Reports of Cases

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

18 October 2023 *

(Competition – Agreements, decisions and concerted practices – Modafinil market – Decision finding an infringement of Article 101 TFEU – Patent dispute settlement agreement – Restriction of competition by object – Characterisation – Restriction of competition by effect – Conditions for exemption under Article 101(3) TFEU – Fines)

In Case T-74/21,

Teva Pharmaceutical Industries Ltd, established in Petah Tikva (Israel),

Cephalon Inc., established in West Chester, Pennsylvania (United States),

represented by D. Tayar, S. Ortoli and A. Richard, lawyers,

applicants,

v

European Commission, represented by G. Conte, T. Franchoo and C. Sjödin, acting as Agents,

defendant,

THE GENERAL COURT (Third Chamber, Extended Composition),

composed of F. Schalin (Rapporteur), President, M. Jaeger, P. Škvařilová-Pelzl, I. Nõmm and D. Kukovec, Judges,

Registrar: M. Zwozdziak-Carbonne, Administrator,

having regard to the written part of the procedure,

further to the hearing on 14 December 2022,

gives the following

* Language of the case: English.

Judgment

1 By their action under Article 263 TFEU, the applicants, Teva Pharmaceutical Industries Ltd ('Teva') and Cephalon Inc., seek annulment of Decision C(2020) 8153 final of the European Commission of 26 November 2020 relating to a proceeding under Article 101 TFEU and Article 53 of the EEA Agreement (Case AT.39686-CEPHALON) ('the contested decision') and, in the alternative, the cancellation or reduction of the fines.

I. Background to the dispute

2 Cephalon is a United States-based biopharmaceutical company supplying both originator and generic pharmaceutical products worldwide. Cephalon's principal activities encompass research and development and bringing to the market medicinal products with a particular focus on central nervous system disorders, including sleep disorders, pain, oncology, inflammatory disease and regenerative medicine.

3 Teva is a multinational pharmaceutical company which is active in the development, production and marketing of generic medicinal products as well as innovative and speciality pharmaceuticals, active pharmaceutical ingredients and over-the-counter products.

4 In October 2011, after the Commission approved the notified concentration, by Decision C(2011) 7435 final (Case COMP/M. 6258 – Teva/Cephalon) of 13 October 2011 pursuant to Article 6(1)(b) of Council Regulation (EC) No 139/2004 of 20 January 2004 on the control of concentrations between undertakings ('the EC Merger Regulation') (OJ 2004 L 24, p. 1), Cephalon was acquired by Teva.

A. The relevant product and the applicable patents

5 The present case concerns medicinal products containing the active pharmaceutical ingredient ('API') modafinil. Modafinil is a long-acting wake-promoting agent used for the treatment of certain sleep disorders.

6 Modafinil was discovered by Laboratoire Lafon, a French pharmaceutical company, in 1976. Lafon first registered its modafinil product under the brand name Modiodal, on 24 June 1992 in France, then under the brand names Provigil, Vigil and Modasomil in other countries.

7 In 1993, Cephalon obtained exclusive rights to modafinil from Lafon and ultimately, in 2001, acquired the entire company. In 1997, Cephalon started selling modafinil under the brand name Provigil in the United Kingdom. By 2005, it was selling modafinil in several countries in the European Economic Area (EEA).

8 In the EEA, Cephalon's various national compound patents for modafinil API expired at the latest in 2003, while data protection in relation to that active API expired at the latest in 2005.

9 Although the compound patents for modafinil had expired, Cephalon still owned particle size secondary patents and other modafinil-related patents with an expiry date in 2015 in the EEA.

10 Provigil was the most important product in Cephalon's portfolio in terms of sales. In the light of the imminent entry on the market of generic products and in order to protect its business in the area in question, Cephalon also worked on a second-generation product (named Nuvigil), based on modafinil API, which it planned to place on the market to replace Provigil from 2006 onwards, first in the United States and subsequently in the EEA. In addition, Cephalon had planned to launch another modafinil-based medicinal product, named Sparlon. Ultimately, Cephalon launched neither Nuvigil nor Sparlon in the EEA. Moreover, the latter has not been authorised in the United States.

11 When, at the end of 2002, four generic companies (including Teva) applied for regulatory authorisation to market their generic modafinil products in the United States, Cephalon initiated patent infringement proceedings against them in the United States.

12 Teva launched its generic modafinil product in the United Kingdom in June 2005.

13 On 6 July 2005, following an exchange of letters, Cephalon initiated patent court proceedings against Teva before the High Court of Justice (England & Wales) (United Kingdom) and applied for an interim injunction to prevent Teva from selling its generic modafinil product in the United Kingdom. Teva then filed a counterclaim for revocation.

14 Prior to the hearing on the request for an interim injunction scheduled for 11 July 2005, Teva agreed to stop selling generic modafinil products in the United Kingdom. In exchange, Cephalon agreed to provide a bond of 2.1 million pounds sterling (GBP) (that is approximately EUR 3.07 million) in the event that Teva succeeded in the court proceedings and was entitled to claim damages for foregone profit.

15 The negotiations for a settlement agreement started at the end of November 2005.

B. The agreement at issue

16 On 8 December 2005, Cephalon and Teva concluded a settlement agreement ('the settlement agreement'). They also entered into the settlement agreement for their affiliates and that agreement became effective on 4 December 2005.

17 The agreement provides, inter alia, that, under Article 2, Teva commits not to enter the market independently and not to compete with Cephalon in the modafinil market ('the non-compete clause') and not to challenge Cephalon's modafinil patent rights ('the non-challenge clause') (together 'the restrictive clauses').

Articles 2.2 to 2.6 of the settlement agreement provide for a package of transactions relating to:

– a licence from Teva to Cephalon in respect of Teva's intellectual property rights;

– a licence from Cephalon to Teva to use the data (known as CEP-1347) codeveloped by Cephalon in the connection with studies on the treatment of Parkinson's disease;

– the supply by Teva to Cephalon of the modafinil API;

– payments from Cephalon to Teva for avoided litigation costs;

– the distribution by Teva of Cephalon's products in the United Kingdom.

18 Similarly, Article 3 of the settlement agreement provides for generic rights to be granted to Teva. Under that article, Cephalon grants to Teva a non-exclusive licence to launch its generic modafinil product, including in the EEA, from 2012 (or earlier, in the event that any other entity were to enter the market with a generic modafinil product).

19 In accordance with Article 4 of the settlement agreement, Teva and Cephalon undertook to end immediately their modafinil litigation in the United States and the United Kingdom.

20 The settlement agreement also includes the amounts or royalties involved in the various transactions referred to in paragraphs 17 and 18 above.

C. Contested decision

21 On 26 November 2020, the Commission adopted the contested decision.

22 The Commission found that the applicants had infringed Article 101 TFEU and Article 53 of the EEA Agreement by participating in the settlement agreement in the pharmaceutical sector in exchange for a reverse payment. The infringement covered Austria, Belgium, Bulgaria, Cyprus, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Spain, Sweden and the United Kingdom, and lasted from 4 December 2005 to 12 October 2011, except for Bulgaria and Romania, where the infringement started on 1 January 2007, and Hungary, where it ended on 14 June 2011 (Article 1 of the contested decision).

23 For the abovementioned infringement, the Commission imposed fines on Cephalon and Teva amounting to EUR 30 480 000 and EUR 30 000 000 respectively (Article 2 of the contested decision).

II. Forms of order sought

24 The applicants claim that the Court should:

– annul the contested decision in its entirety;

– in the alternative, cancel the fines imposed on them;

– in the further alternative, with respect to Teva, substantially reduce the fine imposed on it;

– order the Commission to pay the costs.

25 The Commission contends that the Court should:

– dismiss the application;

– order the applicants to pay the costs.

III. Law

A. The form of order seeking annulment or partial annulment of the contested decision

26 The applicants put forward four pleas in law. According to the first plea, the Commission erred legally and factually in so far as it characterised the settlement agreement as a restriction of competition by object. According to the second plea, the Commission erred legally and factually in so far as it characterised the settlement agreement as a restriction of competition by effect. The third plea, raised in the alternative, is based on an erroneous application of Article 101(3) TFEU. Last, by the fourth plea, raised in the alternative also, the applicants seek cancellation of the fines imposed on them or, at least, substantial partial cancellation of the fine imposed on Teva.

1. The first plea, alleging that the Commission erred legally and factually in so far as it characterised the settlement agreement as a restriction of competition by object

27 In their first plea, the applicants submit that the Commission erred legally and factually in characterising the settlement agreement as a restriction of competition by object.

28 The applicants claim that the Commission misapplied the two-part test specified in the judgment of 30 January 2020, *Generics (UK) and Others* (C-307/18, EU:C:2020:52). It follows from that judgment that a settlement agreement providing for transfers of value qualifies as a restriction by object only if, first, the transfer of value 'cannot have any explanation other than the commercial interest of both the holder of the patent and the party allegedly infringing the patent not to engage in competition on the merits' and, second, the agreement does not entail 'proven pro-competitive effects capable of giving rise to a reasonable doubt that it causes a sufficient degree of harm to competition'.

29 The present plea is divided into four parts. In the first part, the applicants submit that the first prong of the test mentioned in paragraph 28 above should be understood as meaning whether 'each commercial transaction has a plausible explanation other than market sharing'. The applicants complain that the Commission substituted that test with a counterfactual test which seeks to ascertain whether the applicants would have entered into the same transactions on the same terms if the settlement agreement had not been concluded. In the second part of the plea, the applicants complain that the Commission failed to satisfy that prong of the test by not refuting the evidence they had submitted in the administrative procedure, showing that each transaction could be explained by factors other than the parties' interest in refraining from engaging in competition on the merits. In addition, in the third part of the plea, which refers to the second prong of the test referred to in paragraph 28 above, the applicants submit that the settlement agreement had 'proven pro-competitive effects' by providing for Teva's early market entry. Lastly, in the fourth part of the plea, the applicants complain that the Commission erred in its assessment of the context and terms of the settlement agreement.

(a) First part of the first plea, alleging failure to apply the proper legal test

30 According to the applicants, the Commission distorted the test established in the judgment of 30 January 2020, *Generics (UK) and Others* (C-307/18, EU:C:2020:52), confirmed by the judgment of 25 March 2021, *Lundbeck* v *Commission* (C-591/16 P, EU:C:2021:243), in two ways, namely (i) by rejecting the express teaching of the judgment of 30 January 2020, *Generics (UK)*

and Others (C-307/18, EU:C:2020:52), that payment by the manufacturer of originator medicines to the manufacturer of generic medicines as reasonable consideration for the supply of services or goods precluded a finding of an infringement by object and (ii) by adopting and applying a counterfactual test that falls within a by-effect analysis.

31 According to the applicants, thus referring to their arguments put forward in the context of the second part of the present plea, each commercial transaction covered by the settlement agreement was justified independently of the restrictive clauses and had a 'plausible' explanation other than 'solely' as consideration for Teva's delayed entry into the modafinil market.

32 Furthermore, introducing a counterfactual analysis into the assessment of an alleged restriction of competition by object is not consistent with the case-law. The determination of the counterfactual scenario is a complex task which should take into consideration not only the legal and economic context of an agreement at the time it was concluded but also any subsequent developments. Moreover, the counterfactual analysis falls within the assessment of agreements as restrictions of competition by effect. In the judgment of 30 January 2020, *Generics (UK) and Others* (C-307/18, EU:C:2020:52), the Court did not apply a counterfactual test; rather, it applied a straightforward factual test requiring a plausible explanation for the business deals that actually occurred.

33 The Commission also erred in evaluating the commercial transactions contained in the settlement agreement as a 'package', 'irrespective of [the] exact quantification and the actual contribution of each transaction to the overall value transfer'. The Commission thus ignores the contribution from the judgment of 30 January 2020, *Generics (UK) and Others* (C-307/18, EU:C:2020:52), that each alleged value transfer should be assessed for a plausible explanation other than solely as consideration for restrictive clauses.

34 In the reply, the applicants complain that the Commission erred in law by basing the contested decision on subjective evidence only, whereas it follows from the case-law that an infringement by object can be established only on the basis of objective factors. The Commission ignored the objective reasonableness of the consideration, the business purpose and the context in which the business deals were negotiated.

35 Lastly, the Commission erred in law with regard to the burden of proof by requiring the parties to demonstrate with subjective evidence that they would have completed the transactions at issue in the counterfactual scenario where no settlement agreement had occurred and litigation had continued. However, the burden of proof lies with the Commission. Moreover, the evidence contemporaneous with the facts and the expert reports produced before the Commission provide a plausible explanation for the business deals that the Commission cannot not reject in the absence of significant experience to the contrary.

36 The Commission disputes the applicants' arguments.

37 It follows from the case-law that the concept of 'restriction of competition by object' can be applied only to some forms of coordination between undertakings which reveal, by their very nature, a sufficient degree of harm to the proper functioning of normal competition for the view to be taken that it is not necessary to assess their effects (see, to that effect, judgment of 30 January 2020, *Generics (UK) and Others*, C-307/18, EU:C:2020:52, paragraph 67 and the case-law cited).

38 As regards, specifically, settlement agreements, similar to the settlement agreement, relating to disputes over a process patent for the manufacture of an API that is in the public domain and concluded between a manufacturer of originator medicines and several manufacturers of generic medicines, which had the effect of delaying the entry of generic medicines on the market in return for pecuniary or non-pecuniary transfers of value from the former to the latter, the Court has held that such agreements cannot be considered, in all cases, to be a 'restriction by object' for the purpose of Article 101(1) TFEU (see, to that effect, judgment of 30 January 2020, *Generics (UK) and Others*, C-307/18, EU:C:2020:52, paragraphs 84 and 85).

