and that the 947 patent was invalid. This strong conviction led the applicant, first, to invite Servier to sue it for process patent infringement before the High Court of Justice (England & Wales), Chancery Division (Patents Court), in order to 'clear the way' and, secondly, to seek a declaration of invalidity of the 947 patent before the EPO, while still aiming to manufacture a product that did not infringe that patent. The Commission submits that, while it is true that the applicant was not able to challenge the 947 patent before the national courts, Servier never brought an action for infringement of that patent. It adds that the fact that the 947 patent was invalidated following the action brought by Apotex confirms that the barrier related to that patent was not insurmountable. The Commission points out that the process patents were not protected in four European Union Member States.

99 As regards the alleged technical and regulatory barriers to market entry, the Commission infers from the timeline of events, as substantiated and set out in the contested decision, that, despite the difficulties faced, it is clear from the documents in the file that Niche, Matrix and their business partners were actively working to resolve the technical problems detected and considered, as did Servier, that the marketing authorisation would be granted. The Commission submits in particular, as regards Matrix, that the Niche/Matrix agreement was suspended as a result of the settlement

agreement with Servier and not because of any concerns about technical or regulatory issues with the product. The Commission also disputes the probative value of the expert report upon which the applicant bases the claims made in the application, pointing out that Niche commissioned the report from one of its former employees for the purposes of the present action, as was the case with the expert report annexed to the reply, and drawing particular attention to the fact that it makes a selective assessment of the existing evidence and, moreover, that that evidence does not adequately support its claims. Lastly, the Commission adds that an application to vary the marketing authorisation obtained in the Netherlands could have been made, but this was made impossible after the Agreement.

100 As regards the alleged commercial barriers to market entry, the Commission contends that the applicant cannot rely on the requirements of an agreement which restricts competition to conclude that it was not a potential competitor. It submits moreover that Azad Pharmaceutical Ingredients AG may have constituted an alternative source of API supply.

(2) Findings of the Court

101 It should be borne in mind that, in the contested decision, the Commission considered that 'Niche/Unichem' was a prominent potential competitor of Servier that had the intention and the ability to enter the market within a short period of time (recitals 1282, 1292 and 1298), on the basis of the following five considerations.

102 First, the Commission noted that 'Niche/Unichem' had for several years invested resources — together with Matrix — in order to develop a product which could be launched as a generic alternative to Servier's perindopril, and that venture was well progressed. That was shown, first, by the work towards obtaining marketing authorisations, which were expected to be obtained in 2005 and one of which had actually been obtained in the Netherlands by a customer of Niche in May 2005, and, secondly, by the commercial batches of API which were being prepared for the expected commercial launch and which Matrix regarded as sufficient to satisfy the anticipated orders (recital 1283 of the contested decision).

103 Secondly, the Commission pointed out that Niche had concluded 14 agreements with business partners that were keen on selling generic perindopril in Europe, which showed its belief that it would be able to market perindopril within a short period of time. It noted that the deficiency letters sent to Niche and its customers by regulatory authorities were being answered. The Commission also stated that, in October 2004, Niche had requested one of its customers to indicate its launch orders for 2005 in order to plan its production for 2005 and that, just a few days before the conclusion of the Agreement, it was negotiating a supply agreement with one of the largest generic companies, Teva (recital 1284 of the contested decision).

104 Thirdly, according to the Commission, a contemporaneous document suggests that market entry by 'Niche/Unichem' (and Matrix) would have been economically viable, in view of the gross annual profit expected for the financial year 2003/2004 (recital 1285 of the contested decision).

105 Fourthly, the Commission found that Servier itself considered that 'Niche/Unichem' was a generic threat, relying inter alia on due diligence carried out by Servier with a view to acquiring Niche, highlighting the latter's financial situation (recital 1286 of the contested decision).

106 Fifthly, the Commission referred to the patent litigation in which Niche had engaged. As regards the litigation before the High Court of Justice (England & Wales), Chancery Division (Patents Court), concerning Servier's process patents, it is apparent from several of Niche's statements that it was confident that it would succeed (recitals 1288 and 1289 of the contested decision). As regards the dispute in relation to the 947 patent, Niche opted for an action before the EPO and did not bring an action before a national court, despite an attempt in 2004 (recitals 1290 and 1291 of the contested decision).

107 Lastly, the Commission added, in response to various allegations made by Niche and Servier during the administrative procedure, that there had been no rejection of the marketing authorisation, despite the deficiency letters, that the financial difficulties alleged by Niche had to be qualified, in view of the funds obtained, or which could be obtained, during the period in question, and that a potential competitor did not have to have a readily marketable product, as long it was able to enter the market sufficiently quickly and did not face problems which, taken together, would constitute insurmountable difficulties. The absence of such difficulties in the present case was shown by the continuing cooperation between Niche and Matrix to resolve any outstanding problems (recitals 1293 to 1297 of the contested decision, referring inter alia to recital 471 et seq. of that decision).

108 It should be emphasised, as a preliminary point, that the applicant does not dispute that its partner Matrix had begun to prepare perindopril API batches for a commercial launch, that it had taken steps towards obtaining a marketing authorisation (see paragraph 102 above) and that it had concluded 14 agreements with commercial partners seeking to sell generic perindopril in Europe (see paragraph 103 above).

109 Those elements, since they show steps to achieve the production and the imminent marketing of perindopril, show that Niche not only intended to take the risk of entering the European market, but also had the ability to enter it.

110 It must therefore be determined whether the applicant's arguments concerning the barriers linked to Servier's patents and to the technical, regulatory, financial and commercial difficulties are capable of calling into question the applicant's ability and intention to enter the market, as inferred from the abovementioned elements, and thus its real concrete possibilities of competing with Servier (see, to that effect, judgment delivered today, *Servier and Others* v *Commission*, T−691/14, paragraphs 386 and 441).

(i) The barriers linked to Servier's patents

111 The applicant relies on the case-law and the Commission's decision-making practice in order to challenge the assessment in the contested decision that the patents did not constitute insurmountable barriers to potential competition and, in particular, the fact that, in making that assessment, the Commission took into account the parties' subjective perceptions of the infringing or valid nature of the patents and alternative routes to the market, such as launching at risk or adapting the product (see paragraph 88 above). It also argues that, contrary to the Commission's finding, it did not have real concrete possibilities of entering the market because of Servier's patents (see paragraph 91 above).

112 As a preliminary point, it is necessary to rule on the admissibility of Annex A.24 to the application, entitled 'Patent Issues Memorandum', disputed in the present case by the Commission. That annex, dated 22 September 2014, was drawn up by a lawyer at the law firm representing the applicant in the present case and presented the patent system and the applicant's strategy in the context of the patent proceedings between it and Servier. The applicant refers to that annex in the application in order to dispute the Commission's alleged view that patents are uncertain or potential rights and not clearly defined exclusive rights, specifying in a footnote — in respect of each of the recitals of the contested decision expressing that view — the part of the annex setting out arguments concerning the recital in question. It also refers to it, in the application and the reply, in support of its arguments in relation to Servier's 947 patent.

113 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 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. 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 (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).

114 Whilst the body of the application may be supported and supplemented on specific points by references to certain passages in 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).

115 Consequently, in the present case, the Court may take Annex A.24 to the application into consideration only in so far as it supports or supplements pleas or arguments expressly set out by the applicant in the body of its application and in so far as it is possible for the Court to determine precisely the matters contained in that annex that support or supplement those pleas or arguments (see, to that effect, judgment of 17 September 2007, *Microsoft* v *Commission*, T−201/04, EU:T:2007:289, paragraph 99).

116 It follows that the arguments set out in that annex and to which the applicant merely refers by invoking one or more sections of that annex, without presenting them in any way, even summarily, are inadmissible. However, the information contained in that annex intended to support the arguments set out in the application and the reply are admissible.

117 As to the substance, it must be borne in mind that the Commission considered in the contested decision 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 Guidelines on the application of Article [101 TFEU] to technology transfer agreements (OJ 2004 C 101, p. 2, 'the 2004 Guidelines on technology transfer agreements'), which, moreover, were not applicable in the present case (recitals 1167 and 1168 and footnote 1638).

118 The Commission added that, in any event, first, the generic companies could challenge 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 generic medicinal products, 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 predating or contemporaneous with the conclusion of the agreements at issue (recital 1172 of the decision).

119 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 of the contested

decision). The generic companies remained free to launch perindopril at risk, that is to say with the risk that the originator company 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).

120 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.'

121 Contrary to the applicant's assertions, those findings of the Commission are not vitiated by any errors.

122 Although, as the applicant states, the exclusive right conferred by a patent 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), 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; of 14 July 1981, *Merck*, 187/80, EU:C:1981:180, paragraph 9; and of 16 July 2015, *Huawei Technologies*, C−170/13, EU:C:2015:477, paragraph 46), 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).

123 Ruling on the appeal brought against the judgment of 1 July 2010, *AstraZeneca* v *Commission* (T−321/05, EU:T:2010:266), the Court of Justice itself acknowledged, in its judgment of 6 December 2012, *AstraZeneca* v *Commission* (C−457/10 P, EU:C:2012:770, paragraph 108), that potential competition could exist in a market even before the expiry of a patent. More specifically, the Court of Justice held, in that judgment, to which the Commission referred in recitals 1165 and 1169 of the contested decision, 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).

124 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 company's patent.

125 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 (recitals 1169 to 1171), 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 should be noted that the same lack of a presumption of infringement applies in the event of a declaration of validity of the patent in question 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.

126 It is therefore possible for an operator to take the risk of entering the market, including with a product that potentially infringes 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).

127 It may also be noted in that regard that, contrary to the applicant'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 125 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 of bringing litigation to challenge the patents concerned and thus clear a path to the market, it may be considered that those patents do not constitute insurmountable barriers to access and, accordingly, do not prevent potential competition from taking place.

128 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, including those of the applicant, were infringing.

129 Those findings are not called into question by the case-law or the other Commission decisions cited by the applicant.

130 As regards the case-law cited, it must be noted that 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 122 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).

131 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 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.

132 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) (OJ 1994 L 309, p. 1) and Commission Decision C(2013) 8535 final of 26 November 2013, relating to a proceeding under Article 6 of Council Regulation (EC) No 139/2004 (Case COMP/M.6944 —

Thermo Fisher Scientific/Life Technologies), to which the applicant refers, do not contradict the contested decision. 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 122 to 128 above and paragraphs 135 to 140 below), it cannot be ruled out that the Commission could, in some of its decisions, including inter alia the abovementioned decision, 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.

133 Contrary to the applicant's assertions, the fact that the Commission mentioned alternative means of accessing the market, namely launching at risk or altering the product in order to avoid infringement (see paragraph 119 above), does not distort the rules applicable to determining whether there is potential competition. By referring to these alternatives in the part of the contested decision setting out the rules that it intended to apply in order to determine whether the generic companies in question were potential competitors, the Commission merely referred to possibilities of entering a market on which patents are in force. Subsequently, in its analysis of each of the agreements at issue, it examined whether those possibilities could be regarded as real and concrete in view of the specific features of each of the generic companies. It did not, however, infer from the mere existence of those alternative possibilities that the generic companies, and in particular the applicant, had real concrete possibilities of entering the market.

134 Nor, contrary to the applicant's assertions, does the fact that the Commission took into account, in the contested decision (recital 1172; see also paragraph 118 above), the parties' subjective perceptions of the patent litigation conflict with an examination of the real concrete possibilities of entering the market, which is necessary in order to determine whether there is potential competition on the market in question (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 a decision of a public authority in relation to the infringement and to the validity of Servier's patents, the assessments made by the parties themselves as regards the possibilities of those patents being declared invalid or being infringed are liable to shed light on their 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 125 above and paragraph 241 below). Since intention is regarded as a relevant criterion for determining whether there are real concrete possibilities of entering the market (see paragraphs 74 and 75 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 therefore be compared with elements on the basis of which the ability to enter the market can be assessed as well as, where appropriate, other elements also capable of showing a company's intentions as regards market entry, in order to determine whether it may be concluded that there are real concrete possibilities of overcoming the patent-related barriers (judgment delivered today, *Servier and Others* v *Commission*, T−691/14, paragraph 384).

135 In the present case, the applicant relies exclusively on documents showing its own perception or

that of its advisers that its product infringed Servier's process patents and 947 patent and infers from this that those patents were insurmountable barriers to its market entry.

136 As can be seen from paragraphs 128 and 134 above, those subjective assessments of the existence of an infringement cannot equate to a decision of a public authority finding an infringement, nor a fortiori to a final decision to that effect, making those patents insurmountable barriers, and must be compared with other evidence in the file in order to determine whether it may be concluded that there are no real concrete possibilities of overcoming the barriers linked to those patents.

137 As regards the process patents, the applicant relies on one of its internal documents, dated 10 June 2004, giving a status update on the development of its product and on an email that it sent to Matrix on 10 August 2004, from which it follows, according to the applicant, that it had 'legal concerns' concerning the infringement of those patents. It must be noted, however, that although the first document indeed indicates that it would be better to make some changes to its manufacturing process in order to ensure that there is no infringement, it also notes that those changes were made, as the second document also confirms. Moreover, it is apparent from the contested decision (recital 490) and from the application itself, as the Commission rightly emphasises, that the applicant invited Servier, by letter of 27 April 2004, to acknowledge that it did not infringe any of its process patents and, in doing so, took the initiative to 'clear the way' by essentially asking Servier to bring an action against it for infringement of those process patents so that it could have that action dismissed and thus have the lack of infringement confirmed by a competent authority. It follows that it cannot be inferred from the documents cited by the applicant that it did not intend to enter the market because of an excessively high risk of infringing Servier's process patents.

138 As regards the 947 patent, the applicant refers to its efforts to develop a product that could limit the risk of infringing that patent and mentions several documents showing the failure of those attempts, since the level of the alpha form remained significant in the product obtained. However, it is also clear from the only document amongst those cited by the applicant that shows its own position, namely the notes of a meeting held between Niche and Matrix on 5 November 2004, that an action for the revocation of the 947 patent was made necessary by the risk that the applicant's product would infringe that patent. The applicant thus filed an opposition against the 947 patent before the EPO in November 2004 (recitals 522 and 1290 of the contested decision) and served on Servier, in the context of the proceedings concerning the infringement of Servier's process patents, a counterclaim for the annulment of the 947 patent on 9 July 2004 (recital 499 of the contested decision), which it had also announced in its abovementioned letter of 27 April 2004 (see paragraph 137 above). It is therefore irrelevant that in the two other documents produced by the applicant, one dated 5 February 2005 from one of its external counsels and the other detailing a statement made by a Unichem director in February 2005, those two individuals had warned the applicant of the cost and likely duration of litigation against Servier. As regards the alleged risk of interim injunctions, it must be pointed out that that risk is not sufficiently substantiated, since the applicant merely refers to Servier's aggressiveness as demonstrated by its subsequent applications for interim injunctions against Apotex and Krka, and that, in addition, it could not, by itself and given the circumstances of the case, preclude the classification of the applicant as a potential competitor. Interim injunction proceedings entail the continuation and the swift resolution of the litigation and provide real concrete possibilities for the alleged infringing parties to defend themselves (see, to that effect, judgment delivered today, *Teva UK and Others* v *Commission*, T-679/14, paragraph 142 and 143), and the applicant had already made use of them by challenging the validity of the patent on which the injunction proceedings were based. It follows that it also cannot be inferred from the allegations and the documents put forward by the applicant that it did not intend to enter the market because of an excessively high risk of infringing Servier's 947 patent.

139 It also follows from the arguments and documents relating to the infringement of the process patents and of the 947 patent examined above that the applicant took both technical steps — consisting in the alteration of the manufacturing process and the form of its product — and legal

actions — consisting in actions intended to 'clear the way' and challenge the validity of patents — in order to limit the risks of entering the market with its product and that, in doing so, it had, at the very least, the intention, and even the materialised and not merely theoretical intention, to overcome the patent-related barriers in question.

140 The applicant's arguments in relation to the barriers linked to Servier's patents cannot, therefore, call into question its real concrete possibilities to compete with Servier.

(ii) Technical barriers

141 It should be noted, at the outset, that, since assessing the real concrete possibilities of manufacturing a product is not the same as assessing the real concrete possibilities of obtaining a marketing authorisation, but some manufacturing problems may have consequences as regards the grant of a marketing authorisation, the applicant's arguments concerning its technical difficulties must be considered before those relating to the difficulties in obtaining the requested marketing authorisations.

142 It should be noted that those technical difficulties are only briefly mentioned by the Commission in the part of the contested decision specifically devoted to the assessment of the applicant as a potential competitor (recitals 1282 to 1298; see also paragraphs 101 to 107 above) and that the Commission does not discuss them in the part of the contested decision setting out the criteria for assessing potential competition (recitals 1156 to 1183). However, those difficulties are examined in detail in the part of the contested decision describing the agreements that Servier concluded with Niche and Matrix and the circumstances in which they were concluded (recitals 463 to 479) and it is apparent that the Commission primarily relied on the efforts made to find solutions to the technical difficulties in question and the lack of evidence that those difficulties were insurmountable (recital 479; see also recital 1296).

143 The applicant does not dispute that it, together with Matrix, worked to obtain a marketable product and solely submits, in essence, that the technical barriers involved in manufacturing its product were insurmountable. In support of its submission, it relies essentially on two reports ('the N. report' and 'the J. report') which it commissioned for the purposes of the present proceedings. Those reports shall be taken into consideration only in so far as they support or supplement pleas or arguments expressly set out by the applicant 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 (see paragraph 115 above).

144 It must be pointed out, first of all, that those two reports do not support the conclusion that Niche and Matrix faced insurmountable difficulties in manufacturing their product.

145 It is true that the N. report and the J. report show significant difficulties concerning fundamental aspects of the product and the haphazard and misdirected efforts made by Niche and Matrix to resolve them. Nevertheless, they refer to those difficulties being impossible to resolve solely as a possibility and essentially highlight the resulting delays in the manufacturing and regulatory approval process. Those delays do not demonstrate, in themselves, that it was impossible to develop or to produce generic perindopril, or even that market entry could not take place sufficiently quickly, since they occurred at an advanced stage of the collaboration between Niche and Matrix, which began in March 2001, and they thus affected, in the present case, the last efforts of Niche and Matrix before the completion of the regulatory steps preceding market entry (judgment delivered today, *Servier and Others* v *Commission*, Case T−691/14, paragraph 459).

146 In addition, and even if the N. and J. reports had indicated that the development of the product of Niche and Matrix was faced with insurmountable difficulties, they could not — since they were drawn up by experts, one of whom worked for the applicant, at the latter's request and for the purposes of the present proceedings — take precedence over the factual information

contemporaneous with the events at issue, as described below.