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

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

41 It follows that the characterisation of agreements, such as the settlement agreement, as a 'restriction by object' presupposes an assessment of the specific characteristics of those agreements, which must be used to infer the potential particular harmfulness of the agreements for competition, where necessary as a result of a detailed analysis of those agreements, their objectives and the economic and legal context, in the context of which the amount of the transfers of value is of particular importance (see, to that effect, judgment of 30 January 2020, *Generics (UK) and Others*, C-307/18, EU:C:2020:52, paragraph 89).

42 In the present case, it is apparent from Section 5 of the contested decision, and in particular from recitals 544 to 580, that the Commission explained on the basis of the existing case-law, including the case-law cited in paragraph 37 et seq. above, which analysis it was to carry out. In Section 6 of the contested decision, the Commission, in accordance with the case-law and the principles set out in Section 5, examined whether the transactions contained in the settlement agreement and the related transfers of value were an incentive for Teva to accept the restrictive clauses.

43 Thus, it is apparent from the case-law cited in paragraph 37 et seq. above that it is appropriate to proceed to an overall assessment including the interests and incentives of the parties concerned, in order to ascertain whether the commercial transactions contained in a settlement agreement, such as those referred to in paragraph 17 above, could have any explanation other than the commercial interest of both the patent holder and the party allegedly infringing the patent not to engage in competition on the merits.

44 In that regard, it should be noted – and this is not disputed by the applicants – that a transfer of value to the manufacturer of generic medicines may take various forms, such as a direct payment or an indirect payment, which are incorporated into business transactions between the manufacturer of originator medicines and the manufacturer of generic medicines. Such a business transaction may therefore provide the manufacturer of generic medicines with benefits which it would not obtain under normal market conditions, either because such a transaction would not have been carried out under normal market conditions or because that transaction was carried out under more favourable conditions than normal market conditions. In addition, it must be pointed out that, under normal market conditions, it is not usual for the consideration for a transaction to consist of a non-compete and a non-challenge commitment.

45 Accordingly, the Commission was required to ascertain whether the commercial transactions covered by the settlement agreement would also have been concluded, on equally favourable terms, absent the restrictive clauses. If the Commission is able to find that the transactions in question would not have been concluded or would not have been concluded on such favourable terms absent those clauses, it can be concluded that those transactions cannot have any explanation other than the commercial interest of the holder of the patent at issue and of the party allegedly infringing the patent not to engage in competition on the merits.

46 In order to determine whether the only plausible explanation for each of the commercial transactions was to induce Teva to accept the restrictive clauses and thus to refrain from competing with Cephalon on the merits or whether those transactions would have been concluded in any event under normal market conditions, the Commission had to compare what had actually happened with what would have happened absent the restrictive clauses. It follows that the argument that the Commission applied an incorrect counterfactual analysis must be rejected as unfounded.

47 Similarly, contrary to what the applicants claim, the legal test applied by the Commission does not amount to a counterfactual analysis falling within the assessment of agreements as restrictions by effect.

48 The Commission only examined whether the commercial transactions in question would have been concluded without the restrictive clauses in order to ascertain whether they constituted an incentive for Teva to refrain from competing with Cephalon on the merits.

49 As is apparent from the case-law cited paragraph 37 et seq. above, the assessment to be made in order to establish whether or not an agreement is to be characterised as a 'restriction by object' is not intended to identify and to quantify the anticompetitive effects of a practice, but solely to determine its objective seriousness, which can justify precisely there being no need to assess its effects (see, to that effect, judgment of 25 March 2021, *Arrow Group and Arrow Generics* v *Commission*, C-601/16 P, not published, EU:C:2021:244, paragraph 86).

50 The fact that that assessment must be carried out, where necessary following a detailed analysis of the agreement concerned and in particular of the incentive effect of the transfers of value for which it provides, but also of its objectives and the economic and legal context of which it forms part does not also imply an assessment of the anticompetitive effects of that agreement on the market. It involves solely carrying out a detailed overall assessment of the complex agreements themselves in order not only to rule out their being characterised as a 'restriction by object' where there is doubt as to whether they are sufficiently harmful to competition, but also to preclude agreements from failing to be characterised as a 'restriction by object' by reason of their

complexity alone and even though the detailed assessment of those agreements demonstrates that they reveal, objectively, a sufficient degree of harm to competition (judgment of 25 March 2021, *Arrow Group and Arrow Generics* v *Commission*, C-601/16 P, not published, EU:C:2021:244, paragraph 87).

51 As regards the applicants' argument that the restriction-by-object test applied by the Commission in the contested decision is contrary to the judgment of 30 January 2020, *Generics (UK) and Others* (C-307/18, EU:C:2020:52), on the ground that each ancillary transaction had a reasonable remuneration paid by the manufacturer of originator medicines to the manufacturer of generic medicines for the supply of services or goods, it should be borne in mind that, in that judgment, the Court did not in fact rule out the possibility that, in certain cases, a settlement agreement involving either pecuniary or non-pecuniary transfers of value might not be characterised as a 'restriction by object'. That would be the case if those transfers of value could prove to be justified, that is to say, appropriate and strictly necessary having regard to the legitimate objectives of the parties to the agreement. However, admittedly, that question must be examined in the context of the second part of the present plea, in which the applicants claim that the transactions concluded alongside the settlement agreement had a plausible explanation other than that of serving solely as consideration for the restrictive clauses.

52 As regards the claim that the Commission based its assessment in the contested decision solely on the subjective intention of the parties, it must be recalled that, in order to assess whether an agreement involves a restriction 'by object', regard must be had to the content of its provisions, its objectives and the economic and legal context of which it forms a part. It also follows from the case-law that, although the parties' intention is not a necessary factor in determining whether an agreement 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 2 April 2020, *Budapest Bank and Others*, C-228/18, EU:C:2020:265, paragraph 53 and the case-law cited). The question whether the Commission relied solely on subjective factors in its assessment will be examined in the context of the second part of the present plea.

53 As regards the burden of proof, it is for the Commission to demonstrate that, in the relevant context, the non-compete and non-challenge clauses concluded in the context of the settlement agreement concerned gave rise to an agreement that restricts competition by object and therefore to demonstrate that it is plain from the examination of that agreement that the transfers of value provided for therein cannot be have any explanation other than the commercial interest of both the holder of the patent at issue and the party allegedly infringing the patent not to engage in competition on the merits (see case-law already cited in paragraph 39 above).

54 However, contrary to the applicants' contention, the Commission can only rely on legal and economic elements taken into account by them during the negotiations leading to the settlement agreement, including the commercial transactions. Elements subsequent to the conclusion of the settlement agreement cannot form part of the relevant framework, as the parties could not have taken them into account when they decided to conclude that agreement.

55 In so far as the applicants argue that there was a lack of experience in EU law, at the time of the adoption of the contested decision, to characterise the agreement at issue as a 'restriction by object', it is sufficient to refer to the judgment of 30 January 2020, *Generics (UK) and Others* (C-307/18, EU:C:2020:52), and to that of 25 March 2021, *Lundbeck* v *Commission* (C-591/16 P, EU:C:2021:243). In the first judgment, the Court indicated the conditions under which a

settlement agreement should be characterised as a 'restriction by object'. In the second judgment, the Court pointed out, in paragraph 130, that it is in no way necessary that the same type of agreement has already been censured by the Commission in order for such agreements to be considered to be restrictive of competition by object, and that remains the case even if they occur in a specific context, such as that of intellectual property rights. Consequently, that argument cannot succeed.

56 As regards the argument that the Commission assessed the commercial transactions as a 'package', it is sufficient, at this stage, in the first place, to note that the commercial transactions contained in the settlement agreement were concluded as forming part of a package. The fact that the settlement agreement and the transactions included therein are concluded concomitantly or that there is a contractual link between them is an indication that those agreements form part of a single contractual framework. In that case, there is a risk that the linking of a business deal with a settlement agreement containing non-marketing and non-challenge clauses, which are, by themselves, restrictive of competition, is actually intended – under the guise of a commercial transaction, taking the form, as the case may be, of a complex contractual arrangement – to induce the company manufacturing generic medicines to accept those clauses, through a transfer of value provided for in the side deal. In that context, as already indicated in paragraph 45 above, the question whether such a transaction would also have been concluded under normal market conditions forms part of the assessment which the Commission must carry out. In the second place, it should be noted that, after such an assessment, it is the net gain of the transfers of value made in the context of the transaction package that matters, as is apparent from the case-law cited in paragraph 40 above.

57 It follows from the foregoing that, subject to certain arguments to be examined in the context of the second part of the present plea, the first part of the first plea must be rejected as unfounded.

(b) Second part of the first plea

58 In the second part of the first plea, the applicants claim that the transactions concluded alongside the settlement agreement had a plausible explanation other than that of serving solely as consideration for the restrictive clauses.

59 Each of the transactions finds it origins not in the evolution of negotiations over the entry of Teva's modafinil product on the market for generic medicines, but rather in the well-documented and pre-existing legitimate business needs of both parties. For each transaction, Teva or Cephalon was either the only party with which to do business (as in the case of Teva's modafinil intellectual property rights and Cephalon's clinical data) or a potential partner with uniquely suitable experience (as in the case of Teva's modafinil API capacity or Teva's United Kingdom distribution platform).

60 The Commission disputes the applicants' arguments.

61 In the light of the complaints put forward by the applicants, it is necessary to ascertain, at the outset, whether, for each of the commercial transactions provided for in the settlement agreement, the Commission made an error of assessment in concluding that the purpose of that transaction was to serve as a transfer of value from Cephalon to Teva in consideration for Teva's commitment not to enter independently the market for generic medicines and not to compete with Cephalon on modafinil.

(1) The licence to Teva's intellectual property rights in modafinil

62 Under Article 2.2 of the settlement agreement, Cephalon agreed to purchase from Teva a (non-exclusive) licence to the latter's intellectual property rights ('the IPRs') for a total amount of 125 million United States dollars (USD) (approximately EUR 92.9 million).

63 In recital 864 of the contested decision, the Commission concluded that Teva had obtained a significant value by licensing its IPRs to Cephalon. As regards Cephalon, the Commission stated that it was not interested in acquiring Teva's IPRs, had no real need to acquire those rights prior to the settlement agreement and had no incentive to pay significant amounts for an IPR licence that was of no value or at most of limited value to Cephalon. In the Commission's view, the facts therefore strongly suggest that Cephalon would not have entered into that transaction at all or, in any event, would not have done so on the same terms, absent the settlement agreement, and that the purpose of the transaction was to serve as a transfer of value from Cephalon to Teva in consideration for the latter's commitment not to enter the modafinil markets independently and not to compete with Cephalon on the merits. The Commission also considered that alternative explanations provided by the parties for the transaction were not plausible. The licence to Teva's IPRs therefore involved an unjustified transfer of value to Teva, which Teva would not have been able to obtain absent the settlement agreement.

64 The applicants dispute the Commission's assessment in the contested decision that, at the time of the settlement agreement, Cephalon did not consider Teva's IPRs as a serious threat and had never previously shown any interest in acquiring them.

65 According to the applicants, the scientific evidence shows that Cephalon's modafinil products were likely to be found to infringe Teva's United States patent application for 'Form III' modafinil (a crystalline form of modafinil, filed in 2000 and published in 2002).

66 The applicants maintain that Cephalon's Vice President, Mr M., also in charge of Worldwide Chemical Research and Development, immediately focused on Teva's claims to modafinil polymorphs after reading those applications. Cephalon then commissioned a study, completed in March 2003, from Crystallics BV, received the results of a study conducted by Professor C. of the University of Rouen (France) in 2004 and received the preliminary results of a study carried out by Solid State Chemical Information, Inc. (SSCI) in January 2006.

67 Through those studies, Cephalon sought to ascertain whether its own processes created the polymorphs that Teva was claiming, and the likelihood that Form III would remain during the commercial manufacturing process.

68 According to the applicants, the scientific evidence that Cephalon collected from 1995 to 2005 led to incremental learning that revealed an infringement risk.

69 In addition, the applicants state that Cephalon also called on the expert opinion of Professor M. of the Massachusetts Institute of Technology (MIT), who concluded that Cephalon ran the risk that Form III, the subject of Teva's patent applications, would be detected in its final product. The applicants claim the following, in particular:

– Teva was very likely to prevail in any United States Patent and Trademark Office legal or 'interference' proceedings that challenged its patent rights to Form III, so the Commission should not have called into question Cephalon's business judgment to remedy that risk;

– the fact that Cephalon had launched Provigil in the United States in advance of Teva's patent application priority date did not alleviate the risk posed to Cephalon, as the Commission erroneously claims;

– the Commission's assertion that no infringement risk existed simply because Cephalon had not actually detected Form III in its final product by December 2005 ignores the state of science;

– as regards the absence of documents, it is common practice in the United States not to document infringement concerns for fear that those documents will be used at trial to prove not only infringement, but in addition, wilful infringement subject to treble damages;

– the royalty payable by Cephalon under the licence agreement in respect of Teva's IPRs was reasonable and the Commission has provided no evidence to the contrary.

70 The Commission refutes the applicants' arguments.

71 It is apparent from the contested decision that the Commission, in support of its finding that the licence to Teva's IPRs had involved an unjustified transfer of value to Teva (see paragraph 63 above), relied, inter alia, on the one hand, on evidence contemporaneous with the conclusion of the settlement agreement, which shows that Cephalon did not really feel threatened by Teva's IPRs and had never before shown any interest in acquiring them, and, on the other hand, on Cephalon's lack of due diligence.

72 As can be seen from the file, Cephalon had known since 2002 that Teva had filed a patent application for Form III, that some residual amounts of the forms could, as the case may be, be detected in Cephalon's final product, that Form III could fuse between two Form I crystals (this is referred to as 'twinning' of Forms I and III modafinil) and that Form III was a patentable subject matter. The fact remains that there are no strong indications that Cephalon was genuinely concerned, at the material time, about the possible consequences of Teva's patent application for Form III.