147 According to settled case-law, the activity of the Court of Justice and of the General Court is governed by the principle of the unfettered evaluation of evidence and it is only the reliability of the evidence before the Court which is decisive when it comes to its evaluation (see Opinion of Judge Vesterdorf, acting as Advocate General, in *Rhône-Poulenc* v *Commission*, T-1/89, EU:T:1991:38, p. 954 and the case-law cited). Thus, regard should be had to the credibility of the account it contains and, in particular, to the person from whom the document originates, the circumstances in which it came into being, the person to whom it was addressed and whether, on its face, the document appears to be sound and reliable (judgments 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 1838, and of 27 September 2012, *Shell Petroleum and Others* v *Commission*, T-343/06, EU:T:2012:478, paragraph 161). In particular, the fact that documents were drawn up in the same period as the events in question and clearly without any thought for the fact that they might fall into the hands of third parties must be regarded as having great significance (Opinion of Judge Vesterdorf, acting as Advocate General, in *Rhône-Poulenc* v *Commission*, T-1/89, EU:T:1991:38, p. 956).

148 It is apparent precisely from the factual information contemporaneous with the events at issue, as can be seen from the documents in the administrative file debated by the parties, that the technical difficulties encountered by Niche and Matrix did not constitute an insurmountable barrier to the development of a product ready to be marketed.

149 As regards the impurities detected, the applicant essentially concludes that they represented an insurmountable barrier because of the cessation of production and Unichem's rejection of certain batches of its product following the detection of those impurities.

150 However, it cannot be inferred from the cessation of production requested by Niche in January 2005 that the impurities detected in its product constituted an insurmountable barrier to the continuation of its development process. It is clear from the email, dated 4 January 2005, sent by Niche to Unichem and Matrix, that Niche asked Matrix to continue its research in relation to the origin of the impurity, taking into account Unichem's different analysis in that respect, and to stop its production, if possible, until a solution was found to the impurity problem, in the event that the rate of impurity in the material already produced was higher than 0.1%. The cessation of production requested by Niche was therefore hypothetical and the Commission submits, moreover, that an actual cessation was not established, relying on an email sent by Niche to Matrix on 7 March 2005, which indicated that the manufacturing process was stopped only after the Agreement was concluded (see also recital 626 of the contested decision). In addition, and in any event, that cessation of production was temporary, since it was limited to the time required to resolve the technical difficulty in question, and it is clear from the file that the resolution of that difficulty — which concerned the fact that the rate of impurity was slightly higher than the required threshold — had already begun. It is apparent from the documents adduced by the applicant itself that the impurity rate exceeded the threshold of 0.1% by between 0.01% and 0.03% and that Matrix was in close contact with Unichem in order to provide it with results of analyses and advice in relation to the performance of product analyses, as shown by the email exchanges between Matrix and Unichem from 17 to 24 January 2005. Above all, even if that cessation of production had led to the 'worst case scenario' referred to by Niche, that is to say having to 'start production afresh' (recital 474 of the contested decision), it must be pointed out that the possibility of starting afresh demonstrates precisely that the impurity problem was not insurmountable.

151 Similarly, it is true that Unichem rejected several batches of the product because the rate of impurities exceeded the threshold of 0.1%. However, even if, as the applicant submits, that rejection occurred before the conclusion of the Agreement, it is apparent from the documents in the file

showing the rejection of those batches that Unichem requested Matrix to investigate why that threshold was not respected and requested Matrix's subcontractor to examine the manufacturing process and to check the level of impurities in all future batches that would be provided to it, thereby suggesting that the impurities issue did not preclude that Niche and Matrix would supply perindopril to it in the future and, thus, that the process of developing that perindopril would continue.

152 As regards the stickiness of the API and the hardness of the tablets, the applicant merely cites a passage from an email sent by Niche's consultant to Niche on 17 January 2005, which it incorrectly presents as an extract from an email sent by Niche to Matrix on 4 January 2005, according to which 'the changes in the blending process did not seem to overcome the stickiness problem systematically'. However, it omits to cite another passage from that email, from which it is apparent that that consultant was pursuing several options to resolve the stickiness and hardness issues and requested Niche to approve them so that they could be implemented.

153 It must be noted that it is clear from the file and from the contested decision that the difficulties encountered in relation to the dissolution profile had either been resolved or were being resolved. In response to worries expressed by Niche at the end of 2004 as to whether the new dissolution profile was consistent with the bioequivalence studies carried out with the originator company's medicinal product (recital 472 of the contested decision), Niche's consultant indicated, by email of 8 February 2005, that there were no compliance problems as regards one batch and that, since the other batch did have such a problem, a new batch had to be manufactured, which should have taken between 30 and 45 days according to Matrix's estimates in the minutes of a meeting held between Niche and Matrix in January 2004, which the applicant submitted as an annex to the application. The applicant does not call into question the contents of that email, which the applicant itself submitted as an annex to the application, and merely refers, relying on the N. report, to the mere possibility that a new bioequivalence study might be necessary, a study which, as can be seen from the foregoing, was ultimately not necessary given the decision of Niche and Matrix to manufacture batches whose dissolution profile would be consistent with the previous bioequivalence studies.

154 Consequently, the Court finds that the applicant has not established that the technical difficulties encountered were insurmountable, even without it being necessary to rely on the statements made by Niche and Matrix and their relationships with other customers, which, according to the applicant, should not be taken into account in the present case because, in essence, they were intended to conceal, to the outside world and inter alia to their partners, the difficulties faced by Niche and Matrix (see paragraph 93 above).

155 It should be noted, in addition, that the Commission did not erroneously take account of those statements and relationships. Technical difficulties are, by their very nature, exclusively internal to the businesses concerned, with the result that the consideration of information from those businesses cannot be precluded in assessing those difficulties. In addition, the Commission correctly took into account the statements and relationships in question as one piece of evidence amongst others in its assessment, examining them in the light of inter alia the various internal exchanges mentioned above and the circumstances in which they were made or arose, in order to be able to assess, in the most objective manner possible, whether there were insurmountable technical barriers to the market entry of Niche and Matrix. Thus, in particular, it rightly took into account the fact that the Niche-Matrix agreement was not terminated (recitals 477 and 1297 of the contested decision) through the invocation of the termination clause, which allowed the termination of the agreement in the event that the delays in some phases of the development and marketing of the product were likely to delay the project to such an extent as to make the launch of the product non-viable. Likewise, the Commission rightly rejected, since they were made during the positioning phase on the conclusion of the Agreement and with a view to that positioning, the notes of a Unichem director referring to Matrix's inability to supply commercial quantities meeting the approved specifications in the following months and to stability batch failures and rightly paid particular attention to internal

exchanges within Niche showing the lack of concerns regarding the stability of the API (see also paragraph 175 below).

156 The applicant's arguments relating to the technical difficulties encountered with its product cannot, therefore, call into question its real concrete possibilities of competing with Servier. It follows in particular from the foregoing that, even though they allegedly arose after Matrix had prepared batches of API for the commercial launch and after Niche had concluded several supply agreements, those technical difficulties are not capable of calling into question the relevance of that preparation for a commercial launch and of the conclusion of those supply agreements for the purposes of establishing Niche's real concrete possibilities of entering the market.

(iii) Regulatory barriers

157 It should be noted, as a preliminary point, that the Commission did not deny, in the contested decision, that the regulatory barriers linked to the procedure for granting marketing authorisations could constitute insurmountable barriers to entry. It nevertheless considered that the absence of a marketing authorisation did not mean that the product could not reach the market, as long as the generic company continued its efforts to obtain regulatory approval and these attempts did not face objectively insurmountable problems at the time of the settlement (recitals 1180 and 1181).

158 It may also be noted that, in the judgment of 6 October 1994, *Tetra Pak* v *Commission* (T-83/91, EU:T:1994:246, paragraphs 110 and 133), and in the Commission decisions (Decision C(2009) 804 of 4 February 2009 relating to a proceeding under Article 6 of Regulation No 139/2004 (Case COMP/M.5253 — Sanofi/AventisZentiva, paragraphs 213 and 214) and Decision C(2010) 5514 of 3 August 2010 relating to a proceeding under Article 6 of Regulation No 139/2004 (Case COMP/M.5865 — Teva/Ratiopharm, paragraph 55)) cited by the applicant, it was not considered that the need to obtain a marketing authorisation in order to enter the market and the lack of such a marketing authorisation formed an insurmountable barrier to market entry; the General Court judgment did not refer to any regulatory barrier of that nature and the two Commission decisions described the marketing authorisation procedure as a 'significant' or 'high' barrier to entry and concluded that the time necessary to enter the market would be at least one or two years.

159 Next, it must be held that the arguments put forward by the applicant do not establish that it faced objectively insurmountable problems in the marketing authorisation procedure.

160 First, the applicant relies primarily on the technical difficulties encountered in manufacturing its perindopril (particle size, hardness of tablets, impurities, dissolution profile), which — it has been held — were not insurmountable and, accordingly, did not prevent the development of a product capable of entering the market (see paragraph 156 above). It can therefore be concluded that, even if the studies and other additional actions which those technical difficulties allegedly made necessary in order to obtain the marketing authorisation would have delayed the grant of that marketing authorisation (see, to that effect, paragraph 162 below), they would not have made that grant impossible. It should also be noted that the applicant has itself established that it had, at the very least, begun some of those additional steps in the context of the marketing authorisation procedure, since it produced, in annex to the application, an internal exchange preparing a consistent response to regulatory authorities' questions concerning particle size following the positive reaction of the Netherlands' authority as regards the explanations given in that respect.

161 Secondly, the applicant refers, in the reply, to a letter from the United Kingdom regulatory authority dated 19 April 2005, from which it infers, relying on the J. report, that the information requested by that authority implied a return 'to the drawing board' for the applicant. Apart from the fact that the applicant mentions only one request of that nature whereas it had initiated marketing authorisation procedures in several European countries (Czech Republic, Denmark, France, Hungary, the Netherlands, Portugal, Slovenia, Sweden, the United Kingdom; see recital 454 of the contested decision), it should be noted that, as the Commission submits, it is apparent from a letter of 13 May

2005 from Niche to Matrix, which the J. report overlooks, that the applicant was confident that it could respond to most of the requests and that it would leave it to Matrix to answer two of them. It follows that the applicant maintained its efforts to obtain the marketing authorisation concerned — encouraged in that respect by the success of one of its partners which obtained a marketing authorisation for its product in the Netherlands in the same period — and that it cannot be inferred from the request of the United Kingdom regulatory authority that the applicant's attempts to obtain a marketing authorisation in that country faced objectively insurmountable problems.

162 Lastly and above all, it must be emphasised that the applicant, as well as the N. and J. reports on which it relies, refer only to the delay in obtaining the marketing authorisation, and not to the impossibility of obtaining that marketing authorisation. Since competitive pressure is likely to be exerted from the submission of the application for a marketing authorisation and for as long as efforts are made to obtain the marketing authorisation without encountering objectively insurmountable problems, the delays suffered in the marketing authorisation procedures do not suffice, by themselves, to preclude the classification of the marketing authorisation applicants concerned as potential competitors. In addition, since the marketing authorisation procedure generally precedes market entry and since the grant of a marketing authorisation allows, in principle, immediate market entry and thus effective competition, a requirement that the marketing authorisation be obtained quickly or without any delays would amount to denying the difference between actual competition and potential competition (see judgment delivered today, *Servier and Others* v *Commission*, T-691/14, paragraph 478 and the case-law cited).

163 Moreover, it is irrelevant whether, as the applicant alleges, those delays limited its commercial interest in entering the market, given that numerous generic companies would probably enter the market subsequently and the price of perindopril would fall accordingly. Such an 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, which must be examined in the light of the economically viable strategy criterion (see paragraph 73 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. The interest invoked by the applicant in being the first to enter the market is therefore irrelevant for assessing the alleged delays and, a fortiori, inferring from those delays that the grant of a marketing authorisation faced objectively insurmountable problems (see, to that effect, judgment delivered today, *Servier and Others* v *Commission*, T-691/14, paragraph 340 and the case-law cited).

164 The applicant's arguments relating to the regulatory difficulties encountered cannot, therefore, call into question its real concrete possibilities of competing with Servier.

(iv) Financial barriers

165 It must be borne in mind that, in recital 1294 of the contested decision, in response to the applicant's allegation that it was in a weak financial position and that it would probably have been dissolved had it not concluded the Agreement, the Commission noted that an invoicing arrangement entered into in December 2004 had provided the applicant with additional working capital (see also footnote 869 of the contested decision), that in January 2005 the applicant had received from Servier a non-refundable deposit of between EUR 0 and 5 million in the context of its planned acquisition by Servier (see also recital 535 of the contested decision) and that it could have improved its financial situation by asking its parent company for a guarantee, or by requesting that future litigation costs be shared (see also paragraph 107 above). The Commission also noted that the applicant had concluded 14 agreements with commercial partners that were keen on selling its perindopril and was negotiating a future supply agreement with Teva just a few days before the Agreement was concluded (recital 1284 of the contested decision; see also paragraph 103 above).

166 It follows that the Commission considered that the applicant's market entry was not faced with the insurmountable financial barrier that its insolvency would represent, and that moreover it had the requisite financial capacity to achieve that market entry.

167 The applicant disputes the Commission's assessment in that respect, invoking the risk of a cessation of payments which it faced.

168 It must be noted at the outset that such a cessation of payments, even if it were established, corresponds to a temporary inability to meet debts out of available assets and does not amount to a permanent inability to meet all debts, whether due or not yet due, out of all assets, which characterises an insolvency situation and which, alone, could represent an insurmountable financial barrier to its market entry.

169 However, since a state of cessation of payments necessarily has an impact on an undertaking's financial capacity and, thus, on its capacity to enter the market, it is necessary to examine the arguments put forward by the applicant in support of its allegation that it faced a risk of a cessation of payments.

170 The applicant relies, in that respect, primarily, on two reports drawn up by its own accountants for the purposes of the present proceedings ('the F. reports'), which concluded that a cessation of payments was imminent at the time the Agreement was concluded. It also refers to the significant financial risks that it faced as a result of its patent disputes and the agreements concluded with its commercial partners, and emphasises its difficulties in obtaining external financing, from its parent company, Unichem, amongst others, because of the problems with its perindopril, which was its main commercial project.

171 As regards, first, the F. reports, they shall be taken into consideration only in so far as they support or supplement pleas or arguments expressly set out by the applicant 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 (see paragraph 115 above) and, furthermore, those reports cannot take precedence over the factual information contemporaneous with the events at issue, since those reports were drawn up by the applicant itself for the purposes of the present proceedings (see paragraphs 146 and 147 above).

172 In the present case, the applicant merely presents figures from the F. reports in relation to the losses that it suffered in January 2005 and during the financial year ended in March 2005, whereas it can be seen from its own financial statements, which are annexed to the defence and which the applicant does not dispute, that, during the last quarter of the 2003/2004 financial year, it had made a pre-tax profit of GBP 100 000 and its financial results remained generally positive on 31 March 2005, even after deducting the amounts which had to be paid on that date under the Agreement (Clause 13) and under the agreement concluded between Niche and Biogaran.

173 In addition, the applicant does not dispute that it received or had at its disposal, before the conclusion of the agreements with Servier and Biogaran on 8 February 2005 — and thus irrespective of whether the amounts received under those agreements are taken into account — funds from various sources of financing. Thus, as can be seen from the F. reports cited by the Commission in the defence, the applicant received several payments from its parent company Unichem (GBP 2 million as share capital, GBP 1 million as an unsecured loan, and subsequently GBP 350 000 in August 2004), and from its management (GBP 250 000 as share capital and subsequently GBP 29 000 in August 2004) and secured a discounting facility, whereby 80% of the value of the invoices for sales to customers in the United Kingdom was lent to it (which corresponded to a loan of GBP 400 000 to 500 000), as well as a mortgage of GBP 148 000 from a bank. Furthermore, the applicant also does not dispute that it received a sum of between EUR 0 and 5 million from Servier in January 2005, or that it entered into the abovementioned invoicing arrangement in December 2004, even though it stresses that those measures were not sufficient to

cover its working capital needs (see paragraph 165 above).

174 In addition, as regards the email sent on 29 October 2004 by one of its directors, allegedly intended to warn Unichem that it was close to a cessation of payments, the applicant fails to indicate that, in that email, its finance director stated that he was confident that it would obtain two expected sources of funding and thus that it was unlikely that it would need further funding from Unichem.

175 As regards, secondly, the litigation costs that the applicant could allegedly be required to pay, it must be noted that the applicant merely cites a letter which one of its directors sent a few days before the conclusion of the Agreement and which was intended, as is apparent from the applicant's internal email explaining the aim of that letter, to convince Unichem and the other directors of the applicant of the interest in concluding the Agreement. Thus, even though in that letter the director emphasised, inter alia, the costs incurred in the patent litigation, no objective inference can be made from it as regards the impact of those costs on the applicant's financial situation. The same applies to the note of one of Unichem's directors, which the applicant also refers to, since it merely repeats the abovementioned letter from Niche's director and states, without evidence, that pursuing the litigation would be financially ruinous.

176 The applicant also refers to estimates taken from the F. reports concerning the litigation costs involved in main proceedings to challenge the 947 patent (GBP 1 million) and appeal proceedings against a decision finding an infringement of the process patents (GBP 300 000 to 400 000) before the United Kingdom courts. Aside from the fact that no such proceedings had been brought when the Agreement was concluded, it must be noted that those estimates do not take into account either the payments and loans made in August 2004 by Unichem and the applicant's management in order to cover the litigation costs, amounting to more than GBP 350 000 (see paragraph 173 above), or the envisaged sharing of litigation costs, which was expressly excluded from the analysis in the F. reports on the ground that the applicant was unable to meet its debts as they became due, regardless of the additional litigation costs and the sharing of those costs.

177 As regards, thirdly, the agreements which the applicant concluded with commercial partners, the applicant has not established that it was, at the time that the Agreement was concluded, about to be faced with numerous requests for reimbursement from those partners that would have imperilled its financial stability. It merely submits that it did not wish to reveal its difficulties to its partners and notes the termination of the contractual relationship by one customer and the fears of another of its 14 customers mentioned in the contested decision (recital 1284). It may also be added that the alleged amount of the reimbursement mentioned in the application is not in any way apparent from the F. reports, to which the applicant nevertheless refers.

178 As regards, fourthly, the perindopril project of the applicant and of Matrix, it follows from the abovementioned considerations in relation to the patent-related, technical and regulatory barriers that the applicant had, with Matrix, real concrete possibilities of overcoming those barriers and entering the market with its perindopril sufficiently quickly (see paragraphs 140, 156 and 164 above). Thus, even if, as the applicant submits, perindopril was its main commercial project, it cannot be considered that the difficulties which it faced with Matrix in bringing that project to fruition were such as to undermine its possibilities of obtaining external financing.

179 As regards, fifthly, those possibilities of obtaining external financing, the applicant has in no way established that Unichem refused to provide it with its guarantee as parent company. The applicant relies primarily on documents demonstrating its own perception of the possibility of such a guarantee and the only documents from Unichem that it adduces were either drawn up for the purposes of the present proceedings (statement of a Unichem director, dated September 2014), or do not show any refusal to provide a guarantee (extract from the notebook of that director dated 5 August 2004).

180 It may be added, as the Commission submits, that if the applicant's financial situation had

deteriorated to the extent claimed by the applicant, it would not have begun the costly extension of its Irish facility. It must be emphasised, in that respect, that contrary to the applicant's submission, it does not follow from the minutes of the meeting of Niche's board of directors of 27 October 2004, to which it refers, that that extension was necessary in order to increase its capacity and to continue to meet demand. On the contrary, according to those minutes, work on that extension was not to begin until Niche's financial situation was more stable, with the result that the fact that the work in question was carried out does not support the allegation that the applicant faced an imminent cessation of payments but rather supports the conclusion that no such cessation of payments was imminent.

181 It should be added that the Commission did not disregard either its obligation to state reasons, or the applicant's rights of defence, by referring to the work carried out by the applicant in its Irish facility for the first time in its written pleadings before the Court. The Commission is entitled to respond to the arguments whereby the applicant seeks to establish, on the basis of documents other than those which it adduced before the Court — in this case the F. reports mentioning the large share of the costs incurred by the applicant represented by the abovementioned extension work — that the Commission's assertion is incorrect in fact (see, to that effect, judgments of 8 July 2004, *JFE Engineering* v *Commission*, T-67/00, T-68/00, T-71/00 and T-78/00, EU:T:2004:221, paragraph 176, and of 13 July 2011, *ThyssenKrupp Liften Ascenseurs* v *Commission*, T-144/07, T-147/07 to T-150/07 and T-154/07, EU:T:2011:364, paragraphs 146 to 149).

182 Moreover, if Niche had been so unable to enter the market because of its imminent cessation of payments situation, Servier would not have had any interest in concluding the Agreement providing for the payment of an amount corresponding to a non-negligible proportion of its value, as can be seen from the due diligence report carried out in the context of the planned acquisition of Niche (recital 532 of the contested decision).

183 It follows from the foregoing that the applicant has not established that it faced an imminent cessation of payments when the Agreement was concluded and therefore has not called into question its financial capacity to enter the market, nor a fortiori the absence of insurmountable financial barriers to that entry, as found by the Commission in the contested decision.

(v) Commercial barriers

184 It should be noted at the outset that the applicant's line of argument in relation to the existence of commercial barriers to its market entry cannot succeed.

185 The applicant submits that it was prevented from entering the market because of Matrix's refusal to supply it the perindopril API and to assist it in completing its file in order to obtain a marketing authorisation. It follows from the contested decision that, as the applicant itself confirms, that refusal occurred in June 2005, when Matrix suspended with immediate effect the Niche-Matrix agreement (recital 631 of the contested decision).

186 It follows that the alleged commercial barrier evoked by the applicant, if it were indeed sufficient to prevent Niche from entering the market, occurred after the conclusion of the Agreement of 8 February 2005 and pursuant to that agreement. It cannot therefore preclude the classification of Niche as a potential competitor, which must be assessed with respect to the time the Agreement was concluded (see judgment delivered today, *Servier and Others* v *Commission*, T-691/14, paragraph 385 and the case-law cited).

187 Accordingly, none of the applicant's arguments concerning the barriers linked to Servier's patents and to the applicant's technical, regulatory and financial difficulties are capable of calling into question its ability and its intention to enter the market, as established by the Commission in the contested decision (see paragraph 109 above).

188 Consequently, the plea alleging errors of law and of assessment in the analysis of the applicant as a potential competitor must be rejected.

4. The pleas alleging errors of law and of assessment in classifying the Agreement as a restriction of competition

(a) Arguments of the parties

(1) The inapplicability of Article 101(1) TFEU to the settlement agreements

(i) The applicability of the objective necessity test

189 The applicant submits that it is clear from the case-law and from the 2004 Guidelines on technology transfer agreements that patent dispute settlement agreements fall outside the scope of Article 101(1) TFEU where they are bona fide agreements, they aim to resolve a genuine dispute and the restrictions they impose are within the scope of the intellectual property right at issue. The restrictive clauses of such agreements do no more than reflect a public law right to exclude other companies from the market and are objectively necessary in order to settle a legitimate dispute.

190 The applicant, first, infers from this that, contrary to what is stated in the contested decision, the Commission cannot simply conclude that all settlements are covered by Article 101(1) TFEU but, rather, must assess whether the objective necessity test is satisfied, ascertaining whether the restrictions imposed by the settlement have gone beyond what was necessary and proportionate to its legitimate aim of settling the dispute. It states that the objective necessity test does not involve a review of the economic terms of an agreement and in particular the size of the value transfer. The applicant criticises, moreover, the fact that the Commission relied, in support of its assessment, on the judgment of 25 February 1986, *Windsurfing International* v *Commission* (193/83, EU:C:1986:75, paragraph 92), relating to a patent licence and ruling, accordingly, on the essential subject matter of patents and not on that of settlements; on the judgment of 27 September 1988, *Bayer and Maschinenfabrik Hennecke* (65/86, EU:C:1988:448, paragraphs 15 to 17), which states only that some settlements may be contrary to Article 101(1) TFEU and relates to an agreement that is not restrictive of competition and does not apply to settlements before a court such as the one reached in this case; and on the judgment of 20 November 2008, *Beef Industry Development Society and Barry Brothers* (C−209/07, EU:C:2008:643, paragraph 21), which relates to restrictions by object not requiring an objective necessity analysis.

191 Secondly, the applicant submits that the Agreement satisfies the objective necessity test since settlements pursue the legitimate objective of efficiently settling disputes which are costly for the companies involved and a burden on the courts, the non-marketing and non-challenge clauses are necessary in order for a settlement to be reached and the terms of those clauses are proportionate to the settlement objective pursued.

192 The Commission submits, at the outset, that it was expressly recognised in the contested decision that where a settlement of a patent dispute is reached on the basis of each party's assessment of the patent case before them, such a settlement was unlikely to infringe Article 101(1) TFEU and that Article 101(1) TFEU may be infringed where an agreement is reached not on account of the strength of the patent but as a result of the payment of a substantial sum of money from the patent holder so that a potential competitor stays out of the market. It also submits that the case-law, including that cited by the applicant, did not apply the objective necessity test to agreements such as the one at issue in this case and applied competition law to the exercise of intellectual property rights. The Commission adds that the applicant distorts the Court's doctrine of ancillary restraints – according to which, if a main operation falls outside the scope of Article 101(1) TFEU, so too does the ancillary restraint which is objectively necessary to that operation – by attempting to apply the doctrine to settlement agreements even though settlement agreements are not excluded from the scope of Article 101(1) TFEU, particularly where the settlement is reached as a result of a payment.

193 The Commission then emphasises, first, the relevance of the judgments cited in the contested decision, its reliance on which was criticised by the applicant. Accordingly, the judgment of 25 February 1986, *Windsurfing International* v *Commission* (193/83, EU:C:1986:75), illustrates that an agreement, whether it is a settlement agreement or not, may be restrictive if it affects the possibility of competition unrestrained by a given patent. Similarly, the judgment of 27 September 1988, *Bayer andMaschinenfabrik Hennecke* (65/86, EU:C:1988:448), expressly included settlement agreements within the scope of Article 101(1) TFEU in cases, such as the one at issue, where the national court has, in fact, merely given its approval of the settlement. Lastly, the judgment of 20 November 2008, *Beef Industry Development Society and Barry Brothers* (C−209/07, EU:C:2008:643), is relevant in this case since it concerned agreements pursuing a legitimate objective, which, according to the Court, should be taken into consideration when assessing the applicability of Article 101(3) TFEU.

194 Secondly, the Commission argues that, in any event, the Agreement did not satisfy the objective necessity test since the non-marketing and non-challenge clauses, and above all the value transfer, were neither necessary nor proportionate to achieve any legitimate objective of settling the dispute.

(ii) The applicability of the 2004 Guidelines on technology transfer agreements

195 The applicant criticises the Commission for not applying, in this case, the 2004 Guidelines on technology transfer agreements, paragraph 209 of which states that the objective necessity test does apply to patent settlement agreements. It submits that Clause 6 of the Agreement granted it a de facto licence to use the technology covered by the 947 patent. The applicant adds that, by not applying the tests required by the 2004 Guidelines on technology transfer agreements to the Agreement, the Commission infringed the principle of equal treatment between the applicant and other companies involved in technology transfers.

196 The Commission contends that it cannot be inferred, first, from the 2004 Guidelines on technology transfer agreements that Article 101(1) TFEU does not apply to non-challenge clauses agreed as a result of a substantial payment and extending beyond the scope of the dispute and, secondly, from Clause 6 of the Agreement, that the Agreement granted the applicant a de facto licence.

(2) The erroneous classification of the Agreement as a restriction of competition by object

(i) The errors of law in classifying the Agreement as a restriction of competition by object

197 The applicant submits, primarily, on the basis of the judgment of 27 September 1988, *Bayer and Maschinenfabrik Hennecke* (65/86, EU:C:1988:448, paragraphs 17 and 19), that, if a settlement agreement falls under Article 101(1) TFEU, it can only be restrictive by effect, on the basis of an exhaustive commercial analysis of its effects, and cannot be restrictive per se, by object. Accordingly, the applicant complains that the Commission did not apply the solution identified in that judgment and that it continued to apply that set out by the judgment of 25 February 1986, *Windsurfing International* v *Commission* (193/83, EU:C:1986:75), which is not relevant in this case.

198 The applicant argues, in the alternative, that the Commission did not take into account the relevant criteria for assessing restrictions of competition by object and based its assessment of whether the patent settlements are restrictions by object on the fulfilment of conditions which are not consistent with those criteria. Those conditions were formulated to be applicable to all market circumstances, whereas restrictions by object must be interpreted strictly, and the Commission itself acknowledged in the contested decision that the vast majority of patent settlement agreements do not raise concerns with regard to competition rules. Moreover, in order to establish whether the first condition, relating to potential competition between the parties to the settlement, and the second condition, relating to a limitation on entering the market, are satisfied, there must be an assessment of the validity or infringement of the patents at issue, which could not be carried out by the Commission, so that settlements cannot be considered to be inherently injurious. Similarly, the third condition relating to

the existence of an inducement does not make it possible to distinguish between agreements which restrict competition and those which do not, since settlement agreements by their nature involve financial or commercial benefits, and, therefore, the existence of those benefits does not indicate a sufficient degree of harm to competition. Lastly, the Commission disregards the proper economic and legal context by making, in the contested decision, a series of unsubstantiated statements which are incorrect as a matter of patent law or unsupported by the case-law.

199 First of all, the Commission criticises the applicant's interpretation of the judgment of 27 September 1988, *Bayer and Maschinenfabrik Hennecke* (65/86, EU:C:1988:448), from which it is apparent only that, on the facts of that case, the Agreement concerned did not reveal a sufficient degree of harm to competition such that it could be regarded as a restriction by object. It also states that, in the judgment of 25 February 1986, *Windsurfing International* v *Commission* (193/83, EU:C:1986:75), the Court of Justice did not hold that all non-challenge clauses were restrictive of competition.

200 The Commission then contends that it did apply the relevant criteria for assessing restrictions of competition by object in accordance with the case-law. It points out in particular that its assessment is consistent with the restrictive interpretation of restrictions of competition by object. The Commission notes, however, that, according to the applicant's line of argument concerning the first and second conditions subject to which settlement agreements may be classified as restrictions by object, provided that there is some kind of dispute between two parties, they would be free to enter into a settlement agreement on any terms, ignoring the distinction between potential and actual competition. As regards the third condition, the Commission states that it expressly recognised in the contested decision that, in certain cases other than the present case, settlement agreements involving value transfers, including from the originator company to the generic company, are not contrary to Article 101(1) TFEU. The Commissions explains that it cannot be inferred from that, however, that the payment made to the generic company should not be taken into account, particularly since that payment was an essential term of the Agreement.

(ii) The errors of assessment in classifying the Agreement as a restriction of competition by object

– *The lack of restrictions going beyond the scope of the patents at issue*

The assessment of the non-marketing clause

201 The applicant submits that the Commission was wrong to take the view in the contested decision that the Agreement prevented it from launching a generic version of perindopril in the European Union, regardless of whether it infringed Servier's patents. In support of that claim, the applicant argues that the 'substantially similar process', in connection with which marketing is prohibited by the Agreement, refers to a patent-infringing process, that Matrix's decision to break off its cooperation with the applicant was made independently of the Agreement, and that the obligations under the Agreement in respect of its customers and the marketing authorisations related only to patent-infringing perindopril. The applicant also states that the Commission misinterpreted Clauses 3 and 6 of the Agreement as preventing its entry into the perindopril market until 2021, well after the expiry of the process patents.

202 As a preliminary point, the Commission states that it is irrelevant whether or not the restrictions laid down in the Agreement fall within the scope of the patents, since an agreement is anticompetitive by object where a potential competitor agrees to stay out of the market in exchange for a substantial payment from the patent holder, rather than as a result of the strength of that patent. It then submits that the non-marketing clause applied not only to the API manufacturing process developed by Matrix, but also to any process which had not yet been developed and was considered to be substantially similar. The Commission adds that the obligations under the Agreement in respect of the applicant's customers and the marketing authorisations fell outside the scope of the process patents. Lastly, the Commission states that market entry has been prevented since 2008

under Clauses 3 and 6 of the Agreement, since the Agreement contains no clause allowing it to market a product manufactured on the basis of the 947 patent as of 2008.

The assessment of the non-challenge clause

203 The applicant submits that the non-challenge clause did not prevent it from challenging the validity of Servier's patents.

204 The Commission contends that the applicant could not challenge the patents at issue, namely the process patents and the 689, 948 and 947 patents, other than as a defence in the context of an infringement action, and that this undoubtedly went beyond the scope of the patents at issue.

The assessment of the value transfer

205 The applicant argues that the Commission should have analysed the principal commercial incentives driving each party to settle, and particularly the asymmetric risks involved in the market entry of generic companies, in order to conclude that Servier derived commercial value from the value transfer other than that of the non-marketing and non-challenge clauses, namely, the value in persuading the generic company to settle the patent dispute.

206 The Commission maintains that it examined, in the contested decision, all the evidence relating to the purpose of the value transfer provided for in the Agreement, viewed in its legal and economic context, to conclude that the Agreement involved a net value transfer of GPB 11.8 million without any value transferred in return to Servier save for the non-marketing and non-challenge clauses, and that the purpose of this transfer was clearly linked to the restrictions placed on Niche's market entry, making the Agreement an income-sharing arrangement between Servier and Niche in return for those restrictions.

– *The lack of anticompetitive intent*

207 The applicant argues that, contrary to the view taken by the Commission in the contested decision, it concluded the Agreement not with anticompetitive intent, but in order to secure early market entry in 2008 and to avoid costly litigation.

208 The Commission contends that the fact that concluding the Agreement was a rational option which was in the applicant's commercial interests is not a justification under competition law. The Commission refers, moreover, to its response to the previous objections in order to dispute the applicant's assertion regarding early market entry.

(3) The erroneous classification of the Agreement as a restriction of competition by effect

209 The applicant submits that the Commission misapplied the legal test for demonstrating that the Agreement has an appreciable anticompetitive effect. In particular, the Commission did not take into account the actual conditions in which the Agreement was concluded in the light of the wider economic and legal context, first, by wrongly considering the applicant to be an actual or potential competitor to Servier, secondly, by defining incorrectly the relevant market and concluding on that basis that Servier had a significant market share and, thirdly, by carrying out a flawed counterfactual analysis. The applicant refers primarily, as regards the first part of the present plea, to its arguments put forward in the context of the plea relating to potential competition and presents, in support of the second and third parts, the arguments set out below.

(i) Incorrect definition of the relevant market

210 The applicant states, on the basis of a critical study of the relevant market definition in this case entitled 'Economic Critique of the Relevant Product Market Definition', which is annexed to the

application and which, according to the applicant, is admissible, that the Commission misapplied the test of substitutability by asserting that the relevant market was confined to perindopril and its generic substitutes only, whereas substitution between ACE inhibitors such as perindopril and other therapies available for the treatment of heart failure was also possible.

211 In particular, the Commission committed a manifest error of assessment in disregarding the gradual substitutability between perindopril and other ACE inhibitor medicines when so-called 'lock-in' effects and 'doctors' inertia', which are related to the fact that perindopril is an 'experience good', do not prevent competition with other goods. It was also wrong to ignore, first, the results of a study submitted by Servier illustrating that the majority of perindopril patients stopped treatment before the end of the five-year treatment cycle, secondly, hospital sales and, lastly, Servier's promotional activities which are compelling evidence that other therapies competed with perindopril. The Commission also committed a manifest error in its assessment of the results of a prescriber survey, which, contrary to the Commission's conclusions, illustrated significant substitution among continued use patients and treatment-naïve patients. Lastly, the Commission erred in relying on a 'natural events analysis' and on Servier's ability to maintain price levels, disregarding, notably, pricing controls and regulations.

212 First of all, the Commission argues that the arguments contained in the abovementioned annex to the application, but which were not set out in the application itself, are inadmissible.

213 The Commission then contends that it based its analysis on a detailed examination of the supply and demand structure, taking into consideration in particular the rules and practices for prescribing medicines, the specific technical and qualitative features of perindopril, the characteristics of relevant regulatory systems, and price and volume developments relating to perindopril and certain other products. It states in particular that it took full account of evidence of switching treatments over time, including, notably, the abovementioned study submitted by Servier, which should nevertheless be compared with other studies. The Commission submits that the results of the prescriber survey reflect the positive perception of perindopril as a treatment for hypertension and the fact that, once the perindopril treatment proved to be successful for a given patient, that patient was unlikely to be switched away to another treatment for a prolonged period of time. The Commission argues that hospital sales of perindopril were rightly excluded from the analysis, given the limited turnovers in question. The Commission adds that, according to the case-law, a natural events analysis may be an appropriate tool in defining the relevant market and that, in using such an analysis, it was not overlooking Servier's promotional activities.

(ii) The erroneous counterfactual analysis carried out by the Commission

214 The applicant criticises the Commission for basing its counterfactual analysis on mere assumptions which, moreover, it rejects on the basis of the arguments it put forward in support of the plea relating to potential competition.

215 The Commission refers to the arguments it put forward in response to that plea to conclude that, in the absence of the Agreement, the applicant would have been able to enter the relevant market.

(b) Findings of the Court

216 The applicant criticises, in essence, the Commission for having committed several errors of law and of assessment by classifying the Agreement as a restriction of competition by object and by effect.

217 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 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).

218 It is therefore appropriate to begin by examining the applicant's complaints criticising the Commission's assessment that the Agreement is restrictive of competition by object.

219 It should be borne in mind, in that regard, that, in the contested decision, the Commission analysed at length 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).

220 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).

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

222 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).

223 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).

224 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).