73 Cephalon was aware as early as 1999 that Form III modafinil was created during the manufacturing process, but that it then turned into Form I modafinil during that process (according to Lafon studies).

74 It is true that Cephalon, after becoming aware of Teva's patent application for Form III modafinil and before the settlement agreement was concluded, commissioned research.

75 In the first place, there was a request to Crystallics for a study to understand better the influence of the conditions of the various polymorphs and the process monitoring. The outcome of the study, completed in 2003, showed that, under the vast majority of crystallisation conditions, the resulting modafinil was a mixture of Forms I and III.

76 In the second place, Cephalon received, in 2004, the results of a study conducted by Professor C. of the University of Rouen, which, however, had not been requested by Cephalon. The study showed that the structures of Form I and Form III modafinil were very similar and that the two polymorphic forms had a propensity to grow as twin crystals.

77 However, it is apparent from the file that those studies and their results did not give rise to any particular concern on Cephalon's part.

78 An internal presentation in 2003, referring to Teva's claims in relation to crystalline forms of modafinil, showed that Cephalon assumed that there would probably be an 'interference proceeding' between Cephalon and Teva, but that it had the earlier rights, such that there was no cause for concern.

79 Similarly, in an internal email of August 2005, Dr H., Cephalon's Chief Patent Counsel, stated that he knew, and has long be familiar with the 'patent landscape' for modafinil in the United States and Europe and that there was no reason to be concerned about 'potential infringement problems'.

80 In the third place, as regards the study carried out by SSCI, which was requested by Cephalon before the settlement agreement was concluded, it should be noted that the preliminary results were not received by Cephalon until after the agreement was concluded, namely on 6 January 2006. Consequently, those results could not have been taken into account by Cephalon in assessing whether there was a risk of infringement upon entering into the settlement agreement and they are not relevant in determining whether Cephalon had an interest in Teva's IPRs.

81 In the fourth place, the same conclusion must be drawn as regards the M. report (namely an opinion by Professor M. of MIT) requested by the applicants during the administrative procedure, dated 2018.

82 The applicants' argument that it involves 'incremental learning' is not convincing, nor is the argument that Cephalon was very concerned 'at the end of 2005'. In that regard, it must be stated that Cephalon did not take any steps with regard to Teva between 2003 and 2005, even though it did not lack the necessary knowledge to do so. As a result, the patentability decision of the United States Patent and Trade Mark Office of September 2005 does not explain the alleged sudden concern, given that Cephalon was itself seeking, in 2003, to patent Form III modafinil, which confirms that it knew at least in 2003 (see paragraph 72 above) that it was a patentable subject matter. In addition, at the time of the settlement agreement, Cephalon had not detected any trace of polymorphic Form III modafinil, either in its modafinil API or in the final Provigil product.

83 Moreover, there is no documentary evidence of any concern on Cephalon's part. The applicants' argument that the lack of evidence contemporaneous with the facts is explained by United States procedural law must be rejected.

84 In that regard, in the first place, in so far as a document falls under the 'legal privilege' rule, it is protected and cannot be disclosed before the United States courts.

85 In the second place, by contrast, it is apparent from the file that certain evidence contemporaneous with the facts corroborates the fact that Cephalon considered that its products did not infringe Teva's IPRs. Moreover, like the Commission, it must be held that, if Cephalon had genuinely perceived a risk of infringement of Teva's IPRs, it would have acted to address that risk, which it did not do. Moreover, even at the time Teva approached Cephalon in July 2005 to discuss a licence for its IPRs, Cephalon did not express any interest in such a licence outside the scope of the settlement agreement.

86 Finally, Cephalon's failure to perform due diligence in that respect can be explained if it is assumed that the grant of a licence to Teva's IPRs to Cephalon was essentially intended to induce Teva to accept the restrictive clauses. In particular, it is clear from the above that Cephalon had

not shown any real interest, outside the scope of the settlement agreement, in obtaining a licence. Furthermore, Cephalon's assertion that it was well aware of the patent situation with regard to modafinil is not convincing. Indeed, it fails to explain why Cephalon agreed to purchase the licence to Teva's IPRs without evaluating the amount of royalties to be paid and why Cephalon immediately paid a substantial part of those royalties unconditionally, without being certain that Teva's patent application would actually be granted. Finally, it should be noted that standard provisions protecting Cephalon's interests were not even stipulated in the licence agreement.

87 Accordingly, it must be held that the Commission was fully entitled to conclude, in the contested decision, that the level of the transfer of value made by the licence to Teva's IPRs does not have any explanation other than the fact that it constituted consideration for Teva's acceptance of the restrictive clauses.

(2) The modafinil API supply agreement

88 Under Article 2.4 of the settlement agreement, Teva and Cephalon undertook to enter into a supply agreement, pursuant to which, in the first place, Teva would supply Cephalon with a minimum volume of 10 000 kg of modafinil API per year between 2007 and 2011 (at least 50 000 kg in total) and, in the second place, Cephalon would pay Teva a fixed minimum price, explicitly designed to reflect Teva's approximate manufacturing costs, plus 30%, for a total amount of USD 28 million between 2007 and 2011. Consequently, on 7 November 2006, Teva, through its subsidiary Plantex, and Cephalon entered into a contract implementing the conditions set out in Article 2.4 of the settlement agreement ('the modafinil API supply agreement').

89 In recital 781 of the contested decision, the Commission concluded that, for Teva, the terms of the modafinil API supply agreement represented a guaranteed stable revenue stream for five years, which it could not have obtained without agreeing to the non-compete and non-challenge commitments in the settlement agreement. With regard to Cephalon, the Commission concluded, in the contested decision, that it would not have agreed to enter into the modafinil API supply agreement without those commitments, since it would not have been economically rational for it to do so in the light of its supply and demand situation at the time and of the terms of that agreement.

90 The applicants dispute the Commission's finding with regard to Cephalon. Cephalon was facing the risk of undersupply of modafinil API, which is also apparent from documents contemporaneous with the facts such as the email of 29 December 2005. In addition, the applicants complain that the Commission based its decision on a selective and imbalanced review of the record as regards Cephalon's supply capacity and the pricing terms agreed with Teva.

91 In this context, the applicants explain that, in late November 2005, in the wake of an announcement by the Food and Drug Administration (FDA, United States) that Sparlon was likely to be approved, Cephalon increased its internal estimates of modafinil API needs for the production of Provigil, Nuvigil and Sparlon – of which the latter two medicinal products were due to be launched imminently – from 96 000 kg to 138 500 or 148 000 kg, when supply capacity left little room to handle increased demand or an unexpected reduction in output. In that regard, the applicants observe that, as regards the two Cephalon facilities located in Mitry-Mory (France), one (namely the C-1 facility) was old and the other (namely the C-2 facility), although new, still required regulatory approval, and that it was also unlikely that its external supplier, Helsinn, would have been able to increase its output.

92 The more prudent and safer course to take in order to hedge this risk of undersupply was therefore to enter into an agreement with Teva. According to Cephalon, Teva was a logical partner since it had advanced modafinil production capabilities from its own efforts to launch modafinil products. Moreover, the total amount payable under that agreement was only a small fraction of the losses that Cephalon would have incurred if its API supply had been insufficient.

93 The Commission disputes the applicants' arguments.

94 First, it should be noted that the applicants do not question Teva's interest and that their criticism concerns only Cephalon's interest in entering into the supply agreement.

95 Second, the claim that the Commission called into question Cephalon's business judgment or carried out a selective and imbalanced review of the record cannot succeed. In that regard, it must be noted that, in the contested decision, the Commission based its conclusion on documents contemporaneous with the facts, most of which came from Cephalon itself. The Commission subsequently confined itself to verifying the plausibility of the applicants' claims in the light of the facts which emerged from the evidence.

96 It is indeed clear from the evidence in question that Cephalon's estimated supply capacity from 2007 onwards was sufficient to meet its projected demand.

97 It is apparent in that regard (see paragraph 91 above) that Cephalon's supply chain consisted of its facilities in Mitry-Mory, namely the existing C-1 facility and the new C-2 facility, as well as an external supplier, Helsinn.

98 It can be seen from Cephalon's documents, which are contemporaneous with the facts, that at the end of 2005 it estimated its claims for modafinil API:

– for 2006, between 115 000 and 148 000 kg, when it could have access to a total of approximately 146 000 kg (namely 37 000 kg from the C-1 facility, 29 400 kg from the C-2 facility and 80 000 kg from its supplier Helsinn);

– for 2007, between 117 000 and 146 000 kg, when it could have access to a total of approximately 230 000 kg (namely 37 000 kg from the C-1 facility, 74 000 kg from the C-2 facility and 120 000 kg from Helsinn);

– for 2008, between 137 000 and 160 000 kg, when it could have access to a total of approximately 230 000 kg (namely 37 000 kg from the C-1 facility, 74 000 kg from the C-2 facility and 120 000 kg from Helsinn).

99 From those figures, it can be inferred, as regards 2007 and 2008, that Cephalon's forecast supply capacity exceeded forecast demand and that therefore there was no long-term undersupply issue. Accordingly, the Commission was entitled to conclude that undersupply concerns were not a plausible explanation for Cephalon entering into the agreement.

100 In addition, there is no trace in the file of any concern on the part of Cephalon about a possible under-capacity to supply modafinil API on the long term.

101 Admittedly, it is apparent from an email of 29 December 2005, referred to by the applicants, that there were concerns about supply. However, those concerns related only to the beginning of 2006, and not to the following period. As a result, the modafinil API supply agreement concluded with Teva could not alleviate those concerns for 2006, as it related to the supply for the period from 2007 to 2011. In addition, it is apparent from the email that an internal solution to remedy the problem reported for the first half of 2006 was available, namely, slowing down or stopping production of R-modafinil (that is to say the Nuvigil API) for two to three months to build up some modafinil inventory to support any increases in demand for Provigil and any increases in projected sales for Sparlon after its launch.

102 Moreover, the email of 29 December 2005 postdates the signature of the settlement agreement. If there had been a real concern about a possible long-term undersupply issue, it would have been mentioned in that email, as would the choice of Teva as a new source of supply.

103 As regards the applicants' criticism of the pricing analysis agreed between Cephalon and Teva (recitals 404 to 407, 749, 750 and 765 of the contested decision), it is sufficient to note that it is apparent from the foregoing that Cephalon's conclusion of the API modafinil supply agreement had not been motivated by genuine concerns about the lack of sufficient long-term modafinil API supply. Given that the arguments relating to pricing are based on the premiss that Cephalon rightly sought an additional source of supply in order to protect itself against the risk of shortage, they can be rejected as ineffective.

104 In any event, it follows from the analysis carried out by the Commission in the contested decision, based on the evidence in the file, that the modafinil API prices stipulated in the modafinil API supply agreement were 100 to 300% higher than the prices paid to Helsinn or the internal prices that Cephalon would have paid using its own Mitry-Mory production facilities. Similarly, Teva's prices were even higher than the prices offered by Helsinn in its alternative proposals for a possible new agreement for the supply of modafinil API or by other alternative suppliers. Moreover, the API modafinil supply agreement as it had been concluded represented for Cephalon an inflexible 'take or pay' commitment to purchase fixed volumes of modafinil API at a time when future demand for its pipeline modafinil products (namely Nuvigil and Sparlon) was uncertain because it did not yet have regulatory approvals.

105 It follows from the foregoing that the Commission did not err in considering that the motives relied on by Cephalon to justify behind entering into the modafinil API supply agreement were neither to choose the more prudent nor the safer course to take in order to hedge the risk of undersupply.

106 It also follows from the foregoing that the Commission was fully entitled to conclude that the agreement for the modafinil API supply agreement had contributed to induce Teva to accept the restrictive clauses.

(3) The CEP-1347 arrangement

107 In accordance with Article 2.3 of the settlement agreement, Cephalon granted Teva a licence for clinical and safety data co-developed by Cephalon in connection with studies on the treatment of Parkinson's disease ('the CEP-1347 data'), which Teva needed for the commercial launch of its medicinal product Azilect (which had no connection with modafinil), in exchange for USD 1 million.

108 In recital 810 of the contested decision, the Commission found that access to Cephalon's CEP-1347 data was very valuable for Teva because it could accelerate the commercial launch of its medicinal product Azilect, from which it could expect significant additional sales and profits. As regards Cephalon, the Commission found that it had not evaluated or negotiated independently the price of providing access to CEP-1347 data and that it had used the data as leverage in the negotiations on the settlement agreement, refusing to grant a licence until the agreement was finalised. Consequently, the Commission concluded, in recital 811 of the contested decision, that it was not plausible that Cephalon had given access to the CEP-1347 data in December 2005, absent the non-compete and non-challenge commitments contained in the settlement agreement or, at least, not on the same terms. Accordingly, the Commission concluded that the CEP-1347 arrangement was an unjustified transfer of value, which had contributed to inducing Teva to enter into those commitments in the broader context of the settlement agreement.

109 The applicants submit that the CEP-1347 arrangement did not contribute to the unjustified transfer of value and did not serve as an unlawful reverse payment, as Cephalon transferred the CEP-1347 data at market price.

110 The applicants also dispute the Commission's calculation, in recital 789 of the contested decision, that a one-year delay in the commercial launch of the medicinal product Azilect would have caused a revenue loss in the order of USD 200 million for Teva. In the reply, the applicants submit, on that point, that that estimate is overstated because the Commission relies on a misinterpretation of the regulatory process in the United States. The Commission wrongly starts from the premiss that a delay in FDA approval of Azilect would have cut off a year of Teva's Azilect exclusivity and therefore cost Teva a year of revenue.