225 The Commission then applied the three criteria referred to in paragraph 224 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.

(1) The incorrect classification of the Agreement as a restriction by object

226 The applicant submits, in particular, that some of the patent settlement agreements do not fall within the scope of Article 101(1) TFEU, since the effects of their restrictive clauses are indissociable from those of the patents and those clauses are objectively necessary in order to settle a legitimate dispute. It criticises the Commission, in that respect, for failing to apply the ancillary restraints doctrine, 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.

(i) Restrictions on competition by object

227 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).

228 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.

229 It follows that, contrary to the applicant's assertions, the fact that an agreement is not prima facie or undoubtedly sufficiently harmful, and that a concrete and individual examination of its content, objective, legal and economic context is necessary in order for the Commission and the EU judicature to be able to identify a restriction of competition by object does not preclude such a classification (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).

230 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).

231 Having set out the conditions for applying the concept of restriction of competition by object, it must be noted that, in the present case, the Agreement was intended, according to the applicant, to settle disputes between the contracting parties and was concluded in the specific context of patent law, since the disputes in question concerned Servier's 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 228 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 Agreement in particular, in the light of their objective of settling patent disputes and their specific context, namely that of patents, in order to verify whether the Commission, correctly and in accordance with legally appropriate criteria, classified the Agreement as restrictive of competition by object.

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

232 The specific purpose of 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. As the applicant emphasises, the mere possession by an undertaking of 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).

233 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 Guidelines of 28 March 2014 on the application of Article 101 of the Treaty on the Functioning of the European Union to technology transfer agreements (OJ 2014 C 89, p. 3; 'the 2014 Guidelines on technology transfer agreements'), states as follows:

'[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.'

234 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).

235 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).

236 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) and 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).

237 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).

238 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 '[t]he measures provided for in this Directive should not be used to restrict unduly competition in a manner contrary to the Treaty' (recital 12).

239 As the applicant submits, 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).

240 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, pp. 71 and 72). 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 consequence of a restrictive agreement (judgment of 31 October 1974, *Centrafarm and de Peijper*, 15/74, EU:C:1974:114, paragraphs 39 and 40).

241 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 rules that do not fall within the scope of EU law but under national law or the European Patent Convention (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 Servier's 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.

242 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).

243 Lastly, it must be noted that intellectual property rights are protected by the Charter of Fundamental Rights of the European Union. 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), '[e]veryone has the right to own, use, dispose of and bequeath his or her lawfully acquired possessions', '[n]o 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 '[t]he 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 '[i]ntellectual 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 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).

(iii) Patent dispute settlements

244 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, Servier 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 Servier's patents or the infringing nature of the product developed by the generic company.

245 First of all, it should be noted that, as the applicant submits, 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.

246 Likewise, paragraphs 204 and 209 of the 2004 Guidelines on technology transfer agreements, cited by the applicant, 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 '[t]he 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 '[s]ettlements can also save courts and/or competent administrative bodies effort in deciding on the matter and can therefore give rise to welfare enhancing benefits'.

247 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 (EC) 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).

248 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 also laid down in Articles 6 and 13 of the Convention for the Protection of Human Rights and Fundamental Freedoms, signed in Rome on 4 November 1950. 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 has 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.

249 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 presumed to be valid and an undertaking's ownership of that right is presumed 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.

250 It follows from all of 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.

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

– *Error of law*

251 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).

252 The applicant also acknowledged that it was found in the judgment of 27 September 1988, *Bayer and Maschinenfabrik Hennecke* (65/86, EU:C:1988:448, paragraph 15), that settlement agreements do not fall entirely outside the scope of Article 101(1) TFEU and may infringe that provision, but it disputed the applicability of that finding to the present case, arguing that the Court of Justice excluded settlements reached before a national court which constitute a judicial act — such as the Agreement, which gave rise to a consent order delivered by the High Court of Justice (England & Wales), Chancery Division (Patents Court) — from its analysis of settlements. However, it must be found in the present case that, even if the Court had wished to exclude settlements reached before a national court from its analysis, on the ground that the judicial confirmation of a settlement created a presumption of legality, the Agreement could not be regarded as a judicially confirmed settlement. As the Commission submitted, without being contradicted in that respect by the applicant, the abovementioned consent order was not drafted by a judge, simply refers to the Agreement, which is not attached to the order, nor a fortiori confirmed, and merely notes the withdrawal of Servier's infringement action in the United Kingdom without ruling on the costs. It follows that that consent order did not eliminate the contractual nature of the Agreement and that the Commission, in the contested decision (see inter alia recital 1122), rightly mentioned and applied the approach taken in the judgment of 27 September 1988, *Bayer and Maschinenfabrik Hennecke* (65/86, EU:C:1988:448).

253 The Court of Justice has held, in particular, in the judgment of 27 September 1988, *Bayer and Maschinenfabrik Hennecke* (65/86, EU:C:1988:448, paragraphs 14 to 16), 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, 'm[ight], in the light of the legal and economic context, restrict competition' within the meaning of Article 101(1) TFEU.

254 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 228 above).

255 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.

256 The agreements at issue in the present case, and in particular the Agreement, 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.

257 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).

258 First, as the applicant submits, 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 '[i]t 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.

259 Secondly, as the applicant also submits, 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 232 above). 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.

260 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 256 above). Contrary to the applicant's submission in that respect, in the contested decision, the Commission did not infer from the judgment of 25 February 1986, *Windsurfing International* v *Commission* (193/83, EU:C:1986:75, paragraphs 92 and 93), that non-challenge clauses always infringed Article 101(1) TFEU since it merely reproduced the analysis of the Court of Justice according to which, in the particular context of a patent licence agreement prohibiting the licensee from challenging the validity of the patent in question, such a non-challenge clause unlawfully restricted competition.

261 Moreover, the Commission itself stated, in the contested decision, that non-challenge clauses and non-marketing 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 256 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 232 above) and that a valid patent must, in principle, allow a transfer of value to its holder, 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 291 to 293 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 241 and 242 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, judgment of 31 October 1974, *Centrafarm and de Peijper*, 15/74, EU:C:1974:114, paragraphs 7 and 8; see also, by analogy, judgment 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 256 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 inter alia in recitals 1139 and 1140 of the contested decision. Contrary to the applicant's assertions (see paragraph 190 above), the Commission rightly classified such agreements as market exclusion agreements, like the agreements examined in the judgment of 20 November 2008, *Beef Industry Development Society and Barry Brothers* (C-209/07, EU:C:2008:643). The finding of an inducement in those agreements implies that the market exclusion of generic companies which they entail results, not from the effects of the patents at issue and the legitimate objective of settling the disputes in relation to those patents, but rather from a payment or another commercial benefit, representing the consideration for that exclusion (see paragraph 267 above), like the financial consideration paid to the undertakings which agreed to leave the Irish beef market at issue in the case that gave rise to that judgment.

272 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. Furthermore, that market exclusion is augmented, in such agreements, by the fact that it is not possible for the generic company to challenge the patent at issue.

273 It follows from all of 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.

274 Thus, where a patent settlement agreement contains non-marketing and non-challenge clauses whose inherently restrictive nature (see paragraph 256 above) has not been validly called into question, the existence of an inducement for the generic company to agree to those clauses permits the conclusion that there is a restriction by object, and does so even if there is a genuine dispute, the settlement agreement includes non-marketing and non-challenge clauses whose scope 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.

275 In the contested decision, the Commission rightly examined whether each settlement agreement 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.

276 It must also be considered that, contrary to the applicant's submission (see paragraphs 197 and 198 above), by adopting that classification of a restriction by object in the contested decision, the Commission did not disregard the distinction between restrictions by object and restrictions by effect and the relevant criteria for assessing restrictions by object.

277 First, it cannot, as the applicant submits, be inferred from the judgment of 27 September 1988, *Bayer and Maschinenfabrik Hennecke* (65/86, EU:C:1988:448), that the settlement agreements could only be restrictive by effect, and not by object.

278 It is true that, according to paragraph 19 of the judgment of 27 September 1988, *Bayer and Maschinenfabrik Hennecke* (65/86, EU:C:1988:448), if the national court were to consider that the non-challenge clause contained in the licence granted subject to payment of royalties did involve a limitation of the licensee's freedom of action, it would still have to verify whether, given the positions held by the undertakings concerned on the market for the products in question, the clause is of such a nature as to restrict competition to an appreciable extent.

279 However, it follows from the very wording of the judgment of 27 September 1988, *Bayer and Maschinenfabrik Hennecke* (65/86, EU:C:1988:448), that that reference to the analysis of the non-challenge clause's restrictive effects on competition concerns the situation where such a clause is included in a licence agreement subject to payment of royalties agreed in the context of a settlement. It therefore cannot be inferred from that judgment that all settlement agreements necessarily require an examination of their restrictive effects and cannot be restrictive solely by their object, nor a fortiori that that should be the case for settlement agreements that involve an inducement to accept a non-challenge clause.

280 Next, the Commission also did not disregard the case-law relating to the restrictive interpretation of the concept of restriction of competition by object.

281 It must be borne in mind in that respect that, in the judgment of 11 September 2014, *CB* v *Commission* (C−67/13 P, EU:C:2014:2204, paragraph 58), cited by the applicant, 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 and, consequently, held that the General Court had erred in law in finding that the concept of infringement by object should not be given a strict interpretation. 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 (see Opinion of Advocate General Trstenjak in *Beef Industry Development Society and Barry Brothers*, C−209/07, EU:C:2008:467, point 46).

282 It should also be noted that the Commission's analysis did not, a priori, have to apply a more restrictive approach than that entailed by the criteria of the concept of restriction of competition by object, but it required the identification of a restriction of competition showing, by its very nature, a

sufficient degree of harm with regard inter alia to its economic and legal context (see paragraphs 227 and 228 above).

283 Contrary to the applicant's submission, the Commission correctly took into account each of those components of the definition and of the assessment of restrictions by object.

284 As regards the 'sufficient degree of harm', the applicant misunderstands the concept of inducement when it states that an inducement is not enough to distinguish sufficiently harmful agreements from those which are not sufficiently harmful. In support of that assertion, it argues that the benefits to each of the parties, whether they consist in the payment of a sum of money or in the grant of other commercial benefits, are indispensable for the conclusion of a settlement. However, it is apparent from paragraphs 268 and 275 above that the Commission did not take the view that any benefit or value transfer was indicative of an object restrictive of competition, but rather that only agreements involving an inducement in the form of a benefit or value transfer, that is to say those in which the restrictive clauses can be explained by that inducement and not by the effects of the patents and the settlement of patent disputes, were sufficiently harmful to be classified as restrictions of competition by object (see also paragraph 270 above).

285 As regards the harm caused to competition 'by its very nature', it must be borne in mind that the non-challenge and non-marketing clauses included in the settlement agreements at issue in the contested decision are by themselves restrictive of competition (see paragraph 256 above), which may lead to the classification of those agreements as restrictions of competition by object if the restrictions of competition introduced by those clauses can be explained by an inducive value transfer, irrespective of whether the disputes at issue are genuine and irrespective of the validity or the infringement of the patents concerned (see paragraphs 270 and 274 above).

286 As regards the consideration of the 'economic and legal context' of the settlement agreements which, in the present case, is patent law, it must be pointed out, in response to the arguments put forward in that respect in the application itself (see paragraphs 115 and 116 above) that the principles and rules governing patents were fully taken into account and respected, as is apparent both from the analysis of the generic companies as potential competitors (see paragraphs 117 to 134 above) and the analysis of the patent settlement agreements (see inter alia paragraphs 267 and 268 above). It also follows that, in view in particular of that analysis of the patent settlement agreements, from which it is clear that only illegitimate settlement agreements showing abnormal use of the patents in question constitute restrictions by object, that it cannot be maintained that the Commission rendered the grant of patents meaningless and discouraged, by a broad prohibition of patent settlements, the conclusion of such settlements.

287 It follows from all the foregoing that the Commission did not vitiate the contested decision by an error of law in 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.

– *The errors of assessment*

288 The Commission also did not make an error of assessment in finding that the Agreement constituted a restriction of competition by object.

289 Contrary to the applicant's submission, the Commission validly found that the Agreement contained an inducement for the applicant to accept the non-marketing and non-challenge clauses set out in the Agreement.

290 It should be noted, in that regard, that the applicant does not call into question the existence of non-marketing and non-challenge clauses in the Agreement. It disputes, however, that the value transfer provided for in Clause 13 of the Agreement could be regarded as an inducive value transfer.

291 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 1333 to 1337 of the contested decision).

292 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.

293 It may be considered 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.

294 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).

295 In the present case, 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, '[i]n 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.

296 Moreover, that interpretation of the wording of the Agreement is not called into question by the applicant's allegation that the envisaged value transfer was solely intended to persuade it to settle the dispute (see paragraph 205 above), since the sum of GBP 11.8 million is clearly presented as the consideration for the commitments restricting competition at issue and since the payment of only those costs inherent in, and thus justified by, the settlement agreement would have been enough, by definition, to persuade it to conclude that agreement (see paragraphs 291 and 292 above). Nor is it called into question by the alleged asymmetry between the risks for the originator company and those to which the generic company is exposed. It is true that such an asymmetry of risks 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 (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).

297 Furthermore, it is irrelevant in this case that Clause 13 of the 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 Servier and, thus, the existence of an inducement for the applicant to accept those clauses.

298 Those other expenses, described in the 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 the applicant itself, during the administrative procedure, as covering the costs of developing its perindopril, including the legal costs, and the compensation due to its customers for breach of its contractual obligations to them (recitals 601 and 1326 of the contested decision). Such costs cannot, a priori and in the absence of any justification put forward to that effect by the applicant, be regarded as inherent in the settlement of a patent dispute (see paragraph 294 above). Furthermore, according to the applicant's evaluation

of those costs in the present case — varying from GBP 2 to 3 million — they amount to significantly less than GBP 11.8 million.

299 It follows that the Commission validly found that the Agreement contained an inducement for the applicant to accept the non-marketing and non-challenge clauses set out in that agreement.

300 It also follows that, in view of the foregoing (see, in particular, paragraphs 265 to 274 above), the Commission rightly inferred from that finding that the Agreement restricted competition by object.

301 It is therefore irrelevant whether, as the applicant alleges, the non-marketing and non-challenge clauses did not exceed the scope of the patents at issue. It must be borne in mind that the existence of an inducement for the generic company to accept non-marketing and non-challenge clauses justifies a finding of a restriction of competition by object, even if the settlement agreement includes clauses whose scope does not go beyond that of the patent at issue (see paragraph 274 above). The applicant's arguments intended to establish that the obligations imposed by the non-marketing and non-challenge clauses did not go beyond the scope of the patents at issue (see paragraphs 201 and 203 above) must therefore be rejected as ineffective (see, to that effect, judgment of 8 September 2016, *Lundbeck* v *Commission*, T−472/13, under appeal, EU:T:2016:449, paragraph 495).

302 It should be added that, if the applicant's argument as regards compliance with the scope of the patents at issue must be interpreted as disputing the restrictive nature of the non-marketing and non-challenge clauses, it cannot succeed.

303 As regards the non-marketing clause, it may be noted, first, that the applicant does not dispute that Clause 3 of the Agreement prohibited it from manufacturing and marketing the perindopril that it had developed with Matrix and, secondly, that it follows from the very wording of Clause 6 of the Agreement that the envisaged marketing possibility was intended only to clarify the end of that prohibition, by stipulating that the applicant could manufacture and sell that perindopril and any perindopril falling within the scope of the process patents after their expiry, but not that it could sell perindopril falling within the scope of the 947 patent before its expiry, without facing actions for the infringement of that patent brought by Servier. It is clear from Clause 5 of the Agreement that Servier undertook not to bring actions for the infringement of the 947 patent solely with regard to infringements prior to the conclusion of the Agreement. Moreover, the applicant itself recognised the utility and the commercial logic of Clause 6 of the Agreement, regardless of the interpretation that it put forward in the present action, by indicating that that provision was intended to prevent, by authorising the marketing of perindopril manufactured after the expiry date of the patents at issue, a situation in which the generic companies would be able to market their product immediately after that expiry. The Commission therefore rightly considered, in recital 1312 of the contested decision, that Clause 6 of the Agreement did not allow early market entry by Niche before the expiry of the 947 patent, contrary to the applicant's submission (see paragraph 201 above).

304 As regards the non-challenge clause, it must be borne in mind that, although it allows the applicant to defend itself against infringement actions brought by Servier, it above all provides for a general prohibition on litigation intended to 'clear the way', in the context of an at-risk launch, namely invalidity actions and actions for a declaration of non-infringement of the patents.

305 The applicant's allegation concerning the lack of anticompetitive intent and the pursuit of legitimate objectives (see paragraph 207 above) must also be rejected as ineffective. That allegation 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 Agreement. 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 Agreement constituted a restriction by object.

306 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 230 above).

307 In addition, since the 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 that 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 230 above).

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

308 The applicant also criticises the Commission for failing to examine the Agreement in the light of the criterion of the objective necessity of the stipulated restrictions, by applying the ancillary restraints doctrine.

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

310 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).

311 It should be noted, in the first place, that it cannot be inferred from the settled case-law according to which the settlement of a dispute does not exempt the parties from the application of the competition rules (see paragraph 251 above) that the precondition for the application of the objective necessity test, namely the existence of an operation which is neutral or positive for competition, cannot be fulfilled as regards patent settlements. That 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 (see paragraph 255 above). The application of the objective necessity test presupposes that the main operation or activity at issue in the case at hand 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. Thus, it is 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 245 to 248 above).

312 Thus, contrary to the Commission's submissions, it cannot be inferred from the judgment of 30 January 1985, *BAT Cigaretten-Fabriken* v *Commission* (35/83, EU:C:1985:32), nor, moreover, from the judgment of 27 September 1988, *Bayer and Maschinenfabrik Hennecke* (65/86,

EU:C:1988:448), that it is necessary to reject, in principle, any possibility of applying the ancillary restraints doctrine to the settlement of disputes. While it is apparent from the judgment of 27 September 1988, *Bayer and Maschinenfabrik Hennecke* (65/86, EU:C:1988:448, paragraph 21), 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. Likewise, in the judgment of 30 January 1985, *BAT Cigaretten-Fabriken* v *Commission* (35/83, EU:C:1985:32), the Court of Justice also acknowledged the lawfulness and the utility of agreements which serve to delimit, in the mutual interests of the parties, the spheres within which their respective marks may be used, in order to avoid confusion or conflict between them, while holding that the delimitation agreement before it restricted competition.

313 However, 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 also 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).

314 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).

315 Non-challenge and non-marketing clauses are, in principle, 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 258 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 — are necessary for the settlement of a dispute concerning that patent and must, consequently, be regarded as capable of satisfying the first condition of the exception provided by the ancillary restraints doctrine.

316 However, where it found that there has been an inducement, the parties may no longer rely on their recognition, in the context of the settlement, of the validity of the patent. In that case, it is the inducement, and not the recognition by the parties to the settlement of the validity of the patent, which is the real reason for the restrictions on competition introduced by the non-marketing and non-challenge clauses (see paragraphs 263 to 270 above). Those restrictions cannot therefore be regarded as objectively necessary and thus as ancillary to the settlement.

317 It should be noted, first, that that inducement is not in itself a restriction, but that it breaks the link of necessity between the settlement and the restrictive clauses, and, secondly, that the establishment of that inducement is based not only on a quantitative analysis of the amount of the value transfer,

but also, and primarily, on a qualitative analysis of the costs compensated by that value transfer (see paragraphs 291 to 294 above).

318 It may be added, moreover, that, as a result also of the inducement for the generic company to accept such restrictive clauses, the agreements at issue are market exclusion agreements (see paragraph 271 above) and not genuine settlement agreements, thus precluding a finding in the present case of a neutral or positive operation as regards competition.

319 Moreover, although the applicant also submits that the restrictive clauses in the agreements were ancillary to the achievement of an objective consisting in the protection of the originator company's intellectual property rights, relying on the case-law relating to the specific subject matter of intellectual property law (see paragraph 239 above), it suffices to note that inducing a competitor to accept non-marketing or non-challenge clauses is an abnormal use of the patent (see paragraph 267 above), which is not covered by the specific subject matter of the patent and, thus, not objectively necessary for its protection (see, to that effect, judgment of 8 September 2016, *Lundbeck* v *Commission*, T−472/13, under appeal, EU:T:2016:449, paragraph 458).

320 The Commission was therefore correct not to rely on the ancillary restraints doctrine, since it treated the inducement as a criterion on the basis of which agreements constituting restrictions by object could be identified and found such an inducement in the present case.

321 It also follows that, even if, as the applicant submits, the 2004 Guidelines on technology transfer agreements provided for the application of the objective necessity test to patent settlement agreements and they were applicable to the Agreement (see paragraph 195 above), the Commission was still not required to apply that criterion, as provided for in those guidelines, and therefore did not breach the principle of equal treatment by rejecting the application of those guidelines to the Agreement.

322 It follows from all of the foregoing that the plea alleging errors of law and of assessment in relation to the classification of the Agreement as a restriction of competition by object must be rejected in its entirety.

(2) The incorrect classification of the Agreement as a restriction by effect

323 It should be noted 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 (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).

324 As noted in paragraph 217 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.

325 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 that decision, inasmuch as 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.

326 In the present case, it is clear from the examination of the plea alleging errors of assessment and of law in relation to the classification of the Agreement as a restriction of competition by object that the applicant has not established 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.

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

5. The plea alleging infringement of Article 101(3) TFEU

(a) Arguments of the parties

328 The applicant criticises the Commission for failing to consider that the Agreement could be exempt under Article 101(3) TFEU.

329 The applicant submits, first, that the Agreement generated pro-competitive efficiencies by enabling it to redirect the resources that would otherwise have been devoted to the dispute with Servier so that it could launch new products on the market, secure early entry on the market for its generic perindopril in 2008 without running the risk of having an action for infringement of the 947 patent brought against it, and continue to exist whilst maintaining and extending its generic portfolio to the benefit of consumers and competition.

330 Secondly, the applicant argues that those efficiencies were passed onto consumers, who benefited from the early market entry of its generic perindopril and the introduction of other generic products.

331 Thirdly, the applicant maintains that the non-marketing and non-challenge clauses were indispensable to achieving those efficiencies, since Servier would not have entered into the Agreement if the patents had not been protected by such clauses.

332 Fourthly, the applicant submits that there was no elimination of competition since the Agreement permitted it to launch non-infringing perindopril for the lifetime of the Agreement and to launch its perindopril as from 2008 and that the Agreement even enabled it to avoid insolvency and therefore to enhance competition in that sector.

333 The Commission contends that it established in the contested decision that neither the applicant nor Servier had submitted sufficient evidence showing that the four requirements for exemption provided for in Article 101(3) TFEU were fulfilled by the Agreement.

334 As regards the efficiencies, the applicant's claim that it had avoided litigation costs was not substantiated in any way, and nor was the assertion that the GBP 11.8 million, which far exceeded those costs, did not simply serve to increase its profitability. The Commission also contends that it correctly classified the applicant's continued existence and the maintenance of its generic portfolio as indirect efficiencies. Moreover, the Commission reiterates its criticism of the applicant's claim that the Agreement allowed early market entry.

335 The claim that efficiencies were passed onto consumers is not substantiated in any way, also taking into account the fact that there is no evidence of the applicant's profits being redirected and that the Agreement did not authorise early market entry. The Commission adds that development of other generic products is an activity which all generic companies are engaged in, and is not sufficient to prove that specific efficiencies were passed on to consumers.

336 As regards the claim that the clauses of the Agreement were indispensable, the Commission observes that the non-marketing and non-challenge clauses go beyond the scope of Servier's patents and contends that the applicant does not even try to explain how the amount of GBP 11.8 million could have been indispensable.

337 The Commission submits that the claim that competition was not eliminated is inconsistent with the terms of the Agreement and that the applicant never attempted to enter the market after the term of the Agreement.

(b) Findings of the Court

338 Article 101(3) TFEU provides for a derogation from the provisions of Article 101(1) TFEU by virtue of which agreements covered by paragraph 1 which satisfy the requirements of paragraph 3 are not prohibited.

339 The requirements laid down in Article 101(3) TFEU are as follows: first, the agreement concerned must contribute to improving the production or distribution of the goods in question, or to promoting technical or economic progress; secondly, consumers must be allowed a fair share of the resulting benefit; thirdly, it must not impose on the participating undertakings any restrictions which are not indispensable; and, fourthly, it must not afford them the possibility of eliminating competition in respect of a substantial part of the products in question.

340 Those requirements were reiterated in paragraph 34 of the Guidelines on the application of Article [101(3) TFEU] (OJ 2004 C 101, p. 97, 'the Guidelines on Article 101(3) TFEU'). They are cumulative (judgments of 13 July 1966, *Consten and Grundig* v *Commission*, 56/64 and 58/64, EU:C:1966:41, p. 350; of 17 January 1984, *VBVB and VBBB* v *Commission*, 43/82 and 63/82, EU:C:1984:9, paragraph 61; and of 15 July 1994, *Matra Hachette* v *Commission*, T−17/93, EU:T:1994:89, paragraph 104).

341 Pursuant to Article 2 of Regulation 1/2003 '[t]he undertaking or association of undertakings claiming the benefit of Article [101(3) TFEU] shall bear the burden of proving that the conditions of that paragraph are fulfilled'.

342 The Court of Justice — relying on Regulation No 1/2003 and, in particular, on recital 5 thereof, according to which, first, it is for the party or the authority alleging an infringement of the competition rules to prove the existence thereof and, secondly, it is for the undertaking or association of undertakings invoking the benefit of a defence against a finding of an infringement to demonstrate to the required legal standard that the conditions for applying that defence are satisfied — has held that, although according to those principles the legal burden of proof is borne either by the Commission or by the undertaking or association concerned, the factual evidence on which a party relies may be of such a kind as to require the other party to provide an explanation or justification, failing which it is permissible to conclude that the burden of proof has been discharged (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 78 and 79).

343 Thus, in some cases, the facts relied on by the undertaking invoking the benefit of the exemption under Article 101(3) TFEU may be such as to oblige the Commission to provide an explanation or justification, failing which it is permissible to conclude that the burden of proof has been discharged (judgments of 6 October 2009, *GlaxoSmithKline Services and Others* v *Commission and Others*, C−501/06 P, C−513/06 P, C−515/06 P and C−519/06 P, EU:C:2009:610, paragraph 83, and of 8 September 2016, *Lundbeck* v *Commission*, T−472/13, under appeal, EU:T:2016:449, paragraph 711).

344 Lastly, it must also be noted that any agreement which restricts competition, whether by its effects or by its object, may in principle benefit from an exemption under Article 101(3) TFEU (see, to that effect, judgments of 13 July 1966, *Consten and Grundig* v *Commission*, 56/64 and 58/64, EU:C:1966:41, pp. 342 and 343 and 347 to 350; of 13 October 2011, *Pierre Fabre Dermo-Cosmétique*, C−439/09, EU:C:2011:649, paragraphs 49 and 57; and of 15 July 1994, *Matra*

Hachette v *Commission*, T−17/93, EU:T:1994:89, paragraph 85).

345 In the present case, the Commission focused its examination on the first requirement for the application of Article 101(3) TFEU. More specifically, it examined three types of efficiency gains concerning the applicant. As regards, first, the efficiency gain arising from the avoided litigation costs, the Commission took the view that the alleged savings from the litigation avoided had not been substantiated by the applicant and that it had also not been demonstrated that those savings had had a pro-competitive effect rather than simply increasing its profits. It added that the Agreement was not indispensable in order to achieve the alleged savings, since they could have been achieved by a settlement without a reverse payment (recitals 2074 to 2077 of the contested decision). As regards, secondly, the efficiency gain from Niche's continued commercial existence, the Commission considered, first, that Niche's continued existence and its ability to launch new products at more competitive prices was an indirect efficiency gain and, secondly, that the economic survival of Niche constituted a subjective efficiency gain for the latter and did not produce any pro-competitive effects on the market (recitals 2109 to 2111 of the contested decision). It should be noted that the third efficiency gain, linked to the early market entry of Niche, was not examined specifically as regards the applicant's specific case and the consequences of the Agreement, but rather was examined generally, as part of the consequences of patent settlements in general (recitals 2112 to 2122 of the contested decision).

346 The applicant disputes in particular the Commission's analysis of the first requirement for the application of Article 101(3) TFEU (see paragraph 329 above).

347 It should be borne in mind, in that respect, that, in order to meet that first requirement, an agreement must contribute to improving the production or distribution of goods or to promoting technical or economic progress. That contribution is not identified with all the advantages which the undertakings participating in the agreement derive from it as regards their activities, but with appreciable objective advantages, of such a kind as to offset the resulting disadvantages for competition (judgment of 13 July 1966, *Consten and Grundig* v *Commission*, 56/64 and 58/64, EU:C:1966:41, p. 348; see, also, judgment of 27 September 2006, *GlaxoSmithKline Services* v *Commission*, T−168/01, EU:T:2006:265, paragraph 247 and the case-law cited; paragraph 50 of the Guidelines on Article 101(3) TFEU).

348 It is therefore for the Commission to examine whether the factual arguments and the evidence submitted to it show, in a convincing manner, that the agreement in question must enable appreciable objective advantages to be obtained (see judgment of 27 September 2006, *GlaxoSmithKline Services* v *Commission*, T−168/01, EU:T:2006:265, paragraph 248 and the case-law cited).

349 In the present case, the applicant disputes the Commission's analysis of the three efficiency gains referred to above.

350 The first two efficiency gains, one arising from the avoided litigation costs and the other from the applicant's continued commercial existence, which primarily concern the applicant, were, for that reason, rightly regarded by the Commission as not constituting appreciable objective advantages for competition.

351 The efficiency gains referred to in Article 101(3) TFEU consist in the production of pro-competitive effects on the market, and thus in objective advantages, and not just subjective benefits for the parties such as an increase of their profits (see judgment of 8 September 2016, *Generics (UK)* v *Commission*, T−469/13, not published, under appeal, EU:T:2016:454, paragraph 354 and the case-law cited; paragraph 49 of the Guidelines on Article 101(3) TFEU).

352 In addition, although the applicant submits that the costs avoided and its continued commercial existence allowed it to maintain, or even extend, its portfolio of generic products for the benefit of

consumers and competition, it must be borne in mind that the undertaking seeking to benefit from an exemption must demonstrate with a sufficient degree of probability that the agreement in question would make it possible to obtain an appreciable objective advantage of such a kind as to offset the disadvantage which it entailed for competition (see, to that effect, judgment of 6 October 2009, *GlaxoSmithKline Services and Others* v *Commission and Others*, C−501/06 P, C−513/06 P, C−515/06 P and C−519/06 P, EU:C:2009:610, paragraphs 93 to 95; paragraph 54 of the Guidelines on Article 101(3) TFEU).

353 However, in order to call into question the Commission's finding that, in essence, those alleged objective efficiency gains were not sufficiently established (recitals 2109 and 2110 of the contested decision), the applicant merely refers, without any further explanation, to an annex to the application and, in addition, invokes the failure to comply with paragraph 43 of the Guidelines on Article 101(3) TFEU.

354 Regarding the reference to the annex to the application, it has already been held that the arguments set out in that annex and to which the applicant merely refers by invoking one or more sections of that annex, without presenting them in any way, even summarily, are inadmissible (see paragraph 116 above).

355 As for the alleged failure to comply with paragraph 43 of the Guidelines on Article 101(3) TFEU, in that the Commission wrongly failed to take account of the benefits obtained by the markets for other medicinal products produced by Niche, it should be noted that the paragraph in question, which provides that efficiencies achieved on separate markets can be taken into account, is not enough, by itself, to establish a link between the benefits flowing from the Agreement and the development of those other medicinal products.

356 As regards the third efficiency gain, linked to the applicant's market entry in 2008, which it also invokes, it should be noted that the Agreement provides no possibility for Niche to sell perindopril falling within the scope of the 947 patent before the expiry of that patent, in 2021 (see paragraph 303 above).

357 It follows that the Commission rightly held that the first requirement laid down in Article 101(3) TFEU was not met by the Agreement.

358 It also follows that, given the cumulative nature of the four exemption requirements (see paragraph 340 above), the Commission rightly decided that the Agreement could not enjoy an exemption under Article 101(3) TFEU.

359 It follows from all the foregoing considerations that the plea alleging infringement of Article 101(3) TFEU must be rejected.

6. The pleas, raised in the alternative, relating to the setting of the amount of the fine

(a) Breach of the principle of equal treatment

(1) Arguments of the parties

360 The applicant submits, in the first place, that the Commission infringed the principle of equal treatment by using different methods to calculate the fine imposed on it and that imposed on Servier, which resulted in Servier's fine being based on 11% of its perindopril sales over a period of three to four years, while the fine imposed on the applicant was equivalent to 100% of its projected perindopril sales over 10 years. The Commission calculated Servier's fine on the basis of its perindopril sales in the territories concerned in the last business year, and the fine imposed on the applicant was based on the value transferred under the Agreement, in accordance with point 37 of

the Guidelines on the method of setting fines imposed pursuant to Article 23(2)(a) of Regulation No 1/2003 (OJ 2006 C 210, p. 2, 'the Guidelines on the method of setting fines'). The applicant argues, in that regard, that the Commission's discretion under point 37 of the Guidelines on the method of setting fines does not permit it to use a different calculation method in circumstances where, as in this case, the Commission knew precisely its projected perindopril sales in the relevant territories for the period of the infringement, since the value transferred under the Agreement was calculated by reference to those projections.

361 The applicant submits, in the second place and in the alternative, that the Commission treated it in a way that was discriminatory by comparison with the treatment given to Servier in its assessment of the gravity of the infringement and the factor applied for the deterrent effect of the fine.

362 As regards the gravity of the infringement, the applicant complains that the Commission applied to Servier a gravity factor reflecting a serious infringement, whereas, by basing its calculation on the amount of the value transfer in accordance with point 37 of the Guidelines on the method of setting fines, it imposed on the applicant a fine reflecting a very serious infringement. The applicant also submits that the Commission's method did not permit it to take into account the gravity of the infringement and the specific circumstances of the case.

363 As regards the deterrence factor, the applicant submits that the fine imposed on it exceeds the value of the supposedly unlawful profits earned, taking into account the various costs which should be reflected. It also complains that the Commission did not take account of its effective economic capacity to cause significant damage to competition, having regard in particular to its size and the financial difficulties it was facing.

364 The Commission contends, in the first place, that the applicant was in a very different situation to that of Servier, since it had not made any sales of perindopril in the relevant geographic areas in the previous business year, precisely because it had agreed, under the Agreement, to stay out of the market, and that the use of the calculation method proposed by the applicant would mean that the applicant would get to keep the vast majority of the GBP 11.8 million which it received under the Agreement.

365 In the second place, the Commission disputes the applicant's claim that it suffered discriminatory treatment in respect of the gravity of the infringement and the deterrent effect of the fine. As regards the gravity of the infringement, the Commission maintains that it set the amount of the fine, for both Servier and the applicant, to reflect a serious infringement. As regards the deterrence factor, the Commission maintains that the level of fine set for the applicant was necessary in order to ensure a deterrent effect in that case, and states that, in assessing the level of the fine, it was not under any obligation to deduct taxes paid and other costs incurred.

(2) Findings of the Court

366 As a preliminary point, the applicant relies on paragraph 273 of the judgment of 5 April 2006, *Degussa* v *Commission* (T-279/02, EU:T:2006:103) which, according to the applicant, requires the Commission to take account of the effective capacity of the offenders to cause significant damage to competition and the resources of the parties at the time the fine is imposed.

367 As regards first of all the effective capacity of the offenders to cause significant damage to competition, it should be noted that paragraph 273 of the judgment of 5 April 2006, *Degussa* v *Commission* (T-279/02, EU:T:2006:103) merely refers to the conditions set out in 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). Those conditions are not applicable in the present case. The Guidelines on the method of setting fines adopted in 2006 — which no longer mention the need to take account of 'the effective economic capacity of offenders to cause significant damage to other operators' in order to assess the gravity of an infringement (see, to that effect, judgment of 28 June

2016, *Telefónica* v *Commission*, T−216/13, EU:T:2016:369, paragraph 272) — are applied, in accordance with point 38 thereof, in all cases where a statement of objections is notified after the date of publication of those guidelines, which is the case here.

368 As regards, next, the resources of the parties, it should be noted that paragraph 273 of the judgment of 5 April 2006, *Degussa* v *Commission* (T−279/02, EU:T:2006:103), does not mention those resources. However, point 35 of the Guidelines on the method of setting fines adopted in 2006 — which is not relevant in the present case since the Commission rightly applied point 37 of those guidelines (see paragraph 377 below) — provides, in any event, for the reduction of the fine in view of the undertaking's inability to pay only 'on the basis of objective evidence that imposition of the fine as provided for in these Guidelines would irretrievably jeopardise the economic viability of the undertaking concerned and cause its assets to lose all their value'. The applicant has not established that such a situation exists.

369 The applicant's remaining complaints may be divided into two branches. First, it argues that the method adopted by the Commission was not justified. Secondly, it indicates that the Commission infringed the principle of equal treatment by treating Servier more favourably than the applicant.

370 It is appropriate to begin by examining the first branch.

371 First, as regards the allegedly unjustified application of point 37 of the Guidelines on the method of setting fines, it should be noted that the Commission may, for the purpose of fixing the fine, have regard both to the total turnover of the undertaking, which gives an indication, albeit approximate and imperfect, of the size of the undertaking and of its economic power, and to the proportion of that turnover accounted for by the goods in respect of which the infringement was committed, which gives an indication of the scale of the infringement (judgment of 22 October 2015, *AC-Treuhand* v *Commission*, C−194/14 P, EU:C:2015:717, paragraph 62).