111 The Commission disputes the applicants' arguments.

112 It is common ground that Teva contacted Cephalon in order to obtain the right to use the CEP-1347 data. In that regard, it is not disputed that Teva needed the data in order to obtain regulatory approval in the United States, Canada and Australia for its innovative medicinal product Rasagiline, an equivalent of Azilect, in 2006. In 2005, the final approval procedure for the marketing of Azilect, brought by Teva before the FDA, was ongoing. In the context of that approval procedure, the FDA had asked questions about the side-effects profile of Azilect and had requested that further dermatological tests be carried out. A meeting was scheduled in that regard between the FDA and Teva on 7 December 2005. Given that Teva was not in a position to carry out those tests before that date and that it had learned that Cephalon had data that might be important to it, it contacted Cephalon on several occasions.

113 In addition, the evidence shows that Cephalon was aware of Teva's need and that Teva had considered Cephalon's CEP-1347 data to be 'very helpful' and 'crucial' both for the planned meeting with the FDA and for the approval of Azilect in Australia.

114 It is also common ground that Cephalon refused to provide the data to Teva on account of the ongoing patent litigation in which they were involved.

115 In that regard, Teva stated that 'Cephalon took the apparently firm position that it would not provide any data to Teva for its meeting with the FDA until Teva and Cephalon had fully and finally resolved all pending litigation and other issues relating to modafinil'.

116 As the Commission rightly observed in the contested decision, this indicates that Cephalon had made the disclosure of the CEP-1347 data to Teva conditional on the settlement of the ongoing patent litigation, for which the non-compete and non-challenge commitments were essential.

117 As regards the Commission's calculation in recital 789 of the contested decision, it must be noted that that calculation is based on an internal Teva document contemporaneous with the facts and containing Teva's sales projections for Azilect for 2006 to 2009. On the basis of these estimates, it is easy to calculate foregone profit in the event of a delay in the launch of Azilect on the market, as is apparent from the contested decision and the additional explanations provided by the Commission in its written submissions. It follows that such a delay would have resulted in a loss of revenue of the order of USD 200 million and that even a delay of one week would have had significant consequences. This shows that it was important for Teva to have access to the CEP-1347 data as soon as possible.

118 The argument, put forward for the first time in the reply, that the Commission had misunderstood the United States regulatory framework must be rejected as unfounded, without there being any need to examine its admissibility in the light of Article 84(1) of the Rules of Procedure of the General Court.

119 Apart from the fact that there is nothing to indicate that the Commission misunderstood the United States regulatory framework, it is clear from that framework that a patent is valid for a limited period and that restoration can be granted only once. In the present case, it is Teva's perception at the material time that must be taken into account. Since it had already applied for a patent for Rasagiline (the API for Azilect) in 1994, it was aware that exclusivity was temporary and that the duration of the necessary procedures for the approval of Azilect could reduce the duration of that protection. For Teva it was therefore crucial to have the necessary data as soon as possible in order to secure FDA approval.

120 It follows from the foregoing that the Commission was fully entitled to conclude that the CEP-1347 transaction contributed to inducing Teva to accept the restrictive clauses.

(4) The United Kingdom distribution agreement

121 Under Article 2.6 of the settlement agreement, Cephalon undertook, first, to appoint Teva's United Kingdom subsidiary as the exclusive distributor for all its modafinil products in the United Kingdom for five years, with a 20% distribution margin, and, second, to make a one-time payment of EUR 2.5 million to Teva upon Teva's commercial launch of Cephalon's modafinil products.

122 In recital 946 of the contested decision, the Commission concluded that the distribution agreement was valuable for Teva because Teva expected to earn, under that agreement, a minimum profit of EUR 10.5 million from its appointment as exclusive distributor in the United Kingdom (namely a one-time payment of EUR 2.5 million and EUR 8 million profit as a distributor), a profit which it would not have been able to obtain under normal market conditions, at least not for the full amount, absent the settlement agreement. According to the Commission, the facts also clearly show that, from Cephalon's point of view, the transaction has no plausible explanation other than to induce Teva to conclude the settlement agreement. As such, the transaction therefore contributed to the unjustified transfer of value, which constituted consideration for Teva to enter into the commitments in the broader context of the settlement agreement.

123 The applicants dispute the Commission's findings in the contested decision in that regard.

124 After pointing out that Cephalon and Novartis had decided, at the end of 2005, not to renew their distribution agreement, which meant that Cephalon needed a new distribution partner for its modafinil products in the United Kingdom, the applicants argue that Teva, which had already begun distributing its generic modafinil product in the United Kingdom, was the obvious choice. The applicants dispute the Commission's objection that Teva was a competitor, with which the distribution agreement was concluded, because once the parties had decided to conclude a settlement agreement, they were no longer competitors.

125 The applicants submit that the commercial terms of the United Kingdom distribution agreement were reasonable. In that regard, they complain that the Commission focused on the sum of EUR 2.5 million as an upfront commission payment and made much of the fact that the parties could not, ten years later, provide detailed accounting information. Furthermore, they argue that the Commission's assertion that Cephalon did not receive any value in exchange for the one-time payment is false. If Cephalon had, for example, agreed to include the EUR 2.5 million in the running commission, taking Teva's commission from 20% to 25%, there is nothing in the record the Commission can point to that would suggest the compensation was irrational. According to the applicants, and as the settlement agreement makes clear, Cephalon agreed to up-front payment 'in recognition of the cost and expense involved in Teva's preparation for such launch'.

126 The Commission disputes the applicants' arguments.

127 In the context of the examination of the first part of the present plea (see paragraph 45 above), the Court noted that, in order to ascertain whether one of the transactions concluded between the parties under the settlement agreement was, in fact, consideration for Teva's acceptance of the restrictive clauses, or whether that transaction could be explained otherwise, the Commission had to consider whether the parties would have concluded that transaction, or would have concluded it on the same terms, absent those clauses.

128 In the present case, as the Commission rightly pointed out in the contested decision, at the material time Teva had already launched its generic modafinil product on the United Kingdom market and was therefore a direct competitor of Cephalon on that market, which it would have remained without the settlement agreement and the United Kingdom distribution agreement. This finding was not challenged by the applicants.

129 In those circumstances, the Commission was able to conclude, in recital 930 of the contested decision, that 'outsourcing the distribution of [Cephalon's] modafinil products to the biggest rival on the market [created] a conflict of interest' and that, 'absent Teva's non-compete and non-challenge clauses that effectively put an end to Teva's independent modafinil activities worldwide (including the United Kingdom), it would not [have been] economically rational for Cephalon to grant the distribution of [its] modafinil products to Teva, the closest competitor and rival on the market for modafinil in the United Kingdom.'

130 In that regard, the applicants' argument that they were no longer competitors once they had decided to conclude the settlement agreement and, therefore, that their interests were aligned, cannot succeed. The distribution agreement forms part of the settlement agreement and was concluded in the context thereof. Following the applicants' logic would mean taking the view that the Commission could not assess whether a commercial transaction, such as a distribution agreement, constitutes consideration, at least in part, for agreeing to non-compete commitments

contained in a settlement agreement, if that transaction were part of that agreement. That logic also runs counter to the judgment of 30 January 2020, *Generics (UK) and Others* (C-307/18, EU:C:2020:52). In that judgment, the Court of Justice held, in paragraphs 90 and 91, that it was important to take into consideration all the transfers of value, whether of a pecuniary or a non-pecuniary nature, made between the parties, which may involve taking account of indirect transfers resulting, for example, from profits to be obtained by the manufacturer of generic medicines from a distribution contract concluded with the manufacturer of originator medicines enabling the former manufacturer to sell a possibly defined quota of generic medicines manufactured by the manufacturer of originator medicines.

131 Accordingly, as the Commission correctly submitted, it was required to examine whether the parties would have concluded the United Kingdom distribution agreement absent the non-compete and non-challenge commitments.

132 Given that the applicants do not dispute the finding that, absent such commitments, Teva would have remained Cephalon's closest competitor on the market for modafinil in the United Kingdom, it must be held, as the Commission did, that it is highly unlikely that Cephalon would have chosen its closest competitor, Teva, as its exclusive distributor in the United Kingdom without the settlement agreement.

133 In other words, if Teva was able to conclude with Cephalon the distribution agreement at issue, which was to earn it at least EUR 8 million in commission annually, it is solely because it had accepted the restrictive clauses.

134 Accordingly, the Commission did not err in finding that the distribution agreement had contributed to increasing the level of the overall transfer of value under the settlement agreement in order to provide Teva with sufficient consideration to induce it to accept the restrictive clauses.

135 That conclusion is also confirmed by Cephalon's internal documents relating to the settlement agreement, referred to in recital 944 of the contested decision, in which it is stated that 'the consideration in the UK includes a distribution and supply agreement …' (internal document of 8 December 2005) and that, in '[the] UK, Teva will distribute Provigil and in return will not launch generic modafinil until 2012' (internal document of mid-2006).

136 Next, as regards the one-time payment of EUR 2.5 million under the distribution agreement, it should be noted that, according to Article 2.6(a)(i) of the settlement agreement, that payment was to be made in recognition of the cost and expense involved in Teva's preparation for the commercial launch by Teva of Cephalon's modafinil product in the United Kingdom and in recognition of the IPR licence.

137 In that regard, it must be noted that the Commission, in the contested decision, calls into question not the commission at the rate of 20% of the sales price of modafinil products in the United Kingdom for Teva, but the one-time payment. According to the Commission, Cephalon did not receive anything of value or any commercial benefit in exchange for the one-time payment.

138 In the first place, it should be noted that it is common ground that the one-time payment relates only to Teva's alleged costs and expenses. During the administrative procedure, the applicants acknowledged that the payment was not made in recognition of a licence to IPRs, although Article 2.6(a)(i) of the settlement agreement indicates this as one of the reasons for the one-time payment.

139 In the second place, the Court notes that there is nothing in the evidence contemporaneous with the facts to indicate how the parties determined Teva's 'cost and expense involved in Teva's preparation for [the launch of Cephalon's modafinil product]' which should have been compensated by Cephalon, as well as the exact amount of those costs, or which services Cephalon could have expected from Teva.

140 It is apparent from the contested decision that, during the administrative procedure, the Commission asked the applicants on several occasions to explain the rationale for the one-time payment. However, the applicants were never able to identify the services that Cephalon allegedly received in exchange for the one-time payment, or to explain how the amount of that payment was calculated, or even to demonstrate that Cephalon had requested clarification about the costs incurred by Teva during the settlement agreement negotiations.

141 As the Commission has argued, Teva's United Kingdom distribution model confirms that Teva did not provide services to Cephalon in connection with the launch of Cephalon's modafinil products, nor did it incur the costs of that launch. Teva's tasks as a distributor under the distribution agreement, were limited to taking orders from customers, placing orders with Cephalon, receiving the products from Cephalon, warehousing and storing the products, and ensuring their transportation to customers. All other tasks, such as transporting the products to Teva's warehouse, product packaging, marketing, advertising and promotional activities, were carried out by Cephalon.

142 Accordingly, the Commission was entitled to find that the agreement in question had contributed to the unjustified transfer of value.

(5) Litigation cost avoidance payments

143 Under Article 2.5 of the settlement agreement Cephalon is required to make two payments to Teva in recognition of Cephalon's savings (in terms of avoidance of costs, expenditure of time and resources, etc.) as a result of the discontinuance of ongoing litigation in the United Kingdom and avoided potential modafinil litigation between the two parties on other markets, namely:

– a payment of GBP 2.1 million (approximately EUR 3.07 million) to put an end to the ongoing litigation in the United Kingdom (Article 2.5(b) of the settlement agreement);

– a payment of EUR 2.5 million to prevent future patent or other litigation in European and other markets outside the United States or the United Kingdom (Article 2.5(c) of the settlement agreement).

144 According to Article 2.5(b) of the settlement agreement, the release from the obligation in question took account of the need to avoid the future costs that Cephalon would have incurred and which it was thus able to save, namely 'costs, expenditure of time and resources, disruption and burden associated with prosecuting such litigation in the United Kingdom'.

145 In accordance with Article 4.2 of the settlement agreement, Cephalon and Teva bore their own costs with respect to the settlement of the litigation in the United Kingdom.

146 Accordingly, the Commission concluded, in the contested decision, that the settlement agreement did not provide for Teva's compensation for the litigation costs actually incurred. The payments amounting to EUR 5.57 million served to end litigation in the United Kingdom and to refrain from any future litigation between the parties on other markets outside the United Kingdom and the United States. The Commission therefore considered, in recitals 898 and 899 of the contested decision, that those two payments contributed to the unjustified value transfer to Teva.

147 The applicants submit that nowhere in the judgment of 30 January 2020, *Generics (UK) and Others* (C-307/18, EU:C:2020:52), does the Court hold that genuine litigation cost avoidance payments are not permissible.

148 In addition, they refer to the courts of the United Kingdom and the United States which they claim would have accepted avoided litigation costs.

149 The Commission disputes the applicants' arguments.

150 In paragraph 86 of the judgment of 30 January 2020, *Generics (UK) and Others* (C-307/18, EU:C:2020:52), the Court held that, in the context of a settlement agreement, a transfer of sums could be justified where it corresponds in fact to compensation for the costs of or disruption caused by the litigation between the parties. However, the Court did not rule in that judgment that that justification could also apply to all costs associated with any future judicial proceedings.

151 In the present case, it is common ground that Teva obtained payment of an amount of EUR 5.57 million from Cephalon for no consideration.

152 Moreover, the payments of the amount in question are not linked to any costs incurred by Teva.

153 In that regard, it is common ground that the applicants agreed that each of them would bear their own costs (see paragraph 145 above).

154 Similarly, if Cephalon and Teva had continued their ongoing proceedings in the United Kingdom, or if they had initiated new proceedings in other jurisdictions, they would both have incurred additional litigation costs.

155 However, beyond this, it was agreed that Cephalon would pay additional amounts to Teva (see paragraph 143 above).

156 As the Commission argued in its written submissions and as it stated in the contested decision, it did not make any sense for Teva, in addition to avoiding future litigation costs, like Cephalon, to receive also two cash payments allegedly corresponding to the litigation costs avoided by Cephalon.

157 Consequently, those cash payments cannot correspond 'in fact to compensation for the costs of or disruption caused by the litigation', as required by the case-law cited in paragraph 150 above.

158 It should also be noted, as the Commission did, that the applicants do not dispute the fact that there is nothing in the file to show that the amounts of those sums were agreed on the basis of an estimate by the parties of the costs avoided by Cephalon. It is apparent from the documents before the Court that the payments were dissociated from any actual or potential litigation. In particular, the applicants do not dispute that the payment relating to avoided litigation costs corresponded to an amount calculated on the basis of anticipated modafinil sales in the United Kingdom, as established by Teva during the court proceedings (see the first indent of paragraph 143 above), and that that amount was unrelated to any avoided litigation costs. Nor do they dispute that, where the amount of the sum to be paid for avoided litigation costs in other jurisdictions (see the second indent of paragraph 143 above) was increased, the one-time payment for the United Kingdom distribution agreement was reduced accordingly, which led to the reallocation of the sums in question in two ostensibly unrelated payments.

159 As regards the argument that, before other courts, such as those of the United States, payments corresponding to saved costs are accepted, it should be recalled that, according to the case-law cited in paragraph 150 above, as a rule, only compensation granted by the manufacturer of originator medicines for actual litigation or other costs incurred by a manufacturer of generic medicine may be regarded as justified and, as such, they do not constitute reverse payments.

160 Even if payments for avoidance of future litigation costs were to be regarded in certain cases as justified, the fact remains that the parties have not provided any information relating to the calculation or estimate of the avoided costs that could serve as justification.

161 Accordingly, the Commission was right to find that the payments obtained by Teva for the litigation costs avoided by Cephalon had no plausible explanation other than to increase the level of the overall transfer of value to Teva under the settlement agreement with a view to providing Teva with sufficient consideration to induce it to enter into the restrictive clauses.

162 It follows from the foregoing that, in the contested decision, the Commission applied the appropriate legal test by establishing that each of the commercial transactions provided for in the settlement agreement had no other purpose than to increase the level of the overall transfer of value to Teva under the settlement agreement with a view to inducing it to agree to the restrictive clauses. In that respect, the Commission examined, for each commercial transaction, inter alia, the rationale for the alternative explanations put forward by the applicants and the interest of both Cephalon and Teva in carrying out the related transfer of value. In addition, it was right to find that the package of transactions was sufficient to induce Teva to accept the non-compete and non-challenge commitments.

163 It is not disputed that those transactions were negotiated concomitantly and in an interrelated manner. It must also be noted that the settlement agreement was concluded as a single, legally binding agreement forming the basis of all the acts concluded by the applicants. Moreover, it is apparent from the course of the negotiations, as analysed by the Commission in the contested decision on the basis of the evidence, that both Cephalon and Teva sought to find a combination of transactions representing a certain overall value that was sufficiently beneficial for Teva to accept the restrictive clauses.

164 In that context, it should be recalled that, as is apparent from the case-law cited in paragraph 40 above, what matters for the purposes of examining whether a settlement agreement between manufacturers of originator medicines and manufacturers of generic medicines can be characterised as a 'restriction by object' is the net gain of the transfers of value made in the context of all the transactions between them.

165 Accordingly, the argument by which the applicants criticise the Commission for having assessed the commercial deals contained in the settlement agreement as a 'package', 'irrespective of [the] exact quantification and the actual contribution of each transaction to the overall value transfer', must be rejected.

166 It follows from all of the foregoing that the first part and the second part of the first plea must be rejected in their entirety.

(c) Third part of the first plea

167 The third part of the first plea concerns the second criterion established by the judgment of 30 January 2020, *Generics (UK) and Others* (C-307/18, EU:C:2020:52), according to which the existence of pro-competitive effects that are demonstrated, relevant and specifically related to the agreement concerned and sufficiently significant, so that they justify a reasonable doubt as to whether the agreement concerned caused a sufficient degree of harm to competition, precludes a finding of a restriction of competition by object for the purposes of Article 101(1) TFEU (see, to that effect, judgment of 30 January 2020, *Generics (UK) and Others*, C-307/18, EU:C:2020:52, paragraphs 107 and 111).

168 In Section 6.9 of the contested decision, which corresponds to recitals 974 to 1012 of that decision, the Commission examined the second criterion of the judgment of 30 January 2020, *Generics (UK) and Others* (C-307/18, EU:C:2020:52), and reached the conclusion that the settlement agreement could not produce pro-competitive effects that were demonstrated, relevant, sufficiently significant and not uncertain, which would be capable of casting reasonable doubt as to the anti-competitive object of that agreement.

169 More specifically, in the contested decision, the Commission rejected the alleged pro-competitive effects of the generic rights granted to Teva by Cephalon, on the ground that it was a delayed and controlled market entry (recitals 977 to 981 of the contested decision), that those rights had rendered entry on those markets by other manufacturers of generic medicines less likely (recitals 982 to 992 of the contested decision), that Cephalon's Nuvigil strategy had undermined any alleged pro-competitive effects (recitals 993 to 995 of the contested decision) and that the generic rights granted to Teva were not the main purpose of the settlement agreement (recitals 996 to 1001 of the contested decision).

170 The applicants submit that the settlement agreement had pro-competitive effects, precluding a restriction of competition by object. Those effects stem from the generic rights granted to Teva, which allowed Teva's independent and early entry into the modafinil market at least three years before Cephalon's particle size patents expired (compared to the situation where Teva would not win the court proceedings against Cephalon). The pro-competitive effects stemming from this early entry into the modafinil markets are relevant, certain and sufficiently significant, as is also clear from the decision authorising the merger between Teva and Cephalon (see paragraph 4 above). In that regard, the applicants emphasise that that decision finds that, from October 2012, 'Teva [was] free to launch modafinil in the EEA, without facing litigation by Cephalon' (recital 95

of that decision) and that, because of its generic rights, 'Teva … was the only competitor that had the guaranteed right to enter EEA markets between October 2012 and October 2015' (recital 126 of that decision), which, in the Commission's view, this made Teva 'the most likely competitive constraint on Cephalon at least in the period from October 2012 to October 2015'. According to the applicants, it also follows that pro-competitive effects form an integral part of the settlement agreement.

171 The Commission's position, as set out in the contested decision, that its findings in the decision authorising the merger should be cast aside in the present case is not credible, according to the applicants. The decision authorising the merger clearly analyses the pro-competitive effects associated with the certainty of Teva's early entry into the modafinil markets as directly stemming from the settlement agreement, in so far as it examines the possibility of Teva entering the modafinil markets without facing litigation, whereas other manufacturers of generic medicines would still face the threat of litigation.

172 In addition, according to the applicants, if the settlement agreement did not have such pro-competitive potential, the Commission would not have required Teva to divest its rights relating to modafinil to a third party as a condition for its acquisition of Cephalon.

173 The applicants also dispute the Commission's other findings that Teva's generic rights led to delayed and controlled entry, rendered market entry by other manufacturers of generic medicines less likely, were undermined by Cephalon's Nuvigil strategy and were not the main purpose of the agreement.

174 The Commission disputes the applicants' arguments.

175 As is apparent from paragraph 18 above, Teva's generic rights form part of the settlement agreement. Under Article 3 of the settlement agreement, Cephalon undertook to grant Teva a non-exclusive right under the 'listed patents' to manufacture, use, market and sell its generic modafinil product in the United States and other markets (including the EEA market) and to do the same with respect to the supply of modafinil API for finished pharmaceutical products that have modafinil as their API, starting in 2011 in the United States and starting in 2012 in other markets, including the EEA. Article 3.1.1 of the settlement agreement establishes that Teva's generic rights apply, with respect to other markets, including the EEA, no earlier than 6 October 2012 or the date which is three calendar years prior to the expiration of the exclusivity patents. According to that provision, Teva has to pay Cephalon a royalty equal to 10% of all net profits from the sale of modafinil generic products by Teva or its affiliates in the United States and on other markets on the effective date of those generic rights.

176 Articles 3.1.2 and 3.1.3 of the settlement agreement cover, in particular, the mechanisms triggered by the possible early entry of third parties into the modafinil markets. These provisions allowed Teva to launch its own generic version of modafinil as soon as any other company manufacturing generic medicines enters the market, whether or not Cephalon has authorised such entry. If Teva, in accordance with the above provisions, launched its generic product on the modafinil markets prior to the effective date of those rights, it would have to pay increased royalties of 15% (if entry was authorised by Cephalon) or 20% (if it was an 'at risk' entry, without authorisation by Cephalon) during the relevant period. The scenarios envisaged in the provision include Cephalon requesting a temporary restraining order or other relief. In those cases, Teva's generic rights would be suspended (Article 3.1.3.3(a) of the settlement agreement) and Cephalon would buy back the inventory from Teva at agreed prices (Article 3.1.3.3(b) of the settlement agreement).

177 First, the Court finds, as the Commission did, that the applicants' assertion that the settlement agreement accelerated Teva's independent market entry compared to the situation in which it did not win in the court proceedings against Cephalon must be rejected. It follows from the case-law that, in order to determine whether pro-competitive effects preclude a finding of a restriction by object, it is not necessary to examine other scenarios, such as those where one or other party is successful in a patent dispute. It is sufficient for the Commission, in order to characterise the agreement as a restriction by object, to establish that it reveals a sufficient degree of harm to competition, in view of the content of its provisions, its objectives and the economic and legal context of which it forms part (see, to that effect, judgment of 25 March 2021, *Lundbeck* v *Commission*, C-591/16 P, EU:C:2021:243, paragraphs 140 and 141).

178 Second, it is common ground that, prior to the conclusion of the settlement agreement, Teva was Cephalon's most advanced potential competitor on the modafinil market. Teva had concrete possibilities to enter that market well before 2012 (specifically, in 2005) as an independent entrant. The settlement agreement eliminated that possibility.

179 It is true that the settlement agreement and Teva's related generic rights do not provide for Teva's entering the modafinil market until 2012. That entry does not occur as a result of free competition, but as a result of concerted approach between the parties. Accordingly, it is not an early entry with a pro-competitive effect, as the applicants claim. It is merely a contractually agreed entry, which the settlement agreement delayed for seven years and which guaranteed Cephalon that it would not face any competition from Teva during that period.

180 Furthermore, Teva's entry into the modafinil market, starting in 2012, cannot be equated with the entry into that market of an independent player engaging in direct competition with Cephalon. Teva's planned market into the modafinil market relied on a licence granted by Cephalon and, moreover, it was subject to significant royalties, which represented 10 to 20% of the net profits from the sale of all of Teva's modafinil generic products. As a result, strong price competition between Teva and Cephalon was unlikely.

181 Third, the applicants' arguments relating to the decision authorising the merger between Teva and Cephalon must be rejected.

182 In the first place, it must be stated that the reference framework of the decision authorising the merger is different from that on which the analysis of the settlement agreement in the light of Article 101(1) TFEU is based. Whereas in the contested decision the Commission assessed the restriction of competition caused by the settlement agreement and compared the impact thereof with a counterfactual scenario in which the settlement agreement was not concluded, the decision on the merger between Teva and Cephalon takes the settlement agreement for granted and assesses the likely impact of the parties' merger on competition in the foreseeable future under EU merger control rules, starting in 2011.

183 In the second place, in that context, it is not surprising that the Commission took account of the existence of the settlement agreement and of Teva's generic rights and concluded that Teva obtained some 'benefits' stemming from the settlement agreement, such as being able to launch generic modafinil products in the EEA without facing litigation by Cephalon, whereas the other manufacturers of generic medicines lacked those benefits and faced pending patent litigation which also involved injunctions. This explains why the Commission, in recital 98 of the decision authorising the merger, expressed doubt as to whether manufacturers of generic medicines other than Teva, between October 2012 and October 2015, were able to exert a significant competitive

pressure on Cephalon's generic modafinil product. Accordingly, the fact that the Commission, in the decision authorising the merger, found that after and despite the conclusion of the settlement agreement Teva was still the most likely competitive constraint on Cephalon does not mean that it considered that Teva's generic rights had a pro-competitive effect.

184 Nor does the fact that the Commission accepted Teva's commitments in the context of the merger control proceedings mean that the Commission concluded that the settlement agreement and Teva's related generic rights had pro-competitive effects. On the contrary, such commitments are intended, as the Commission has rightly argued, to reinstate the competitive constraint on Cephalon, which the merger had removed, on the modafinil market.

185 In so far as the applicants criticise the Commission for failing to take account, in the contested decision, of the judgment of 12 December 2018, *Krka* v *Commission* (T-684/14, not published, under appeal, EU:T:2018:918), because it considered that entry under a licence amounted to controlled entry, that complaint cannot succeed. The case which gave rise to that judgment differs from the present case. Whereas, in that case, the manufacturer of generic medicines was authorised to enter the markets in question immediately, in the present case the harm to competition stems from the fact that the settlement agreement delayed Teva's entry by almost seven years.

186 Lastly, the Court must reject the applicants' line of argument by which they dispute the findings in the contested decision that (i) Teva's generic rights rendered market entry by other manufacturers of generic medicines less likely, (ii) Cephalon's Nuvigil strategy undermined any alleged pro-competitive effects of Teva's generic rights and (iii) those rights were not the main purpose of the settlement agreement.

187 In that regard, it should be noted that, contrary to the applicants' claims, the Commission did not require Teva to pursue litigation. Nor did the Commission argue that Teva's being successful in the patent litigation would have allowed the other manufacturers of generic medicines to enter the modafinil market immediately. The fact remains that a finding of invalidity of Cephalon's patents would have removed a barrier to entry to that market, which was an obstacle for both Teva and the other manufacturers and that, if Teva were successful, the other manufacturers could also have benefited from it.