372 Thus, point 13 of the Guidelines on the method of setting fines states that '[i]n determining the basic amount of the fine to be imposed, the Commission will take the value of the undertaking's sales of goods or services to which the infringement directly or indirectly … relates in the relevant geographic area within the EEA'. Point 6 of those guidelines states that '[t]he combination of the value of sales to which the infringement relates and of the duration of the infringement is regarded as providing an appropriate proxy to reflect the economic importance of the infringement as well as the relative weight of each undertaking in the infringement'.

373 It follows that point 13 of those guidelines pursues the objective of adopting, in principle, as the starting point for the setting of the fine 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 (judgment of 22 October 2015, *AC-Treuhand* v *Commission*, C−194/14 P, EU:C:2015:717, paragraph 64).

374 As can be seen from the judgment of 22 October 2015, *AC-Treuhand* v *Commission* (C−194/14 P, EU:C:2015:717, paragraph 65), point 37 of the Guidelines on the method of setting fines states however that, '[a]lthough these Guidelines present the general methodology for the setting of fines, the particularities of a given case or the need to achieve deterrence in a particular case may justify departing from such methodology'.

375 In the present case, it is common ground that, by reason of the very purpose of the Agreement, which is a market exclusion agreement, Niche was not present on that market during the infringement period.

376 Accordingly, the Commission was not able to take the value of sales made by Niche on the relevant market during the infringement and, in particular, during the last full business year of its participation in the infringement, that is to say the period to which reference is made in point 13 of

the Guidelines on the method of setting fines.

377 Those particular circumstances entitled the Commission, on the basis of point 37 of the Guidelines on the method of setting fines, to depart from the methodology set out in those guidelines (see, to that effect, judgments of 22 October 2015, *AC-Treuhand* v *Commission*, C-194/14 P, EU:C:2015:717, paragraph 67, and of 6 February 2014, *AC-Treuhand* v *Commission*, T-27/10, EU:T:2014:59, paragraphs 301 to 305).

378 The Court has, moreover, already held, in similar circumstances, that it could not seriously be disputed that, in view of the lack of sales on the market by a generic company, the Commission was obliged to depart from that methodology (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 421).

379 Secondly, as regards the Commission's alleged failure to take into account the gravity of the infringement, 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).

380 The factors capable of affecting the assessment of the gravity of the infringements include the conduct of each of the undertakings, the role played by each of them in the establishment of the agreement, decision or concerted practice, the profit which they were able to derive from it, their size, the value of the goods concerned and the threat that infringements of that type pose to the objectives of the European Union (judgments of 7 June 1983, *Musique Diffusion française and Others* v *Commission*, 100/80 to 103/80, EU:C:1983:158, paragraph 129, 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 242).

381 However, it should be noted that the value chosen by the Commission in the present case for the purpose of determining the basic amount of the fine, namely, the amount of the value transfer received by the generic company, is equivalent to the price that Servier was prepared to pay to exclude a competitor from the market and the price that the generic company was ready to accept to withdraw from the market, which, in the light of the case-law cited in the paragraph 380 above, gives a reliable indication of the gravity of the infringement and the particular circumstances of the case. That value is the result of negotiations in which the generic company participated and reflects the conduct of that company, the role that it played in the infringement and the benefit that it gained from it, as well as the value of the goods concerned, as estimated by the parties to the Agreement.

382 The value used by the Commission in order to set the amount of the fine in view of the gravity of the infringement is, in any event, more appropriate than that proposed by the applicant.

383 The amount of the value transfers, regarded as inducive, which Niche received under the Agreement, provides a better estimate of the profits that Niche obtained from its participation in the infringement than the value of the projected sales that it would have made during the infringement period if it had not participated in that infringement.

384 In addition, the amount of the value transfer ultimately used in the Agreement is, as is apparent from paragraph 381 above, the result of a negotiation in which Niche participated. Accordingly, it is a better reflection of Niche's conduct and the role that it played in the infringement than the method

proposed by the applicant, which is based on the value of sales that were not made during the infringement.

385 Lastly, the method proposed by the applicant does not reflect the economic significance of the infringement as adequately as the Commission's method. The applicant's method is based on the price of the perindopril that the generic company would have sold if it had entered the market, whereas the economic significance of the infringement depends, to a large extent, on the — in principle, higher — price of perindopril sold by the originator company during the infringement period. The economic significance of the infringement is therefore reflected more adequately in the amount of the fine through the method used by the Commission, since the parties necessarily took into account the maintenance of the price of perindopril in order to evaluate the amount of the value transfer to be granted to Niche.

386 In that respect, it must be noted that the economic significance of the infringement is one of the elements referred to in point 6 of the Guidelines on the method of setting fines, which may usefully be taken into account in the present case, even though the Commission did not apply the method laid down in those guidelines, since that element is not indicated in the part of those guidelines dedicated to the description of that method, but rather in the introduction.

387 It follows from the foregoing that the first part of the plea must be rejected.

388 It is necessary to examine the second branch of the plea, which specifically concerns the breach of the principle of equal treatment.

389 As a preliminary point, it should be noted that, according to the settled case-law of the Court of Justice, when the amount of the fine is determined, there cannot, by the application of different methods of calculation, be any discrimination between the undertakings which have participated in the same infringement of Article 101 TFEU (see judgment of 12 November 2014, *Guardian Industries and Guardian Europe* v *Commission*, C−580/12 P, EU:C:2014:2363, paragraph 62 and the case−law cited).

390 It should also be noted that, according to settled case-law, the principle of non-discrimination or equal treatment, which is a fundamental principle of law, prohibits comparable situations from being treated differently or different situations from being treated in the same way, unless such difference in treatment is objectively justified (see judgment of 8 January 2003, *Hirsch and Others* v *ECB*, T−94/01, T−152/01 and T−286/01, not published, EU:T:2003:3, paragraph 51 and the case-law cited; see also, to that effect, judgment of 8 October 1986, *Christ-Clemen and Others* v *Commission*, 91/85, EU:C:1986:373, paragraph 19).

391 The applicant submits, in essence, that the Commission treated Servier more favourably than it treated the applicant.

392 As a preliminary point, it should be borne in mind that 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 companies (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).

393 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 of those guidelines 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 the Guidelines on the method of setting fines, 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 those guidelines. Next, pursuant to point 25 of the Guidelines on the method of setting fines, 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).

394 However, the method adopted with regard to the generic companies does not provide for all those stages, given that the Commission directly used the value transfers made by Servier as the basic amount for the fine, but also as the final amount of the fine, subject to the application of the ceiling of 10% of turnover laid down in Article 23(2) of Regulation No 1/2003 (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).

395 By its argument, the applicant asks the Court, first, to evaluate the amount of the fine that would have been imposed on it if the Commission had applied a method analogous to that applied to Servier, but based on the projected value of its sales, and, secondly, to make a finding — based on the difference between the amount thus obtained and the amount of the fine imposed on the applicant — of unjustified adverse treatment.

396 In that respect, it must be emphasised that, given the very purpose of the Agreement, which is a market exclusion agreement concluded between an originator company and a generic company, the infringing conduct imputed to each of the parties to the Agreement is fundamentally different, unlike the situation, for example, in a market sharing or price fixing agreement. The originator company which has succeeded in preventing the market entry of the generic company sells its products at a price which is, as a rule, higher than that which it could have applied in the absence of an agreement, whereas the generic company does not enter the market but enjoys compensation in exchange for its agreement not to enter that market.

397 In view of the foregoing, it would be paradoxical to establish the amount of the fine to be imposed on the generic company excluded from the market on the basis of the value, even estimated, of its sales, since the infringement consists precisely, for that company, in not selling its products. The use of a method of calculating the fine based on that value therefore would not adequately take into account the nature of the infringement in question.

398 In addition, given the lack of sales made by the generic company during the infringement period, any method of calculating the fine based on the value of those sales would necessarily be artificial and hypothetical and would not take into account the gravity of the infringement adequately and precisely.

399 The only objective and certain element available to the Commission, and subsequently the EU judicature, is the amount of the value transfer which, as can be seen from paragraph 381 above, adequately reflects the gravity of the infringement and the particular circumstances of the case.

400 Therefore, in principle, the fine to be imposed on the generic company may most adequately be calculated on the basis of that amount.

401 As regards the originator company however, the taking into account of the value of its sales, in view of the very nature of its infringing conduct, appropriately reflects the gravity of the infringement and is an adequate method of calculating the fine.

402 The above reasoning is supported by the fact that, because of the differences in the infringing conduct of the originator company and the generic company, the profits that they obtain from the

infringement are different in nature. Thus, the profit for the originator company depends on the earnings linked to the sales of its product during the course of the infringement period, whereas the profit for the generic company is disconnected from any sale.

403 In view of the considerations set out in paragraphs 396 to 402 above, it must be pointed out that Niche and Servier are not in a comparable situation, which justifies the decision not to apply to Niche a method of calculating the fine analogous to that applied to Servier.

404 Thus, the finding of a difference between the amount of the fine imposed on Niche and that which would have been imposed if the Commission had applied a method analogous to that applied to Servier, but based on the projected value of Niche's sales, shows neither unequal treatment nor discrimination.

405 For the sake of completeness, it should be pointed out that the method that the applicant wishes to see applied to itself differs, in an unjustified manner, from that applied to Servier.

406 The method proposed by the applicant is based on the price of the perindopril that the generic company would have sold if it had entered the market, whereas, as mentioned in paragraph 385 above, the economic significance of the infringement depends, to a large extent, on the — in principle, higher — price of perindopril sold by the originator company during the infringement period. Thus, whereas the method which the Commission applied to Servier is based, rightly, on the price of the perindopril sold by the latter during the infringement period, the applicant seeks to have a method applied to itself which is both more favourable and less representative of the significance of the infringement.

407 It may be added that it is appropriate to take into account, as the Commission rightly did 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, it was justified, in order to avoid a potentially disproportionate result, 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 amount of the fine.

408 As regards the applicant's line of argument put forward in the alternative, concerning the need to reduce by two-thirds the amount of the value transfer for the purpose of determining the amount of the fine, it should be noted that, according to the applicant, that reduction is justified by the fact that the proportion of the value of sales used for the purpose of calculating Servier's fine was only 11%, whereas it could have been up to 30%. The gravity being the same, it is therefore appropriate, in its submission, to apply the same factor of approximately one third to the amount of the value transfer.

409 In essence, the applicant thus asks the Court to apply, by analogy, the method set out in the Guidelines on the method of setting fines, even though, first, that method, based on the value of sales, does not appropriately apply to Niche's situation given the very purpose of the agreement that it concluded with Servier (see paragraphs 375, 376 and 382 to 385 above) and, secondly, the amount of the value transfer gives, without the need to apply a reduction coefficient, an appropriate indication of the gravity of the infringement committed by Niche (see paragraph 381 above).

410 The applicant's line of argument must therefore be rejected.

411 The line of argument put forward in the further alternative, alleging that the Commission should have deducted the legitimate expenses incurred by Niche from the amount of the value transfer, must also be rejected.

412 First of all, the applicant has not established that the reverse payment provided for in the Agreement was intended to compensate the expenses which it invokes in order to obtain a reduction of the fine, namely the costs generated by the termination of the perindopril supply agreements

concluded by the applicant, as well as lawyer fees, development costs, salary costs and taxes paid. If a reverse payment provided for in a settlement agreement containing clauses which restrict competition is not to be regarded as inducive, it must be intended to compensate costs incurred by the generic company (see paragraph 292 above).

413 Even if the expenses invoked by the applicant were those which the reverse payment provided for in the Agreement was intended to compensate (see paragraph 295 above), they cannot be regarded — a priori and in the absence of any justification to that effect from the applicant — as inherent in the settlement of a patent dispute (see paragraph 298 above). As regards, in particular, lawyer fees, it should be pointed out that the legal costs that the reverse payment was intended to compensate were presented by the applicant itself, during the administrative procedure, as corresponding to the costs of developing its perindopril (see paragraph 298 above).

414 In addition, the purpose of a fine is not simply to remove the benefits that an undertaking has obtained through its anticompetitive conduct, but also, as is apparent from point 4 of the Guidelines on the method of setting fines, to deter that undertaking and other undertakings from engaging in such conduct (judgment of 8 September 2016, *Xellia Pharmaceuticals and Alpharma* v *Commission*, T−471/13, not published, under appeal, EU:T:2016:460, paragraph 429). If the purpose of the fine were to be confined merely to negating the expected profit or advantage, insufficient account would be taken of the fact that the conduct in question constitutes an infringement of Article 101(1) TFEU and the punitive nature of the fine in relation to the actual infringement committed (see, to that effect, judgment of 27 September 2006, *Archer Daniels Midland* v *Commission*, T−329/01, EU:T:2006:268, paragraph 141).

415 In the present case, if the basic amount of the fine imposed on Niche were set at a level below that of the inducive benefit that it enjoyed because of the infringement, the fine would not have a deterrent effect.

416 Admittedly, since the Agreement is an exclusion agreement, it entails, for the excluded generic company, a loss as regards the profits it could have made by entering the market.

417 However, that loss is the direct result of the unlawful conduct of the generic company. Indeed, it is the necessary and foreseeable consequence of the choice, made by that company, not to enter the market. That loss cannot be taken into account for the purposes of reducing the basic amount of the fine intended to penalise that infringement.

418 Moreover, at the time a generic company is in a position to enter the market or, on the contrary, receive a value transfer not to do so, the payments arising under an agreement entered into with an originator company are certain, whilst the profits that might result from market entry are subject to the vagaries of a commercial operation of that kind (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 432), vagaries which are all the greater in the case of an at risk entry.

419 Thus, if the basic amount of the fine imposed on a generic company were set at a lower level than that of the inducive benefit which it enjoyed as a result of an infringement, that company might find it preferable to conclude an agreement with an originator company allowing it, even where that agreement gave rise to a penalty, to retain a part of the inducive benefit resulting from the infringement, rather than to enter the market at risk.

420 In the light of the foregoing considerations, the deterrent effect of the fine justifies the fact that its amount is not less than the amount of the value transfer inducement provided for in the agreement.

421 Consequently, the expenses mentioned in paragraph 411 above should not be deducted, for the purpose of calculating the fine, from the amount of the value transfer received by Niche.

422 Furthermore, it is necessary to reject the applicant's reliance on its small size and financial difficulties as circumstances precluding discriminatory treatment by comparison with the treatment given to Servier, since no such discriminatory treatment has been found (see paragraph 404 above). In any event, those circumstances did not entitle the Commission to depart from the method that it applied to the other generic companies, all the more so since, in the present case, the dissuasive effect of the fine required that it not set the fine amount lower than the amount of the inducive value transfer (see paragraphs 414 to 420 above).

423 As regards, lastly, the applicant's argument alleging that the Commission could have applied a method based on the price differential between the perindopril sold before and after the market entry of generic products, allowing it to calculate the profit that Servier obtained from the infringement more precisely, it suffices to point out that the method set out in the Guidelines on the method of setting fines was adapted to Servier's situation and that the concurrent application of a necessarily different method to Niche did not give rise to a breach of the principles of equal treatment and of non-discrimination (see paragraphs 396 to 404 above). In any event, it has not been established that the application of the method proposed by the applicant would be less favourable to Servier in that it would necessarily lead the Commission to impose a larger fine on it than it did in the contested decision.

424 It follows from the foregoing that the second branch of the present plea in law, and therefore that plea in its entirety, must be rejected.

(b) Breach of the principle of proportionality

425 The applicant submits that the Commission breached the principle of proportionality by failing to take sufficient account of several mitigating circumstances.

(1) Novelty of the infringement

(i) Arguments of the parties

426 The applicant submits that the Commission breached the principle of proportionality by failing to take sufficient account of the novelty of the infringement at issue, evidenced in particular by the fact, as acknowledged by the Commission, that the applicant sought legal advice on the legality of the Agreement. The applicant criticises in particular the fact that the Commission equated the Agreement to an agreement excluding a potential competitor from the market, submitting that the Agreement is not analogous to the agreements at issue in the judgment of 20 November 2008, *Beef Industry Development Society and Barry Brothers* (C-209/07, EU:C:2008:643), that the restrictions under the Agreement were not obviously anticompetitive and that it could not have anticipated that it would be regarded as a potential competitor.

427 The Commission refers to the contested decision and to the arguments it put forward in response to other pleas in the present action in order to conclude, in particular, that the notion that a settlement agreement such as that in the present case constitutes a restriction by object is not novel, even if the Commission has not previously adopted decisions to that effect.

(ii) Findings of the Court

428 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).

429 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).

430 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).

431 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).

432 It should be added that the need for professional advice appears all the more evident where, as was the case here, it is a question of preparing and drafting an agreement intended to prevent or to settle a dispute.

433 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 between Servier and Niche, the latter 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).

434 In particular, Niche could assume that accepting non-marketing and non-challenge clauses, by themselves restrictive of competition, on the basis of an inducement and not the recognition of the validity of the patent, rendered the inclusion of such clauses in a patent settlement agreement entirely illegitimate and constituted abnormal use of the patent, unrelated to its specific purpose (see paragraphs 267 and 270 above). Niche 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).

435 In addition, it must be noted that, well before the date of conclusion of the Agreement, 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).

436 In that regard, it should be noted, first of all, that 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 was not affected by Article 101 TFEU, the conditions under which those rights could be exercised might nevertheless fall within the prohibitions contained in that article and that this might be the case whenever the exercise of such a right appeared to be the object, the means or the consequence of a restrictive agreement (judgment of 31 October 1974, *Centrafarm and de Peijper*, 15/74, EU:C:1974:114, paragraphs 39 and 40).

437 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.

438 Moreover, it must be pointed out that, by the Agreement, Niche and Servier actually decided to conclude a market exclusion agreement (see paragraph 271 above). Although it was only in a judgment delivered after the conclusion of the Agreement that the Court of Justice held that market exclusion agreements, in which the 'stayers' are to compensate the 'goers', constitute a restriction of competition by object, it nonetheless made clear that that type of agreement conflicted '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 an agreement, the applicant could not, therefore, have been unaware of the anticompetitive nature of its conduct.

439 While it is true that, because the Agreement was concluded in the form of a patent settlement, its unlawful nature 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.

440 Thus, the applicant cannot validly invoke the lack of any precedent and the novelty of the infringement in order to call into question the imposition of a fine and the amount of that fine.

441 That conclusion is not called into question by the other arguments submitted by the applicant.

442 In the first place, although the applicant refers to the existence of a legal opinion that it sought, mentioned in recital 3074 of the contested decision, it has not adduced sufficient evidence to support a conclusion that there was genuine uncertainty concerning the infringing nature of the Agreement in the light of the EU competition rules.