188 Similarly, the applicants cannot deny that Teva's generic rights allowed Teva to be the first to enter the market for generic modafinil medicinal products, before the expiry of Cephalon's patents and without the risk of facing litigation. This position of first entrant on the market for generic modafinil medicinal products was likely to give Teva the opportunity to strengthen its position, which would then have put it in a position to make it more difficult for any competitor to enter that market, for example by means of an aggressive pricing strategy, in addition to the fact that a new entrant may have faced litigation from Cephalon or encountered other obstacles.

189 As regards Cephalon's strategy of redirecting patients from modafinil-based Provigil to its second generation, armodafinil-based product Nuvigil (a strategy designed to offset the expiry of patents entailing competition from generic medicines), the Commission was right to take that strategy into account, given that, from an *ex ante* perspective, Teva's generic rights would, at most, have allowed it to enter under license in what remained of the modafinil patient market by 2012. The Commission was therefore entitled to assume that, even if the generic rights granted to Teva had pro-competitive effects, those effects were very limited and insufficient to call into question the characterisation of the settlement agreement as a restriction of competition by object.

190 The Commission also rightly rejected, in recitals 996 to 1001 of the contested decision, the applicants' claim that Teva's generic rights constituted the main purpose of the settlement agreement and were pro-competitive, although the restrictive clauses were only ancillary to that agreement. In that regard, the argument that the settlement agreement was primarily pro-competitive in nature must be rejected in the light of the foregoing findings, since Teva's entry into the modafinil markets must be characterised as a delayed, controlled and limited entry into those markets, rather than an early entry, as the applicants maintain (see paragraphs 178 to 180 above). The same is true of the argument based on the allegedly ancillary nature of the restrictive clauses, since it follows from the case-law that the conclusion that an agreement must be characterised as a 'restriction by object' cannot be rebutted on the ground that the undertakings that have entered into that agreement argue that the restrictions stemming from that agreement are merely ancillary (judgment of 30 January 2020, *Generics (UK) and Others*, C-307/18, EU:C:2020:52, paragraph 96).

191 Accordingly, the third part of the first plea must be rejected as unfounded.

(d) Fourth part of the first plea

192 In the context of the fourth part of the first plea, which includes two complaints, the applicants submit that the Commission erred in fact and in law in assessing the economic and legal context of the settlement agreement (i) by distorting the parties' perception of the litigation, and (ii) by considering that the restrictive clauses in the settlement agreement were 'out of scope'.

193 As regards the first complaint, the applicants claim, in essence, that the Commission made too many assumptions in the contested decision, based on little evidence, about Teva being convinced that Cephalon's particle size patents were invalid and that its product did not infringe them, and that, consequently, the Commission concluded that Teva's acceptance of the restrictive clauses was not motivated by its perception of the strength of Cephalon's patent or of its chances of success more generally, but by the value that the commercial transactions allegedly transferred to Teva.

194 As regards the second complaint, the applicants submit that the conclusion, set out in recitals 667 to 678 of the contested decision, that the scope of Teva's non-compete commitment exceeds the scope of Cephalon's patents is incorrect and illogical. In that regard, the applicants point to the fact that, as shown by the studies, in order to achieve essential similarity with Provigil, it was necessary to use modafinil particles falling within the size range claimed in Cephalon's patents. Accordingly, the non-compete agreements did not reach beyond the potential scope of the patents.

195 The Commission disputes the errors alleged by the applicants.

196 As regards the first complaint, it is apparent from the contested decision that the Commission relied on several factors in order to conclude that Teva had doubts concerning Cephalon's patent position.

197 In that regard, the contested decision states, inter alia, that:

– Teva began developing its generic version of the modafinil which it launched at risk in the United Kingdom in 2005 (recitals 152, 158 and 610 of the contested decision);

– Teva stated on several occasions that Cephalon's particle size patents were invalid or that its modafinil generic product did not infringe those patents (recitals 153 to 155 of the contested decision);

– Teva's scientific expert stated, in April 2003, that 'Teva [had] succeeded in showing bioequivalence [with Cephalon's modafinil] by formulating a material which [was] outside the scope of the Cephalon patent' (recitals 157 and 611 of the contested decision);

– the tests carried out by a laboratory in the United States, chosen by Cephalon, on samples of Teva's modafinil during the patent court proceedings in the United Kingdom show that Teva's modafinil did not infringe Cephalon's particle size patents (recitals 159 and 611 of the contested decision).

198 Consequently, the applicants' claim that the Commission did not substantiate its assertions in the contested decision with evidence relating to Teva's internal position is unfounded. Moreover, Teva's perception of Cephalon's patent position is also an indication that it is not the strength of Cephalon's patents or the uncertainty in relation to the outcome of the litigation, but rather the financial incentives that played a role in the conclusion of the settlement agreement.

199 As regards the second complaint, it must be borne in mind that, according to the non-compete clause, Teva undertook not to produce, market or import finished medicinal products containing modafinil as their API.

200 The commitment not to compete ensured that Teva would cease all manufacturing and marketing of modafinil products, whether or not the manufacturing and marketing process was based on a technology that infringed Cephalon's existing patents.

201 The applicants do not dispute that the non-compete commitment covers all modafinil products.

202 Given that the commitment relates to 'any finished pharmaceutical product', and not to any finished product likely to infringe Cephalon's modafinil patents, the Commission was entitled to find that Teva's commitment was an agreement concerning its market conduct and not simply a commitment not to infringe Cephalon's patents, especially since it is possible to develop a generic modafinil product that does not fall within the scope of Cephalon's patents. As the Commission correctly pointed out, Cephalon could never have legally obtained such broad non-compete commitments through successful enforcement of the particle size patents. Accordingly, the Commission did not err in finding that commitment to be outside the scope of the patents.

203 Moreover, contrary to what the applicants claim, the Commission was not required to prove that Teva could have or would have developed a non-infringing version. It was sufficient to show that Teva had real concrete opportunities to enter the modafinil markets and was therefore a potential competitor. Moreover, as has already been stated in paragraph 197 above, Teva considered that it had succeeded in 'showing bioequivalence [with Cephalon's modafinil] by formulating a material which [was] outside the scope of the Cephalon patent'. Moreover, the tests carried out on Teva's sample, which date back to 2005, did not demonstrate any infringement of Cephalon's patents.

204 Finally, even if the settlement agreement contained no commitments allegedly falling 'within the scope' of Cephalon's modafinil patents, this does not preclude the finding of a restriction by object. In the present case, the purpose of the settlement agreement was to keep Teva out of the modafinil markets through transfers of value of an overall level that was sufficiently high to

induce Teva to postpone its independent efforts to enter those markets. Such an agreement, which determines the future conduct of potential competitors on the market, has the object of restricting competition, regardless of whether or not Cephalon could, under patent law, have obtained the same exclusion by a court decision (see, to that effect, judgment of 8 September 2016, *Lundbeck* v *Commission*, T-472/13, EU:C:2016:449, paragraphs 491 to 499).

205 It follows from the foregoing that the fourth part of the first plea must also be rejected and, consequently, the first plea must be rejected in its entirety.

2. The second plea, alleging that the Commission erred legally and factually in so far as it characterised the settlement agreement as a restriction by effect

206 By their second plea, which is divided into two parts, the applicants claim that the Commission wrongly concluded that the settlement agreement constituted a restriction of competition by effect for the purposes of Article 101(1) TFEU. Although the rejection of the applicants' first plea, whereby they challenged the characterisation of the settlement agreement as constituting a restriction of competition by object, makes it unnecessary, a priori, to examine their second plea (see, to that effect, judgment of 4 June 2009, *T-Mobile Netherlands and Others*, C-8/08, EU:C:2009:343, paragraphs 28 to 30 and the case-law cited), the Court considers it appropriate, in the circumstances of the present case, to continue its examination.

207 In the context of the first part of that plea, the applicants submit, referring to the judgment of 12 December 2018, *Krka* v *Commission* (T-684/14, not published, under appeal, EU:T:2018:918), that by relying on the potential effects of the settlement agreement without seeking to demonstrate the actual effects thereof, the Commission applied an incorrect legal test.

208 Specifically, the applicants dispute the approach taken by the Commission, in recital 1030 of the contested decision, according to which, in order 'to establish the existence of restrictive effects on competition, it is sufficient to determine the potential effects of the agreement on competition'. In that regard, the applicants claim that the assessment of agreements which have not yet been implemented must indeed consider the potential effects that the agreements are 'likely' to have, whereas the assessment of agreements which have already been implemented must consider the effects the agreements 'in fact' have had on competition. Since the settlement agreement had already been implemented, the Commission should have analysed, as follows from the case-law cited in paragraph 207 above, the actual effects that the settlement agreement had on competition.

209 In the second part of that plea, the applicants submit that the Commission failed to establish sufficiently appreciable effects on the competition parameters on the relevant markets. In the first place, they dispute specifically the counterfactual scenario applied by the Commission. In the second place, they claim that, in the contested decision, the Commission does not establish any negative effect of the settlement agreement.

210 As regards the counterfactual scenario, although the Commission, in recital 1215 of the contested decision, uses the continuation of the United Kingdom litigation between Teva and Cephalon as its counterfactual scenario, it did not establish which party would have won or when the litigation would have come to an end. Nor did it find that a less restrictive settlement would have been concluded.

211 Similarly, they argue that the Commission is required to demonstrate a difference in on-market prices, output, innovation or the variety or quality of modafinil between those that would have ensued had the parties continued to litigate and those that did ensue following the settlement agreement. However, the Commission has not demonstrated that there was a price difference at the time of the market entry of generic modafinil products. Nor has it demonstrated any differences concerning the other competition parameters as between the scenarios with or without the settlement agreement.

212 As regards the negative effects, the applicants claim that the Commission has not identified a single negative effect on competition parameters following the settlement agreement compared to the counterfactual scenario of continued litigation between the parties.

213 In that context, the applicants submit, in essence, that the Commission identified the dates on which Teva received marketing authorisations for modafinil in five countries, but that it does not find that Teva in fact would have entered any of those countries before it was permitted to do so under the settlement agreement. Similarly, the Commission did not put forward any evidence that another supplier of generic medicines could have entered 'with a reasonable degree of probability' the sale of modafinil and it failed to demonstrate that another manufacturer of generic medicines was affected by the settlement agreement. As regards the state of the market in the event of 'continued litigation', that is to say, in the situation corresponding to the Commission's counterfactual scenario, the applicants observe that Teva simply would not have entered that market because it had accepted, in the context of the litigation in the United Kingdom, the preliminary injunction not to sell modafinil in that country pending the United Kingdom patent court proceedings, as acknowledged by the Commission. The settlement agreement therefore did not, as such, have any effect on competition parameters on the modafinil markets. Without actual entry of generic products on the markets, modafinil prices and all other competition parameters would have remained the same, by the Commission's own analysis, in the scenario of the settlement agreement and that of continued litigation between the parties.

214 The Commission maintains that the two parts of the present plea are unfounded and must be rejected.

215 By their second plea, both parts of which should be examined together, the applicants dispute the Commission's finding, in the contested decision, that the settlement agreement also constituted a restriction of competition by effect.

216 As a preliminary point, it should be noted that, in Section 7 of the contested decision, the Commission recalled the general principles governing the analysis to be carried out in order to determine whether an agreement, and a patent settlement agreement specifically, constitutes a restriction of competition by effect for the purposes of Article 101(1) TFEU and that, in Section 8 of that decision, it applied them to the present case. In the latter section, it first defined the product market and its geographic scope (Section 8.1 of the decision) and identified the market structure and the position of Cephalon, Teva and other potential competitors on that market. It follows that Cephalon had market power as the sole producer of modafinil and that Teva was the most advanced competitor (Section 8.2 of the decision). The Commission then presented an analysis of the non-compete and non-challenge restrictive clauses and the way in which they arose and influenced Teva's market conduct. It follows that those clauses restricted Teva's independence, thus preventing it from entering the modafinil market with generic products and restricting its ability to continue to challenge Cephalon's patents (Section 8.3 of the decision). In

Section 8.4 of that decision, the Commission refers to the competitive situation that would have existed without the settlement agreement and, in Section 8.5 of the decision, it concludes that the settlement agreement restricted competition by effect.

217 The applicants do not dispute the market definition, the market structure or Teva's or Cephalon's position on that market.

218 The applicants therefore do not dispute that Teva was a potential competitor of Cephalon.

219 Accordingly, the second plea is limited to the question whether (i) the demonstration of the potential effects of the settlement agreement on competition on the modafinil markets was sufficient for the Commission to find, in the contested decision, that there was a restriction of competition by effect (first part of the plea) and (ii) the counterfactual scenario applied by the Commission in that decision was appropriate and enabled the Commission to demonstrate negative effects on competition on the modafinil markets stemming from the settlement agreement (second part of the plea).

220 It should be recalled that Article 101 TFEU prohibits agreements and concerted practices which have as their object or effect the prevention, restriction or distortion of competition within the internal market.

221 As the Commission has recalled in recital 1020 of the contested decision, in order to establish whether an agreement is to be considered to be prohibited by reason of the distortion of competition which is its effect, the competition in question should be assessed within the actual context in which it would occur in the absence of that agreement (see judgment of 11 September 2014, *MasterCard and Others* v *Commission*, C-382/12 P, EU:C:2014:2201, paragraph 161 and the case-law cited).

222 To that end, it is necessary to take into consideration the actual context in which the practice at issue is situated, in particular the economic and legal context in which the undertakings concerned operate, the nature of the goods or services affected, as well as the real conditions of the functioning and the structure of the market or markets in question (see, to that effect, judgment of 11 September 2014, *MasterCard and Others* v *Commission*, C-382/12 P, EU:C:2014:2201, paragraph 165 and the case-law cited).