443 In the second place, the argument alleging the existence of a Commission practice according to which a considerable degree of uncertainty regarding the infringing nature of the conduct in question was taken into consideration by the Commission as a mitigating circumstance cannot be upheld since, as mentioned in paragraph 434 above, Niche could reasonably have foreseen that, in acting as it did, that is to say by agreeing to be paid to stay out of the market, its conduct was caught by the prohibition laid down in Article 101(1) TFEU.

444 In addition, as mentioned in paragraph 438 above, Niche could not have been unaware of the anticompetitive nature of its conduct.

445 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, such as symbolic fines for infringements of an unprecedented nature, 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).

446 In the third place, contrary to the applicant's submissions, the Commission rightly referred to the judgment of 20 November 2008, *Beef Industry Development Society and Barry Brothers* (C−209/07, EU:C:2008:643), and did not, in doing so, disregard the fact that the Agreement concerned intellectual property rights implemented in the context of a dispute settlement.

447 The finding of an inducement implies that the market exclusion of the applicant entailed by the Agreement results, not from the effects of the patents at issue and the legitimate objective of settling the disputes in relation to those patents, but rather from a value transfer, representing the financial consideration for that exclusion, in the same way as the exclusion of certain undertakings from the Irish beef market resulted from financial consideration paid to them by their competitor in the case that gave rise to the judgment of 20 November 2008, *Beef Industry Development Society and Barry Brothers* (C−209/07, EU:C:2008:643) (see paragraph 271 above).

448 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 a financial inducement and not on the recognition of the validity of the patent (see also paragraph 286 above).

449 In the fourth place, contrary to the applicant's assertions, the non-marketing and non-challenge clauses in the Agreement had to be perceived by the parties to that agreement as restrictions on competition.

450 As regards the non-marketing clause, first, the applicant does not dispute that Clause 3 of the Agreement prohibits it from manufacturing and marketing the perindopril that it had developed with Matrix and, secondly, it is apparent from the very wording of Clause 6 of the Agreement that the marketing possibility provided for in that clause was intended merely to clarify the end of that prohibition (see paragraph 303 above).

451 As regards the non-challenge clause, it must be borne in mind that, although it allowed the applicant to defend itself against infringement actions brought by Servier, it above all provided for a general prohibition on litigation intended to 'clear the way' in the context of an at-risk launch, namely invalidity actions and actions for a declaration of non-infringement of the patents (see paragraph 304 above).

452 Lastly, even if it were established that the non-marketing and non-challenge clauses did not exceed the scope of the patents at issue, those clauses had to be perceived by the parties to the Agreement as restrictions on competition.

453 Niche, in particular, could reasonably foresee that accepting non-marketing and non-challenge clauses, by themselves restrictive of competition, on the basis of an inducement and not the recognition of the validity of the patents at issue, rendered entirely illegitimate the inclusion of such clauses in a patent settlement agreement and constituted abnormal use of the patent, unrelated to its specific purpose, even if the scope of those clauses did not exceed that of the patents (see paragraphs 430 and 434 above).

454 In the fifth place, it is necessary to reject the applicant's argument alleging that it was not foreseeable that the Commission would find that there was potential competition between Servier and Niche. In view of the analysis of the plea relating to the finding of potential competition between Servier and Niche (see paragraphs 101 to 188 above) and taking into account the case-law of the Court of Justice, which allows for the gradual, case-by-case clarification of the rules on criminal liability by judicial interpretation (see paragraph 430 above), Niche could reasonably foresee that it would be regarded by the Commission as a potential competitor of Servier. It should

be added that the very presence in the Agreement of a non-marketing clause is a factor which also justifies the conclusion that Niche saw itself as at least a potential competitor of Servier.

455 It follows from all of the foregoing that the present complaint must be rejected.

(2) Servier's foreclosure strategy

(i) Arguments of the parties

456 The applicant submits that, when setting the amount of the fine, the Commission should have taken account of the fact that it was merely a victim of Servier's strategy to foreclose generic companies from the market. It adds that, by failing to take Servier's conduct into account, the Commission also treated the applicant in a discriminatory manner in comparison with its practice in treating companies that concluded vertical agreements.

457 The Commission contends that patent dispute settlement agreements are not inherently anticompetitive and that the applicant was in no way forced to enter into a settlement agreement containing terms that restrict competition.

(ii) Findings of the Court

458 In the first place, the applicant submits that it was forced to sign the Agreement by Servier, without any possibility of resisting, and should therefore have received a lighter penalty.

459 However, it has not been established that the applicant was forced in that way. Indeed, the very existence of an inducive benefit, which was found in paragraph 299 above, shows that Niche benefited from the Agreement, which contradicts the argument that Servier forced it to enter that agreement. That argument is even less credible given that the amount of the value transfer received by Niche, GBP 11.8 million, is large, which is an indicator of the influence that it had in the negotiation.

460 In any event, even if Servier exerted irresistible pressure on Niche to the extent that it was forced to sign the Agreement, the latter could have reported the pressure to the competent authorities and lodged a complaint with the Commission under Article 7(2) of Regulation No 1/2003 (see, to that effect, judgments 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, paragraphs 369 and 370; of 8 December 2011, *Chalkor* v *Commission*, C−386/10 P, EU:C:2011:815, paragraph 79; and of 6 April 1995, *Sotralentz* v *Commission*, T−149/89, EU:T:1995:69, paragraph 53). Niche was therefore still able to prevent the implementation of the infringement in question. Since it chose not to report that infringement, the Court considers that it should not benefit from a reduction of the fine for mitigating circumstances (see, to that effect, judgments 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, paragraphs 367 to 370, and of 5 October 2011, *Romana Tabacchi* v *Commission*, T−11/06, EU:T:2011:560, paragraph 212).

461 In the second place, as regards the reliance on the Commission's decision-making practice in relation to vertical agreements between a supplier and its distribution network, it has been held that the Commission's practice in previous decisions does not itself serve as a legal framework for the fines imposed in competition matters and that decisions in other cases can give only an indication for the purpose of determining whether there is discrimination (judgment of 19 April 2012, *Tomra Systems and Others* v *Commission*, C−549/10 P, EU:C:2012:221, paragraph 104).

462 In addition, it should be noted that the applicant's argument is based on the premiss that, in the cases in question, the supplier received a larger fine than its distributors whereas, in the present case, Niche was treated as severely, if not more severely, that Servier. In that respect, it should be noted

that a fine of EUR 131 532 600 was imposed on Servier in respect of the Agreement, whereas the fine imposed on Niche was only EUR 13 968 773. The applicant's argument has, therefore, no basis in fact.

463 It follows from all of the foregoing that the present complaint must be rejected.

(3) Geographic scope of the infringement

(i) Arguments of the parties

464 The applicant submits that it is disproportionate to impose on it a fine covering the entire European Economic Area (EEA) when the evidence adduced by the Commission as to its ability to obtain a marketing authorisation and successfully overcome the patent-related barriers relates only to the United Kingdom.

465 The Commission maintains that it took into account the particularly wide geographic scope of the Agreement, which covered the entire European Union, and refers to the arguments it put forward in response to the plea relating to potential competition in order to reject as irrelevant the applicant's arguments that evidence had been adduced only in respect of the United Kingdom.

(ii) Findings of the Court

466 In essence, the applicant submits that the existence of potential competition is established, at the very most, only in respect of the United Kingdom.

467 It is appropriate to refer to the considerations set out in response to the plea in law challenging the analysis of potential competition on the market (see paragraphs 73 to 87 and 101 to 188 above).

468 In particular, as regards the barrier represented by Servier's patents in Member States other than the United Kingdom, it must be noted that the applicant does not refer to any final decision, adopted by the date of the conclusion of the Agreement, ruling on an infringement action and finding that Niche's product was infringing.

469 As regards the barrier represented by the fact that marketing authorisations had not been obtained in any Member States other than the United Kingdom, it must be pointed out that there is a mutual recognition procedure under which the Member States recognise the validity of a marketing authorisation granted in another Member State. In that respect, it is indicated, in recital 12 of Directive 2001/83, that 'a marketing authorization for a medicinal product granted by a competent authority in one Member State ought to be recognized by the competent authorities of the other Member States unless there are serious grounds for supposing that the authorization of the medicinal product concerned may present a risk to public health'. Thus, in view of the Court's conclusion that the applicant's arguments relating to the regulatory difficulties encountered did not call into question its real concrete possibilities of obtaining the marketing authorisations required in order to enter the United Kingdom market (see paragraphs 161 and 164 above), and in the absence of any indication of particular difficulties in obtaining a marketing authorisation in certain other Member States, there is no reason to doubt the existence of potential competition in all of the Member States in respect of which the Commission found an infringement.

470 In addition, as the Commission rightly submits, the restrictive clauses in the Agreement apply to all the Member States in respect of which the Commission found an infringement. Thus, Niche, in exchange for an inducive value transfer, agreed to limit its efforts to enter the markets of all of those Member States, and not merely that of the United Kingdom.

471 It must also be pointed out that, contrary to the applicant's submission, the Commission did not impose a fine on it covering the EEA in its entirety. It is apparent inter alia from Article 1 of the

contested decision that the infringement found by the Commission against the applicant covered 'all Member States except Italy and Croatia'.

472 Lastly, it should be added that Niche represented a sufficient competitive threat outside the United Kingdom that Servier was ready to conclude an agreement with it precisely in order to exclude it from the markets in question and, through that agreement, to transfer the sum of GBP 11.8 million to it in order to neutralise that threat (see paragraph 80 above).

(4) The applicant's cooperation

(i) Arguments of the parties

473 The applicant takes issue with the Commission for having considered that it had not voluntarily submitted information that helped the Commission significantly to establish the infringement, although it had in fact provided legally privileged information, under the mistaken belief that it was under an obligation to do so (see paragraph 56 above), which the Commission used as a basis to establish the existence of a restriction by object. It adds that, contrary to the Commission's assertion, a reduction of fines for cooperation during the administrative procedure should not be granted only in exceptional circumstances.

474 The Commission submits that the applicant did not cooperate with the Commission in a manner going beyond its legal obligations to cooperate, since the documents concerned were submitted in response to a Commission Request for Information. According to the Commission, it was fully justified, therefore, in not applying the fourth indent of point 29 of the Guidelines on the method of setting fines.

(ii) Findings of the Court

475 The applicant submits in essence that the Commission was wrong to refuse to grant it a reduction of the amount of the fine by reason of its cooperation.

476 However, in order for the applicant to be able to claim the benefit of the fourth indent of point 29 of the Guidelines on the method of setting fines, it must establish that its cooperation went beyond its legal obligation to cooperate and was of objective use to the Commission, which was able to rely, in its final decision, on evidence which the applicant submitted to it in the context of its cooperation, without which the Commission would not have been in a position to penalise the infringement in question in whole or in part (see, to that effect, judgments of 17 May 2011, *Arkema France* v *Commission*, T−343/08, EU:T:2011:218, paragraphs 168 to 171, and of 15 July 2015, *Socitrel and Companhia Previdente* v *Commission*, T−413/10 and T−414/10, EU:T:2015:500, paragraphs 328 to 330).

477 That is not the case here.

478 The only document from Niche mentioned in the recitals of the contested decision to which the applicant refers is an email in which a legal advisor of Niche gives an opinion on the settlement agreement envisaged with Servier.

479 The applicant merely submits that, without that email, the Commission 'may not' have been able to substantiate the existence of a restriction by object since, in certain recitals of the contested decision, that email is used by the Commission 'as a general basis to establish its "by object" theory of harm' and therefore 'to apply [the judgment of 20 November 2008, *Beef Industry Development Society and Barry Brothers* (C−209/07, EU:C:2008:643)] by analogy'.

480 The applicant's assertion is too unspecific to justify the application to it, in the light of the case-law cited in paragraph 476 above, of a reduction under the fourth indent of point 29 of the Guidelines on

the method of setting fines.

481 In addition, the provisions cited in paragraph 480 above cannot be applied where, as in the present case, the undertaking concerned merely alleges that the 'evidence' meant to establish its cooperation helped the Commission to develop the legal reasoning on which it based its decision and not that it enabled it to establish the existence of the infringement.

482 Lastly, it cannot be maintained that the email at issue was used by the Commission as 'a general basis to establish its "by object" theory of harm', even if it may have enabled it to support its analysis relating to the reference, by analogy, as regards the agreements at issue, to the judgment of 20 November 2008, *Beef Industry Development Society and Barry Brothers* (C-209/07, EU:C:2008:643).

483 Whereas that part of the Commission's reasoning is set out in recitals 1133 to 1144 of the contested decision, the reference to the email in question appears only incidentally in recital 1140, in which it is indicated that:

'The European Court of Justice in *Irish Beef* concluded that the arrangements in question, premised on exclusionary payments, were a restriction by object. Advocate General Trstenjak characterised the arrangement as "the 'buying off' of competition". That is close to how one of the settlements had been described internally, as well as by a third party, as the generic company "taking the money in exchange for being bought out" by Servier.'

484 In addition, the reference made by the applicant to paragraph 104 of the judgment of 6 December 2005, *Brouwerij Haacht* v *Commission* (T-48/02, EU:T:2005:436), is not relevant in the present case, because that paragraph concerns the application of the Commission notice on the non-imposition or reduction of fines in cartel cases (OJ 1996 C 207, p. 4), since replaced by the Commission Notice on Immunity from fines and reduction of fines in cartel cases (OJ 2002 C 45, p. 3). The fourth indent of point 29 of the Guidelines on the method of setting fines expressly provides that that provision applies only where the undertaking concerned has cooperated with the Commission outside the scope of the Commission Notice on Immunity from fines and reduction of fines in cartel cases.

485 It follows from all the foregoing that the present complaint, as well as the plea in its entirety, must be rejected.

(c) Infringement of Article 23(2) of Regulation No 1/2003

(1) Arguments of the parties

486 The applicant complains that the Commission infringed Article 23(2) of Regulation No 1/2003 by calculating the maximum amount of the fine imposed on the applicant by reference to the worldwide turnover of its parent company, Unichem. A parent company's turnover may be taken into account for the calculation of the 10% fine cap only when the parent is a single economic entity with the subsidiary, which was not shown by the Commission to have been the case either in the period during which Unichem had a 60% shareholding in Niche, or in the period of Unichem's 100% ownership of Niche.

(i) The period during which Unichem held 60% of the applicant's shares

487 The applicant argues that the Commission has not established that, during that period, Unichem exercised, or could have exercised, decisive influence over the applicant's commercial strategy.

488 First, the fact that Unichem appointed the majority of the applicant's board members did not, as such, give Unichem the power to exercise decisive influence over the commercial behaviour of its

subsidiary. Secondly, Unichem's veto rights allowed it only to ensure that the value of its investment in its subsidiary would not be degraded. Thirdly, the fact that Unichem exercised financial supervision does not show that it exercised decisive influence over the applicant's strategic commercial decisions. Fourthly, the information flows between the applicant and Unichem in respect of the perindopril project and the settlement are justified on the basis of Unichem's separate legitimate interest in being kept informed, as an investor in the applicant and a manufacturer of perindopril tablets under the Unichem/Matrix agreement. The same applies as regards Unichem's signature of the Agreement. Fifthly, Unichem's stated purpose of using the applicant in the context of 'driving the internationalism of its business' is not sufficient as such to establish that Unichem actually exercised decisive influence over the applicant during the relevant period.

489 The Commission contends that it clearly established, in the contested decision, that Unichem exercised a decisive influence over the applicant during the period of Unichem's 60% shareholding.

490 It states, first, that the applicant does not explain why the fact that the majority of its shareholders were appointed by Unichem is irrelevant and does not mention the other evidence of strong links between Unichem's and the applicant's boards. Secondly, it points out that Unichem's veto rights did cover, precisely, strategic commercial decisions. Thirdly, the Commission submits that Unichem's monitoring of the applicant's financial performance is certainly a relevant factor in this case, as is the fact that the applicant's accounts were consolidated with Unichem's. Fourthly, it claims that Unichem's own interest in the Agreement was not just as an investor and tablet manufacturer, as is shown by the fact that the applicant sought Unichem's approval prior to signing. Fifthly, the Commission notes that the applicant does not mention the practical effects of its essential role in Unichem's strategy in Europe.

(ii) The period during which Unichem held 100% of the applicant's shares

491 The applicant submits that the alleged rebuttable presumption that Unichem exercised decisive influence over the applicant's commercial strategy for the period of Unichem's 100% ownership of the applicant from December 2006 is irrelevant in this case, since the infringement ended in May 2005 when Matrix terminated the Niche/Matrix agreement, thus preventing the applicant from entering the market regardless of the Agreement.

492 The Commission contends that there is no logical reason why Matrix's termination of the Niche/Matrix agreement should prevent Unichem from being liable as the parent company of the applicant, which had implemented and continued to be bound by the Agreement.

(2) Findings of the Court

493 It should be borne in mind, as a preliminary point, that in the contested decision the Commission considered that Unichem had to be held liable for the infringement for its direct participation in it, but also as the parent company of Niche, which had itself also taken part in that infringement. It relied on six considerations which, in its view, demonstrated that Unichem exercised decisive influence over Niche, in which it held a 60% shareholding, from before the conclusion of the Agreement until the acquisition of 100% of Niche's shares in December 2006, as of when the presumption of decisive influence applied (recitals 3015, 3023 and 3024 of the contested decision).

494 First, the Commission pointed out that the majority of the members of Niche's board of directors were appointed by Unichem and that that board of directors included, amongst others, Unichem's executive director as well as the chairman of Unichem's board of directors, who was also the chairman of Niche's board. It added that Niche's board of directors met regularly, dealt with issues relating to perindopril and controlled the activities of Niche's chief executive officer (CEO) (recital 3017 of the contested decision).

495 Secondly, according to the Commission, Niche required Unichem's prior consent in a number of

matters, including for financial and commercial decisions (recital 3018 of the contested decision).

496 Thirdly, the Commission inferred from the need for Unichem's prior consent in order for Niche to obtain certain funding, from the regular communication of accounts and reports, from the submission of Niche's annual business plan to Unichem and from the consolidation of Niche's accounts with those of Unichem that the parent company monitored its subsidiary's financial performance (recital 3019 of the decision).

497 Fourthly, the Commission referred to the information flows from Niche to Unichem, particularly in relation to the agreements envisaged by Niche, as an additional indication of decisive influence (recital 3020 of the decision).

498 Fifthly, the Commission noted that Unichem and Niche were co-signatories of the Agreement with Servier, which implied that Unichem had agreed to the restrictions imposed on Niche in the context of the Agreement (recital 3021 of the contested decision).

499 Sixthly, the Commission underlined that the stated aim of Unichem's acquisition of Niche was not only to invest in the latter but more importantly to enter the European market and expand its business (recital 3022 of the contested decision).