223 The scenario envisaged on the basis of the hypothesis that the agreement in question is absent must be realistic. From that perspective, it is permissible, where appropriate, to take account of the likely developments that would occur on the market in the absence of that agreement (see, to that effect, judgment of 11 September 2014, *MasterCard and Others* v *Commission*, C-382/12 P, EU:C:2014:2201, paragraph 166).

224 It is also settled case-law that the restrictive effects on competition may be both real and potential but they must, in any event, be sufficiently appreciable (see judgment of 30 January 2020, *Generics (UK) and Others*, C-307/18, EU:C:2020:52, paragraph 117 and the case-law cited).

225 In the present case, the applicants complain that the Commission applied an incorrect legal test in the contested decision, in that it relied solely on the potential effects of the settlement agreement.

226 In the light of the case-law cited in paragraph 224 above, that argument cannot succeed.

227 It follows from that case-law that it is possible to rely on the potential competition represented by a potential entrant eliminated by the agreement in question and on the structure of the relevant market.

228 As noted in paragraph 218 above, the applicants do not dispute that, at the time of the settlement agreement, Teva was a potential competitor of Cephalon on the modafinil markets. Consequently, as the Commission observed in recitals 1027 to 1032 and 1244 to 1257 of the contested decision, the implementation of the settlement agreement had the effect of eliminating potential competition between Teva and Cephalon.

229 In that regard, it follows from the case-law that Article 101 TFEU is designed to protect not only existing competition, but also potential competition (judgment of 14 April 2011, *Visa Europe and Visa International Service* v *Commission*, T-461/07, EU:T:2011:181, paragraph 68).

230 In addition, it is apparent from the contested decision that the Commission took into account the way in which the settlement agreement was in fact implemented and the way in which the market subsequently evolved (see paragraph 247 below).

231 Next, the applicants' argument that the Commission failed, in its counterfactual scenario, to determine which party would have won the dispute between Teva and Cephalon in the United Kingdom or when that dispute would have come to an end must also be rejected. The same applies to their complaint that the Commission did not find that a settlement agreement less restrictive of competition than the settlement agreement could have been concluded between the parties.

232 In the contested decision, taking into account the economic and legal context in which the applicants operated and, in particular, the point of view that was theirs at the material time on their respective patent positions, as well as the real conditions of the functioning and the structure of the modafinil markets, including Teva's position as Cephalon's most advanced competitive threat, the Commission considered that the likely counterfactual scenario, in the absence of the settlement agreement, was the continuation of the patent litigation between the applicants.

233 The Commission therefore proceeded on the assumption that potential competition between Teva and Cephalon would remain and that there were real concrete possibilities for Teva to enter the modafinil markets. Therefore, it compared the competitive situation stemming from the settlement agreement with the competitive scenario that would likely have happened in the absence of the settlement agreement.

234 In that regard, it follows from the case-law that, in a situation such as that in the present case, the establishment of the counterfactual does not involve any definitive finding in relation to the chances of success of the manufacturer of generic medicines in the patent proceedings or the probability of the conclusion of a less restrictive agreement (judgment of 30 January 2020, *Generics (UK) and Others*, C-307/18, EU:C:2020:52, paragraph 119).

235 The sole purpose of the counterfactual is to establish the realistic possibilities with respect to the conduct of that manufacturer of generic medicines in the absence of the agreement at issue. Accordingly, while that counterfactual cannot be unaffected by the chances of success of that manufacturer in the patent proceedings or in relation to the probability of conclusion of a less restrictive agreement than that actually concluded between that manufacturer and the

manufacturer of originator medicines, those factors constitute, however, only some factors among many to be taken into consideration in order to determine how the market will probably operate and be structured if the agreement concerned is not concluded (judgment of 30 January 2020, *Generics (UK) and Others*, C-307/18, EU:C:2020:52, paragraph 120).

236 Consequently, in order to establish that settlement agreements, such as the settlement agreement at issue in the present case, produce appreciable potential or real effects on competition, the Commission does not have to find either that the manufacturer of generic medicines who is a party to those agreements would probably have been successful in the patent proceedings or that the parties to those agreements would probably have concluded a less restrictive settlement agreement (see, to that effect, judgment of 30 January 2020, *Generics (UK) and Others*, C-307/18, EU:C:2020:52, paragraph 121).

237 Finally, the applicants' assertion that the Commission did not identify in the contested decision any negative effects of the settlement agreement for competition on the modafinil markets must be rejected.

238 As has already been stated in paragraphs 223 and 235 above, the Commission was required to establish realistically what the possible competitive situation would have been on the modafinil markets without the settlement agreement.

239 In that regard, as the Commission rightly pointed out, the elimination of an important source of potential competition, by reason of the settlement agreement, and the resulting delay in market entry may, in itself, give rise to negative effects on competition parameters, in particular prices.

240 The negative effects of the settlement agreement on competition on the modafinil markets are illustrated in recitals 1213 to 1253 of the contested decision.

241 In that regard, the Commission refers, in the contested decision, to the fact that Teva was Cephalon's most advanced potential competitor on the modafinil markets and had real concrete possibilities of entering those markets (Sections 8.2.2 and 8.4 and, specifically, recital 1216 et seq. of the contested decision). As is clear from the documents before the Court, at the time of the settlement agreement Teva, which had planned to enter the modafinil markets in various countries (such as France, Germany, the Netherlands, Spain and Sweden), had, to that end, applied for marketing authorisations for its generic modafinil product in those countries, which it had obtained between 2005 and 2009, and had already launched, at risk, that product in the United Kingdom upon receiving the marketing authorisation in that country on 6 June 2005.

242 However, it must be recalled that the restrictive clauses put an end to Teva's entry into the modafinil markets. The non-compete clause prevented Teva from pursuing any commercial activities regarding generic modafinil, while the non-challenge clause eliminated it as a competitive threat (recitals 1200 to 1212 of the contested decision).

243 In addition, those commitments were undertaken in a situation where, in Teva's view, its generic product did not infringe Cephalon's patents and Cephalon's patents were invalid, which implies that the restrictive clauses in the settlement agreement were not the result of a genuine assessment based on the perceived strength of the patent, but rather were induced by the significant transfer of value enshrined in the transactions referred to in Article 2 of that agreement (recitals 691 to 694, 1208 and 1209 of the contested decision).

244 In that regard, it should be borne in mind that challenges to the validity and scope of a patent are part of normal competition in the pharmaceutical sector (see, to that effect, judgment of 30 January 2020, *Generics (UK) and Others*, C-307/18, EU:C:2020:52, paragraph 81).

245 Accordingly, the Commission was entitled to take the view, in recital 1226 of the contested decision, that, without the settlement agreement, Teva would probably have continued to defend its position in the patent proceedings between the two parties in the United Kingdom and have continued its efforts to enter the modafinil markets, which also had an impact on the likelihood of other possible suppliers of generic modafinil products entering those markets.

246 In that regard, as the Commission rightly noted in recital 1245 of the contested decision, by removing Cephalon's main competitive constraint, the settlement agreement had the likely effect of shielding Cephalon from price competition by competing manufacturers of generic medicines. If Teva had entered the market, it would have been likely, in accordance with the normal business model of generic entrants, to compete on prices with manufacturers of originator medicines, such as Cephalon.

247 In Section 8.4.3 of the contested decision (recitals 1244 to 1253 of that decision), the Commission illustrates this price competition by setting out price differentials before and after the entry of manufacturers of generic medicines into the markets for medicines in the countries concerned.

248 In that regard, the Commission established in the contested decision that Teva was not only a potential competitor of Cephalon on the modafinil markets, but also the most advanced competitive threat to Cephalon on those markets. It therefore correctly concluded that the settlement agreement had eliminated the risk of competition and of Teva's entry into the modafinil markets, which had a negative effect on competition in those markets. Such entry would probably have had the effect of reducing the prices of modafinil. An analysis of the developments in the modafinil markets following the entry of other manufacturers of generic medicines a few years later confirms the accuracy of this analysis.

249 The tables in the contested decision, in particular Table 21, indeed show that, at the end of the period of implementation of the agreement, when manufacturers of generic medicines entered the market, the average prices of modafinil fell significantly. It is therefore highly likely that the same effect would have occurred if Teva had not signed the settlement agreement and had entered the modafinil markets earlier with its generic product.

250 As the Commission submits, price effects can be observed only after actual entry, when competition actually occurs, bearing in mind that potential competition does not reduce prices.

251 It was therefore not possible for the Commission to observe the actual effects of the settlement agreement on competition in the modafinil markets by comparing the potential competition in those markets prior to the conclusion of that agreement with the absence of potential competition which prevailed in that market thereafter.

252 In that context, the applicants' argument that Teva could not, in any event, have entered the modafinil market because it had accepted a preliminary injunction in the context of the patent proceedings which were then pending in the United Kingdom cannot succeed. It should be noted, as the Commission did, that Teva's acceptance of that injunction was only for the duration of the proceedings in question and that the counterfactual scenario adopted by the Commission was not based on the fact that the litigation process would be prolonged

indefinitely, but on the fact that, absent the settlement agreement, the continued litigation process and the real concrete possibility of Teva's entry into the modafinil market would have preserved the potential for competition between Teva and Cephalon.

253 Similarly, the applicants' argument that the Commission failed to demonstrate, in the contested decision, that Teva had in fact entered the markets of the countries in which it had received marketing authorisations is irrelevant. The fact that Teva had obtained those authorisations is an illustration of the fact that it was a potential competitor of Cephalon on the modafinil markets and an indication that Teva would have entered those markets had it not concluded the settlement agreement with Cephalon.

254 As regards the applicants' arguments concerning other manufacturers of generic modafinil products, it is true, as is apparent from the analysis carried out by the Commission in the contested decision, that those manufacturers were not yet ready to enter the modafinil market at the time of the settlement agreement. However, it is not disputed that they were in the process of developing their own generic modafinil products with a view to eventually entering this market. Moreover, the main effect of the settlement agreement was the elimination of the potential competition between Cephalon and Teva, which represented Cephalon's main competitive threat on the modafinil markets at the time of the settlement agreement.

255 It follows from the foregoing that the second plea in law must be rejected as unfounded.

3. The third plea, alleging an erroneous application of Article 101(3) TFEU

256 By the third plea, put forward in the alternative, the applicants submit that the contested decision, in so far as it includes a finding that the settlement agreement failed to fulfil the conditions for exemption laid down in Article 101(3) TFEU, is vitiated by an error of assessment.

257 First, according to the applicants, the settlement agreement contributed to improving the production or distribution of generic medicines. In the first place, from an *ex ante* perspective, the settlement agreement was designed to expedite Teva's early entry into the market for generic medicines in the genuinely possible scenario where Cephalon's particle size patents would be upheld. In the second place, the settlement agreement permitted value-enhancing business transactions.

258 Second, they argue that the settlement agreement and the business transactions are beneficial to consumers and to society as a whole. In that regard, the settlement agreement increased competition of generic medicines earlier in time. In addition, the business transactions permitted earlier access to Azilect, to the benefit of patients suffering from Parkinson's disease, as well as more modafinil products to be made available through the provision of additional API capacity, and the avoidance of infringement risk for three valuable modafinil products.

259 Third, the settlement agreement did not impose any restrictions that were not indispensable to achieving the abovementioned efficiencies and benefits.

260 Fourth, the settlement agreement did not afford the possibility of eliminating competition in respect of a substantial part of the products concerned. On the contrary, that agreement was intended to enable Teva's entry on the market. Furthermore, that agreement had no impact on the efforts of other manufacturers of generic medicines to compete on the market.

261 The Commission disputes the applicants' arguments.

262 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.

263 The application of Article 101(3) TFEU requires four cumulative conditions to be satisfied. First, the agreement concerned must contribute to improving the production or distribution of the goods in question, or to promoting technical or economic progress; second, consumers must be allowed a fair share of the resulting benefit; third, it must not impose on the participating undertakings any restrictions which are not indispensable; and, fourth, it must not afford them the possibility of eliminating competition in respect of a substantial part of the products in question.

264 Pursuant to Article 2 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), 'the 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'.

265 The burden of proof thus falls on the undertaking requesting an exemption under Article 101(3) TFEU. However, the facts relied on by that undertaking may be such as to oblige the other party to provide an explanation or justification, failing which it is permissible to conclude that the burden of proof has been discharged (see, to that effect, judgment of 6 October 2009, *GlaxoSmithKline Services and Others* v *Commission*, C-501/06 P, C-513/06 P, C-515/06 P and C-519/06 P, EU:C:2009:610, paragraph 83 and the case-law cited).

266 In the present case, as is apparent from recital 1269 et seq. of the contested decision, the Commission examined the possible application of Article 101(3) TFEU to the present case.

267 The Commission rightly found that the arguments and evidence put forward by the applicants fell short of showing that the settlement agreement, including its accompanying commercial transactions, involved sufficient efficiencies.

268 As regards the applicants' argument relating to the first condition listed in paragraph 263 above, that the settlement agreement brought forward Teva's market entry by three years and permitted value-enhancing business transactions, that argument must be rejected.

269 As was found when examining the first plea, the settlement agreement and the generic rights granted by Cephalon to Teva under that agreement did not bring forward – but rather, delayed – Teva's entry into the modafinil markets and, consequently, competition on those markets from manufacturers of generic medicines.

270 By agreeing to the settlement agreement, Teva abandoned its attempts to enter the modafinil market as an independent operator, even though it had already developed a generic modafinil product which, in its view, did not infringe Cephalon's patents, it had even launched it and had also filed applications for marketing authorisations for that product in several countries. The fact that the outcome of the patent litigation against Cephalon in the United Kingdom was uncertain does not alter that finding in any way. As noted in paragraph 244 above, competition in the pharmaceutical sector is also characterised by challenges to the validity of patents for medicinal products and their APIs.

271 As regards the commercial transactions contained in the settlement agreement, the Commission explained, in recitals 1293 to 1298 of the contested decision, why they had not contributed to improving the production or distribution of generic modafinil products. The applicants do not put forward any argument explaining why the reason given by the Commission was incorrect.