500 It must be borne in mind that, in accordance with settled case-law, the concept of an undertaking covers any entity engaged in an economic activity, regardless of its legal status and the way in which it is financed. That concept must be understood as designating an economic unit even if in law that unit consists of several natural or legal persons. When such an economic entity infringes the competition rules, it is for that entity, according to the principle of personal responsibility, to answer for that infringement (see judgments of 10 September 2009, *Akzo Nobel and Others* v *Commission*, C-97/08 P, EU:C:2009:536, paragraphs 54 to 56 and the case-law cited, and of 19 July 2012, *Alliance One International and Standard Commercial Tobacco* v *Commission*, C-628/10 P and C-14/11 P, EU:C:2012:479, paragraph 42 and the case-law cited).

501 Specifically, the conduct of a subsidiary may be imputed to the parent company in particular where, although having a separate legal personality, that subsidiary does not decide independently upon its own conduct on the market, but carries out, in all material respects, the instructions given to it by the parent company, having regard in particular to the economic, organisational and legal links between those two legal entities (judgment of 10 September 2009, *Akzo Nobel and Others* v *Commission*, C-97/08 P, EU:C:2009:536, paragraph 58; see, also, judgment of 19 July 2012, *Alliance One International and Standard Commercial Tobacco* v *Commission*, C-628/10 P and C-14/11 P, EU:C:2012:479, paragraph 43 and the case-law cited).

502 In such a situation, since the parent company and its subsidiary form a single economic unit and therefore form a single undertaking for the purposes of Article 101 TFEU, the Commission may address a decision imposing fines on the parent company, without having to establish the personal involvement of the latter in the infringement (judgment of 10 September 2009, *Akzo Nobel and Others* v *Commission*, C-97/08 P, EU:C:2009:536, paragraph 59; see, also, judgment of 19 July 2012, *Alliance One International and Standard Commercial Tobacco* v *Commission*, C-628/10 P and C-14/11 P, EU:C:2012:479, paragraph 44 and the case-law cited).

503 It should also be noted that, in order to be able to impute the conduct of a subsidiary to the parent company, the Commission cannot merely find that the parent company is in a position to exercise decisive influence over the conduct of its subsidiary, but must also check whether that influence was actually exercised on the basis of factual evidence, including, in particular, any management power of the parent company over its subsidiary (see, to that effect, judgments of 25 October 1983, *AEG* v *Commission*, 107/82, EU:C:1983:293, paragraph 50; of 11 July 2013, *Commission* v *Stichting Administratiekantoor Portielje*, C-440/11 P, EU:C:2013:514, paragraph 44; and of 26 September

2013, *The Dow Chemical Company* v *Commission*, C−179/12 P, not published, EU:C:2013:605, paragraph 67). It should be noted, in this respect, that the exercise of decisive influence by a parent company over its subsidiary's conduct may be inferred from a body of consistent evidence, even if some of that evidence, taken in isolation, is insufficient to establish the existence of such influence (judgments of 1 July 2010, *Knauf Gips* v *Commission*, C−407/08 P, EU:C:2010:389, paragraph 65, and of 18 January 2017, *Toshiba* v *Commission*, C−623/15 P, not published, EU:C:2017:21, paragraph 47).

504 However, in the specific case where a parent company has a 100% shareholding in a subsidiary which has infringed the EU competition rules, first, the parent company can exercise a decisive influence on the conduct of the subsidiary and, secondly, there is a rebuttable presumption that the parent company does in fact exercise such a decisive influence (judgments of 10 September 2009, *Akzo Nobel and Others* v *Commission*, C−97/08 P, EU:C:2009:536, paragraph 60, and of 8 September 2016, *Merck* v *Commission*, T−470/13, not published, under appeal, EU:T:2016:452, paragraph 433; see also, to that effect, judgment of 25 October 1983, *AEG* v *Commission*, 107/82, EU:C:1983:293, paragraph 50).

505 In those circumstances, it is sufficient for the Commission to prove that the subsidiary is wholly owned by the parent company in order to presume that the parent company actually exercises decisive influence over the subsidiary's commercial policy. The Commission will then be able to regard the parent company as jointly and severally liable for the payment of the fine imposed on its subsidiary, unless that parent company or its subsidiary, which have the burden of rebutting that presumption, adduce sufficient evidence to show that the subsidiary acts independently on the market (judgments of 10 September 2009, *Akzo Nobel and Others* v *Commission*, C−97/08 P, EU:C:2009:536, paragraph 61, and of 8 September 2016, *Merck* v *Commission*, T−470/13, not published, under appeal, EU:T:2016:452, paragraph 434; see also, to that effect, judgment of 16 November 2000, *Stora Kopparbergs Bergslags* v *Commission*, C−286/98 P, EU:C:2000:630, paragraph 29).

506 The applicant submits that it did not form an economic unit with Unichem during the period in which the latter held a 60% shareholding in it and the Commission also could not impute the infringement allegedly committed by the applicant to Unichem in respect of the period during which it held 100% of the applicant's shares. In that context, those two periods must be examined in turn.

(i) The period during which Unichem held 60% of the applicant's shares

507 It must be noted, as a preliminary point, that the Commission, in accordance with the case-law (judgments of 16 June 2011, *FMC* v *Commission*, T−197/06, EU:T:2011:282, paragraph 100, and of 15 July 2015, *HIT Groep* v *Commission*, T−436/10, EU:T:2015:514, paragraph 126; see, also, the case-law cited in paragraph 501 above), concluded that Unichem exercised decisive influence over the applicant on the basis of six factors relating to the economic, organisational and legal links between those companies (recitals 3015 to 3024 of the contested decision, as summarised in paragraphs 493 to 499 above).

508 It should also be borne in mind that the possibility of exercising decisive influence over the commercial policy of an undertaking does not require proof of interference in the day-to-day management of that undertaking's operation, nor of influence over its commercial policy in the strict sense, such as its distribution or pricing strategy, but rather influence over the general commercial strategy which defines the orientation of the undertaking. Thus, a single commercial policy within a group may also be inferred indirectly from the totality of the economic and legal links between the parent company and its subsidiaries. For example, the parent company's influence over its subsidiaries as regards corporate strategy, operational policy, business plans, investment, capacity, provision of finance, human resources and legal matters may have indirect effects on the market conduct of the subsidiaries and of the whole group. Ultimately, the decisive factor is whether the

parent company exercises an influence that suffices to direct the conduct of its subsidiary to such an extent that the two must be regarded as one economic unit (judgment of 9 September 2015, *Toshiba* v *Commission*, T−104/13, EU:T:2015:610, paragraph 121, and Opinion of Advocate General Kokott in *Akzo Nobel and Others* v *Commission*, C−97/08 P, EU:C:2009:262, points 89 to 93; see also, to that effect, judgment of 26 September 2013, *The Dow Chemical Company* v *Commission*, C−179/12 P, not published, EU:C:2013:605, paragraph 64).

509 Thus, a — greater or lesser — degree of autonomy of a subsidiary in its day-to-day commercial management is not necessarily incompatible with the parent company's decisive influence (judgment of 12 December 2012, *1. garantovaná* v *Commission*, T−392/11, not published, EU:T:2012:674, paragraph 48; see also, to that effect, judgments of 8 May 2013, *Eni* v *Commission*, C−508/11 P, EU:C:2013:289, paragraph 64, and of 16 June 2011, *FMC* v *Commission*, T−197/06, EU:T:2011:282, paragraph 122).

510 Likewise, the assessment of whether a parent company exercises decisive influence over its subsidiary is not limited to an examination of the business policy in the strict sense, including the pricing policy, production and distribution activities, sales objectives, gross margins, sales costs, cash-flow, stocks and marketing (see, to that effect, judgments of 12 December 2007, *Akzo Nobel and Others* v *Commission*, T−112/05, EU:T:2007:381, paragraph 64; of 16 June 2011, *FMC* v *Commission*, T−197/06, EU:T:2011:282, paragraph 106; of 27 September 2012, *Nynäs Petroleum and Nynas Belgium* v *Commission*, T−347/06, EU:T:2012:480, paragraph 48; and of 13 December 2013, *HSE* v *Commission*, T−399/09, not published, EU:T:2013:647, paragraph 31). Account must be taken of all the relevant factors relating to the economic, organisational and legal links between the subsidiary and the parent company, which may vary from case to case and cannot therefore be set out in an exhaustive list (judgment of 10 September 2009, *Akzo Nobel and Others* v *Commission*, C−97/08 P, EU:C:2009:536, paragraph 74; see, also, the case-law cited in paragraph 507 above).

511 Since the applicant also disputes each of the factors relating to the economic, organisational and legal links between it and its parent company found by the Commission in the contested decision in order to constitute the body of evidence establishing Unichem's decisive influence over the applicant's conduct, the Court makes the following observations.

512 As regards, in the first place, the composition of the applicant's board of directors, the applicant submits that the prevailing presence on its board of directors of members nominated by Unichem is not sufficient to prove that Unichem could or did exercise decisive influence over the applicant.

513 It must be noted at the outset that the applicant does not dispute that the members nominated by Unichem composed the majority of the applicant's board of directors during the infringement period. It is settled case-law that the participation — and in particular the predominance — of persons nominated by the parent company on the board of directors of its subsidiary is a relevant piece of evidence of the parent company's exercise of effective control over its subsidiary (see, to that effect, judgment of 13 December 2013, *HSE* v *Commission*, T−399/09, not published, EU:T:2013:647, paragraphs 38 and 76 and the case-law cited). Where such a majority exists, the board of directors cannot take any decision without the agreement of the members nominated by the parent company and, conversely, the members of the subsidiary's board of directors who were chosen by the parent company are always in a position to form a majority and to take decisions without obtaining the agreement of the other members (see, to that effect, judgment of 12 December 2012, *1. garantovaná* v *Commission*, T−392/09, not published, EU:T:2012:674, paragraph 40).

514 Nor does the applicant dispute that the chairman of its board of directors was also the chairman and managing director of Unichem's board of directors and that Unichem's executive director, and member of its board of directors, was also a member of the applicant's board of directors (recital 3017 of the contested decision). According to the case-law, the extent of the parent company's

involvement in the management of its subsidiary may also be proved by the presence, in leading positions of the subsidiary, of many individuals who occupy managerial posts within the parent company. Such an accumulation of posts necessarily places the parent company in a position to have a decisive influence on its subsidiary's market conduct since it enables members of the parent company's board to ensure, while carrying out their managerial functions within the subsidiary, that the subsidiary's course of conduct on the market is consistent with the line laid down at management level by the parent company (see, to that effect, judgments of 12 July 2011, *Fuji Electric* v *Commission*, T−132/07, EU:T:2011:344, paragraphs 184 and 199; of 27 September 2012, *Nynäs Petroleum and Nynas Belgium* v *Commission*, T−347/06, EU:T:2012:480, paragraphs 47 and 56; and of 9 September 2015, *Toshiba* v *Commission*, T−104/13, EU:T:2015:610, paragraphs 100 and 115 and the case-law cited).

515 In the second place, the applicant submits that the veto rights that Unichem held are typical investment protection rights and do not prove that it exercised decisive influence over the applicant.

516 It should be pointed out, in that regard, that it is clear from the case-law that the obligation for the subsidiary to engage in prior consultation with the parent company or to obtain its prior approval is a strong indication that that parent company actually exercises decisive influence over its subsidiary. In particular, in a situation where the parent company must approve its subsidiary's proposals, the fact that the subsidiary is required to obtain that approval and therefore the parent company has the right to refuse to give it is evidence of a decisive influence (see, to that effect, judgments of 27 October 2010, *Alliance One International and Others* v *Commission*, T−24/05, EU:T:2010:453, paragraphs 183 to 187, and of 13 December 2013, *HSE* v *Commission*, T−399/09, not published, EU:T:2013:647, paragraph 84).

517 According to the case-law, the veto rights which give the parent company control over its subsidiary are those which relate to decisions on business strategy issues, such as the business plan or the course of action on the market, but also, in view of the need to take into account all of the economic and legal links between the parent company and its subsidiary (see paragraphs 508 and 510 above), to the budget, major investments or acquisitions or the appointment of senior management (see, to that effect, judgments of 12 December 2007, *Akzo Nobel and Others* v *Commission*, T−112/05, EU:T:2007:381, paragraph 82; of 17 May 2011, *Elf Aquitaine* v *Commission*, T−299/08, EU:T:2011:217, paragraph 103; of 7 June 2011, *Total and Elf Aquitaine* v *Commission*, T−206/06, not published, EU:T:2011:250, paragraph 97; and of 18 January 2017, *Toshiba* v *Commission*, C−623/15 P, not published, EU:C:2017:21, paragraphs 71 and 72).

518 According to the provisions of the shareholders' agreement between Niche and Unichem dated 15 April 2002, as set out, in essence, in recital 3018 of the contested decision, the veto rights held by Unichem related precisely to decisions on commercial strategy (transfer of licences or marketing authorisations, initiation of new product development), to decisions concerning the most important assets (purchase or sale of assets valued at more than GBP 50 000) and to management staff (recruitment of new staff whose wage bill exceeded GBP 50 000).

519 As regards, in the third place, the information flows to its parent company, the applicant submits that, as an investor in its subsidiary and a subcontract manufacturer of the perindopril tablets, Unichem had a legitimate interest in receiving such information.

520 It should be noted that, in doing so, the applicant disputes neither the existence of the information exchanges in question, nor the subject matter of those information exchanges (which concerned inter alia the development of the product), nor the regularity of those exchanges (once per quarter in the context of the board of directors and intermittently in the context of informal exchanges). Such a flow of information between a parent company and its subsidiary and, a fortiori, an obligation to report to the parent company, constitutes an indication of the exercise of control over the subsidiary's decisions (see, to that effect, judgments of 20 January 2011, *General Química and*

Others v *Commission*, C−90/09 P, EU:C:2011:21, paragraph 107; of 6 March 2012, *FLSmidth* v *Commission*, T−65/06, not published, EU:T:2012:103, paragraph 31; and the Opinion of Advocate General Mengozzi in *Evonik Degussa and AlzChem* v *Commission*, C−155/14 P, EU:C:2015:529, point 75). Such information and reports show organisational links between the parent company and its subsidiary and allow the parent company to monitor and control the activities of its subsidiary in order to take concrete measures against it. It is also important to note that a parent company may exercise decisive influence over its subsidiary even when it does not make use of any actual rights of supervision and refrains from giving any specific instructions or guidelines following the communication by the subsidiary of that information and those reports. Such instructions are merely a particularly clear indication of the exercise of decisive influence by the parent company over its subsidiary's commercial policy, but the autonomy of the subsidiary cannot necessarily be inferred from their absence (see judgment of 9 September 2015, *Toshiba* v *Commission*, T−104/13, EU:T:2015:610, paragraph 121; see also, to that effect, judgment of 10 September 2009, *Akzo Nobel and Others* v *Commission*, C−97/08 P, EU:C:2009:536, paragraph 73).

521 Accordingly, in the light of the foregoing findings, there is no need to examine the other indicia set out in that regard in the contested decision, the relevance of which has also been challenged by the applicant, and it must be concluded that the Commission proved to the requisite legal standard that Unichem exercised decisive influence over its subsidiary's conduct, in view of the body of evidence composed solely of the following indicia set out in the contested decision: Unichem's nomination of the majority of the members of the applicant's board of directors, the cross-directorships between the subsidiary and its parent company, the veto rights held by Unichem and the information exchanges between the two companies.

522 It follows that the Commission established and considered, without erring in law, that Unichem was not merely a passive investor in the applicant and that it formed an economic unit with its subsidiary during the period in which it held 60% of its shares.

(ii) The period during which Unichem held 100% of the applicant's shares

523 The applicant does not dispute that Unichem has held 100% of its shares since December 2006. Nor has it put forward any argument, nor a fortiori any evidence capable of demonstrating that it acted autonomously on the market during the period following that takeover.

524 It follows that the Commission rightly presumed that Unichem exercised decisive influence over the applicant and, since that presumption was not rebutted, imputed the infringement to Unichem in respect of the period in question.

525 That conclusion is in no way called into question by the applicant's assertion that the infringement cannot be imputed to it, since that infringement came to an end when the Niche/Matrix agreement was suspended in May 2005 (see paragraph 491 above).

526 Besides the fact that that assertion should also have the effect of calling into question the imputation of the infringement to Unichem in respect of a part of the period prior to its acquisition of 100% of the applicant's shares in 2006, but that it was not put forward for that purpose, it must be noted that it is apparent from paragraph 186 above that the Niche/Matrix agreement was suspended in accordance with the Agreement. That suspension thus shows the implementation of the Agreement and, accordingly, does not support the conclusion that the infringement came to an end on that date.

527 It follows from all the foregoing that the Commission established and considered, correctly, that Unichem formed an economic unit with the applicant during the infringement period and that the infringement committed by its subsidiary could be imputed to it. It also follows that the Commission rightly calculated the maximum amount of the fine imposed on the applicant on the basis of

Unichem's total turnover.

528 The present plea, alleging infringement of Article 23(2) of Regulation No 1/2003 must therefore be rejected.

(d) Breach of the obligation to state reasons

(1) Arguments of the parties

529 The applicant complains that the Commission infringed its obligation to state reasons in respect of the calculation of the fine imposed on it, by failing to give the reasons why a much higher gravity and deterrence uplift was used for that fine than for Servier's fine.

530 The Commission refers to the plea relating to the principle of equal treatment to conclude that it was not under any obligation to explain a difference in treatment which it regards as unsubstantiated.

(2) Findings of the Court

531 By this plea in law, the applicant criticises the Commission for failing to justify sufficiently, in the contested decision, the fact that, according to the applicant, it applied a higher 'gravity factor' to the applicant than it applied to Servier — higher even than the maximum of 30% laid down in point 20 of the Guidelines on the method of setting fines.

532 In that respect, it must be noted, as is apparent from the considerations set out in paragraphs 392 to 404 above that, contrary to the applicant's submissions, the Commission did not apply a higher 'gravity factor' to Niche than it applied to Servier. It merely used, rightly, a method which differed from the general method set out in the Guidelines on the method of setting fines precisely in that it was not based on the use of such a factor, and explained the reasons for that choice.

533 The plea must therefore be rejected.

534 In addition, in view of all the foregoing considerations, it must be concluded that the amount of the fine is not disproportionate. There is therefore no need to reduce it.

535 Since none of the pleas in law relied on by the applicant in support of its application for annulment of the contested decision is well founded or effective and since the examination of the arguments put forward in support of its application for reduction of the amount of the fine has not revealed any inappropriate elements in the Commission's calculation of the amount of that fine, the action must be dismissed in its entirety.

Costs

536 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. Since the applicant has been unsuccessful, it must be ordered to pay, in addition to its own costs, the costs incurred by the Commission, in accordance with the form of order sought by the Commission.

On those grounds,

THE GENERAL COURT (Ninth Chamber)

hereby:

1. Dismisses the action;

2. Orders Niche Generics Ltd to pay the costs.

Gervasoni Madise da Silva Passos

Delivered in open court in Luxembourg on 12 December 2018.

E. Coulon S. Gervasoni

Registrar President

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* Language of the case: English.