272 In any event, even if the various transactions in the settlement agreement had some value or a certain commercial logic for the applicants, they did not necessarily involve efficiencies capable of justifying the exemption of that agreement under Article 101(3) TFEU. In that regard, as is apparent from point 49 of the Guidelines on the application of Article [101 (3) TFEU] (OJ 2004 C 101, p. 97), 'efficiencies are not assessed from the subjective point of view of the parties'; only objective benefits can be taken into account.

273 It follows that the Commission rightly held that the first condition for exemption under Article 101(3) TFEU was not satisfied in the present case. Since the four conditions laid down in Article 101(3) TFEU are cumulative, the applicants' arguments concerning the other three conditions must be rejected as irrelevant.

274 Consequently, the third plea must be rejected.

4. The fourth plea, relating to the fines imposed on the applicants

275 In the fourth plea, raised in the alternative, the applicants assert that, in the contested decision, the Commission infringed the principles of legal certainty, non-retroactivity and the protection of legitimate expectations, as well as the principle *nullum crimen sine lege et nulla poena sine lege* by imposing substantial fines on them. By the first part, they claim that the fines should be cancelled in their entirety. By the second part, Teva seeks a substantial partial cancellation of the amount of the fine imposed on it.

(a) First part of the fourth plea

276 The applicants submit that the principles listed in paragraph 275 above require the Commission to refrain from imposing a fine where the undertakings concerned could not reasonably foresee, at the time when the alleged breach was committed, that the conduct at issue infringed EU competition law.

277 According to the applicants, this was the case here. At the time of the settlement agreement, they acted in a legal environment in which Article 101 TFEU had never been applied to that type of agreement. In addition, in the absence of precedents in EU competition law and of any indication on the Commission's position on the legality of patent settlement agreements thereunder, Teva could legitimately rely on the guidance available in the United States.

278 The applicants also submit that the settlement agreement was not an agreement that involved a cash payment from the manufacturer of originator medicines to the manufacturer of the generic medicines. Each of the transactions contained in that agreement had its own independent business justifications, with the result that that agreement was not based on a single overall market-sharing objective. Lastly, they claim that the Commission's assessments in the contested decision contradicted its own conclusions in the seventh report on the monitoring of patent settlements, drawn up in the context of the inquiry into the pharmaceutical sector undertaken pursuant to Article 17 of Regulation No 1/2003 with the aim of identifying, first, the causes of the

decline in innovation in that sector, measured by the number of new products entering the markets for medicinal products and, second, the reasons for the late entry of certain generic medicines into those markets. The Commission noted, in that report, that the assessment from a competition law perspective of settlement agreements concluded between manufacturers of originator medicines and manufacturers of generic medicines was problematic.

279 The Commission disputes the applicants' arguments.

280 It follows from the case-law that a penalty may be imposed on an undertaking for conduct falling within the scope of Article 101(1) TFEU where that undertaking could not be unaware of the anticompetitive nature of its conduct, whether or not it is aware that it is infringing the competition rules of the Treaty. It is sufficient therefore that that undertaking was in a position to determine that its conduct was anticompetitive in the light of Article 101(1) TFEU (see, to that effect, judgment of 25 March 2021, *Lundbeck* v *Commission*, C-591/16 P, EU:C:2021:243, paragraphs 156 to 158).

281 It also follows from the case-law that, while the principle of legal certainty and the principle that penalties must have a proper legal basis require EU legislation to be clear and precise, so as to enable the persons concerned to ascertain unequivocally what their rights and obligations thereunder are and take steps accordingly, they cannot be interpreted as prohibiting the gradual clarification of the rules on criminal liability by means of interpretations in the case-law, provided that those interpretations are reasonably foreseeable (judgment of 25 March 2021, *Lundbeck* v *Commission*, C-591/16 P, EU:C:2021:243, paragraph 166).

282 In the context of the examination of the first plea, it was observed that the settlement agreement was intended to exclude Teva, at least temporarily, from the modafinil markets as a competitor of Cephalon. Market exclusion agreements constitute an extreme form of market sharing and of limitation of production, which are expressly prohibited by Article 101(1) TFEU.

283 Accordingly, the applicants could not have been unaware of the fact that entering into the settlement agreement, in so far as it contained non-compete and non-challenge clauses, was problematic under EU competition law.

284 The other arguments put forward by the applicants cannot call that finding into question.

285 In particular, the applicants' argument that the prevailing legal view in the United States courts at the time of the settlement agreement was that patent settlement agreements did not infringe antitrust rules is irrelevant. Only EU competition law mattered in this case, as regards the application of Article 101 TFEU, such that the decisions of the United States judicature did not have to be taken into account. In addition, as the Commission correctly noted in recital 1364 of the contested decision, at the time of the settlement agreement, United States case-law was not unanimous and the Federal Trade Commission (United States) was challenging reverse payment settlement agreements under United States antitrust law, with the result that the applicants could not, in any event, rely on clear guidance from United States antitrust law.

286 Similarly, the applicants' argument that the contested decision contradicted the conclusions of the report on the monitoring of patent settlements cannot succeed. The fact that the Commission had found, in that report, that the assessment of the settlement agreements concluded between the manufacturers of originator medicines and the manufacturers of generic medicines was problematic from a competition law perspective did not mean that those agreements fell outside

competition law or that they necessarily complied with it. In addition, it is clear from that report that the Commission was of the opinion that settlement agreements providing, a priori, for the early entry of a generic medicine onto the market should, in reality, be seen as limiting such an entry where entry is not immediate and where the conditions attached to the entry cancelled out, in practice, any positive effects thereof on competition. This was precisely the case with the settlement agreement.

287 Moreover, the fact that, at the time of the settlement agreement, the Commission had not yet imposed fines for similar infringements is irrelevant. It has already been ruled that the imposition of fines exceeding a nominal level in no way infringed the principle of legal certainty, notwithstanding the novel and complex nature of the issues raised by the settlement agreements and the lack of precedents (see, to that effect, judgment of 25 March 2021, *Lundbeck* v *Commission*, C-591/16 P, EU:C:2021:243, paragraph 165).

288 As regards the alleged infringement of the principle of the protection of legitimate expectations claimed by the applicants, it should be borne in mind that, according to well-established case-law, the right to rely on the principle of protection of legitimate expectations extends to any individual in a situation where it is clear that the EU authorities have caused him or her to entertain legitimate expectations, it being understood that no one may plead infringement of that principle unless precise, unconditional and consistent assurances, from authorised, reliable sources, have been given to him or her by the authorities (see judgment of 8 September 2010, *Deltafina* v *Commission*, T-29/05, EU:T:2010:355, paragraph 427 and the case-law cited).

289 In the present case, it is sufficient to note that the applicants do not claim, let alone establish, that the Commission gave them such assurances.

290 As regards the applicants' argument that the principle of non-retroactivity was infringed, it is sufficient to state that it is not substantiated in any way.

291 Finally, the applicants' argument that the settlement agreement involved no cash payment from Cephalon to Teva is irrelevant. In the context of the examination of the first plea, it has been established that the payments provided for in the commercial transactions contained in the settlement agreement had no plausible explanation other than to induce Teva to accept the restrictive clauses of that agreement and thus to refrain from competing with Cephalon on the merits on the modafinil markets.

292 Consequently, the first part of the fourth plea must be rejected.

(b) Second part of the fourth plea

293 By the second part of the fourth plea, Teva complains that the Commission imposed on it a fine of a completely arbitrary and unjustified amount because the pecuniary transfer of value was not high enough, thus infringing the principles of legal certainty and the protection of legitimate expectations.

294 The Commission disputes Teva's arguments.

295 As a preliminary point, it should be recalled that 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') are based on the taking into account of the value of

the sales of the goods or services concerned in relation to the infringement penalised for the purpose of setting the basic amount of the fines to be imposed. Those guidelines provide, in paragraphs 6 and 13, that the value of those sales, combined with the duration of the infringement, are intended to 'reflect the economic importance of the infringement as well as the relative weight of each undertaking in [that] infringement'.

296 However, that method may sometimes prove unsuited to the particular circumstances of a case. That is the case, in particular, where an undertaking found to have infringed Article 101 TFEU has no turnover on the relevant markets. In such a situation, the Commission is entitled to use to a calculation method other than that described in the Guidelines on the method of setting fines and, in accordance with point 37 thereof, to set the basic amount of the fine imposed on the undertaking concerned as a lump sum (see, to that effect, judgment of 22 October 2015, *AC-Treuhand* v *Commission*, C-194/14 P, EU:C:2015:717, paragraphs 65 to 67).

297 In the present case, it is common ground that, because of the very purpose of the settlement agreement, which is an agreement to exclude Teva from the relevant market, Teva was not present on that market during the infringement period and therefore had not made any sales on that market.

298 Accordingly, the Commission was unable to use the value of Teva's sales on the relevant market during the infringement, and that particular circumstance allows it, pursuant to point 37 of the Guidelines on the method of setting fines, to depart from the methodology set out in those guidelines.

299 It is true that, in other cases concerning patent settlement agreements which infringed Article 101 TFEU and in which the undertakings in the sector of generic medicines had not made any sales on the markets for those medicinal products, the Commission had set the fines by taking into account the value which had been transferred to the manufacturer of generic medicines by the manufacturer of originator medicines, as an incentive to remain outside the relevant markets, without estimating the turnover of the manufacturer of generic medicines.

300 However, the Commission was not bound by its previous decision-making practice, and that practice does not, in any event, constitute a legal framework for calculating the amount of fines (see, to that effect, judgment of 25 October 2005, *Groupe Danone* v *Commission*, T-38/02, EU:T:2005:367, paragraph 153 and the case-law cited).

301 In addition, in recitals 1386 to 1391 of the contested decision, the Commission explained why Teva's fine could not be based on the transfer of value that it had received under the settlement agreement and the commercial transactions contained therein. The transfer of value was embedded into those transactions. Apart from the fact that it was difficult to estimate accurately the value transferred to Teva under four of the five transactions covered by Article 2 of the settlement agreement, this proved impossible with regard to the provision of the CEP-1347 data. At the material time, the disclosure of those data had constituted an important incentive for Teva to accept the restrictive clauses, which the Commission could not ignore when it determined the level of the fine imposed on Teva, otherwise the deterrent effect of that fine would be undermined.

302 Given the particular circumstance that the transfer of value to Teva could not be estimated with sufficient precision and in order to achieve a satisfactory level of deterrence, the Commission opted for a fixed amount for the fine imposed on Teva.

303 The applicants cannot, however, claim that the amount is arbitrary.

304 The Commission took, as appropriate, as a reference point for setting the amount of the fine imposed on Teva, the amount of the fine imposed on Cephalon before the application of the limit of 10% of its turnover. In that respect, as follows from recitals 1393 to 1395 of the contested decision, the Commission found that:

– the gravity and duration of the infringement were the same for both Teva and Cephalon;

– the fine imposed on Teva should not be higher than that imposed on Cephalon, bearing in mind that its foregone profits would probably be less than Cephalon's actual profits;

– other factors also had to be taken into account, such as the fact that Teva was a larger undertaking (in 2010, the last full year of the infringement and the year before Teva actual acquired Cephalon, its worldwide turnover was EUR 12.16 billion, while Cephalon's worldwide turnover was approximately EUR 2.12 billion) and that it enjoyed a strong negotiating position.

305 In so far as the applicants complain that the Commission infringed the principle of legal certainty, that argument must be rejected. As is apparent from the case-law cited in paragraph 300 above, the Commission is not bound by its previous practice. As regards the infringement of the principle of the protection of legitimate expectations alleged by the applicants, it is sufficient to note that they do not even claim, in accordance with the case-law cited in paragraph 288 above, that the Commission gave them, in any way whatsoever, precise, unconditional and consistent assurances concerning the calculation method which it was going to use to set the amount of the fine imposed on Teva.

306 It follows from the foregoing that the second part of the fourth plea and, consequently, the fourth plea in so far as it seeks cancellation of the fines imposed on the applicants must be rejected.

307 In the light of all the foregoing considerations, the applicants' form of order seeking annulment of the contested decision must therefore be rejected.

B. The form of order seeking a variation of the fine imposed on the applicants

308 By their second and third heads of claim, the applicants claim that the Court should cancel or reduce the amount of the fine.

309 In that respect, it should be borne in mind that as regards the judicial review of Commission decisions imposing a fine for infringement of the competition rules, the review of legality is supplemented by the unlimited jurisdiction that is conferred on the EU judicature by Article 31 of Regulation No 1/2003, in accordance with Article 261 TFEU. That jurisdiction empowers the Courts, in addition to carrying out a mere review of the lawfulness of the penalty, to substitute their own appraisal for the Commission's and, consequently, as the case may be, to cancel, reduce or increase the amount of the fine or periodic penalty payment imposed.

310 However, the Court considers, in the exercise of its unlimited jurisdiction, that none of the elements relied on by the applicants in the present case nor any ground of public policy justifies it making use, pursuant to Article 261 TFEU and Article 31 of Regulation No 1/2003, of its unlimited jurisdiction to reduce the amount of the fines set by the Commission.

311 The form of order seeking the cancellation of or reduction in the amount of the fines imposed on the applicants must therefore be rejected and, consequently, the action must be dismissed in its entirety.

IV. Costs

312 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 applicants have been unsuccessful, they must be ordered to pay the costs, in accordance with the form of order sought by the Commission.

On those grounds,

THE GENERAL COURT (Third Chamber, Extended Composition)

hereby:

1. Dismisses the action;

2. Orders Teva Pharmaceutical Industries Ltd and Cephalon Inc. to pay the costs.

Schalin Jaeger Škvařilová-Pelzl

Nõmm Kukovec

Delivered in open court in Luxembourg on 18 October 2023.

V. Di Bucci M. van der Woude
Registrar President